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THE INFLUENCE OF CULTURE ON FOOD SAFETY REGULATIONS AND INTERNATIONAL TRADE DISPUTES

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Summary

This thesis investigates the role of consumer based and cultural influences in the area of food regulation and international trade. Firstly, the thesis endeavours to identify the essence and manifestation of these influences. Secondly, the thesis investigates whether or not they have been incorporated into existing food regulatory measures, and if so, their impact on the actual food regulatory measures enacted. The thesis progresses the analysis by investigating whether or not these cultural influences have any role to play in the drafting and application of international trade laws by analysing the operation of the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

Chapter 1 introduces how cultural influences affect people's attitudes and behaviours towards the food supply. In order to exemplify the arguments made in Chapter 1, Chapter 2 initiates the comparative element of this thesis which compares the EU and US food safety regulatory systems. The analysis in Chapter 2, combined with aspects of the analysis in Chapters 3, 4 and 5, discovers a number of significant cultural differences between the EU and US approaches to regulation in this area. Highlighting these differences is important in confirming the existence of cultural regulatory divergences and understanding the reasons for their existence.

Proponents of scientific certainty would view cultural considerations as anathema and as a result in Chapter 4, as a counterbalance to the analysis of culture in Chapter 3, the concept of science based risk regulation is introduced. Chapter 4 examines the role of science in food safety law. Chapter 5 sets out why the concept of 'risk' is important to food safety analysis and elucidates the role of public risk perception in creating cultural regulatory divergences.

The analysis in the preliminary chapters of this thesis confirms the existence of cultural regulatory divergences. Under EU food safety regulation, culture has a role to play in all its forms. There is an acknowledgment that scientific risk assessment does not provide all of the information necessary for the formulation of the most appropriate sanitary measures. In stark contrast, US food safety regulation is almost wholly reliant on science. In addition, the analysis of the SPS Agreement contained in Chapter 6 confirms that scientific risk analysis is central to global regulation in this area. This is significant because the analysis in Chapter 3 confirms that a regulation is more likely to be accepted by a legal system if it aligns with the

cultural environment characterizing that legal system. Therefore, these cultural regulatory divergences are likely to stymie any attempt at the successful application of a uniform global food safety law.

This thesis utilises the *Beef Hormones Dispute* to exemplify all of the issues concerned. In most EU Member States, food culture is a particularly well entrenched aspect of national identity. The analysis in this thesis confirms that there was an insufficient cultural-match between EU food culture and the consumption of beef treated with growth hormones. Scientific risk assessment alone was insufficient to assuage EU consumer concern regarding the safety of hormone residue in meat. As a result, the EU enacted legislation banning the use of animal growth hormones and the importation of meat containing hormone residues. The US authorities viewed the ban as protectionist and contrary to the spirit of free trade.

By way of introduction to the analysis of the *Beef Hormones Dispute*, Chapter 7 describes animal growth hormones and the EU and US legislation governing them. The analysis of the *Beef Hormones Dispute* in Chapter 8 evidences the interplay between the EU, the US, and the WTO food regulatory frameworks. Chapter 8 contains an in-depth analysis of how the WTO Dispute Settlement Body interpreted the SPS Agreement while endeavouring to come to terms with these cultural regulatory divergences.

In conclusion, Chapter 9 outlines the main findings on the interaction between culture, science, and food law, along with various recommendations, by utilising the lessons learned from the aforementioned analysis. Culture influences the formulation and application of food law and creates regulatory divergences. This creates difficulties with the application of aspects of international trade law when states and global regulatory systems do not recognise the legitimate role played by these cultural biases. As a result, certain international trade disputes cannot be resolved satisfactorily under the existing WTO dispute resolution construct.

In addition to identifying the consequences of the omission of consumer based and cultural considerations from aspects of international trade law, this thesis also provides some practical suggestions as to how matters could be ameliorated either prior to or during the formal WTO dispute resolution process.

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Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health [2012] OJ L136/1

Directives

Council Directive 64/433/EEC of 26 June 1964 on health problems affecting intra-Community trade in fresh meat [1964] OJ L121/2012

Commission Directive 70/50/EEC of 22 December 1969 based on the provisions of Article 33 (7), on the abolition of measures which have an effect equivalent to quantitative restrictions on imports and are not covered by other provisions adopted in pursuance of the EEC Treaty [1970] OJ L13/29

Council Directive 71/118/EEC of 15 February 1971 on health problems affecting trade in fresh poultry-meat OJ L055/23

Council Directive 77/99/EEC of 21 December 1976 on health problems affecting intra-Community trade in meat products OJ L26/85

Council Directive 81/602/EEC of 31 July 1981 concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action [1981] OJ L222/32

Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products [1985] OJ L201/29

Council Directive 85/649/EEC of 31 December 1985 prohibiting the use in livestock farming of certain substances having a hormonal action [1985] OJ L382/228

Council Directive 88/146/EEC of 7 March 1988 prohibiting the use in livestock farming of certain substances having a hormonal action [1988] OJ L70/16

Council Directive 88/299/EEC of 17 May 1988 on trade in animals treated with certain substances having a hormonal action and their meat, as referred to in Article 7 of Directive 88/146/EEC [1988] OJ L128/36

Council Directive 90/496 of 24 September 1990 on nutrition labelling for foodstuffs [1990] OJ L276/40

Council Directive 91/495/EEC of 27 November 1990 concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat OJ L268/41

Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products [1992] OJ L268/1

Council Directive 92/47/EEC of 16 June 1992 on the conditions for granting temporary and limited derogations from specific Community health rules on the production and placing on the market of milk and milk-based products [1992] OJ L 268/33

Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs [1993] OJ L176/29

Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stock-farming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC [1996] OJ L125/03

Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC [1996] OJ L125/10

Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC [2001] OJ L106/1

Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to veterinary medicinal products [2001] OJ L311/1

Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements [2002] OJ L183/51

Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists [2003] OJ L267/17

Decisions

Commission Decision 96/239/EC of 27 March 1996 on emergency measures to protect against bovine spongiform encephalopathy [1996] OJ L78/47

Commission Decision 97/579/EC of 23 July 1997 setting up Scientific Committees in the field of consumer health and food safety [1997] O.J. L237/18

United States

Presidential Proclamation

US Presidential Proclamation No. 5759 of 24 December 1987 (102 Stat. 4942)

Statutes

Federal Meat Inspection Act 1906, 4 Stat. 674, Pub. L. 59-242, 21 USC. §§ 601

Federal Food, Drug and Cosmetic Act 1938, 52 US Stat. 1040, Pub.L. 75-117, 21 USC. §§ 301

Poultry Products Inspection Act 1957, 71 Stat. 441, 21 USC. 451

Colour Additive Amendment 1960, 74 Stat. 405, Pub. L. 86-618, 21 USC. §§ 379

Fair Packaging and Labelling Act 1966, 80 Stat. 1296, Pub. L. 89-755, 15 USC. § 1451.

Wholesome Meat Act 1967, 34 Stat. 1260, Pub. L. 90-201, 21 USC. § 601

Comprehensive Drug Abuse Prevention and Control Act 1970, 84 Stat. 1236, Pub. L. No. 91-513, 21 USC. § 801.

Egg Products Inspection Act 1970, 84 Stat. 1620, Pub. L. 91-597, 21 USC. §§ 1031

Federal Advisory Committee Act 1972, 86 Stat. 770, Pub. L. 92-463, 5 USC. App. §§ 1 - 16

Government in the Sunshine Act 1976, 90 Stat. 1241, Pub. L. 94-409, 5 USC. § 552b

Codified Legislation

21 CFR Part 133 – Cheeses and Related Cheese Products

21 CFR Part 510 – New Animal Drugs
21 CFRS.510.600: Names, addresses, and drug labeler codes of sponsors of approved applications

21 CFR Part 514 – New Animal Drug Applications
21 CFRS.514.4: Substantial Evidence

21 CFR Part 522 – Implantation of Injectable Dosage Form New Animal Drugs
21 CFR S.522.840(c)(3): Limitations on the Use of Estradiol
21 CFR S.522.842: Estradiol benzoate and testosterone propionate
21 CFR S.522.850: Estradiol valerate and norgestomet in combination
21 CFR S.522.1940: Progesterone and estradiol benzoate
21 CFR S.522.2476: Trenbolone acetate
21 CFR S.522.2477: Trenbolone acetate and estradiol
21 CFR S.522.2478: Trenbolone acetate and estradiol benzoate
21 CFR S.522.2680: Zeranol

21 CFR Part 558 – New Animal Drugs for Use in Animal Feeds
21 CFR S.558.342: Melengestrol

21 CFR Part 582 – Substances Generally Recognised as Safe
21 CFR S.582.1 – Substances that are Generally Recognised as Safe

21 CFR Part 1240 – Control of Communicable Diseases
21 CFR S.1240.61 – Mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption.

United Kingdom

Assize of Bread and Ale 1266 (51 Hen.3 Stat. I)

Adulteration of Tea and Coffee Act 1724 (II Geo I c.30)

Food and Drugs (Adulteration Act) 1928 (18 & 19 Geo.5 ch.31)

The Animals and Animal Products (Examination for Residues and Maximum Residue Limits) (Amendment) Regulations 2006 (SI 2006/755)

Ireland

The Animal Remedies Act 1956 (1956 No.41)

The Animal Remedies (Control of Oestrogenic Substances) Regulations, 1962 (SI No. 96 of 1962)

WTO

Agreements

Agreement on Technical Barriers to Trade (1868 U.N.T.S. 120)

Agreement on Implementation of Article VI of the General Agreement on Tariffs and Trade 1994 ('Anti-Dumping Agreement') (1868 U.N.T.S. 201)

Agreement on Agriculture (1867 U.N.T.S. 410)

Agreement on the Application of Sanitary and Phytosanitary Measures (1867 U.N.T.S. 493)

General Agreement on Tariffs and Trade 1947 (55 U.N.T.S. 194)

General Agreement on Tariffs and Trade 1994 (1867 U.N.T.S. 187)

International Bovine Meat Agreement (1869 U.N.T.S. 508)

Marrakesh Agreement Establishing the World Trade Organization (1867 U.N.T.S. 154)

Understanding on Rules and Procedures Governing the Settlement of Disputes ('Dispute Settlement Understanding') (1869 U.N.T.S. 401)

International Conventions

Vienna Convention on the Law of Treaties 1969 (1155 U.N.T.S. 331, 8 I.L.M. 679)

United Nations Convention on Biological Diversity 1992 (1760 U.N.T.S. 79, 143; 31 I.L.M. 818)

List of Abbreviations

AB - Appellate Body

ALINORM – Codex Committee meeting report

BSE - bovine spongiform encephalopathy

CAC - Codex Alimentarius Commission

CFR – Code of Federal Regulations

DSB – World Trade Organisation Dispute Settlement Body

DSU – World Trade Organisation Understanding on Rules and Procedures Governing the Settlement of Disputes (Dispute Settlement Understanding)

EC - European Communities

EC Hormones - EC Measures Concerning Meat and Meat Product, WT/DS26

EFSA – European Food Safety Authority

ERS – Economic Research Service of the United States Department of Agriculture

EU – European Union

FAO – Food and Agriculture Organisation of the United Nations

FDA – United States Food and Drug Administration

FMIA – United States Federal Meat Inspection Act 1906

FSIS – United States Food Safety and Inspection Service

GAIN – Global Agricultural Information Network

General Food Law - European Parliament and Council Regulation (EC) No 178/2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L 31/1

GATT - General Agreement on Tariffs and Trade

IDF - International Dairy Federation

MOU - Memorandum of Understanding

SPS - Sanitary and Phytosanitary Measures

SPS Agreement - Agreement on the Application of Sanitary and Phytosanitary Measures

TBT - Technical Barriers to Trade

TBT Agreement - Agreement on Technical Barriers to Trade

TFEU – Treaty on the Functioning of the European Union

TRIPS - Trade-Related Aspects of Intellectual Property Rights

US – United States of America

USC – United States Code

US – Continued Suspension - United States Continued Suspension of Obligations in the EC Hormones Dispute, WT/DS320

UNTS - United Nations Treaty Series

USDA – United States Department of Agriculture

WHO – World Health Organisation

WTO – World Trade Organisation

WTO Agreement - Marrakesh Agreement Establishing the World Trade Organization

Abstract

This thesis examines whether the absence of recognition of the role played by cultural influences in creating regulatory divergences between states (cultural regulatory divergences) gives rise to inherent difficulties in the application of aspects of international trade law. It does this by uncovering the existence of cultural regulatory divergences and then analysing the application of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) to domestic measures and laws. To aid the analysis, this thesis examines in particular, the way in which divergences of opinion over the use of hormones in beef production has created a series of trade difficulties at the international level.

The analysis contained in this thesis enables an understanding of how this failure to accept cultural regulatory divergences as legitimate, means that certain international trade disputes cannot be resolved satisfactorily under the existing WTO dispute resolution construct. It is here suggested, that this could be ameliorated by the granting of increased recognition to consumer based and cultural considerations in the drafting and application of such international laws. The present over emphasis on scientific considerations will, it is contended, only lead to continued recourse to dispute resolution mechanisms.

CHAPTER 1

INTRODUCTION

1.1 Introduction

Food traditions and attitudes towards the food supply are learned, shared and transmitted among groups of human beings from generation to generation.[1] Food is therefore part of our identity; it is anthropological – it helps define who we are. It is as representative of our civilisation as our morals, values, customs, or habits.[2] This importance results from personal beliefs – biases based on historically developed societal values and patterns of behaviour. If we think of culture in the broadest sense as the customs, civilisation and achievements of a people, then food is inextricably linked with it.[3] Any particular culture can be seen as a set of shared values and supporting social institutions. Societies and nation-states come to develop different beliefs regarding what they deem safe to eat. Therefore, local areas, individual countries, and indeed federalised entities such as the European Union (EU) and the United States (US) each have their own unique food culture.[4] Domestic or localised variations also exist within these economic areas. However, at the national level, an identifiable uniformity in food culture is still apparent.

Therefore, in each geographical location food culture is always indigenous. However, it is also in a constant state of flux. This state of flux ensures an inexorable change in food culture. Cataclysmic events can cause sudden dramatic shifts. For example, the food sector was transformed beyond recognition with the shifting of food production from the home to

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[1] S. Mennell, A. Murcott & A. H. van Otterloo, *The Sociology of Food: Eating, Diet and Culture* (London: SAGE Publications, 1992), p.20.
[2] *Ibid*, p. 28.
[3] A. Wildavsky & M. Douglas, *Risk and Culture: An Essay on the Selection of Technical and Environmental Dangers* (Los Angeles: University of California Press, 1982), p. 14.
[4] Throughout this thesis the European Union shall be referred to using the designation 'EU'. For clarification, it is noted that with the entry into force of the Treaty on European Union (Treaty of Maastricht) in 1993, the European Economic Community (EEC) was renamed the European Community (EC). Upon the entry into force of the Treaty of Lisbon in 2009, the EC became the European Union (EU). At the date of writing this thesis, in accordance with the Treaty of Lisbon the EU is now the official legal personality.

the factory.[5] This cataclysmic event would act as the impetus for wholesale change in food safety regulation.[6] From the late 1940s onwards, consumers were no longer buying ingredients from trusted neighbours in their community, but from remote food processors and manufacturers. When food was produced locally – food production and food culture were concomitant. Based on an intimate knowledge of the provenance of their food, people knew whether or not it was safe for consumption. For the consumer, the relationship between food production and culture was easily discernible. Sophisticated food safety regulation was unnecessary.[7]

In addition to changes brought about through commerce, technological change and globalisation have also played a role. The food industry has been transformed by improvements in seed, cultivation, fertilisers, pesticides, methods of storage, preservation and transportation.[8] Divergent attitudes exist between food cultures towards the use of technology in the food supply. Differences of opinion have arisen due to the potentially yet unknown health hazards posed by the advent of biotechnological processes, in particular genetic modification.

Globalisation has reshaped how our food is produced, marketed, and distributed. In any large supermarket anywhere in the world, one will find foods that were produced in many different countries. Our food has been internationalised. Whereas previously, consumer concerns had extended only as far as the 'visibles' – inaccurate weight, size discrepancies, misleading labelling or poor quality – suddenly the consumer has become cognitive of the so-called 'invisibles'- invisible health hazards such as micro-organisms, pesticide residues, environmental contaminants and food additives. As a result, the way we eat has changed

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[5] M. T. Law, "The Origins of State Pure Food Regulation" (2003) *The Journal of Economic History*, Vol. 63, p.1105.

[6] Throughout this thesis, the terms 'food safety regulation', 'food law', 'food regulation' and 'sanitary measures' will be used interchangeably. Depending on the precise context in which it is used, the use of one or other of the terms is more appropriate. Later in this thesis, when the analysis moves mainly to the *Beef Hormones Dispute*, the term sanitary measures will be used more frequently as it is the more accurate description in that arena.

[7] Food safety regulations can be described as mandatory controls designed to govern the quality attributes of a final product in order to minimise the potential detrimental effect on human health by food handling, preparation, or consumption. See, N. H. Hooker, "Food safety regulation and trade in food products" (1999) *Food Policy*, Vol. 24, Issue 6, p. 653.

[8] C. Counihan & P. Van Esterick, *Food and Culture: A Reader* (New York & London: Routledge, 1997), p.12.

more in the last eighty years than it did in the previous ten thousand years. Our diet is now determined for us by a complex interplay of social, economic and technological forces.[9]

Due to globalisation and the complexities inherent in modern production methods and food supply chains, information asymmetries have emerged that have increased the consumer's sense of uncertainty regarding food safety. Modern developments in the food supply including technological and other kinds of change influence the way people look at the world, including the legal world, and this affects the level of demands people make on a legal system.[10] Through globalisation and trade liberalisation, when foreign produce is imported into their territory, EU citizens are subjected to food practices that are alien to their food culture. Indeed, domestic regulation becomes less effective as it is less able to govern the policies of foreign producers.[11] EU citizens cannot feel confident towards the provenance of the food that they eat especially when that food has been imported from countries (such as the US) that possess a divergent food culture. The more ardent critics argue that globalisation has separated food from culture, commoditised it as an input for urban diets while at the same time residualising rural society for the provision of labour and natural resources for industrial society.[12]

When it comes to the food itself, now more than ever before, consumers are also concerned with the ethical values of their food. The food should be produced and processed with respect for the environment and for the welfare of the food producing animal. People are concerned about the environmental footprint that the agrifood industry leaves.[13] As a result sustainable methods of food production are more important than ever.[14]

Consumer anxiety has also been heightened by recent well publicised health scares. These have elevated the importance of food safety in the minds of consumers. The food chain has withstood attack from various sources including, bovine spongiform encephalopathy (BSE)

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[9] E. Schlosser, *Fast Food Nation* (New York: Penguin Books, 2002), p.3.
[10] L. M. Friedman, "Total Justice: Law, Culture, and Society" (1986) *Bulletin of the American Academy of Arts and Sciences*, Vol. 40, No. 3, p. 28.
[11] F. van Warden, "Taste, Traditions, Transactions, and Trust: The Public and Private Regulation of Food" in C. Ansell & D. Vogel (eds), *What's the Beef? The Contested Governance of European Food Safety* (Massachusetts: The MIT Press, 2006), p.37.
[12] P. McMichael, "The Impact of Globalisation, Free Trade and Technology on Food and Nutrition in the New Millennium", (2001) *Proceedings of the Nutrition Society*, Vol.60, Issue 2, p. 215.
[13] Agrifood encompasses food production activities on farms and the processing of those products into added value food items.
[14] D. Holland & H. Pope, *EU Food Law & Policy* (The Hague: Kluwer Law International, 2004), p.1.

in beef, foot-and-mouth disease, *e.coli* poisoning, avian influenza, and dioxin contamination. Therefore, the internationalisation of food combined with health concerns has undermined consumer confidence in food safety.

We have witnessed an increase in genuine public concern for the quality and safety of the food supply. Yet, consumers continue to expect the global food business to supply them with products that offer not just the requisite nutritional content, but that are also safe to eat. The innate food culture of a region and its people, combined with extrinsic factors such as the use of technology in the food supply, the effects of globalisation, and food health scares, all combine and crystallise to form a peoples' cultural bias towards food produce. This determines what a consumer is willing and unwilling to purchase. Cultural biases traverse the economic, kinship, political and legal domains of our lives and bind them to one another. As a result, culture lends us the capacity to create the categories of our own experience. To the members of any given culture, collective experience appears as not only logical, but immanent and natural.[15]

These cultural biases affect consumer concerns regarding food safety and their perceptions of the risk associated with any particular food. Some cultural biases take the form of an emotional attachment to a food tradition, such as the purchase of locally produced potatoes, the manufacture of raw-milk cheese, or the purity of beer. At the national level, some countries specialise in large scale mass production, while others specialise in high-quality niches. One industry may depend more on chemical additives, whereas the other may favour exclusive quality seals.[16]

Some food products are emblematic of national cultural identity. For example, if one considers the provisions legitimising the marketing of raw-milk cheeses on an EU-wide basis.[17] Unpasteurized milk, often called 'raw milk' is prized by many cheesemakers who claim that it adds a special richness of flavour. Some EU Member States refused to allow the sale of these cheeses in their country. France successfully fought against any EU requirement

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[15] L. Rosen, *Law as Culture: An Invitation* (Princeton NJ: Princeton University Press, 2006), p.4.
[16] van Warden, note 11 above, p.35.
[17] Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products, [1992] O.J. L 268/1, and Council Directive 92/47/EEC of 16 June 1992 on the conditions for granting temporary and limited derogations from specific Community health rules on the production and placing on the market of milk and milk-based products, [1992] O.J. L.268/33. Raw-milk cheeses are of course mostly produced by France.

for mandatory pasteurization of cheese or an equivalent sanitising measure. At the international level, since 1949, US law has banned the sale of cheese made from unpasteurized milk unless the cheese has been aged for at least 60 days.[18] S. 1240.61 Title 21 of the Code of Federal Regulations (CFR) provides for 'mandatory pasteurization for all milk and milk products in final package form intended for direct human consumption' and stipulates that no person shall cause to be delivered into interstate commerce, distribute or sell any milk or milk product for direct human consumption unless the product has been pasteurized.[19] There are some exceptions made under Part 133 Title 21 for the curing of certain cheese varieties. A number of EU cheeses are traditionally made with raw milk and are aged for less than 60 days. As a result, unpasteurized versions[20] of these products cannot be sold in the US.[21] The United States Food and Drug Administration (FDA) advises that it is 'unsafe to eat soft cheeses such as Brie and Camembert, and Mexican-style soft cheeses such as Queso Fresco, Panela, Asadero and Queso Blanco made from unpasteurized milk'.[22] It would be difficult to envisage the European Food Safety Authority (EFSA) opining in a similar manner. It is immediately apparent that a dramatic divergence in trans-Atlantic cultural bias towards this food product exists. Due to cultural biases, consumers and their food regulatory authorities differ in their sensitivity to certain food practices.

It is therefore only natural that based on the cultural biases extant in any region, a food regulatory system will be biased towards certain risks and downplaying others.[23] Cultural biases inform the food regulatory measures enacted. In Europe, the prevailing cultural bias is augmented by a political landscape where private individuals (organized via consumer groups) have more institutional access to, or a greater ability to influence the EU regulatory process. An organized consumer lobby can affect decisive political influence. It is public

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[18] It is believed that after 60 days, acids and salts in the cheese naturally prevent the development of pathogens such as listeria, salmonella, and e-coli.

[19] This does not prevent individual States from permitting the sale of raw-milk products within their state borders and indeed some states permit the sale of certain raw-milk products.

[20] e.g. most Brie or Camembert.

[21] The controversy that surrounded raw-milk cheese, provides a good illustration of disparities in food safety regulation. It also illustrates that food safety and cultural sovereignty are intertwined, both nationally between EU Member States and also internationally between the EU and the US. Furthermore, as will be outlined in greater detail later in this thesis, it elucidates the clash between small traditional producers and large science advocating corporate producers.

[22] See FDA 'The Dangers of Raw Milk: Unpasteurized Milk Can Pose a Serious Health Risk', Available at: http://www.fda.gov/Food/ResourcesForYou/consumers/ucm079516.htm [Accessed: 26 August, 2012]

[23] A. Wildavsky & M. Douglas, note 3 above, p. 194.

pressure made effective through the EU privilege of institutional access to the European Parliament.[24]

At the microeconomic level, internationally, cultural biases or preferences are affected by more insidious forces. In order to maintain or expand market-share, food companies are constantly finding new ways to influence what we eat. Their obvious methods are advertising and public relations. In countries with more industry-centred food sectors, food companies are able to exert more leverage influencing the political and administrative process. Some businesses aggressively strive to convince government officials, nutrition professionals and the media that certain of their products possess health enhancing powers or at least do no harm. As a result of these divergent influences on the political process, food safety standards develop differently.[25]

Therefore, due to our desire to protect our food, local influences based on cultural biases are always evident in food safety law. The legislation enacted is unique to the food culture extant in its jurisdiction. As a result, food safety legislation is likely to differ from country to country. This thesis terms these divergences in national and supranational[26] legislation which have been brought about by cultural influences as 'cultural regulatory divergences'.

It is in this manner that a nation's food culture is reflected in the essence of the food safety regulations enacted. Our culture influences everything that we do.[27] A cultural bias results from the national or regional authorities' preconceptions of the effect that certain food practices or technologies have on our health. Very often these are technologies that enhance produce yields – technologies that promise greater profits to the producer such as animal growth hormones, the use of pesticides and biotechnology. Unlike US consumers, EU consumers are considerably more alert to, and wary of the use of these modern technologies

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[24] However, in contrast, it is believed that in countries with more commercialised or industrialised food sectors, producers possess the ability to exert more influence on an economy's regulatory process than consumers, because industrial interests are more concentrated and easier to mobilise. See M. Olson, *The Logic of Collective Action: Public Goods and the Theory of Groups* (Cambridge, MA: Harvard University Press, 1971), p. 141.

[25] Indeed, when legislating to deal with these concerns, governments must take care not to stifle the creative expression achieved through food or to destroy the heritage of its citizens.

[26] In this thesis, rather than denoting a specific legal definition, the term 'supranational' is used loosely to describe a union of individual states/jurisdictions, where each state's political and legal system is somewhat autonomous from the federal government ; such as that found in the European Union, the United States, and the Australian States/Territories.

[27] A. K. Syn, "Human Rights and Asian Values: What Lee Kuan knew and Li Peng don't understand about Asia" (1997) *The New Republic*, Vol. 217, p. 33.

in food production. Many EU citizens are desirous of reassurance that some form of esoteric technology was not used as an aid to producing or indeed creating the food. On the one side the ardent advocates of biotechnology, who are predominantly located in the US, argue that food products created using these processes are good, wholesome to eat, and that we can all look forward to the benefits of productivity and a more certain food supply.[28] On the other side, frequent representations have been made in the media by consumer associations/interest groups in the EU, voicing their fears over the long term health and environmental effects of eating genetically modified foods or beef from animals raised on artificial growth hormones.

In order to meet these challenges and safeguard their agrifood sector, more and more countries are enacting domestic food safety laws and establishing food inspection and control agencies. These food safety laws are strongly influenced by the domestic collective cultural bias towards food. As a result, food security must be combined with the requisite element of national decision-making.[29] Food sovereignty emerges with an emphasis on the centrality of national decision-making in determining food and agricultural policy. It is a nationalistic strategy that places the responsibility for international trade with national governments rather than relinquishing that power to international or foreign bodies. However, national food sovereignty expressed in law and implemented by administrative means is the final element in the process which allows cultural biases to be expressed at the international level in the form of cultural regulatory divergences.

When an exporting nation interprets these cultural regulatory divergences as nothing more than non-tariff barriers to trade disguised as food safety measures, then trade disputes arise. To the individual producer/farmer in the US who uses modern food technologies, and to his country's government, it is all too difficult to differentiate these foreign consumer preferences from protectionism. Therefore, the contentious effect of culture, influencing measures regulating the production and sale of food, is more pronounced when it comes to global trade. The resultant domestic food safety regulations, influenced by cultural biases and attitudes such as public risk perception, can lead to international trade conflict when sovereign idiosyncrasies in the domestic regulations have the effect of acting as non-tariff

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[28] See generally, A. Alemanno, *Trade in Food: Regulatory and Judicial Approaches in the EC and the WTO*. (Cameron May, 2007), p. 221.

[29] See, G. Tansey & T. Rajotte (eds), *The Future Control of Food: A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security* (London: Earthscan, 2008), p. 177.

barriers to free trade.[30] By definition, cultural regulatory divergences are 'legitimate' food safety measures. In other words, they are not deliberately designed as an underhand mechanism for the imposition of barriers to trade. They represent measures which are motivated by a genuine domestic concern, whether real or perceived, regarding the deleterious effects on human health of some aspect of a food or food production process.

Therefore, this thesis contends that culture matters in the formulation and application of law. It is largely for this reason that cultural regulatory divergences can have the effect of impeding the adoption of a law or by default, cause a breach of the terms of a multinational agreement such as the SPS Agreement. As outlined in Chapter 3 of this thesis, it is not possible to fully understand the mechanism by which legal change happens without studying the cultural context in which legal reforms occur. The idea is that a regulation will be adopted into a legal system provided it conforms to the cultural environment characterizing that legal system.[31]

This thesis submits that because of the visceral nature of human attachment to the food supply, any law which has the effect of constraining the free hand of domestic food culture is likely to encounter opposition. A 'cultural-match' between the new legal norm being imposed and the domestic platform is an important factor in successfully affecting the transfer or implementation of a legal norm that is alien to the target society. Indeed, the same principle applies when domestic government enacts law. A new legal rule is likely to cause cultural resistance or be refused outright if the adoption of it would threaten the traditional values of society. Chapter 5 of this thesis deals with risk and it provides an outline of how public risk perception influences the way a legal system regulates given activities. Where a risk is seen as high, a new legal norm will be adopted enthusiastically provided the cultural-match is right with the regulatory solution offered.

Neither culture nor any other single factor can fully explain something as complex and multi-causal as legal change, and while the interaction of a number of forces are critical, it is evident that a cultural incentive is crucial for a successful transference of an extrinsic legal

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[30] Where the exporting party wants to either sell a technologically-advanced or novel food product in an economic area that is subject to different cultural norms and a different regulatory system.

[31] E.A. Feldman, "Culture of Legal Change: A Case Study of Tobacco Control in Twenty-First Century Japan" (2006) *Michigan Journal of International Law*, Vol.27, p.743.

norm to occur.[32] It is for this reason that it is contended that the findings contained in this thesis are applicable to not only international food safety law, but other aspects of international trade law.

The issue of cultural regulatory divergences give cause for analysis under several aspects of this thesis. Firstly, what is the degree of divergence, or alternatively cultural-match, between the EU food regulatory system and the US food regulatory system?; secondly, do domestic EU norms (and indeed those of the US) diverge from those instilled under the tenets of the SPS Agreement; thirdly, as a case study specific to identifying the importance of cultural-match in preventing trade disputes, was it the lack of a cultural-match between EU food culture and the consumption of beef treated with growth hormones that led to the *Beef Hormones Dispute*?[33]

Oftentimes at the international level, the existence of cultural considerations has not limited the appeal of science as a resource for risk decision making where international institutions employing global regulatory constructs seek the acceptance of their determinations as neutral and universally valid.[34] However, this thesis argues that an over-reliance on science as a basis for legal reasoning will divest a legal system of other attributes. In other words, an over-reliance on science means that there is no capacity to accommodate cultural regulatory divergences. This is because it is not uncommon for those involved in a given legal system to act as if 'the law' is quite separable from other elements of cultural life. However, context is crucial. For example, when we hear a court speak of 'the conscience of the community' or 'the reasonable man', we realise that the definition of these terms are likely to vary from one society to another. Therefore, law is a cultural domain. In order to understand a culture, one cannot fail to consider law, and to consider law one cannot fail to see it as part of culture.[35]

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[32] *Ibid*, p.749.

[33] There were two stages to the *Beef Hormones Dispute* when it came before the WTO Dispute Settlement Body: *EC Measures Concerning Meat and Meat Products ('EC-Hormones')* WT/DS26, and *United States – Continued Suspension of Obligations in the EC – Hormones Dispute ('US-Continued Suspension')* WT/DS320. The *Beef Hormones Dispute* arose when the US opposed the EU ban on the importation of meat from animals treated with growth hormones and took the dispute to the WTO. The *Beef Hormones Dispute* is examined in detail later in this thesis.

[34] V. Walker, "The Myth of Science as a 'Neutral Arbiter' for Triggering Precautions", *Boston College International & Comparative Law Review* 26 (2003) p. 197-8.

[35] L. Rosen, note 15 above, p.5.

Therefore, unless the existing international food regulatory framework makes allowance for cultural regulatory divergences, this thesis argues that it can never successfully achieve its primary goal of facilitating free trade, while at the same time promoting international harmonisation of food standards and thereby minimising the incidence of trade-disputes. These goals are likely to remain conflicted while disputed cultural regulatory divergences exist between trading nations. This thesis argues that the existence of culture as a factor means that science alone would rarely be sufficient as a basis for credible and legitimate food risk decision-making under international law.

The references in this thesis to science, especially in Chapter 4, refer to both science in the form of food technology, and also science as the basis for food safety risk analysis dictating the nature of the food regulatory measures enacted. In the context of science as food technology, a close alignment between science and the commercial side of the food industry is noticeable. In particular, the more industrialised food sectors extol the virtues of science because it is due to the technical sophistication of their food production methods that they have succeeded. Large food companies are synonymous with the application of science in food as it through advances in food processing techniques that they compete with their rivals and increase profitability. They often see cultural considerations as something that can only restrain their capitalist agenda. Therefore, in effect, culture interacts with science on two separate but interconnected fronts – (a) science based food safety risk analysis; and (b) science in the form of food technology/commerce.

In addition to the overall analysis contained in this thesis, a specific analysis of the *Beef Hormones Dispute* is used in order to investigate and exemplify the validity of these arguments. Throughout the 1980s and 1990s, the EU promulgated a number of provisions that banned the use of animal growth hormones in beef production throughout the EU. As of March 1988, the use of all growth hormones for cattle fattening purposes had been banned in the EU. In particular, this included a ban on the importation into the EU of meat or live cattle, treated with animal growth hormones. The ban is still in place. In stark contrast to the EU ban, animal growth hormones are used extensively in beef production in the US and have been approved for use there since the 1950s.

The analysis contained in this thesis of the *Beef Hormones Dispute* provides a window through which we can view in action, a World Trade Organisation (WTO) framework

designed to promote international free trade while also arbitrating on the legitimacy of national food safety concerns. The *Beef Hormones Dispute* was the first ruling to interpret the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).[36] WTO Members such as the EU and the US must show compliance with the SPS Agreement. The investigation of the *Beef Hormones Dispute* contained in this thesis analyses the application of the SPS Agreement to domestic measures and laws, thereby potentially allowing an identification of why it is important to acknowledge and accommodate cultural regulatory divergences in international trade law.

1.2 Comparative Analysis: EU and US Food Safety Regimes

This thesis utilises the concept of comparative legal methodology in examining the sanitary food safety regimes extant in the EU and in the US. The comparative overview of sanitary measures in these jurisdictions will be central to the analysis. This comparative overview will not be so much of a once-off endeavour as it will be sporadic, because referral to these differences will be required from time to time throughout the analysis in this thesis. At first sight, in the food production context there seem to be many similarities between these two food producing giants. The reasons for choosing the EU and the US for the comparative analysis is because these two regions are the world's largest and most sophisticated food producers. They both possess highly developed food safety systems. In addition, the *Beef Hormones Dispute* arose between the EU and the US. They are both WTO Members. One of the central objectives of this thesis is to exemplify and then reach an understanding of cultural regulatory divergences as they exist between the EU and the US. For the purposes of this thesis it is not necessary to include a substantive analysis of the food safety systems operating in other global regions. However, based on the analysis contained in this thesis, if cultural regulatory divergences exist between the EU and the US, it is reasonable to assume they also exist between other trading nations.

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[36] Agreement on the Application of Sanitary and Phytosanitary Measures (1867 United Nations Treaty Series 493). 'Sanitary' measures or regulations are measures that restrict or prohibit the importation and marketing of certain animals or animal meat or other products manufactured from those animals, in order to prevent a potential danger to human health. 'Phytosanitary' regulations operate on the same basis in relation to certain plant species, or food products manufactured with those plants, so as to prevent contamination or danger to human health by any plant pests or pathogens that the plants may be carrying.

However, on occasion it may be necessary to refer briefly to other jurisdictions in order to fully understand the global nature of this sector and its connectivity worldwide. There will be an investigation of WTO governance of the food trade with particular emphasis on the SPS Agreement, in order to identify the areas of convergence and divergence between the domestic and global constructs. Indeed, it has been posited that one can no longer disregard the doctrinal developments of the WTO in this area, even if one's primary interest rests with EU developments in the equivalent context.[37]

The importance of the cultural analysis within this comparative law study cannot be over-emphasised. This examination of not only the rules but also the legal system and culture of each jurisdiction will provide an insight into the main global spheres of decision and influence in food. It will exemplify the main differences between the food regulatory systems and the philosophical and political motivation behind law-making in this area.

1.3 Research Question: Objectives and Aim

Firstly, this thesis endeavours to discover if cultural regulatory divergences exist between the EU and US food regulatory constructs and the reasons underlying the manifestation of those divergences. This investigation is undertaken predominantly through the aforementioned comparative element of this thesis. It is submitted that this study provides a more comprehensive comparative study of this aspect of the two food safety regimes than the current academic writings have provided. The overall objective of the study is to identify whether the absence of recognition between states of the legitimate role played by cultural biases in creating cultural regulatory divergences, gives rise to inherent difficulties in the application of aspects of international trade law. This thesis does this by analysing the application of the SPS Agreement to domestic measures and laws. To aid the analysis, this thesis examines in particular, the way in which divergences of opinion over the use of hormones in beef production created a series of trade difficulties at the international level.

The analysis contained in this thesis enables an understanding of how this failure to accept cultural regulatory divergences as legitimate sanitary measures, means that certain

[37] J. H. H. Weiller, *The EU, the WTO, and the NAFTA : towards a common law of international trade* , (Oxford: OUP, 2000) , p.3

international trade disputes cannot be resolved satisfactorily under the existing WTO dispute resolution construct.[38] It is contended that there is at present an over emphasis on scientific considerations and that this will only lead to continued recourse to dispute resolution mechanisms. Therefore, the aim of this thesis is to discover a means of improving the efficacy of the international dispute resolution framework. It is suggested that this can be achieved through greater deference to the cultural dimension of the disputed measures. In this context, the investigation highlights a need for increased recognition of consumer based and cultural considerations in the drafting and application of these international laws. Consequently, in addition to some practical suggestions for dispute resolution, the final chapters of this thesis provide some invaluable recommendations addressing how best to accommodate these cultural considerations under the existing WTO Agreements.

1.3.1 Thesis: Methodology, Structure and Contribution to Scholarship.

The following section of this thesis outlines the approach taken to the research and the pertinent issues which have been analysed in order to answer the research question. There are several types of legal research: explanatory (explaining the law by examining the historical backgrounds in the comparative research element), empirical (identification of the valid law; determining the best legal means for reaching a certain goal – the 'best solution' in comparative law), hermeneutic (interpretation, argumentation), exploring (searching for new or possibly fruitful paths in legal research), logical (structuring concepts, rules, principles, etc), instrumental (concept-building), and evaluative (testing the applicability of the rules in practice or if they operate in accordance with the goals intended – moral, political or economic aims, or in comparative law, whether a certain harmonisation proposal could work, taking into account other important divergences in the legal system concerned).[39]

The earlier Chapters of this thesis are comprised of mainly explanatory and empirical research in order to proffer an understanding of all the forces at play. The thesis then concentrates on hermeneutical and evaluative research, especially with the Chapter analysing

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[38] 'Sanitary' measures or regulations are measures that restrict or prohibit the importation and marketing of certain animals or animal meat or other products manufactured from those animals, in order to prevent a potential danger to human health.

[39] M. V. Hoecke (ed), *Methodologies of Legal Research: Which Kind of Method for What Kind of Discipline?* (Oxford: Hart Publishing, 2011), p.v.

the *Beef Hormones Dispute*. The evaluative aspect of the research also examines the political genesis of considering 'other factors' in risk analysis under the SPS Agreement. The main structure of the thesis involves interpreting the relevant food law regulatory frameworks, both within the EU and the US, and also internationally through Codex[40] and the WTO. Arguments are then provided to sustain that interpretation through an analysis of the text, theories, and any relevant cases.

The research in this thesis was conducted as follows: firstly, the research begins by identifying the legal issues and problems. Secondly, following the establishment of the legal issues, various sources (primary and secondary) are collated and consulted. The primary sources used consist mainly of information gleaned from academic articles, legislation, relevant case law, the text of various regulatory documents such as the SPS Agreement and related WTO documents, the text of Codex standards and ancillary Codex Reports, and WTO Panel/Appellate Body Reports in the *Beef Hormones Dispute*. Secondary sources include, for example, text books, edited collections, conference papers, unpublished seminar papers and unpublished research papers. Thirdly, after the collection of all relevant information sources, those sources were assessed through interpretation and analysis. The research conducted in this thesis employs a normative (literature/text analysis) method. Field studies and the like are not appropriate.

This thesis looks at the issue of culture (as defined in this thesis) as it relates to food and the ramifications of its accommodation if any in the sanitary food safety regulations enacted. It involves an analysis of the EU and US food safety regimes, highlighting the divergences between them. In addition, there is a consideration of culture, science and risk insofar as they pertain to food. As a next logical step, the thesis undertakes an examination of the SPS Agreement. The thesis draws all the lessons gleaned from these analyses together in order to round-off the evaluation with an in-depth analysis of how the WTO Panel/Appellate Body interpreted the SPS Agreement during the *Beef Hormones Dispute*, in order to see if and how the influence of cultural biases in the domestic food safety regulations were dealt with. The conclusion reached should elucidate whether or not cultural regulatory divergences were primarily the cause of the *Beef Hormones Dispute* and if the SPS Agreement as it currently

[40] The Codex Alimentarius is a set of internationally recognized standards, codes of practice, guidelines and other recommendations relating to foods, food production and food safety. These Codex standards are of strong persuasive value in many food related legal disputes as they are considered to be a point of reference in the case of trade disputes between WTO Members. They also play a role in the SPS Agreement.

stands is adequate to test the legitimacy of sanitary measures and satisfactorily resolve issues. The findings should be invaluable for other aspects of international trade law. This is the core area of the study contained in this thesis. In order to ensure that one does not stray from this central theme, a number of limitations regarding the areas of examination are in place. In this regard, there is little or no discussion of the cultural regulatory divergences extant between EU Member States because the focus of the thesis relates to how cultural biases give rise to difficulties in free trade at the global level. Moreover, the thesis elaborates on the issues under legal perspective. Other dimensions, such as economic, political, social, and ethical dimensions, are utilised only as cursory supporting information and are not discussed intensively.

Many of the factors involved are inter-related and as such it is not always possible to differentiate between the roles played by science or culture without providing additional reference to some of the same issues, albeit in a new context. The precautionary principle is a good example of this as it permeates many areas for consideration in this thesis and therefore arises time and time again. At times, it may seem that there is an overly close association between some of the central themes of this thesis, especially between culture, science and risk – that they are disparate terms describing one and the same whole. However, as the thesis progresses it will become evident that there is good reason for adopting this approach and the resultant differentiation involved. In addition, this thesis does not purport to address every aspect of culture and science in food safety regulation – merely, those issues which are necessary to allow an adequate analysis of the issues under investigation so as to inform substantive conclusions.

1.3.2 Thesis Structure

This thesis is divided into nine chapters as follows:

Chapter 1 is purely introductory. Chapter 1 has the objective of defining the concept of culture as a force at work in the context of food safety law. The Chapter introduces how cultural influences affect people's attitudes and behaviours towards the food supply. This then affects the nature of the food safety measures enacted. Because the measures enacted differ substantively from similar measures in other trading nations, then should the measures

have the effect of preventing or curtailing the importation of certain produce, a trade dispute is likely to arise. The Chapter also introduces the fact that science plays a role in international food safety regulation.

Chapter 2 provides an overall understanding of the basic structure underpinning food safety regulation both domestically within the EU and in the US, and also internationally by reference to the WTO and Codex constructs. This Chapter confirms some of the major differences between the EU and US food regulatory systems. Highlighting these divergences is important to understanding the existence of cultural regulatory divergences. By providing an introduction to the SPS Agreement, the Codex Alimentarius, and animal growth hormones, this Chapter affords the necessary basic understanding before the more in-depth investigation of these issues in subsequent chapters. By providing an introduction to all of main issues involved in this thesis, this Chapter enables the reader to readily assimilate the analysis provided in the subsequent chapters.

Chapter 3 analyses the place of culture in food safety regulation. An examination of the role of culture is central to the investigation in this thesis. Chapter 3 analyses the effect that industrialisation of the agrifood sector has had on cultural considerations. The Chapter analyses the accommodation of 'tradition' in the food supply and also the administrative culture that exists between EU and US food safety regulation. The different cultures of big business and corporate lobbying are also examined along with an introduction to the cultural background underpinning trade disputes. This Chapter uncovers the nature of and the cultural reasons behind food regulatory divergences as they exist between the EU and the US.

Chapter 4 performs a similar analysis of science to that covering culture contained in Chapter 3. Some would view cultural considerations as anathema to scientific reasoning and as a result the concept of science based risk regulation is introduced. It examines science in EU food safety law and provides an examination of the precautionary principle pertinent to this thesis. A similar analysis in provided in the context of US sanitary food safety law. This chapter emphasises the importance attaching to science based risk regulation in the US and the resultant interaction with cultural considerations. The Chapter examines the role of science in the global food regulatory construct, especially in the SPS Agreement. More particularly, it analyses the interplay between culture and science at Codex in the context of

growth hormones. This also enables a consideration of 'other legitimate factors' under Codex and issues concerning the safety of growth hormones.

Chapter 5 introduces the concept of risk as inherent in food safety analysis. If food did not possess the capacity to pose a risk to human health, then food safety regulation would be largely unnecessary. The human perception of risk associated with food is a core causative factor in the creation of cultural regulatory divergences. It is argued that EU citizens and Americans have differing perceptions of risk which align with each society's prevailing cultural norms regarding food safety. This examination of public risk perception is a logical next step in the investigation contained in this thesis. It provides the raison d'être for the roles played by culture and science in food safety regulation. Consumers perceive the risk associated with any particular food through their own cultural model. The relationship between risk and the SPS Agreement is analysed. The Chapter analyses how divergences in risk perception can play a role in trade disputes and the importance of risk communication, especially in light of adopting a precautionary approach to assuage consumer concern.

Chapter 6 identifies the manner in which scientific risk analysis is incorporated into the SPS Agreement. It provides the first in-depth analysis of the provisions of the SPS Agreement relevant to the objective of this thesis. It allows an understanding of how this area of international trade law is governed. This raises issues regarding the credibility of the WTO dispute mechanism and identifies certain potential shortcomings with the SPS Agreement. Is there scope to include a greater recognition of public risk perception or other cultural considerations within the SPS Agreement?

Chapter 7 identifies and then provides an investigation of the nature of growth hormones and also the specific legislation governing them enacted in the EU and in the US. There is an outline of the main studies on animal growth hormones concerning the potential deleterious effects or otherwise on human health. A commentary on the likely consequences of the two radically divergent approaches taken by the EU and the US is also provided. This aptly provides the foundation to the in-depth analysis of the *Beef Hormones Dispute* contained in the subsequent Chapter.

Chapter 8 draws on many of the lessons learned from the preceding Chapters in order to enable a potentially ground-breaking analysis of the *Beef Hormones Dispute*. The Chapter

begins with an outline of how the *Dispute* arose and the events (especially in the EU) leading up to it. The Chapter then moves on to analysing the Dispute when it was brought before the WTO Dispute Settlement Body. The most informative part of the analysis is the consideration of the various WTO Panel and Appellate Body Reports. In particular, this allows an investigation of the SPS Agreement in operation. Important conclusions are drawn regarding the SPS Agreement but more particularly the roles played by science and culture in international trade law. Can it be said that a cultural regulatory divergence was primarily the cause of the *Beef Hormones Dispute* and is the SPS Agreement as it currently stands adequate to test the legitimacy of sanitary measures and satisfactorily resolve issues for the disputing parties?

Chapter 9 concludes with a round-up of the main findings made in this thesis. This Chapter summarises the main problems and arguments of the thesis, as well as enumerating the outcomes reached. Drawing mainly on the comparative law study of the EU and US sanitary food safety regimes contained in this thesis and the analysis of the *Beef Hormones Dispute* contained in Chapter 8, the final chapter provides some conclusions on the interaction between culture, science, and food law, along with various recommendations.

In conclusion, as outlined above, the research question in this thesis endeavours to identify whether the absence of recognition between states of the legitimate role played by cultural biases in creating cultural regulatory divergences, gives rise to inherent difficulties in the application of aspects of international trade law. This thesis does this by analysing the application of the SPS Agreement to domestic measures and laws. To aid the analysis, this thesis examines in particular, the way in which divergences of opinion over the use of hormones in beef production created a series of trade difficulties at the international level. This is the main contribution of this thesis to scholarship.

It is intended that the analysis contained in this thesis will enable an understanding of how failure to accept the validity of the role played by cultural influences in informing the formulation of sanitary measures, means that certain international trade disputes cannot be resolved satisfactorily under the existing WTO dispute resolution construct.[41] The aim of this

[41] 'Sanitary' measures or regulations are measures that restrict or prohibit the importation and marketing of certain animals or animal meat or other products manufactured from those animals, in order to prevent a potential danger to human health.

thesis is to discover a means of improving the efficacy of the existing international sanitary measure dispute resolution framework. It is posited that this improvement could be achieved by the granting of increased recognition to consumer based and cultural considerations in the drafting and application of such international laws. It is contended that there is at present an over emphasis on scientific considerations and that this will only lead to continued recourse to dispute resolution mechanisms.

CHAPTER 2

FOOD LAW IN THE INTERNATIONAL CONTEXT

2.1 Introduction

The *Beef Hormones Dispute* arose in the 1990s, in the midst of the mad cow disease crisis in Europe.[1] The Dispute began when the EU banned the importation of meat from animals which had been given growth hormones.[2] WTO Members such as the EU and the US must show compliance with the SPS Agreement. Article 2.1 of the SPS Agreement effectively permits such bans, but only where the WTO Member presents evidence proving that the ban is a valid health and safety measure under the terms of the SPS Agreement. The US and Canada opposed the EU ban and took the EU to the WTO Dispute Settlement Body (DSB).[3] The *Beef Hormones Dispute* is not merely a dispute concerning the risk posed to human health by the use of growth hormones in beef production. It represents the inherent difficulties that exist within a much broader issue – the interaction between science[4] and culture in food regulation. The *Beef Hormones Dispute* provides a window through which we can view the international WTO framework in action.

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[1] There were two stages to the *Beef Hormones Dispute* when it came before the WTO Dispute Settlement Body: *EC Measures Concerning Meat and Meat Products ('EC-Hormones')* WT/DS26, and *United States – Continued Suspension of Obligations in the EC – Hormones Dispute ('US-Continued Suspension')* WT/DS320. The *Beef Hormones Dispute* also set the stage for the debate between the EU and US over trade in GMOs. See, C. Carlane, "From the USA with Love: Sharing Home Grown Hormones, GMOs and Clones with a Reluctant Europe", (2007) *Environmental Law*, Vol. 37, No.2, p.308.

[2] Council Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action, [1981] O.J. L222/32; Council Directive 88/146/EEC prohibiting the use in livestock farming of certain substances having a hormonal action, [1988] O.J. L70/16; Council Directive 88/299/EEC on trade in animals treated with certain substances having a hormonal action and their meat, as referred to in Article 7 of Directive 88/146/EEC, [1988] O.J. L128/36; Council Directive 96/22/EC concerning the prohibition on the use in stock-farming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC, [1996] O.J. L 125/03.

[3] The Dispute Settlement Body (which is effectively the WTO General Council in another guise) consists of all WTO members and they appoint a Panel of experts to arbitrate on the matter.

[4] In this context, science also operates in varying guises, especially food technology. This thesis submits that science is more closely associated with commerce as it plays an intrinsic role in the industrialisation of food and the intensification of food production, whereas culture is more closely related to tradition in food.

The investigation of the substantive food law contained in this Chapter will enable the application of a comparative legal methodology approach to investigating the main differences between the EU and the US food regulatory systems and the philosophical and political motivation behind them. This Chapter will also provide an understanding of the WTO global food regulatory construct. The continued utilisation of comparative legal methodology will facilitate an identification of the main areas of convergence and divergence between the EU and the US food regulatory constructs. As posited in the previous Chapter, one of the contentions made in this thesis is that internationally divergences will always exist between food regulatory regimes and that cultural influences play a crucial role in this disparity. The knowledge gleaned from the analysis in this Chapter will be applied occasionally throughout this thesis.

In any attempt to successfully prove the hypotheses that cultural regulatory divergences exist but are not adequately acknowledged by the SPS Agreement, and to understand how the SPS Agreement deals with the legitimacy or otherwise of domestic sanitary measures, it is necessary to examine ostensibly similar food regulatory regimes, yet evidencing ideological differences in food production methods and ideally where trade-conflict has arisen. In pursuit of this objective the food regulatory regimes of the EU and the US have been chosen for the following reasons:

(i) both the EU and the US possess complex agrifood sectors which are of paramount importance to their respective economies;

(ii) both the EU and the US have modern food regulatory regimes comprised of domestic stringent food safety laws bolstered by food inspection/control agencies;

(iii) as a society, the US endorses the use of science and technology in all industrial areas including the food sector. Alternatively, the EU is more closely associated with tradition when it comes to food manufacturing and indeed there has been resistance to some of the latest food technologies most notably GMOs;

(iv) the US is a multicultural federalised society where, when it comes to the agrifood sector, the same ancient cultural links and traditions as those found in Europe do not exist to the same extent. In contrast, the EU is comprised of individual nations, each possessing its own more uniform agrifood tradition;

(v) the US was the main actor, politically, behind the creation of the Codex Alimentarius and the WTO/SPS Agreement. The US continues to be one of most important players in that arena along with the EU;

(vi) the *Beef Hormones Dispute*, in a broader context, represents the interaction between science and culture and the interaction between the EU and the US food regulatory regimes. The *Beef Hormones Dispute* arose between the EU, and the US/Canada. This was the first WTO ruling to interpret the SPS Agreement. The ruling provides a window through which we can examine the WTO framework in action; and

(vii) despite trade-conflict, it is in the interests of both the EU and the US to continue to encourage international trade liberalisation through harmonisation of international food standards.

Therefore, the comparative overview of food law in these jurisdictions will be central to the analysis contained in this thesis. This examination of not only the rules but also the legal system and culture of each jurisdiction will provide an insight into the spheres of decision and influence in their food regulatory systems. It will exemplify the main differences between the various food regulatory systems and the philosophical and political motivation behind law-making in this area. On occasion, it may be necessary to extend the commentary beyond these main players in order to fully understand the global nature of this sector and its connectivity worldwide. The overview will exemplify the conflicts and limitations between the regimes.[5] It will also identify the areas of convergence and divergence between the domestic and global food regulatory constructs. The knowledge gleaned from the analysis will then be applied in identifying the merits and shortcomings of each system so as to reach a conclusion regarding which is the more desirable regulatory regime to inform a model law of international food regulation, or whether a 'third way' is now required.

This comparative element of the thesis will also elucidate the delicate balance that exists between: (a) the preservation of individual consumer preferences through national or regional food regulatory autonomy, and (b) the promotion of global economic integration in the food sector. It is posited that this in turn will confirm the fact that domestic regulations are influenced by local culture and attitudes which can lead to international trade conflict.

[5] For example, the regulation of the production and marketing of genetically modified organisms (GMOs) has been the subject of controversy in many countries.

Indeed, while in pursuit of further trade liberalisation, WTO Members have sometimes failed in global trade talks because the proposed trade liberalisation[6] touched upon fundamental societal values enshrined in longstanding and robust domestic regulations.[7] Any such attempts at remodelling a part of a nation's cultural fabric can be highly controversial.

The comparative analysis will be supported by the examination of the *Beef Hormones Dispute*. This will exemplify the nature of a trade dispute between economic regions where, as this thesis argues, the regulations in question have been heavily influenced by consumer ideas about what is safe to eat. While a number of trade problems were resolved at the bilateral level, without recourse to the WTO Dispute Settlement Body, the same cannot be said of the *Beef Hormones Dispute*.[8]

2.1.1 Defining Food

Although it may at first seem puerile, as a starting point of any analysis of the relationship between culture and food, it is important to establish a definition of food. A proper understanding of this is vital to the analysis presented in this thesis. Food is at once both a cultural and a social concept. It is the social and cultural milieu of the potential consumer that dictates what it is that constitutes food.[9] There are many cooking shows on television and many books about food have become bestsellers. In one way or another, food is often used as an anchor in the sale of other non-food items. The study of food is now at the centre of intellectual discourse. In the historical context, anthropology always regarded food as not just a subject of enquiry in its own right but a medium that illuminated a wide range of other cultural practices. However, nowadays food studies are a recognised sub-discipline of sociology, history, medicine and business.

Food often plays a central role in social and familial bonding, in defining social status, and in religion. By eating together the family unit is strengthened. Food can be offered as a symbol

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[6] On occasion, where disputes have arisen and were brought under the SPS Agreement, mutually agreed solutions have been reached. For example, in *Australia-Quarantine Regime for Imports* WT/DS287: (Request for Consultations dated 9 April 2003) a solution was agreed whereby Australia would enhance transparency of its quarantine regime and instigate new principles of treatment for market access applications from the EU.

[7] T. Bernauer, "Protecting Consumers in an Open World Economy" in "Debate: Consumer Protection in a Global Market" (2000) *Swiss Political Science Review*, Vol.6, Issue No.2, p.79.

[8] On occasion, Members have reached a mutually agreed solution after the Request for Consultations, and before the Panel's deliberations. For example, see *Korea — Measures Affecting the Importation of Bovine Meat and Meat Products from Canada* WT/DS391/9, mutually agreed solution of 19th June, 2012.

[9] P. Belton & T. Belton (eds), *Food, Science and Society* (Heidelberg: Springer-Verlag, 2003), p.1.

of friendship and many social gatherings have food as their centrepiece. We also offer food as a gesture of hospitality. Food can be a means of defining social status and prestige based on the quality and type of food offered. It defines the wealth and good taste of the host. Food has a role in almost all religious rites. Various religions proscribe certain foods or lay down stipulations for the quantity and manner in which they are consumed. In the Christian church, it is the sacramental value and symbolism of food that is paramount. Religious, social and cultural food taboos abound. For example, the banning of the consumption of pork on religious grounds or the fact that in some cultures the consumption of horse and dog meat is regarded as socially unacceptable.

Any definition of food or a specific food product will usually involve reference to two components – matter and human motivation. Examination of the composition of food involves physical and biological science. Examination of the human motivation aspect involves psychology, sociology and cultural studies. This thesis suggests that it is for this reason that there is always a need to take account of non-scientific factors. This thesis argues that, based merely on the one dimensional perspective of food science alone, it would be foolhardy to attempt to persuade consumers that they should behave is a specific manner towards a particular food item.

The main reason food is ingested by the human organism is to satisfy man's physiological or nutritional needs. In addition, quite apart from purposes of nutrition, it may be ingested purely for the pleasure of taste – for 'organoleptic' purposes. Food may also be ingested for therapeutic reasons – i.e. 'pharmaceuticals' or 'medicines'. Of course, other substances are added to nutritious food for organoleptic or therapeutic purposes. Therefore, the boundaries are sometimes blurred between certain product categories. Some medicines may contain a food value. Conversely, for example dietary or dietetic foods, are foods that may have been modified in order to function in a more medicinal capacity. There may be ambiguities between the definitions of food used in the world of food science or nutrition and that used in legislation. Therefore, food law can on occasion govern products or substances which might not be considered 'food' when based on objective criteria. Alternatively, there may be a deliberate exclusion from the particular law of certain food substances which the legislator may choose to deal with under a different sphere of law.

In order to fully understand the interaction between food and science it is useful to consider some additional definitions. For example, 'food science' can be described as the discipline which uses engineering, biological, and physical science methods to study the nature of food, the causes of deterioration, the principles underlying food processing and the improvement of food.[10] The relationship between food and science also comes in another guise – 'food technology'. Food technology can be described as the application of food science to the selection, preservation, modification, processing, packaging and distribution of food produce.[11] Most food technologies are used for purposes which are obviously beneficial, but some are more novel in nature and despite the application of the best available science, the potential risks (to human health) associated with their use are not fully known.

2.1.2 Origins of Organised Food Safety Regulation

Since the dawn of evolution, food has been the driving force behind human existence. The question of when the original hunter-gatherers settled down to develop agriculture remains an issue of scholarly debate. What we do know is that rules governing behaviour and expectations towards what little food supply there was were developed with the advent of stable societies and organized agriculture. This earliest manifestation of food law and policy is likely to have been no more than a simple code of communal practice and understanding towards food.

Evidence from early historical writing indicates that people were already concerned with proscribing dishonest practices in the sale of food in order to protect the consumer.[12] Ancient Assyrian tablets have been discovered which outlined the correct weights and measures for grains, Egyptian scrolls prescribed labelling for certain foods, the Athenians had a system in place whereby they inspected beer and wine for purity and soundness, and the Romans operated a food control system to protect certain of their citizens from fraud or bad produce.[13] Many such primal systems of food regulation, designed to protect the public from unscrupulous producers, operated down through the ages.

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[10] G. Campbell-Platt (ed), *Food-Science and Technology* (Oxford: Wiley-Blackwell, 2009), p.1.
[11] *Ibid*, p.1.
[12] See FAO and WHO, "Origins of the Codex Alimentarius" in *Understanding the Codex Alimentarius* (Rome: Food & Agriculture Org, 1999), ISBN 92-5-104248-9.
[13] *Ibid.*

In 1516, the famous Bavarian beer purity order - the 'Reinheitsgebot'[14] - was adopted by the Bavarian Assembly of Estates.[15] It provided that the only ingredients that could be used in the production of beer were water, barley, and hops. Early English food laws offer a good example of how consumer and political concern was transformed into legislation. In England the early food laws related to the efforts of the medieval guilds seeking to maintain the purity of the commodities manufactured by their members. In or around 1202, King John of England issued an edict fixing the price of bread and in 1266 under Henry III this edict became what was probably the first official English food law - the Assize of Bread and Ale.[16] The Assize was augmented by the Statute Concerning Bakers 1285.[17] The fundamental tenet of this law was a prohibition on the adulteration of bread with ingredients such as ground peas or beans. In the eighteen century, the first sophisticated food laws were enacted. These included the Adulteration of Tea and Coffee Act 1724, the Adulteration of Tea Act 1730 and the Adulteration of Tea Act 1776, the Bread Acts 1882 and 1836, the Corn, Peas, Beans or Parsnips and Cocoa Act 1822, the British Foods Adulteration Act of 1860, the Adulteration of Food Act 1872, and the Sale of Food and Drugs Act 1875.[18] The main provision of the 1875 Act was that nothing 'injurious' might be added to food, and that the food product must be of the nature, substance, and quality demanded by the purchaser.[19] These Acts provided for the appointment of Public Analysts who examined food samples for any adulterations. The 1875 Act remained as the basis of British Food Law until 1955.[20]

Between 1897 and 1911, the Austro-Hungarian Empire developed a sophisticated set of standards and product descriptions for foods, known as the Codex Alimentarius Austriacus. Although it did not form part of the substantive law in the Empire, it was used as a reference by the courts when dealing with disputes over food standards. It was this Alimentarius

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[14] It was only recently, in 1993, that this law was superseded by the Vorläufiges Biergesetz or Provisional Beer Law.

[15] H. Dornbusch, *Bavarian Lager: Beerhall Helles History, Brewing Techniques, Recipes* (Colorado: Brewers Publications, 2000), p.6

[16] 51 Hen. 3, Stat. I.

[17] 51 Hen. 3, Stat.III. See also C. Walford, "Early Laws and Customs in Great Britain regarding Food" (1880) *Transactions of the Royal Historical Society*, Issue 8, p.83. The Statute Concerning Bakers 1285 proclaimed, "here begineth the rule for punishing the infringers of the assise of bread and ale, forestallers, cooks, & c."

[18] See generally B. Levenson, *Habeas Codfish – Reflections on Food and the Law* (Wisconsin: University of Wisconsin Press, 2001), p.14

[19] Monier-Williams, "Historical Aspects of the Pure Food Laws" (1951) *British Journal of Nutrition*, Vol.5, Issue.3, p.364

[20] J. Philips & M. French, "Adulteration and Food Law 1899–1939" (1998) *Oxford Journals, Twentieth Century British History*, Vol.9, Issue 3, p.350

Austriacus that lent its name to the present-day Codex Alimentarius of internationally recognized standards, codes of practice, guidelines and other recommendations relating to foods, food production and food safety. These Codex standards are of strong persuasive value in many food related legal disputes as they are considered to be a point of reference in the case of trade disputes between WTO Members. They also play a role in the SPS Agreement which is central to the analysis contained in this thesis.

Historical evidence from the US indicates that food adulteration was also a very profitable strategy for US manufacturers and distributors of food items.[21] Milk was occasionally cheapened by the addition of water. In addition, maple syrup, one of the most expensive food items at the time, was often adulterated. This was usually achieved by adding beet or cane sugar.[22] The first regulation of food in the US dates from early colonial times. Nearly all of the early US food laws were enacted by state governments.[23] For example, the Massachusetts Food Act which was passed on March 8, 1785. Because food law was initially a matter of city, county, and state jurisdiction, disparities between federal and state food requirements persist to this day.[24]

In 1862 President Lincoln appointed a chemist to serve in the US Department of Agriculture and this was the beginning of the Bureau of Chemistry, the predecessor of the current Food and Drug Administration (FDA).[25] Subsequently, state legislatures began to enact pure food and pure dairy laws in the early 1880s. By 1900 nearly every state had passed some kind of pure food or pure dairy legislation that made it illegal to sell 'adulterated' food products. US food law was now beginning to develop at a steady pace.[26]

The first federal food protections law was enacted by Congress in 1883 to prevent the importation of adulterated tea.[27] 1906 saw the enactment in that year of both the Pure Food and Drug Act[28] and the Meat Inspection Act.[29] These two Acts from 1906 heralded the arrival

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[21] M. T. Law, note 5 Chapter 1 above, p.1115
[22] See "*US Senate Investigation*" in Mark T. Law, note 5 Chapter 1 above, p.1115
[23] N. D. Fortin, JD, *Food Regulation: Law, Science, Policy and Practice* (New Jersey: Wiley, 2009), p.4
[24] P.B. Hutt, "Food Law & Policy: An Essay" (2005) *Journal of Food Law & Policy*, Issue 1, p.5.
[25] See, *FDA Milestones in US Food & Drug Law and History* at, *http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/default.htm* [Accessed October 21, 2011]
[26] *Ibid.*
[27] N. D. Fortin, JD, note 23 above, p.5
[28] 21 USC. 1 *et seq.*
[29] 21 USC. 601 *et seq.*

of the first modern regulatory functions carried out by the Bureau of Chemistry.[30] The Federal Meat Inspection Act 1906[31] required the US Department of Agriculture[32] to inspect all cattle, sheep, swine, goats, and horses at the time of slaughter and during processing into products for human consumption – in other words, to ensure that adulterated livestock was not processed into food and that meat was slaughtered and processed under sanitary conditions.

The larger US food industry stakeholders were calling for more stringent quality product standards in order to ensure a level playing field for all manufacturers. The FDA wanted greater powers.[33] Nonetheless, progress had stalled until the infamous 'Elixer of Sulfanilamide' scandal of 1937. This was a noxious tasting drug and in order to make the elixir taste sweet, the manufacturers added diethylene glycol without performing any tests. The elixir was used to treat strep throat. Nowadays, while there is dispute as to the minimal toxic dose, it is accepted that diethylene glycol is poisonous. At the time, over a hundred people died as a result of taking the elixir.[34] The Sulfanilamide scandal was the catalyst for the resumption of legislative action. In 1938, the Food, Drug, and Cosmetic Act was passed. The Food, Drug, and Cosmetic Act, as amended, is still the cornerstone of US food safety regulation.

An eclectic mix of standards existed across various jurisdictions due to the spontaneous and independent development of food laws and standards. It was inevitable that this would give rise to various forms of trade barriers and this increasingly concerned food traders in the early twentieth century. In due course, as a reaction to these barriers, trade associations were formed. These associations pressured governments to harmonize their various food standards in order to standardise quality and facilitate trade in safe foods. One such association was the International Dairy Federation (IDF) founded in 1903. Its work on standards for milk and milk products was a catalyst in the establishment of the Codex Alimentarius Commission (CAC) and served as a barometer for that Commission in complementing existing standards.

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[30] See, *FDA Milestones in US Food & Drug Law and History*, note 25 above.

[31] The Federal Meat Inspection Act of 1906 was substantially amended by the Wholesome Meat Act of 1967.

[32] The Meat Inspection Act is one of the Acts over which the US Department of Agriculture has exclusive authority for enforcement. Some of the other main Acts where the US Department of Agriculture has exclusive authority, are the Poultry Products Inspection Act 1957 and the Egg Products Inspection Act 1970.

[33] See N. D. Fortin, note 23 above, p.6

[34] For further discussion of this scandal see: N. D. Fortin, JD, note 23 above, p.6

Nowadays, we understand that it is in the interest of food companies to have people believe that there is no such thing as a bad food, that all foods can be incorporated into healthy diets, and that variety and moderation are the key. We expect virtually every food and beverage product to be represented by a trade association or public relations firm whose job it is to promote a positive image of that product. However, in the 1940s consumer scepticism and naivety at the arrival of the food corporation was matched on the regulatory side with the requirement for more sophisticated regulation.[35] The food sector began to exemplify the tense interplay that can sometimes exist between law and science. In response to consumer concerns, consumer groups began to emerge, both internationally and nationally. These groups pressurised governments to elevate the protection of their communities from poor-quality and hazardous foods.

In the late 1940s, the United Nations Food and Agriculture Organization (FAO) and the World Health Organization (WHO) were founded. To a large degree this initiative was motivated by vociferous international concern about the direction of food regulation. The problem was that countries had begun acting independently, with little if any consultation among them with a view to harmonisation of food safety regulations. The Codex Alimentarius Commission (CAC) was established by an FAO Conference resolution in 1961 and a World Health Assembly resolution in 1963. The purpose of the CAC is to implement the Joint FAO/WHO Food Standards Programme. As a constituent part of its remit, the Codex Alimentarius Commission develops and maintains the Codex Alimentarius. The WTO recognises the Codex Alimentarius as an international reference point for the resolution of disputes concerning food safety and consumer protection. Due to the assertion in this thesis that cultural regulatory divergences are likely to exist between the sanitary measures of trading nations, a basic understanding of the WTO is fundamental to the analysis contained in this thesis.

2.1.3 Economic Importance of the EU and the US Food Sectors

Due to their effect on the price of food, trade liberalisation and a secure food supply impinge upon us all financially. Accordingly, the economic importance of food is relevant. The value

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[35] See generally, Marion Nestle, *Food Politics: How the Food Industry Influences Nutrition, and Health*, 2nd edn (Los Angeles: University of California Press, 2007), p.21

of the food sectors corroborates the importance of the role played by the WTO. In its 2000 White Paper on Food Safety,[36] the European Commission acknowledged the significant role that the agro-food sector plays in the EU economy. Back then, the Commission noted that the food and drink industry is a leading industrial sector in the EU, with an annual production worth almost €600 billion, or about 15 per cent of total manufacturing output. Nowadays, the EU food and drink sector has an annual turnover worth almost €956 billion, or about 16 per cent of total EU manufacturing output.[37] On the international stage, the EU is the world's largest producer of food and drink products. From an employment perspective, the food and drink industry is the third-largest industrial employer of the EU with over 2.6 million employees. The agricultural sector has an annual production of about €220 billion and it directly employs approximately 7.5 million people. EU exports of food and drink and agricultural products are worth about €50 billion a year.[38] The Commission went on to comment that the economic importance and the ubiquity of food in European life suggests that the EU must have a prime interest in food safety across all of society, with public authorities and producers being extra cautious.[39]

Total US consumer expenditure on food (including imported produce) is approximately $844.2 billion annually – fast approaching nearly $1 trillion annually.[40] This is nearly 10 per cent of US GDP. Approximately 16.5 million people are employed directly in the US food industry. For 2013, total US agricultural exports (i.e. unprocessed food items) are projected to reach a record value of $143.5 billion. US agricultural imports are projected at $117 billion for 2013. Exports of US agricultural produce to the EU will be worth about $10 billion in 2013.[41] The food manufacturing industry is one of the US' largest manufacturing sectors, accounting for more than 10 per cent of all manufacturing shipments. In 2006, the value of food exports from the US processed food industry alone was $538 billion.[42] Meat products comprised the largest share of this, at $38.7 billion in overall processed food exports in 2007

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[36] *White Paper on Food Safety*, COM (1999) 719 final.

[37] See Food & Drink Europe, "*Data and Trends of the European Food and Drink Industry 2011*" (Brussels, 2011).

[38] In Ireland, the agrifood sector is one of the most important indigenous industries, employing in the region of 50,000 people directly, as well as providing the primary outlet for the produce of 128,000 family farms. The sector accounts for half of purchased Irish goods and services by the manufacturing industry and just over half of exports by indigenous manufacturing industries.

[39] *White Paper on Food Safety*, note 36 above, para 2, p.6.

[40] See United State's Department of Agriculture: 'Factbook 2001-2002'. Available at: http://www.usda.gov/factbook/ Accessed: 12 June 2012.

[41] See the Economic Research Service of the US Department of Agriculture: Outlook for US Agricultural Trade FY2013. Available at: http://www.ers.usda.gov/media/883301/aes75.pdf [Accessed: 12 June 2012]

[42] See US Department of Commerce Industry Report: Food Manufacturing NAICS 311

– 33 per cent of all processed food exports from the US.[43] About a third of the world's top 50 food and beverage corporations have their headquarters in the US.[44] The ten largest US companies in this sector are Kraft Foods, Tyson Foods (meat processing), PepsiCo, Nestle, Anheuser-Busch, General Mills, Dean Foods, Smithfield Foods, ConAgra Foods, and Cadbury Schweppes. The US Department of Agriculture notes that US food industry exports encounter non-tariff barriers in many global markets and these non-tariff barriers include divergent food standards.[45]

2.2 Relationship between Food and Technology

As outlined in Chapter 1, the relationship between food and science comes in a number of guises, most notably, 'food technology'.[46] Most food technologies are used for purposes which are obviously beneficial, but some are more novel in nature and despite the application of the best available science, the potential risks (to human health) associated with their use are not fully known. This thesis argues that a fundamental difference exists between the EU and the US food safety regimes. EU food production espouses traditional food production and processing methods whereas by contrast the US has been more receptive to food technology and somewhat sceptical of traditional methods.[47] The US believes that science in the form of biotechnology[48] will generate enormous economic and social benefits with very few risks. In dramatic contrast, many within the EU regard some biotechnologies as inherently dangerous

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[43] *Ibid.*

[44] The main competitors located outside of the US are Nestle (Switzerland), Unilever (England), Groupe Danone (France), Diageo (England), Kirin Brewery (Japan), SABMiller (South Africa), Cadbury Schweppes (England), Heineken (Netherlands), and Asahi Breweries (Japan).

[45] See United States Department of Agriculture Economic Research Service: Data and Statistics, Available at: http://www.usda.gov/wps/portal/usda/usdahome?navid=datastatistics [Accessed: 12 June, 2012]

[46] Food technology can be described as the application of food science to the selection, preservation, modification, processing, packaging and distribution of food produce. See G. Campbell-Platt (ed), note 10 above, p.1.

[47] One of the main reasons for this is the difference between the EU and US agricultural sectors. In 1995, less than 50 per cent of the total US land area was in farmland. Now, less than 1 per cent of the US population claim farming as an occupation. In stark contrast, in 2007, in the 27 EU Member States, there were 13.7 million agricultural holdings with an average farm size of only 13 hectares of utilised agricultural area (i.e. the proportion of national land available for agricultural use). It is only now that European farms are going through the process of farm consolidation which occurred much earlier in the US. See, United States Department of Agriculture, Agricultural Statistics 1997, Tables 9-2 and 9-7; United States Environmental Protection Agency – Demographies; European Commission, EU Agricultural Economic Briefs – Generational Renewal in EU Agriculture: Statistical Background, Brief No. 6, June 2012.

[48] Biotechnology can be defined as 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use'. See *United Nations Convention on Biological Diversity* 1992.

to both animal and human health and as a potential contributor to environmental disaster.[49] These cultural anomalies between these two giant agrifood producers have been transmitted into the food safety legislation enacted in each of these respective jurisdictions. The US willingness to embrace many of the emerging new technologies fosters a more flexible regulatory system than that existing in the EU because food traditions similar to those existing at national state level in the EU, do not exist in the US.

The use of new technologies in the food industry have led to political and trade conflict and a clash of cultures leading to economic difficulties at a national and supranational level. In the trade arena, conflict arises when one party wants to either sell a technologically-advanced or novel food[50] product in an economic area that is subject to different cultural norms and a different regulatory system. The technology of aiding growth in animals by administering growth hormones is widespread in the US, whereas growth hormones for this purpose are banned in the EU. This thesis' examination of the *Beef Hormones Dispute* will exemplify the position. The long-term manner in which governments deal with these new technologies is central to global governance of the food industry and the liberalisation of free trade.

2.3 Relationship between Food and Culture

Food has always been special to us for cultural reasons. In the study of sociology and anthropology 'culture' can be defined as all that is 'learned, shared and transmitted' among groups of human beings from generation to generation.[51] Part of this is tradition – the passing down of elements of a culture such as a custom or practice. Therefore, when it comes to food, different social groups – especially different societies or nation-states – come to develop, not

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[49] Opponents to the technology within the EU would point to the recognised potential hazards such as food safety, the effect on natural ecosystems, greater reliance on the use of chemicals in agriculture, gene flow into non GM crops, moral/religious concerns, and the economic and social problems associated with corporate control of the food supply.

[50] A 'novel food' is defined as a type of food that does not have a significant history of consumption or is produced by a method that has not previously been used for food. In the EU Novel foods are covered by Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients. In the EU a novel food is one that has no history of "significant" consumption in the European Union prior to 15 May 1997, and they are defined (Article 1) as foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community and the Regulation then goes on to list certain categories under which a potential novel food is to be assessed. Depending on the result of that assessment, the food may be subject to certain import restrictions.

[51] S. Mennell, A. Murcott & A. H. van Otterloo, *The Sociology of Food: Eating, Diet and Culture* (London: SAGE Publications, 1992), p.20.

only different tastes[52] but also different attitudes over time. These attitudes are biases, derived from historically developed societal values and patterns of behaviour.[53] With food produce, these biases are directed at considerations such as presentation, hygiene, ingredients or composition, processing, technology, ethical standards and environmental considerations. More generally, these biases are concerned with the main consideration of whether or not the food is healthy for human consumption. As a result, an intimate association exists between society and food regulation. It is an association derived from culture. This thesis argues that because of our desire to protect food, cultural or local influences are always evident in food safety legislation.

Due to the importance of each nation's agrifood sector and the financial commitment involved nationally, it is no wonder that countries are now keen to protect and indeed promote that investment and those achievements. As a result of this importance attached to a nation's food sector, both for purely economic but also for cultural reasons, food security becomes inextricably associated with the requisite element of national/supranational decision-making. This attribute is often referred to as 'food-sovereignty'.[54] Sovereignty denotes that an emphasis has been placed on the centrality of national decision-making authorities in determining food and agricultural policy. It is a nationalistic strategy that seeks to place regulatory authority and the responsibility for international trade with national governments rather than relinquishing that power to international or foreign bodies. Indeed, this thesis contends that it is national food sovereignty that enables the divergences in food regulatory regimes caused by cultural biases, to be expressed at the international level. A delicate balance must be struck between the preservation of food sovereignty and as Members of the WTO, adherence to WTO obligations and the promotion of international economic integration.

2.4 Role of Science

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[52] For example, 'Culinary culture' is a shorthand term for the ensemble of attitudes and tastes people bring to cooking and eating. See generally, S. Mennell, A. Murcott & A. H. van Otterloo, note 1 Chapter 1 above, p.20.
[53] A. Wildavsky & M. Douglas, *Risk and Culture: An Essay on the Selection of Technical and Environmental Dangers* (Los Angeles: University of California Press, 1982), p. 14.
[54] See, G. Tansey & T. Rajotte (eds), note 29 Chapter 1 above, p. 177.

Due to these complexities, modern societies encounter significant difficulties when making public health policy decisions in the area of food safety. In effect, national and regional policymakers are faced with a situation where they must balance the demands (both cultural and health associated) of their consumer with the forces of globalisation and free-trade. In order to manage those demands it is necessary to achieve specific health or food-safety targets while also simultaneously aiding the importation of foreign food produce. With the aid of food science, risk managers must attempt to predict these risks. It is here that science becomes indispensable. Science allows us to understand the impact on health of different determinants and their complex interactions. This increases the likelihood of identifying the correct policies. When policies have been adopted, again, science allows us to monitor the impact of those decisions and decide if further adjustments are needed on a case by case basis.[55]

However, this thesis contends that there is rarely an instance where science based evidence in risk-analysis can be said to be 100 per cent conclusive. At best, the prevailing scientific consensus is only as good as the research and the statistical processes underlying it.[56] In the EU, the precautionary approach to food safety presupposes an assumption that expert scientific advice alone can only provide a partial identification of potential hazards and it gives credence to the opinions of lay citizens.[57] Indeed, the precautionary principle[58] itself has been described as a 'culturally framed concept that takes its cue from changing social conceptions about the appropriate roles of science, economics, ethics, politics and law in anticipatory environmental protection and management'.[59] This creates a regulatory approach in which science is not absolute and at least allows a possibility for the accommodation of

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[55] V. Silano, "Science Risk Assessment and Decision-Making to Ensure Food and Feed Safety in the European Union" (2009) *European Food & Feed Law Review*, Issue 6, p.400.

[56] In relation to scientific uncertainty, see also Cases T-199/96, *Laboratoires Pharmaceutiques Bergadem SA, Jean-Jacques Goupil v EC Commission* [1998] ECR 11-2805 and *Alpharma Inc v Council* (Case T-70/99) [2002] ECR-II 3495.

[57] However, the precautionary principle cannot be divorced from science, because 'a scientific view of the risk is an essential component of the evaluation of risk that the principle anticipates', See, J. Cameron, "The Precautionary Principle", in G.P. Sampson & W. B. Chambers (eds), *Trade, Environment and the Millennium*, 2nd edn (New York: United Nations University Press, 2002), p. 292.

[58] In the EU the precautionary principle has firmly established the idea that scientific uncertainty about a risk should not be an obstacle to the adoption of precautionary measures when there is a probability, based on scientific evidence, that the risk will result in harmful effects on the health of EU citizens. See, C. MacMaolain, *EU Food Law – Protecting Consumers and Health in a Common Market* (Oxford: Hart Publishing, 2007), p.195.

[59] T. O'Riordan, and J. Cameron, "The History and Contemporary Significance of the Precautionary Principle" in T. O'Riordan and J. Cameron (eds), *Interpreting the Precautionary Principle*, (London: Earthscan Publications Limited, 1994), p.12.

cultural values. Instead science is only one factor relied upon by political officials when taking risk management decisions.[60]

It is not possible by consulting just scientists and food technologists, to predict the way consumers will react to a new food associated risk. While scientists and food technologists handle uncertainty and risk judgements on a daily basis, the perception of the public is different. At the international level, public perception of risk should be of crucial importance for policy makers. In addition, a technical assessment of risk alone is insufficient when introducing a new technology into the food production process.[61]

Now more than ever before consumers are concerned with the quality, taste, appearance, nutritional properties and ethical values of their food. However, because of the uncertainty associated with some food technologies, the internationalisation of food and recent health scares,[62] consumer confidence has been undermined. This has impinged upon cultural values concerning the provenance of the food supply. The consumer is not in control.

2.5 Substantive Food Law of the EU and the US

2.5.1 EU Food Law

Since the early 1990s, new developments in food regulation, including new and more stringent regulations aimed at diminishing food hazards have occurred in many countries around the world.[63] This is particularly apparent in the EU. In relation to the EU's modern approach to food law, the Commission succinctly outlines its position as follows:

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[60] See, Communication from the Commission on the Precautionary Principle, 2 February 2000. COM (2000) 1. In the EU, this Communication has been described as a codification of the law relating to the Precautionary Principle: See Case T-13/1999, *Pfizer Animal Health SA v Council* [2002] ECR II-3305, para 149.

[61] Where uncertainty exists regarding the nature of the risk to human health, protective measures can be taken without having to wait for the reality of those risks to crystallise – See Cases C-18/1996, *United Kingdom v Commission* (BSE) [1998] ECR I-2265 and C-157/1996, *The Queen v National Farmers' Union and others* [1998] ECR I-2211.

[62] Most infamously, bovine spongiform encephalopathy (BSE) in beef, genetically modified vegetables, growth hormones in beef, foot-and-mouth disease, *e.coli* poisoning, avian influenza, and dioxin contamination.

[63] D. Roberts & L. Unnevehr. "Resolving trade disputes arising from trends in food safety regulation: the role of the multilateral governance framework" (2005) *World Trade Review*, Vol.4, p. 470

> [t]he central goal of the European Commission's food safety policy is to ensure a high level of protection of human health and consumers' interests in relation to food, taking into account diversity, including traditional products, whilst ensuring the effective functioning of the internal market. The Commission's guiding principle, primarily set out in its White Paper on Food Safety,[64] is to apply an integrated approach from farm to table covering all sectors of the food chain, including feed production, primary production, food processing, storage, transport and retail sale.[65]

The modern EU Food Safety legislation has been evolving since the early 1970s and it is a reflection of scientific, social, political and economic factors indigenous to the EU.[66] Therefore, at times there have been some deficiencies in its coherence and this has resulted in over complex, fragmented measures with a lack of consistency. However, the EU has dealt with this and there is now a clear policy framework for food law.[67]

The Treaty of Rome 1957 made no reference to guiding principles for food legislation. The initial approach of the European Commission was to concentrate on the obligations set out in Article 3 of the Treaty, to ensure the free movement of foodstuffs within the common market. Much of the food legislation in this period was enacted by the Internal Market Directorate General (DGIII).

In due course, the Commission recognised that it was desirable to endeavour to codify a clear set of guiding principles for EU food legislation. As a first step, in 1985 it produced a communication entitled 'Completion of the Internal Market: Community Legislation on Foodstuffs'.[68] This communication set out a number of objectives for food legislation. These objectives were to:

(i) protect public health;

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[64] *White Paper on Food Safety,* note 36 Chapter 2 above.

[65] See, *Food Safety: From the Farm to the Fork* on the Commission website at, *http://ec.europa.eu/food/food/index_en.htm* [Accessed 2 November 2010]

[66] K. Goodburn. *EU Food Law: A Practical Guide*, (Cambridge: Woodhead Publishing Limited, 2001), p. 2

[67] An analysis of modern EU food law reveals that generally it can be said that the legislation now addresses one or more of three considerations: the product (the food itself), the process (the handling of the food either in production and/or trade) and the presentation (any communication about the food in labelling or advertising). See generally, B. M. J. van der Meulen, "The System of Food Law in the European Union" (2009) *Deakin Law Review*, Vol.14, No.2, p. 308.

[68] D. Holland & H. Pope, note 14 Chapter 1 above, p.5

(ii) provide consumers with information and protection in matters other than health and ensure fair trading (for example by setting appropriate standards for labelling to allow consumers to make informed choices about food products); and

(iii) provide for the adequate and necessary official control of foodstuffs.[69]

The stated objectives of public health and consumer interest were subsequently incorporated into the Single European Act of 1986 and the Maastricht Treaty of 1992. An example of the new direction taken by the Commission is the 1990 Directive on nutritional labelling for foodstuffs[70] which sets out standard requirements and formatting for listing the nutritional content of a food.

The Commission also moved to a more flexible approach as an alternative to detailed and prescriptive legislation. This can be seen in the 1993 General Food Hygiene Directive.[71] In contrast to the pre-existing detailed rules covering specific foodstuffs, now under this Directive all food sectors were subject to a more generic approach, using the Hazard Analysis and Critical Control Point (HACCP) system. This system means that rather than relying on the issuance of detailed requirements from the Commission, individual food businesses now had responsibility to develop HACCP systems appropriate to their needs within a broad framework of minimum hygiene standards and requirements. In addition, the Directive encouraged the development by food businesses of guides on good hygiene practice in conjunction with interested parties such as national food agencies and consumer groups.

2.5.1.1 White Paper on the General Principles of Food Law

By the 1990s the Commission had made a number of important changes in its approach to food legislation, but there was a realisation that in order to meet the objectives set out in the mid 1980s, especially on food safety, it had to do more. The White Paper on the General Principles of Food Law,[72] adopted by the Commission on 12 January 2000, set out the plans for a proactive new EU food policy: modernising legislation into a coherent and transparent set of rules, reinforcing controls from the farm to the table and increasing the capability of the scientific advice system, so as to guarantee a high level of human health and consumer

[69] K. Goodburn, note 66 above, p. 2
[70] Council Directive 90/496 on nutrition labelling for foodstuffs, [1990] O.J. 276/40.
[71] Council Directive 93/43/EEC of 14 June 1993 on the hygiene of foodstuffs [1993] O.J. L176/29.
[72] COM (1999) 719 final, 12 January, 2000.

protection. A number of 'strategic priorities' were set-out in the White Paper including the creation of a European Food Safety Authority and the consistent implementation of a farm to table approach in food legislation. The European Commission then introduced a proposal for a Regulation of the Council and Parliament laying down general principles of food law and establishing the European Food Authority.[73]

2.5.1.2 'General Food Law'

Regulation 178/2002,[74] commonly referred to as 'General Food Law', laid down the general principles and requirements of food law, established the European Food Safety Authority (EFSA), and laid down procedures in matters of food safety. General Food Law articulates the general concepts and principles that serve as the foundation of contemporary EU food law.

The General Food Law Regulation entered into force on the 21 February 2002[75] and must be followed when measures are taken. Certain key provisions set out in Article 11 (food and feed imported into the Community), Article 12 (food and feed exported from the Community) and Articles 14 to 20 (food safety requirements, presentation, responsibilities, traceability, and responsibilities of food business operators for food and feed) did not apply until 1 January, 2005.[76]

The General Food Law covers all stages of production, processing and distribution of food and feed.[77] However, there is an exemption for primary production for private domestic use and the domestic preparation, handling, or storage of food for private domestic consumption.[78] In order to comply with the general framework outlined by it, the Regulation

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[73] Commission Proposal for a Regulation from the European Parliament and the Council laying down the General Principles and Requirements of Food Law establishing the European Food Authority and laying down Procedures in Matters of Food Safety, COM (2000) 716 final.

[74] European Parliament and Council Regulation (EC) No 178/2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, [2002] O.J. L31/1.

[75] *Ibid.*, Art. 65. Art.65 required that the Regulation would enter into force 20 days after its publication in the Official Journal of the European Communities. The Regulation was published in the Official Journal on 1 February 2002.

[76] *Ibid,* Art. 65.

[77] B. M. J. van der Meulen, note 67 above, p.320

[78] Art.1(3).

required that existing food law principles and procedures be adapted by 1 January 2007, at the latest.[79]

The General Food Law covers all stages of production, processing and distribution of food and feed.[80] However, there is an exemption for primary production for private domestic use and the domestic preparation, handling, or storage of food for private domestic consumption.[81] In order to comply with the general framework outlined by it, the Regulation required that existing food law principles and procedures be adapted by 1 January 2007, at the latest.[82]

As introduced in Chapter 1, for the first time under EU law, the General Food Law provides a definition of 'food'. Accordingly, if a product meets this definition, then it is a food under the General Food Law and the General Food Law applies to it.

Under Article 2 of the General Food Law, 'Food' is defined as:

> [....] any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.

It goes on to state that:

> '[f]ood' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

'Food' shall not include:

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[79] Art.4(3).
[80] B. M. J. van der Meulen, note 67 above, p.320
[81] Art.1(3).
[82] Art.4(3).

> (a) feed; (b) live animals unless they are prepared for placing on the market for human consumption; (c) plants prior to harvesting; (d) medicinal products (.....); (e) cosmetics (.....); (f) tobacco and tobacco products (.....); (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971; (h) residues and contaminants.

In relation to the EU's modern approach to food law, the Commission succinctly outlines its position as follows:

> [t]he central goal of the European Commission's food safety policy is to ensure a high level of protection of human health and consumers' interests in relation to food, taking into account diversity, including traditional products, whilst ensuring the effective functioning of the internal market. The Commission's guiding principle, primarily set out in its White Paper on Food Safety,[83] is to apply an integrated approach from farm to table covering all sectors of the food chain, including feed production, primary production, food processing, storage, transport and retail sale.[84]

The EU now has a clear legislative and policy framework governing food.

2.5.1.3 European Food Safety Authority

EFSA[85] is effectively the umbrella risk assessor, with the European Commission, the European Parliament and EU Member States themselves acting as the risk managers. EFSA produces the requisite scientific opinions and advice, and this then allows the political institutions to act as risk managers by producing the resultant European policies and legislation. EFSA's remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health.

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[83] *White Paper on Food Safety*, note 36 Chapter 2 above.
[84] See, *Food Safety: From the Farm to the Fork*, note 63 Chapter 2 above.
[85] EFSA commenced its responsibilities on 1 January 2002 in accordance with Art.64 of Regulation (EC) No 178/2002. Its headquarters are located in Parma, Italy.

The Authority is governed by a Management Board made up of fifteen members. The members of the Board are appointed to act in the public interest and they do not represent any particular government, organization or sector. One Board member represents the European Commission, while the other fourteen are selected on the basis of their expertise, knowledge and experience.

EFSA's main responsibility is to assess and then communicate regarding all risks associated with the EU food chain. In addition to undertaking scientific research of its own initiative, a significant part of EFSA's work is undertaken in response to requests for scientific advice.[86] These requests are received either from the European Commission, the European Parliament or individual EU Member States. In order to ensure the efficacy of EFSA, a collaborative approach is required and therefore EFSA liaises with the communications representative from each national food safety authority across the EU. EFSA Advisory Forum is the group who connect EFSA with the national food safety authorities of all 27 EU Member States. The Forum's members represent each national body responsible for risk assessment in the EU (plus observers from Norway, Iceland, Switzerland and the European Commission).

The Management Board governs EFSA's Scientific Committee and Panels.[87] The Scientific Committee prepares scientific advice in the area of new and harmonised approaches for risk assessment of food and feed, and provides strategic advice to the Executive Director. The Scientific Panels[88] carry out risk assessment work is in the areas of Animal health and welfare; Food additives and nutrient sources added to food; Biological hazards including BSE/TSE-related[89] risks; Food contact materials, enzymes, flavourings and processing aids;

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[86] Regardless of the nature of any individual project, EFSA operates a set of internal mechanisms in order to ensure the independence of its scientific work. In addition, all EFSA experts are required to sign a commitment of independence and an annual declaration of interests which are published on EFSA's website. However, a question has been raised regarding the potential for influence on EFSA's scientific decisions posed by outside factors, based on the composition of its managing board, the autonomy of its scientists, and its relationship with the European Commission. See generally, A. Alemanno, note 28 Chapter 1 above.

[87] In 2008, the Management Board adopted its Strategic Plan for 2009-2013. The plan outlines how EFSA will provide up-to-the-minute scientific advice by maximising the benefits of the scientific expertise at its disposal across Europe while also strengthening its integrated approach to risk assessment. At the end of 2009, EFSA ran a qualitative survey to explore how the work of the Authority was perceived among its audiences.

[88] The Scientific Panels were established in May 2003.

[89] BSE (bovine spongiform encephalopathy) is a disease found only in cattle which belongs to the family of prion diseases known as transmissible spongiform encephalopathies (TSEs). They are a family of rare progressive neurodegenerative disorders that affect both humans and animals. The most common form in humans is Creutzfeldt-Jakob Disease (CJD) - a rare and fatal form of dementia that can present in individuals between the ages of 40 and 80. Therefore, CJD is not a new disease. However, in 1996 scientists discovered a

Contaminants in the food chain; Additives and products or substances used in animal feed; Genetically modified organisms; Dietetic products, nutrition and allergies; Plant protection products and their residues; and Plant health.

Examples of the risk assessment work that the Scientific Panels have undertaken on their own initiative include advice on the origin and occurrence of blue tongue (the viral ruminant disease that spread to northern Europe for the first time in 2006) in order to get a better understanding of how the virus evolved and spread. Other examples are the development of a harmonised EU approach in comparing the risks posed by carcinogenic substances, and guidance on how to assess the safety of the various botanicals (food supplement which are derived from plants, algae, fungi or lichens, such as ginseng) that are now widely available in the EU as food supplements.

The Scientific Panels also set-up working groups comprised of external scientists with relevant expertise. These groups deal with specific issues and assist in producing the scientific opinions for those issues. Public consultations with interested stakeholders (such as consumer groups, non-governmental organizations, farmers, food manufacturers, distributors, processors and science professionals) are also incorporated as part of the ongoing process. Since its establishment, the Scientific Panels have delivered almost 2000 scientific opinions on a wide variety of risk issues.

EFSA's risk assessment activities are also augmented by its Scientific Cooperation and Assistance Directorate. EFSA's Scientific Cooperation and Assistance Directorate manage projects in the areas of scientific co-operation with EU Member States. It is involved in data collection, analyzing emerging risks and verifying assessment methodology. It also deals with specific risk issues by directly involving experts from Member States in collecting and analyzing data on, animal diseases that can be transferred to humans (zoonoses), pesticide residues in food, and a review of the safety of all active substances used in pesticides.[90]

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new strain of CJD (variant CJD, vCJD or new variant CJD, nvCJD) and scientific research has shown that the most likely origin of vCJD is human exposure to the BSE prion or protein by eating food containing traces of the brain, spinal cord or digestive tract of BSE infected carcasses. As with BSE in cattle, vCJD is always fatal in humans.

[90] See generally, *The European Food Safety Authority at a Glance*. Available at: *http://www.efsa.europa.eu/en/aboutefsa/docs/corporatebrochure.pdf* [Accessed November 15, 2010].

2.5.2 US Food Law: Federal Food, Drug and Cosmetic Act 1938

It is not relevant to this thesis to provide an outline of all of the main tenets of US food law. The Federal Food, Drug and Cosmetic Act 1938 (as amended)[91] is the main US food regulatory measure relevant to this thesis and it is also the most important US law governing food. The extent to which a product is regulated under the Act depends greatly on whether it is classed as a food or a drug (or both). Therefore, at this stage of this thesis it is important to note the main definitions contained in this Act. These are contained in S.201.[92] The definitions are as follows:-

'food':-

> (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any other such article.[93]

'drugs':-

> (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals...

'food additive':-

> any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance

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[91] 21 USC. S.321 *et seq.*
[92] 21 USC. S.321.
[93] 21 USC. S.321(f).

> intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food...
>
> .

'dietary supplement':-

> (1) means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake...
>
> (2) means a product that ... is not represented for use as a conventional food or as a sole item of a meal or the diet; and (C) is labelled as a dietary supplement...
>
> .

In the context of this thesis it is important to note that the EU definition of 'food' does not include animal feed. This corresponding US provision refers to 'articles used for food or drink for man or other animals',[94] and this effectively brings humans and animals under the one definition. If under EU law there was a similar categorisation of humans and animals together, then that would have conflicted with European culture. Instead, animal feed in brought within the ambit of EU food law by way of separate provisions under the General Food Law.[95]

In 1958, the Food Additives Amendment to the Food, Drug and Cosmetic Act 1938, was enacted. The amendment required that food additives be evaluated in order to establish safety. In 1958, another amendment to the Food, Drug and Cosmetic Act 1938, was proposed by New York Congressman James Delaney. The 'Delaney Clause' provides that 'the Secretary of the Food and Drug Administration shall not approve for use in food any chemical additive found to induce cancer in man, or, after tests, found to induce cancer in animals'. In 1960, the Colour Additive Amendment to the Food, Drug and Cosmetic Act 1938 was enacted. This amendment required manufacturers to establish the safety of colour

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[94] Federal Food, Drug, and Cosmetic Act, 21 USC S.201(f).

[95] See van der Meulen, note 67 above, p.321. However, 'feed' (or 'feedingstuff') is defined separately under Art.3(4) of Regulation (EC) No 178/2002 as: "[....] any substance or product, including additives, whether processed, partially processed or unprocessed, intended to be used for oral feeding to animals". The definition of 'food law' under Art.3(1) provides that food law does include all stages of "production, processing and distribution of feed produced for, or fed to, food producing animals".

additives in food, drugs and cosmetics and it also contained a Delaney Clause which prohibited the approval of any colour additive shown to induce cancer in humans or animals.

In 1973, FDA promulgated the Low Acid Processing Regulations. This was in response to a number of outbreaks of botulism food poisoning from canned food. In 1982, due to the deaths that were caused by cyanide in Tylenol capsules, FDA introduced Tamper-Resistant Packaging Regulations, making it a federal crime to tamper with packaged consumer products. In more recent times, US public interest in food has been concentrated on nutrition and health issues.[96] Accordingly, measures were required to regulate the health and nutrition claims made by manufacturers for their food products. The 1990 Nutritional Labelling and Education Act (NLEA) requires most packaged foods to bear nutritional labelling, and that health and nutrition claims for foods be consistent with certain terms which are defined by FDA.[97]

The Food Quality Protection Act of 1996 mandated a number of changes such as a uniform health-based standard in respect of pesticide residues in foods, the creation of special protections for infants and children, the streamlining of safe pesticides approval and incentives for the use of crop protection tools by farmers.

The Food and Drug Administration Modernisation Act of 1997 succeeded in instituting quite a number of reforms in the regulation of food, medical products and cosmetics. The most important of these was that the Act rescinded FDA requirement that most packing and other matter coming into contact or in danger of migrating into the food itself, required pre-market approval. Now, the manufacturer can self-determine this issue and then notify FDA of its intention. Then, unless FDA objects within 120 days, the manufacturer can proceed to market the product.[98]

There were many other important US food law enactments such as the publication in 1958 by FDA of the first list of substances generally recognized as safe (GRAS); in 1966 the Fair Packaging and Labelling Act was introduced which requires all consumer products to be honestly and informatively labelled; in 1970 the Environmental Protection Agency was

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[96] N. D. Fortin, JD, note 23 above, p.8
[97] *Ibid*, p.8
[98] *Ibid*, p.31

established and it took over FDA's program for setting pesticide tolerances; since 1992 under the Nutrition Labelling and Education Act of 1990, Nutrition facts (basic per-serving nutritional information) are now required on foods; and the enactment of the Bioterrorism Act of 2002.

Many states have enacted the Uniform Food, Drug, and Cosmetic Bill[99] which was created in 1984 by collaboration between the states working with The Association of Food and Drug Officials (AFDO).[100] Other states have adopted part of the Uniform Bill or have laws based on the 1906 Food and Drug Act. The end result is that most states now had primary food laws that are largely consistent with the federal law.[101] However, many of the largest US cities maintain their own unique ordinances and regulations. In addition, any portion of the US food supply consumed within the state in which it is produced is not directly under the jurisdiction of the Federal Food, Drug and Cosmetic Act. Therefore, the respective local agencies are responsible for policing this portion of the indigenous US food supply.

2.5.2.1 Food and Drug Administration

In 1862 President Lincoln appointed a chemist to serve in the US Department of Agriculture and this event is regarded as the beginning of the Bureau of Chemistry, the predecessor of the current US Food and Drug Administration (FDA).[102] As outlined in Chapter 1, by 1900 nearly every US state had passed some kind of pure food or pure dairy legislation that made it illegal to sell 'adulterated' food products. However, as of yet, no agency was entrusted with the authority to enforce the law and it was acknowledged that in a considerable number of states, especially in the South and West, the enforcement provisions were scant.[103] This led in 1906 to the passing of the Federal Food and Drugs Act which granted the first regulatory functions to the Bureau of Chemistry – the modern era of FDA had begun. The Bureau of Chemistry's name changed to the Food, Drug, and Insecticide Administration in July 1927. In

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[99] The provisions of the Bill are very similar to those contained in the Federal Food, Drug, and Cosmetic Act.
[100] See, Institute of Medicine and National Research Council, *Enhancing Food Safety: The Role of the Food and Drug Administration* (Washington: National Academic Press, 2010), p. 7.
[101] N. D. Fortin, JD, note 23 above, p.29
[102] See, *FDA Milestones in US Food & Drug Law and History*, note 25 Chapter 2 above.
[103] See US Senate Report "*Adulteration of Food Products*", p. 137.

July 1930 the name was shortened to the current title of 'Food & Drug Administration' (FDA).[104]

FDA has a staff of approximately 9,100 employees and a budget of approximately $1.5 billion.[105] FDA is a scientific, regulatory, and public health agency. It has jurisdiction in the area of most food products (other than meat and poultry, which are regulated by the US Department of Agriculture), human and animal drugs, therapeutic agents of biological origin, medical devices, radiation-emitting products for consumer, medical, and occupational use, cosmetics, and animal feed. FDA works in conjunction with other US federal agencies including the Department of Agriculture, the Drug Enforcement Administration, Customs and Border Protection, and the Consumer Product Safety Commission. Local and individual state government agencies work in cooperation with FDA to provide regulatory inspections and enforcement action.

FDA consists of six product centres (one of which is the Centre for Food Safety and Applied Nutrition (CFSAN)), one research centre, and two offices. FDA's two Offices are:- (a) the Office of the Commissioner, which provides leadership and direction to FDA's product centres, research centre, and; (b) the Office of Regulatory Affairs which conducts inspections and enforces FDA regulations.

Regulation of meat is pertinent to this thesis due to the examination of the *Beef Hormones Dispute*. Accordingly, it is important to note that the one exception to FDA's regulatory role is meat products, derived from traditional domesticated animals such as cattle and chickens. Regulation in this area comes under the remit of the US Department of Agriculture Food Safety and Inspection Service. However, certain products which contain minimal amounts of meat are regulated by FDA. Medicines and other products given to all domesticated animals are regulated by FDA through its Centre for Veterinary Medicine.

2.5.2.1.1 Office of Regulatory Affairs

[104] FDA has its headquarters at Silver Spring, Maryland and has 223 field offices and 13 laboratories located throughout the 50 states, the United States Virgin Islands, and Puerto Rico. FDA is led by a Commissioner of Food and Drugs, appointed by the President of the United States, with the advice and consent of the Senate. The Commissioner reports to the US Secretary of Health and Human Services.

[105] FDA states that it oversees items accounting for 25 cents of every dollar spent by US consumers.

The Office of Regulatory Affairs is considered the 'eyes and ears' of FDA. It conducts the greatest share of FDA work. Consumer Safety Officers, colloquially called 'investigators', inspect production and storage facilities, investigate complaints or illnesses, examine documentation and specifications relating to medical devices, drugs, biological products and other items where it may be difficult to conduct a physical examination or take a physical sample of the product concerned.

The Office of Regulatory Affairs (ORA) is divided into five regions, which are further divided into thirteen districts. Districts are based roughly on the geographic divisions of the US federal court system. The ORA works in tandem with the Office of Criminal Investigations (OCI) which investigates criminal cases.

2.5.2.1.2 Centre for Food Safety and Applied Nutrition

FDA's product centre known as the Centre for Food Safety and Applied Nutrition (CFSAN), regulates most foods (except meat and poultry), food additives, infant formulas, dietary supplements, and cosmetics.[106] The Centre provides services to consumers, domestic and foreign industry and other outside groups regarding field programs; agency administrative tasks; scientific analysis and support; and policy, planning and handling of critical issues related to food and cosmetics.

2.5.2.1.3 Food Advisory Committee

The Food Advisory Committee[107] advises the Commissioner of Food and Drugs and other associated officials, on emerging issues relating to food safety, food science, nutrition, and other food-related health issues. In relation to food, the Committee may be charged with making recommendations on broad scientific and technical food issues, the safety of new foods and food ingredients, the labelling of foods, nutrient needs and nutritional adequacy, and safe exposure limits for food contaminants. The Committee may also be asked to provide

[106] The Centre's headquarters are located in College Park, Maryland and the Centre also operates research facilities in Laurel, Maryland and in Dauphin Island, Alabama.
[107] The Food Advisory Committee was established under 15 USC. 1451 et seq.

advice and make recommendations on ways of communicating to the public the potential risks associated with these issues.

The Committee consists of seventeen standing members including the 'Chair'.[108] Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of physical sciences, biological and life sciences, food science, risk assessment, nutrition, food technology, molecular biology, and other relevant scientific and technical disciplines. Of the fifteen members who vote, two are technically qualified members identified with consumer interests. In addition to the voting members, the Committee has two members who are identified with industry interests and these members are non-voting.

In relation to potential conflicts of interest of the Committee members, before appointment to the Committee, FDA apparently reviews an individual's expertise and financial information. In relation to the financial interests of Committee members, before the member participates at a specific Committee meeting, FDA considers whether or not the members financial interest will be affected by the outcome of the meeting and also whether or not the outcome of the meeting might affect the ability or willingness of the funding organization to continue its relationship with that member.[109]

In June 2009, FDA Commissioner Dr. Margaret Hamburg launched FDA's Transparency Initiative. This was in response to public criticism directed at the degree of transparency surrounding the role and activities of FDA. As part of the Initiative, the Commissioner formed an internal task force to develop recommendations for making useful and understandable information about FDA activities and decision-making more readily available to the public in a timely manner and in user-friendly format.

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[108] The Committee is governed by the provisions of US Public Law 92-463 as amended,[108] and the Federal Advisory Committee Act,[108] which sets forth standards for the formation and use of advisory committees. Meetings are open to the public unless determined otherwise by the Commissioner or designee in accordance with the Government in the Sunshine Act[108] and the Federal Advisory Committee Act. At the end of each fiscal year a report is prepared which contains, as a minimum, a list of all Committee members, their business addresses, the dates and places of meetings, and a summary of the Committee's activities and recommendations made during that fiscal year.

[109] As outlined below, this concern was sufficiently acute to warrant the creation of a transparency initiative.

2.6 Global Framework of Food Regulation

Due to globalisation of the food supply, there has been a decline in the capacity of government and national authorities to meet public demand for standards, and yet ironically they are faced with increasing public demand for those standards while also at times protecting their indigenous food-sector interests. While the most obvious solution to this problem is international food standards, this is likely to be highly contested in practice due to the international diversity between cultures, oftentimes displaying diametrically opposed ideas and interests when it comes to food. Nonetheless, we have a number of global institutions and frameworks which produce the rules that shape the world food system.

2.6.1 World Trade Organisation

The most significant development in this area was the creation in 1995 of the World Trade Organization (WTO).[110] The WTO emanated from the Uruguay Round of trade talks. The Uruguay Round of talks were initiated under the General Agreement on Tariffs and Trade (GATT),[111] in 1986. This development was particularly significant because unlike the already existing UN organizations such as the World Health Organisation (WHO) or the Food and Agricultural Organization of the United Nations (FAO), the WTO has a binding dispute settlement mechanism reinforced by its ability to impose sanctions. As a result, when a country fails to follow its rules, that country does so in the knowledge that it could be penalised.[112]

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[110] The WTO headquarters are in Geneva, Switzerland.

[111] The WTO has replaced GATT as an international organization. However, the General Agreement still exists (as updated by the Uruguay Round negotiations) as the WTO umbrella treaty for trade in goods. There is GATT 1994 which is the updated version and at the heart of that Agreement is the original GATT 1947. Annex 1A interpretive note to the WTO Agreement provides that in the event of a conflict between GATT and the SPS Agreement, the provision of the SPS Agreement will prevail. However, 'conflict' has been narrowly construed – See *Turkey – Textiles: Turkey – Restrictions on Imports of Textiles and Clothing Products*, WT/DS34/R, para 9.93.

[112] The organization is currently dealing with a trade negotiation called the Doha Development Agenda (or Doha Round), which was launched in 2001. The Doha Round is intended to enhance equitable participation of many poorer countries representing a majority of the world's population. However, to date the negotiations have been stymied by disagreement between exporters of agricultural bulk commodities and countries with large numbers of subsistence farmers, regarding the precise terms of a 'special safeguard measure' to protect those farmers from any surges in imports.

The WTO deals with regulation of trade between participating countries; it provides a framework for negotiating and formalizing trade agreements, and a dispute resolution process aimed at enforcing participants' adherence to WTO agreements which are signed by representatives of member governments and ratified by their parliaments. Where possible, as a WTO Member, EU food law must conform to WTO obligations.[113] The same obligation applies to US food law.[114]

The WTO Agreement[115] and its Annexes define the rights and the obligations of WTO Members and are designed to direct each member's polices toward economic liberalisation. The WTO is therefore an extremely important international organization which provides the institutional setting required for the negotiation and enforcement of the global rules of international trade and economic activity. The role of the WTO is ever more important as international trade increases, both in absolute terms and as a percentage of total production.

The WTO has 153 Members,[116] representing more than 97 per cent of total world trade and 30 observers, most of which are seeking membership. The WTO is governed by a ministerial conference which meets every two years; a general council which deals with day to day administration and is responsible for implementing the policy decisions taken by the conference; and a director-general[117] who is appointed by the ministerial conference.[118]

The main functions of the WTO are the administration and implementation of the WTO Agreements;[119] the provision of a forum for negotiations and for settling disputes; the

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[113] C. MacMaolain, note 58 above, p.149. However, WTO law does not have direct effect in European Law. In other words, the WTO Agreement cannot be invoked directly before national or European courts. See Case C-377/02, *Léon Van Parys NV v Belgisch Interventie-en Restitutiebureau* [2005] ECR I-1465, para 13.75.

[114] WTO Members must ensure compliance with the WTO Agreements. This applies not only to nation governments but also to non-governmental and regional entities within their territories. See Article 13 of the SPS Agreement and also *Canada-Import, Distribution and Sale of Certain Alcoholic Drinks by Provincial Marketing Agencies*, WT/DS17/R.

[115] The WTO agreements emanate from the 1986–1994 Uruguay Round of trade negotiations. The 1995 Marrakesh Agreement establishing the WTO replaces the General Agreement on Tariffs and Trade (GATT) which commenced in 1948. Attached to the Marrakesh Agreement, is a much lengthier set of four annexes which contain the other international trade agreements together with the rules and procedures governing the operation of the Organization.

[116] As of 31 July, 2008 – according to the WTO website.

[117] GATT had a total of 5 Director-Generals until the WTO was formed in 1995. Irishman, Peter Sutherland, was the last Director-General of GATT (from 1 July 1993 until 1 January 1995 when he became Director General of the WTO), and the first of the WTO. He served as WTO Director General until 1 July 1995. Current Director General, Pascal Lamy, is the fifth Director-General of the WTO. He was appointed on 1 September 2005 for a four-year term. In April 2009, the WTO members reappointed Mr Lamy for a second four-year term, commencing on 1 September 2009.

[118] See "WTO: Members & Observers". Available at: http://www.wto.org/ [Accessed March 22, 2011]

[119] For example, the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).

surveying of individual national trade policies in an effort to ensure coherence and transparency of those policies; assisting developing countries in their transition to WTO rules and disciplines; acting as a centre for economic research and analysis; cooperating closely with the IMF and the World Bank.[120]

The Dispute Settlement Understanding (DSU)[121] of the WTO outlines the procedures for resolving conflict between WTO Members, including a fourteen month timetable within which DSU proceedings are to be completed. In layman terms, what the WTO Members have agreed is that if a fellow-Member violates trade rules, the Members will use the WTO multilateral dispute settlement system instead of taking action unilaterally. To do so, they would refer the matter to the WTO Dispute Settlement Body (DSB).[122] As we shall see in the examination of the *Beef Hormones Dispute*, a WTO dispute proceeds through three main stages: consultation; formal litigation; and, if necessary, implementation.[123]

Usually, a dispute arises when one country implements a change in their trade policy or commits some act which the other WTO Members regard as a breach of the WTO agreements. The offended Member government (the 'complainant') may take a case against another Member government (the 'defendant') setting out its objections to the trade measures of the defendant government.[124] Of course, the preferred solution is for the countries concerned to discuss the issue and hopefully reach a settlement or agreement between themselves. Therefore, as the first stage of the WTO dispute settlement process, in order to try and negotiate a mutually satisfactory solution to the dispute, both parties are required to consult for 60 days. Indeed, a large proportion of the disputes are successfully resolved during these consultations; 46 per cent of all disputes brought to the WTO end at this stage, and three-quarters of those yield at least partial concessions from the defendant.[125]

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[120] The IMF and the World Bank being the other two institutions of the Bretton Woods system – the Bretton Woods system having been conceived at a meeting of 43 countries in Bretton Woods, New Hampshire, USA. in July 1944. The participating countries aimed to help rebuild the shattered post-war economies and ultimately to promote international economic cooperation.

[121] The DSU is an Agreement attached at Annex 2 of the Marrakesh Agreement establishing the WTO. The Marrakesh Agreement is otherwise known as the 'WTO Agreement'.

[122] The Dispute Settlement Body (which is effectively the General Council in another guise) consists of all WTO members.

[123] See, M. Busch & E. Reinhardt, "Testing International Trade Law: Empirical studies of GATT/WTO dispute settlement," in eds. D.L.M. Kennedy & J.D. Southwick, *The Political Economy of International Trade Law: Essays in Honor Robert Hudec* (Cambridge: Cambridge University Press, 2002), p.457.

[124] In addition, a third group of countries can declare that they have an interest in the case, by notifying the WTO and confirming that they have a 'substantial interest' in the case.

[125] See, M. Busch & E. Reinhardt, note 123 above, p.457.

If the consultation process does not result in a solution, the complainant can request a Panel proceeding.[126] This effectively marks the start of the litigation stage. This process typically involves two rounds of testimony, after which the Panel prepares and circulates an 'Interim Report'. The Interim Report offers both sides the opportunity for comment and clarification. The complainant and defendant can still decide to negotiate a settlement at this point. The next step is for the Panel to issue its Final Report. This Report is then adopted by the WTO, unless one of two eventualities arise. Firstly, jointly, both parties could agree not to adopt the Panel report for whatever reason. Secondly, one or both sides (but not third parties) can appeal the Final Report and indeed this is a frequent occurrence.

Either or both parties to the dispute can appeal a Panel's ruling to the Appellate Body. The Appellate Body is a standing body of jurists, designed to ensure greater consistency across its rulings. An appeal must be based on a point of law such as legal interpretation and existing evidence or new issues cannot be either re-examined or dealt with.[127] The appeal can uphold, modify or reverse the Panel's legal findings and conclusions.[128] After a decision is reached against the defendant the action, then that defendant should bring its policy into line with the ruling or recommendation(s) made by the Panel. After such a verdict, the case typically ends. Alternatively, if the verdict favours the complainant, the dispute may proceed to the implementation stage.

If a situation arises where immediate compliance with the recommendation impractical, the member is given a 'reasonable period of time' in order to comply. However, if it fails to act within this period, it is required to enter into negotiations with the plaintiff country in an

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[126] The Dispute Settlement Body has the sole authority to establish "panels" of experts to consider the case. The Dispute Settlement Body monitors the implementation of the rulings and recommendations made by the panel. The Body has the power to authorize retaliation when a country does not comply with a ruling. The panel's report can only be rejected by consensus in the Dispute Settlement Body and therefore its conclusions are difficult to overturn. The panel's findings must be made in accordance with the WTO agreements. For evidence of Members availing of funding to finance expertise in support of their case see *Korea – Anti-Dumping Duties on Imports of Certain Paper from Indonesia*, WT/DS312/R.

[127] Each appeal is heard by three members of the permanent seven-member Appellate Body. The Appellate Body broadly represents the range of WTO membership. Members of the Appellate Body hold office for a four-year term. They are individuals with recognized standing in the field of law and international trade and cannot be affiliated with any particular government.

[128] Normally appeals should not last more than 60 days, with an absolute maximum of 90 days. The Dispute Settlement Body has to accept or reject the appeals report within 30 days — and rejection is only possible by consensus. In addition, in respect of the various Committees attached to the WTO Agreement (e.g. the SPS Committee), the Appellate Body has insisted on its power to review their decisions. See *India–Quantitative Restrictions on Imports of Agricultural, Textile and Industrial Products*, WT/DS90/AB/R, para 103.

effort to determine mutually-acceptable compensation.[129] Then, if after 20 days a package of compensation is not agreed, the complainant can request a second Panel to set the level at which it can 'retaliate' against the defendant. Typically, this retaliation would involve trade sanctions such as imposing tariffs on the defendant's exports.[130] However, in this context it should be noted that the WTO is best understood as a political compromise which was voluntarily agreed to, rather than an international legal system.

If and when sanctions are agreed, they are to be imposed in the same trade sector as that in which the dispute arose. However, if that is not possible, the sanctions may be imposed in a different sector of the same agreement. Likewise, if this is not possible or practicable, and depending on the seriousness of the circumstances, the action can be taken under another agreement. The objective of this approach is to try and minimize the possibility of actions spilling over into unrelated sectors. In general terms, the Dispute Settlement Body monitors how adopted rulings are implemented and each case remains on its agenda until the issue is fully resolved.

Insofar as the WTO deals with contentious disputes, it is true to state that food occupies a central role within it. For example, of the 380 or so disputes initiated between WTO inception in 1995 and 2008, over a third involved food. In this regard, except for 'metals', no other product category came close.[131]

2.6.1.1 Effect of WTO Rules on EU Food Law

Where possible, EU food law must conform to the European Union's WTO obligations.[132] However, it is still early days for the various WTO tribunals in clarifying the full scope of the rights and obligations contained in the WTO agreements affecting food. Accordingly, the circumstances have not yet arisen that would allow important provisions of these agreements to be fully addressed by the Panels and the Appellate Body. Notwithstanding that, the domestic regulation disputes that have arisen to date have revealed that the SPS and TBT

[129] This may take the form of tariff reductions in areas of particular interest to the complainant.
[130] The Dispute Settlement Body must grant this authorization and it must do so within 30 days of the expiry of the 'reasonable period of time' unless there is a consensus against the request.
[131] M. Bronckers & R. Soopramanien, "The Impact of WTO Law on European Food Regulation" (2008) *European Food & Feed Law Review*, Issue 6, p.361.
[132] C. MacMaolain, note 58 above, p.149.

Agreements have far-reaching implications affecting a Member's right to set its preferred levels of regulatory protection.[133]

However, various factors can influence the proper functioning of the system and it always depends on compliance. Issues such as the advancement of member self interest, delays in proceedings and shortcomings in finding effective remedies to issue that arise, continues to weaken the WTO dispute settlement mechanism in its attempts to resolve international disagreements over non-compliance issues which impede global trade in food.[134] However, clearly there are also circumstances in which the very existence of the WTO rules and EU deference as a WTO member, will affect the nature of EU food laws. On occasion, this may even influence the EU to amend already enacted regulations.

If one consider for example Regulation 2081/1992[135] which established a system for the protection of geographical food indications. It was found that a situation existed which amounted to a curtailment of access to the EU registration system for applicants from third countries and as a result the legislation had to be ameliorated. In circumstances such as this, where there is an emphasis on prompt compliance with the findings of panel reports, the dispute resolution process can be deemed a success. However, such situations can be contrasted with the delays that took place in reaching a decision on the EU moratorium on the approval and use of GMOs.[136] The procrastination or obfuscation in that instance only serves to diminish the impact of a ruling once it ultimately arrives.

With regard to the situation regarding GMOs, the EU actions were initiated in the late 1990s, but the WTO Panel Report[137] did not issue until late 2006. This was nearly a decade after the trade inhibiting actions of the EU had first been implemented. By September 2006, EU public concern over the use of GMOs in food production had already died down. To date, the matter has not been finally settled between the nations concerned and the EU has not suffered any sanction as a result of its actions.

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[133] M. Bronckers & R. Soopramanien, note 131 above, p.361.
[134] C. MacMaolain, note 58 above, p.149.
[135] These provisions are now contained in Council Regulation 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs. [2006] O.J. L93/12.
[136] C. MacMaolain, note 58 above, p.150.
[137] Report WT/DS291/R/USA of the World Trade Organisation Dispute Settlement Panel, *European Communities — Measures Affecting the Approval and Marketing of Biotech Products* (29 September, 2006).

Another major issue that influences the manner in which the WTO agreements influence EU food law rests on the nature of the agreements themselves. It is important to note that while the SPS and TBT Agreements share common features, the obvious fundamental difference is that they regulate different subject-matter. The SPS Agreement exclusively covers food related measures dealing with public or animal health, while the TBT Agreement essentially addresses regulatory measures taken in furtherance of objectives other than those of the SPS Agreement.

2.6.1.2 Agreement on the Application of Sanitary and Phytosanitary Measures

The global arena for food safety regulation is represented by the WTO agreements - GATT[138] and the Agreement on the Application of Sanitary and Phytosanitary[139] Measures (SPS Agreement).[140] The short Marrakesh Agreement establishing the World Trade Organization sets up the legal and institutional foundations. Attached to that Agreement is a much lengthier set of four annexes which contain the other international trade agreements together with the rules and procedures governing the operation of the Organization.[141] Annex 1A contains the multilateral agreements[142] on trade in goods, such as the Agreement on Agriculture and the SPS Agreement.[143]

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[138] The WTO has replaced GATT as an international organization. However, the General Agreement still exists (as updated by the Uruguay Round negotiations) as the WTO umbrella treaty for trade in goods. GATT 1994 is the updated version and at the heart of that Agreement is the original GATT 1947.

[139] 'Sanitary' regulations can be defined as general food safety and animal health regulations which restrict or prohibit the importation or marketing of certain food items. 'Phytosanitary' regulations are regulations that restrict or prohibit the importation and marketing of certain plant species, or food products manufactured with those plants, so as to prevent contamination by any plant pests or pathogens that the plants may be carrying.

[140] The SPS Agreement (opened for signature 15 April 1994,1867 UNTS 493), was negotiated during the Uruguay Round of trade talks which also led to the establishment of the WTO. The Agreement entered into force with the establishment of the World Trade Organization on 1 January 1995. It concerns the application of food safety, and animal & plant health regulations.

[141] It is important to note that the WTO Agreement is a 'single undertaking' that has to be interpreted as a whole. In other words, the other Agreements, especially the GATT can effect how the provisions of the SPS Agreement are to be interpreted. *Argentina – Safeguard Measures on Imports of Footwear*, WT/DS121/AB/R, para 81.

[142] These Agreements they comprise the substantive trade policy obligations which all WTO members have accepted.

[143] Annex 1B contains the General Agreement on Trade in Services, Annex 1C contains the Agreement on Trade Related Aspects of International Property Rights, Annex 2 contains the Rules and Procedures Governing the Settlement of Disputes, Annex 3 contains the Trade Policy Review Mechanism, and Annex 4 contains the plurilateral trade agreements such as the International Dairy Agreement and the International Bovine Meat Agreement.

The removal of obstacles to trade has always been the primary objective of the WTO food safety regime. Occasionally, various countries around the world have operated import restrictions either in the form of outright bans, tariffs, or non-tariff barriers to free trade. During the Uruguay Round of trade negotiations, US agricultural exporters and the Cairns Group[144] of countries realised that cross-national differences in food safety standards effectively create a non-tariff barrier to trade. As a result, they were concerned that importing nations, especially in Europe, might arbitrarily change food safety regulations in order to maintain a 'constant level of protection'[145] unless agricultural trade liberalisation was augmented with enforceable provisions to allay such protectionist measures.[146] It was against this background that the SPS Agreement was negotiated simultaneously with the Agreement on Agriculture. The EU and the US were the two most prominent players in these negotiations. The WTO Agreement on Agriculture sets-out its aim of substantial progressive reductions in agricultural support and protection, in order to correct and prevent restrictions and distortions in world agricultural markets.

Consequently, when the SPS Agreement was drawn-up as part of the Uruguay Round negotiations, its main purpose was to ensure that sanitary and phytosanitary measures were not adopted merely as a form of economic protectionism. The Agreement is an enforceable set of rules intended to prevent domestic food safety standards from becoming a protectionist device. The SPS Agreement is an attempt at balancing the competing spheres of domestic regulatory autonomy as against global harmonization of product standards. The SPS Agreement heralded the arrival for the first time in international trade of an agreement which provides that any restrictions on food products imposed with the objective of protecting human or animal health or the environment should be non-discriminatory. The setting of food safety standards is not per se, a goal of the SPS Agreement or the WTO Dispute Settlement Mechanism. The food safety standards arise in a secondary capacity intrinsic to proving that protectionism was not a motive.

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[144] The Cairns Group is an interest-group of 19 agricultural exporting countries composed of Argentina, Australia, Bolivia, Brazil, Canada, Chile, Colombia, CostaRica, Guatemala, Indonesia, Malaysia, New Zealand, Pakistan, Paraguay, Peru, the Philippines, South Africa, Thailand, and Uruguay.

[145] J. Bhagwati, *Protectionism* (Cambridge, Mass: MIT Press, 1989), p. 53.

[146] T. Hale & D. Held (eds), *Handbook of Transnational Governance: New Institutions and Innovations*, (Cambridge: Polity Press, 2011), p. 219.

GATT recognizes that exceptions may be necessary to its main objective of the liberalisation of international trade through non-discrimination between trading partners. The exception is contained in GATT Article XX(b) which states that the GATT does not preclude members from taking measures necessary for the protection of life and health of people, animals and plants.[147] In turn, this exception has been elaborated on, in the SPS Agreement.[148] The inclusion in the GATT Uruguay Round Agreements of an agreement governing sanitary and phytosanitary measures (the SPS Agreement) and the inclusion of the aforementioned exception, was intended to create a means by which a country could impose bona-fide health-related measures or, alternatively, prevent a trading partner from imposing measures for purely protectionist reasons.[149]

The SPS Agreement provides for dispute resolution through the WTO.[150] The use of WTO dispute settlement procedures as a means of resolving trade disputes caused by sanitary measures can be viewed as an indication of the effectiveness of the SPS Agreement. While a number of trade problems have been resolved at the bilateral level, without recourse to a Dispute Settlement Panel, as we shall see, the same cannot be said of the *Beef-Hormones Dispute*.

In the years following the *Beef Hormones Dispute*, a number of developments have taken place in the context of WTO dispute resolution. In particular, WTO Members have been encouraged to consider mediation through the 'good offices' of the Chairperson of the Committee on Sanitary and Phytosanitary Measures (SPS Committee) as a means of resolving some of their differences before the matter develops into a formal dispute.

The first substantial discussion of a more developed approach in this regard took place at the SPS Committee meeting in June 2008. Since then the parties have agreed on a draft procedure document governing the use of the 'good offices' facility. However, in March 2014

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[147] The GATT still has a role to play, forming part of the WTO Agreements. For example, a measure which affected the conduct of private parties was found to be prohibited under GATT. See *Canada-Certain Measures Affecting the Automotive Industry*, WT/DS161/R.

[148] B.M.J. van der Meulen, "Science Based Food Law" (2009) *European Food & Feed Law Review*, p.61.

[149] M.D. Carter, "Selling Science Under the SPS Agreement: Accommodating Consumer Preference in the Growth Hormones Controversy", (1997) *Minnesota Journal of Global Trade*, Vol.6, Issue 2, p.632.

[150] Article 11 of the SPS Agreement provides that 'the provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the WTO Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement'. See, M.D. Carter, note 149 above, p.634.

the SPS Committee deferred reaching a final decision on the matter following a request by India that certain matters be clarified.

2.6.2 Codex Alimentarius

As we have seen, any national sanitary and phytosanitary measures which conform to international standards, such as the Codex Alimentarius Commission, are presumptively valid under the terms of the SPS Agreement. In the EU, Article 5(3) of the General Food Law[151] prescribes that international standards shall be taken into consideration in the development or adaptation of EU food law. The Codex Alimentarius is the most important of these international food standards and guidelines.

The prospect of European regional cooperation on food standards became apparent in 1958 and as a result the US felt the need to garner a broader international effort so as to safeguard against exclusion of their interests.[152] Subsequently, the Codex Alimentarius Commission (CAC) was established by a United Nation's Food & Agriculture Organisation (FAO) Conference resolution in 1961 and a World Health Assembly resolution in 1963, in order to assist in the development of trade in foodstuffs.

Codex is run under the aegis of the FAO and the World Health Organization (WHO). The purpose of the CAC is to implement the Joint FAO/WHO Food Standards Programme. As a constituent part of its remit, the Codex Alimentarius Commission develops and maintains the Codex Alimentarius ('Codex'), a set of international non-binding indicative standards, recommendations and guidelines aimed at food safety and fair trade.[153] The World Trade Organization recognises Codex as an international reference point in its endeavours to resolve disputes concerning food safety and consumer protection. Because virtually all nations of the world are represented in the Codex Alimentarius Commission, the Codex is very useful as a benchmark in comparative food law.[154]

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[151] European Parliament and Council Regulation (EC) No 178/2002, note 72 Chapter 2 above.

[152] D.M. Leive, *International Regulatory Regimes: Case Studies in Health, Meteorology and Food*, (Lexington, M.A.: Lexington Books, 1976), Vol. 1, p. 276.

[153] The complete Codex is set out in volumes covering the various food groups. Each Volume is structured into sections containing general principles, general standards, definitions, codes, commodity standards, methods and recommendations.

[154] B. M. J. van der Meulen, note 67 Chapter 2 above, p.323.

Under its Rules, the Codex Commission is comprised of two subsidiary bodies:

(a) Codex Committees charged with preparing draft standards[155] which are then submitted to the Commission; and
(b) Coordinating Committees which liaise with regions or groups of countries in an effort to coordinate or harmonise their food standards activities.

One of the Codex Committees, the Commodity Committee, has responsibility for developing standards for specific foods or classes of food. These Codex standards are of strong persuasive value in many food related legal disputes as they are considered to be a point of reference in the case of trade disputes between WTO Members.

Codex standards are said to be either 'horizontal' (applying to all foodstuffs) or 'vertical' (applying to specific foodstuffs).[156] Horizontal standards deal with matters such as food labelling, food additives, contaminants in food, methods of analysis and sampling, food hygiene, nutrition and foods for special dietary uses, food import and export inspection and certification systems, residues of veterinary drugs in foods and pesticides residues in food.

The complete Codex is set out in volumes on:- general requirements; general requirements (food hygiene); pesticide residues in foods (general texts); pesticide residues in foods (maximum residue limits); residues of veterinary drugs in foods; foods for special dietary uses (including foods for infants and children); processed and quick-frozen fruits and vegetables; fresh fruits and vegetables; fruit juices; cereals, pulses (legumes) and derived products and vegetable proteins; fats and oils and related products; fish and fishery products; meat and meat products, soups and broths; sugars, cocoa products and chocolate and miscellaneous products; milk and milk products and; methods of analysis and sampling. Each Volume is structured into sections containing general principles, general standards, definitions, codes, commodity standards, methods and recommendations.

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[155] These food standards are commonly known as Codex Standards. Between 1897 and 1911, the Austro-Hungarian Empire developed a sophisticated set of standards and product descriptions for foods, known as the Codex Alimentarius Austriacus. It was this Alimentarius Austriacus that lent its name to the present-day Codex Alimentarius of internationally recognized standards, codes of practice, guidelines and other recommendations relating to foods, food production and food safety.

[156] Under Codex, the 'vertical' foodstuffs are classified as Fats and Oils, Fish and Fishery Products, Milk and Milk Products, Fresh Fruits and Vegetables, Cocoa Products and Chocolate, Sugars, Processed Fruits and Vegetables, Vegetable Proteins, Cereals, Pulses and Legumes, Processed Meat and Poultry Products, Soups and Broths, Meat Hygiene, Natural Mineral Waters.

Under Codex standards precaution is incorporated as an inherent element of the risk analysis and in situations of scientific uncertainty, as a rule no codex standard should be adopted.[157] In effect, this aspect of the issue is left open which is in keeping with Codex's non-binding role as an over-arching template for national legislation.[158]

2.6.2.1 Codex and Harmonisation of Food Safety Standards

In an ever-increasing global food market, it seems self-evident that there are inherent advantages in having universally uniform food standards for the protection of consumers. Commentators often argue that the harmonization of global and regional food standards is a prerequisite to ensuring the protection of consumer health and that it also facilitates the fullest possible degree of international trade. National governments are faced with increasing public demand for those standards.

Yet, due to globalisation of the food supply, there has been a decline in the capacity of government and national authorities to meet public demand for standards. It is on that premise, as noted by the FAO,[159] that both the Uruguay Round Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Technical Barriers to Trade (TBT) Agreement, encourage the international harmonization of food standards.

In the EU, the General Food Law[160] lays down the general principles and requirements of food law and is considered the basis of European food hygiene law since it forms the foundation for all other pertinent Regulations. The General Food Law contains general requirements with which EU legislation on food has to be consistent. For example, Article 5(3) of the General Food Law prescribes that international standards shall be taken into consideration in the development or adaptation of EU food law. The Codex Alimentarius is the most important international standard.

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[157] Codex Alimentarius Commission's *Procedural Manual, 17th ed.*, para's 10 & 11, p.113.
[158] B.M.J. van der Meulen, note 148 above, p.61.
[159] See FAO and WHO, "The Codex system: the Codex Alimentarius Commission and How it Works", note 12 Chapter 2 above.
[160] European Parliament and Council Regulation (EC) No 178/2002, note 74 Chapter 2 above.

Codex standards can be fully accepted, accepted with minor deviations, or accepted by 'free distribution' by the Member Countries of Codex. The FAO has stated that there continues to be a growing world interest in Codex and this indicates global acceptance of the Codex philosophy which embodies the embracing of harmonization, consumer protection and facilitation of international trade.

Globalisation and free trade means that disparate international food standards are a problem. A uniform or model international food law is the most obvious remedy for dealing with this, but it is likely to be highly contested in practice due to the international diversity between cultures, oftentimes displaying diametrically opposed ideas and interests when it comes to food. As a result it can be difficult for some countries to include the Codex standards in their statutory code, because of differing legal systems, political concerns and concepts of sovereign rights impede the progress of harmonization and deter the acceptance of Codex standards.[161] In examining the relationship between the EU and Codex, there is of course a major institutional difficulty due to individual participation of EU Member States. A European Commission delegation participates in Codex as an observer and tries to forge a 'European consensus' among the EU Member States. The Commission itself can neither vote nor officially block consensus. Allowing EU Member States to act independently at the international level is an undesirable situation when EU food safety policy is formulated at the federal level and applies to all EU Member States equally.

Notwithstanding this, the process of harmonization still maintains a certain impetus due to the overriding international imperative of facilitating trade. As a result, countries continue to align either part (especially those relating to safety) or all of their national food standards with those of the Codex Alimentarius. According to the FAO, this is particularly so in the case of the 'invisibles', namely, additives, contaminants and residues.[162]

2.7 Use of Growth Hormones in Beef Production

2.7.1 Introduction

[161] See FAO and WHO, "The Codex system: the Codex Alimentarius Commission and How it Works", note 12 Chapter 2 above.
[162] *Ibid.*

Growth promoting hormones, or 'growth promotants'[163] to use the American term, are used extensively in many countries around the world to enhance beef cattle production. Their use has been legitimate in the US since the 1950s. Their use is also legitimate in Canada. Growth hormones are used extensively in the large cattle-producing regions of Australia, New Zealand, and Argentina.[164] However, the use of growth hormones in meat producing animals is illegal in the EU and the EU continues to ban imports of hormone-treated meat.

In the US, growth hormones are approved for safety and effectiveness under the Federal Food, Drug, and Cosmetic Act.[165] In 2010, there were thirty licensed animal growth-promoting products commercially available in the US.[166] In the US, growth hormones are now believed to be used on approximately two-thirds of all cattle and on about 90 per cent of the cattle in feedlots. In the massive US concentrated animal feeding operations (CAFOs),[167] their use approaches 100 per cent. It has been reported that approximately 95 per cent of US cattle are at some time during their life cycle, implanted with growth hormones.[168]

Most growth hormones come in the form of small pellets that are implanted under the skin at the back of the animal's ear. The pellet slowly releases a gradual hormone dosage over a certain period of time - usually 100 to 200 days, depending on the product used. A minority of growth hormones also come in either powder or liquid form and are administered by mixing the product with the animal's feed.

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[163] These drugs increase the animals' growth rate, the efficiency by which they convert the feed they eat into meat, and the leanness of their meat.

[164] W.A. Kerr & J.E. Hobbs, "The North American–European Union Dispute Over Beef Produced Using Growth Hormones: A Major Test for the New International Trade Regime", (2002) *The World Economy*, Vol.25, Issue 2, p. 285.

[165] 21 USC. 301 et seq.

[166] C.S. Houston, "From the Farm to the Factory: An Overview of the American and European Approaches to Regulation of the Beef Industry", (2005) *Journal of Food Law & Policy*, Issue 1, p. 269.

[167] Aside from the concerns surrounding hormones, United States beef from their CAFO raised cattle can have up to 500 per cent more saturated fat than that of grass-fed cattle – the producers feed a diet that will produce a more marbled meat. Because the cattle are raised in appalling overcrowded conditions, their skin is often covered in faecal matter and bacteria which can be a breeding ground for e.coli. As a result, after slaughter, their meat is sometimes cleaned with chlorine.

[168] E.J. Kuchler, J. McClelland and S.E. Offutt, "Regulating Food Safety: The Cost of Animal Growth Hormones." (1989) 12 National Food Review. Economic Research Service, US Department of Agriculture, pp. 25-33, as cited in, J. L. Lusk, J. Roosen, J. A. Fox, "Demand for Beef from Cattle Administered Growth Hormones or Fed Genetically Modified Corn: A Comparison of Consumers in France, Germany, the United Kingdom, and the United States" (Feb., 2003) 85 *American Journal of Agricultural Economics* 1, p.17.

The hormones in growth promoting implants include estrogens[169] (estradiol and zeranol), androgens[170] (testosterone and trenbolone acetate or TBA) and progestins[171] (progesterone and melengestrol acetate or MGA). The group of six hormones banned by the EU and sanctioned for use by the US and Canada are comprised of three 'natural hormones'[172] (that also occur naturally in the animal) and three 'synthetic hormones'. The three natural hormones are oestradiol-17β (responsible for female characteristics), testosterone (responsible for male characteristics), and progesterone (responsible for maintaining pregnancy). The three synthetic hormones are zeranol, trenbolone acetate (TBA),[173] and melengestrol acetate (MGA).

Growth hormones are used because they have the effect of reducing fat deposition in animals and since fat is so energy dense, food conversion efficiency is increased. Lean tissue growth is also increased.[174] This allows the animals to grow larger, more quickly, on less feed and fewer other inputs, thereby reducing production costs. In addition, advocates of growth hormone use would point out that the resultant leaner carcass is more in line with consumer preferences for lean meat and also for diets with reduced fat and cholesterol.[175]

The economic benefits are substantial. Apparently, growth hormones used in cattle typically increase lean tissue by between 8 – 20 per cent over the cattle-raising cycle.[176] One US study has found that through improving cattle growth rates and feed conversion efficiency, growth hormones have increased annual US beef production by more than 700 million pounds while saving more than 6 billion pounds of feed. In addition, if US beef production practices from 1955 were applied today, an additional 165 million acres of land (an area almost the size of

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[169] Female sex hormones.

[170] Male sex hormones.

[171] A progestin is a synthetic progestogen that has progestinic effects similar to the female hormone progesterone.

[172] Often referred to as 'naturally occurring' hormones.

[173] Zeranol and trenbolone acetate hormones are implanted behind one of the animal's ears as a time-release implant, releasing hormones during key growth stages. The hormones provide a substantial cost saving to the cattle-producer as they may eliminate as much as twenty days feeding equivalent each time they are used.

[174] Recent years have seen research into the effect of growth hormone treatment on the eating quality of beef. Apparently, 'the balanced view on hormone treatments, especially repeat implantations, is that they lead to small reductions in tenderness and eating quality'. See, New South Wales, Department of Primary Industries, *Understanding Hormonal Growth Promotants* (August, 2008) Primefact 790. Available at: http://www.dpi.nsw.gov.au/__data/assets/pdf_file/0008/241856/Understanding-hormonal-growth-promotants.pdf [Accessed: March 8, 2012]

[175] See generally, R. Johnson & C.E. Hanrahan, *The US-EU Beef Hormone Dispute*, (2010) Congressional Research Service, 7-5700, R40449, p.1. Available at: http://www.nationalaglawcenter.org/assets/crs/R40449.pdf [Accessed: May 8, 2011]

[176] See generally C.S. Houston, note 166 above, p. 269.

Texas) would be required in order to equal modern growth hormone assisted beef production in the US.[177]

The FDA and the US Department of Agriculture (USDA) maintain that hormones residues in beef pose no detrimental physiological implications for human health.[178] The majority of the main international scientific bodies such as the World Health Organization's Joint Expert Committee on Food Additives (JECFA),[179] the Food and Agricultural Organization of the United Nations (FAO), the Codex Committee on Residues of Veterinary Drugs in Food,[180] and the Codex Alimentarius Commission[181] itself – have all opined on the safety of growth hormones when used 'in accordance with good veterinary practice'. Similar conclusions were reached by the United Kingdom's 1999 and 2006 Veterinary Products Committee reports[182] and the 2003 Australian review.[183] In addition, neither of the two major EU initiatives – the Lamming Committee[184] scientific expert group and the 1995 Scientific Conference on

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[177] J. Kelzer, "Use of long-acting combination implant to increase growth and efficiency of feedlot steers", (Monday, May, 2011) *Minnesota Farm Guide*. Available at: http://www.minnesotafarmguide.com/news/livestock/use-of-long-acting-combination-implant-to-increase-growth-and/article_171f6cbe-84b0-11e0-8d98-001cc4c03286.html [Accessed: 12 April 2012].

[178] R. Johnson & C.E. Hanrahan, note 175 above.

[179] World Health Organization (WHO), *Evaluation of certain veterinary drug residues in food* (32nd JECFA report) WHO Technical Report Series, No. 763, 1988 (et seq.). The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an international scientific expert committee administered jointly under the aegis of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). It has been meeting since 1956 and its work includes the evaluation of food additives, contaminants, naturally occurring toxicants and residues of veterinary drugs in food.

[180] The Codex Committee on Residues of Veterinary Drugs recommends Maximum Residue Limits (MRLs) for veterinary drugs. A Codex Maximum Limit for Residues of Veterinary Drugs (MRLVD) is the maximum concentration/residue for a veterinary drug that is recommended by the Codex Alimentarius Commission to be legally permitted or acceptable for use in food. An MRLVD (expressed by the Acceptable Daily Intake - ADI) is the amount of residue that does not have any toxicological hazard for human health.

[181] Codex Alimentarius Commission (CAC), *Report of the 8th Session of the Codex Committee on Residues of Veterinary Drugs in Foods*, July 1995 (et seq.), http://www.codexalimentarius.net/download/report/213/AL95_31e.pdf. CAC develops food standards, guidelines and codes of practice under the Joint FAO/WHO Food Standards Programme.

[182] UK's Veterinary Products Committee, "VPC Report - Risk Associated with the Use of Hormonal Substances in Food Producing Animals," July 2006, and "Sub Group on Hormonal Growth Promoters" October 1999, available at http://www.vpc.gov.uk/Public/reportsWG.html. Also see USDA, *UK scientific report questions EU position on beef hormones*, GAIN Report UK6022, July 7, 2006, http://www.fas.usda.gov/gainfiles/200607/146208214.pdf.

[183] Australian Pesticides and Veterinary Medicines Authority, "A Review to Update Australia's Position on the Human Safety of Residues of Hormone Growth Hormones (HGPs) Used in Cattle," July 2003.

[184] The Lamming Committee was an EU expert working group (comprising members of the Scientific Committee for Food and the Scientific Committee for Animal Nutrition - the lead committee for issues concerning growth promoters), that in 1982 reached an interim conclusion that oestradiol and several other growth promoters with a hormonal action were safe for use as growth hormones in cattle.

Growth Promotion in Meat Production[185] – have found any evidence of health risks from the use of growth hormones.

2.7.2 Beef Hormones Dispute

Prior to 1981, there was no official EU policy on the use of growth hormones in animals. However, national policies existed within individual EU Member States. EU antipathy towards growth hormones began in the 1970s with the diethylstilboestrol (DES)[186] scare involving cases of hormonal irregularities[187] in Italian adolescents.[188] Then, there was the discovery in 1980 of 30,000 jars of baby food in Italy containing dethylstilboestrol (DES).[189] The DES scare had created a consumer climate in Europe that was concerned over the potentially harmful health effects of using hormones in livestock production.[190] It was these events together with the discovery that DES was carcinogenic, that prompted European politicians to take action.[191]

From 1980 onwards the Commission began to enforce various bans on the use of growth hormones in animal meat production which eventually culminated in 1988 with Council Directive 88/146/EEC[192], the first blanket ban on all of the six growth hormones concerned. In addition, meat and meat products treated with any of the six specific growth hormones could no longer be imported into the EU.

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[185] European Commission, Proceedings of the Scientific Conference on Growth Promotion in Meat Production, November 29, 1995 (Office for Official Publications for the European Communities, Brussels).

[186] DES was used as a growth hormone in the beef and poultry industry. It was later found to cause cancer and was phased out. From time to time, mainly in the US, allegations surface that some producers continue to use it. See, A.I. Marcus, *Cancer from Beef: Federal Food Regulation, and Consumer Confidence: DES, Federal Food Regulation and Consumer Confidence* (Baltimore, MD: The Johns Hopkins University Press, 1994).

[187] Exposure to the hormone was suspected as the cause for early puberty in girls. However, this has never been verified. See, R. Gandhi & S. Snedeker. "Consumer Concerns About Hormones in Food", Cornell University Program on Breast Cancer and Environmental Risk Factors, Fact Sheet #37 (2000), Available at: http://ecommons.library.cornell.edu/handle/1813/14300 [Accessed: May 10, 2011].

[188] T. Josling, D. Roberts, & A. Hassan, "*The Beef-Hormone Dispute and its Implications for Trade Policy*" (Stanford: Stanford University, 1999), p.3. Available at: http://fsi.stanford.edu/people/timothyejosling/ [Accessed: May 9, 2011].

[189] European Parliament, 1995, "Der illegale Einsatz von Hormonen zu Mastzwecken in Europa". Reihe Umwelt, Volksgesundheit und Verbraucherschutz, W12, Strasbourg: European Parliament., as cited in L. Caduff, *Growth Hormones and Beyond, Working Paper 8-2002* (Zurich: Centre for International Studies, 2002), p.6.

[190] T. Josling, D. Roberts, & A. Hassan, note 188 above.

[191] L. Caduff, *Growth Hormones and Beyond, Working Paper 8-2002* (Zurich: Centre for International Studies, 2002), p.6.

[192] Council Directive 88/146/EEC prohibiting the use in livestock farming of certain substances having a hormonal action, [1988] O.J. L70/16.

2.7.2.1 EC-Hormones

After the new WTO system was launched in 1995, the US brought a complaint to the WTO Dispute Settlement Body (DSB) on the ground that the EU had violated the SPS Agreement by introducing a ban on the importation of beef treated with growth hormones.[193] Subsequently in 1996, DSB Panels were established by the DSB in response to formal complaints relating to the ban having been made by the US[194] and Canada.[195] This stage of the *Beef Hormones Dispute* is often colloquially referred to as '*EC-Hormones*'.

The EU essentially argued that they had assessed the risks associated with growth hormones and concluded that the hormones were unsafe. The EU also claimed that historically it had in any event employed a higher level of protection for its citizens than the current ban and therefore its ban was in keeping with those higher standards and on that basis did not violate the SPS Agreement.

2.8 Conclusion

In order to create an initial understanding of international food regulation and in particular the reasons behind the *Beef Hormones Dispute*, this Chapter provided an overview of the main domestic and international legislative and administrative frameworks involved insofar as the regulation of beef is concerned. As a result, it will be possible, beginning with the next Chapter, to examine the issues involved in greater detail.

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[193] A number of the controversial EU provisions banning growth-promotants were enacted before the coming into existence of the SPS Agreement. However, in *EC-Hormones*, the Appellate Body agreed with the Panel's findings and concluded that 'the *SPS Agreement*, and in particular Articles 5.1 and 5.5 thereof, applies to measures that were enacted before the entry into force of the *WTO Agreement*, but that remain in force thereafter'. Paragraph 253(d) of Appellate Body Reports WT/DS26AB/R and WT/DS48/AB/R

[194] WT/DS26. On 25 April 1996, the US requested the establishment of a panel. A panel was established at the DSB meeting on 20 May 1996. On 2 July 1996, the Panel was composed. The report of the Panel was circulated to Members on 18 August 1997.

[195] WT/DS48. On 16 September 1996, Canada requested the establishment of a panel. The DSB established a panel at its meeting on 16 October 1996. On 4 November 1996, the Panel was composed. The report of the Panel was circulated to Members on 18 August 1997.

The investigations in this Chapter have discovered that the European Commission's food safety policy is expressly designed to ensure a high level of protection of human health and consumers' interests in relation to food, taking into account diversity in the food supply, including traditional products. The European Food Safety Authority is effectively the umbrella risk assessor, with the European Commission, the European Parliament and EU Member States themselves acting as the risk managers. The General Food Law prescribes that international standards shall be taken into consideration in the development or adaptation of EU food law. The Codex Alimentarius is the most important of these international food standards and guidelines.

Globalisation of the food supply has created difficulties in regulating food standards and while the most obvious solution to this problem is international food standards, this is likely to be highly contested in practice due to international cultural diversity. Nonetheless, we have a number of global institutions and frameworks which produce the rules that shape the world food system. The most significant development in this area was the creation in 1995 of the World Trade Organization (WTO).

As we have seen, EU food law must conform to the obligations of the EU as a WTO Member.[196] The implications of this will be investigated in greater detail in subsequent chapters of this thesis. As we have seen, the WTO SPS Agreement has as its main goal the harmonisation of global food regulatory measures in furtherance of trade liberalisation. It is not primarily concerned with food safety.

The use of animal growth hormones use has been legitimate in the US since the 1950s. Their use is also authorised in Canada. Growth hormones are used extensively in the large cattle-producing regions of Australia, New Zealand, and Argentina. However, the use of growth hormones in meat producing animals is illegal in the EU and the EU continues to ban imports of hormone-treated meat.

The next Chapter uses the knowledge of the substantive food safety law gained in this Chapter to analyse the place of culture in food safety regulation. The Chapter analyses the accommodation of 'tradition' in the food supply and endeavours to identify any divergences

[196] Individual EU Member States are WTO members.

in the culture of administration which exist between EU and US food safety regulation. The different cultures of big business and corporate lobbying are also examined along with a brief investigation of the cultural background to the *Beef Hormones Dispute*.

CHAPTER 3

THE CULTURAL BIASES INHERENT IN FOOD AND ITS REGULATION

3.1 Introduction

As stated in the introductory Chapter, the way we eat has changed more in the last eighty years than it did in the previous ten thousand years. Our diet is now determined for us by a complex interplay of social, economic, and technological forces.[1] Some countries specialise in large scale mass production and others specialise in high-quality niches. As a result, their food standards develop differently. One industry may depend more on chemical additives, whereas the other may favour exclusive quality seals.[2] Furthermore, these forces operate on a global basis. In any large supermarket anywhere in the world, one will find foods that were produced in many different countries. There is effectively no such thing as seasonal availability anymore as fruit is brought thousands of miles and then ripened using ethylene gas.[3] We are required to develop a truly global palate in order to consume a food supply that is abundant, varied, inexpensive, and devoid of dependence on geography or season. In 2009, an average US supermarket stocked approximately 48,750 different items on its shelves - a range of products that would have been scarcely imaginable a few decades ago.[4] This cosmopolitan culinary experience doesn't end there, as we've become accustomed to an eclectic choice of restaurants offering exotic dishes.

However, because of this internationalisation of food, consumer confidence in the provenance of the food supply has been undermined. People's food choices are neither

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[1] E. Schlosser, note 9 Chapter 1 above, p.3.
[2] F. van Warden, note 11 Chapter 1 above, p.35.
[3] Ethylene Gas (C2H4) has the ability to affect the growth, ripening, and senescence (aging) of all plants. It is Generally Recognized as Safe (GRAS) by the United States Food and Drug Administration.
[4] US Food Marketing Institute: *Food Marketing Facts – Industry Overview 2009*. 'Dry-grocery food' items comprises the largest portion of sales in a US supermarket, at approximately 25 per cent, with meat/fish/poultry in second place at approximately 13 per cent of supermarket sales. The combined total of 'dry-grocery non-food' items accounts for only 7.15 per cent of sales.

random nor haphazard, but exhibit patterns and regularities.[5] Therefore, people become unnerved when uncertainty arises. Because the food is no longer produced locally by local farmers, information asymmetries have arisen and this has increased consumer mistrust in the market. National or domestic regulation becomes less effective as it is less able to govern the policies of foreign producers.[6] Recent well publicised health scares in the EU have raised questions over the safety of food and elevated the importance of food safety in the minds of consumers. The food chain has withstood attack from various sources including, bovine spongiform encephalopathy (BSE) in beef, foot-and-mouth disease, *e.coli* poisoning, avian influenza, and dioxin contamination. Serious incidents such as these have highlighted the vulnerability of consumers as they go about the very normal activity of purchasing food. Yet, consumers continue to expect the global food business and food safety framework to supply them with products that offer not just the requisite nutritional content, but that are also safe to eat.

In addition to these direct health concerns, differences of opinion have arisen due to the advent of biotechnological processes. In particular, in Europe there is concern over genetic modification (GMOs) and the use of growth hormones in beef production. On one side the ardent advocates of biotechnology, who are predominantly located in the US, argue that food products created using these processes are good, wholesome to eat, and that we can all look forward to the benefits of productivity and a more certain food supply. On the other side the consumer associations/interest groups, especially in the EU,[7] voice their fears of the long term health and environmental effects of eating genetically modified foods and other foods produced with the aid of novel technologies.

As a result, worldwide, consumers are concerned about the food they eat. These consumer concerns and attitudes differ from region to region. Our culture influences everything we do.[8]

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[5] A. Murcott, "The cultural significance of food and eating" (1982) *Proceedings of the Nutrition Society*, Vol.41, p.203.

[6] F. van Warden, note 11 Chapter 1 above, p.37.

[7] Throughout this thesis the European Union shall be referred to using the designation 'EU'. For the sake of consistency and to avoid confusion, 'EU' shall also be used when referring to events that occurred at a time prior to the European Union, during the existence of the 'European Community' (EC) or 'European Economic Community' (EEC). For clarification, it is noted that with the entry into force of the Treaty on European Union (Treaty of Maastricht) in 1993, the European Economic Community (EEC) was renamed the European Community (EC). Upon the entry into force of the Treaty of Lisbon in 2009, the EC became the European Union (EU). At the date of writing this thesis, in accordance with the Treaty of Lisbon the EU is now the official legal personality.

[8] A. K. Syn, note 27 Chapter 1 above, p. 33.

This thesis posits that these divergent cultural influences are always evident in food safety legislation. The end result is the creation both nationally and supranationally of 'cultural regulatory divergences' in food safety legislation. It is likely that these divergences between the food regulatory regimes of trading nations will always exist and that they will continue to give rise to trade disputes.

As outlined in the introductory Chapter, this thesis utilises the concept of comparative legal methodology in order to examine the food safety regimes of the EU and the US. This will enable an identification of the merits and shortcomings of each food regulatory regime in order to inform the potential for a single or model international food regulatory system devoid of regulatory divergences. It will also be of assistance in investigating the WTO sanitary constructs. This comparative overview combined with an investigation of WTO governance of the food trade, allows an identification of the areas of convergence and divergence between the domestic and global constructs. This is necessary in order to fully understand the global nature of this sector and its connectivity worldwide. For example, even when one's primary interest rests with developments in EU food regulation, it has been observed that it is no longer possible to disregard the doctrinal developments of the WTO.[9]

More specifically, the investigation will facilitate an identification and understanding of the main differences between these two regulatory regimes. The comparative overview of food safety law in these jurisdictions is central to analysing a core aspect of this thesis, namely, that cultural influences are always evident in food safety legislation and as a result divergences between the food regulatory regimes of trading nations are likely to always exist. The resultant divergences impede international harmonisation of food standards and thereby increases the likelihood of trade-disputes. The knowledge gleaned from the analysis can also be applied in identifying the merits and shortcomings of each system so as to reach a conclusion regarding which is the more effective and desirable regulatory regime. This knowledge will be useful later in this thesis, especially when analysing the *Beef Hormones Dispute* and the extent to which legislative divergences brought about by cultural biases played a crucial role in precipitating the controversy.[10]

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[9] J. H. Weiller, note 37 Chapter 1 above, p.3

[10] *EC Measures Concerning Meat and Meat Products ('EC-Hormones')* WT/DS26, and *United States – Continued Suspension of Obligations in the EC – Hormones Dispute ('US-Continued Suspension')* WT/DS320.

3.2 Role of Culture in Devising and Applying Law

This thesis contends that culture matters in devising and applying law. It is not possible to fully understand the mechanism by which legal change happens without studying the cultural context in which legal reforms occur.[11] What is known is that cultural context is shaped by the culture of commercial, political and economic interests. It is not feasible to expect the same considerations to have the same effect in different situations.[12] Legal change is a culturally contingent process dependent upon the interaction of the local and the global, rational actions, and cultural dispositions.[13] Sometimes, difficulty is encountered in transferring a foreign legal model to another nation state, because civil society is too strong. Interest groups have the ability to organise themselves and through political representation the consumer can influence political decisions regarding the form of law enacted. Therefore, in democratic societies, culture has a significant impact on the content and form of the laws enacted. For example, it has been shown that human perception ('anxieties and intuitions') about privacy and privacy law differs as between the EU and the US. In each jurisdiction, there are unmistakable divergences in sensibilities about what ought to be kept private. The research undertaken by academics in this area concluded that there was little reason to suppose that Americans would be persuaded any time soon to think of their world of values in a European way.[14]

Most multilateral trade agreements contain at least some element aimed at a 'transfer of law'.[15] A transfer of law can be described as 'the operation by which, through constraint, or its absence, law is transmitted from one society to another'.[16] This can be seen with international legal agreements such as the SPS Agreement, where an international norm is applied as a constraint on the domestic legal culture preventing it from enacting sanitary measures which would act as barriers to free trade. One can interpret the constraint applied by the SPS Agreement as the mere fact that it employs a hybrid form of risk analysis which differs from that operating under the EU food safety system. Therefore, with the SPS

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[11] D. Nelken & J. Feest (eds), *Adapting Legal Cultures* (Oxford: Hart Publishing, 2001), p.9.
[12] *Ibid*, p.29.
[13] E.A. Feldman, note 31 Chapter 1 above, p.746.
[14] See J.Q. Whitman, "Two Western Cultures of Privacy: Dignity versus Liberty", (2003) Yale Law Journal, Vol.113, p. 1155 & p. 1221.
[15] For an overview of the transfer of law theory, see generally N. Rouland, *Legal Anthropology* (London: The Athlone Press, 1994).
[16] *Ibid*, p.292

Agreement, which is effectively a contract entered into by its signatories, in the event of a trade dispute, a transfer of law is applied 'through constraint'. However, because it is by constraint, it has the effect of enforcing a certain, potentially (culturally) unpalatable solution, on the domestic legal system. In this context, it has been found that it is more difficult to impose a foreign law that is more closely identified with local cultural and national symbols.[17] In most EU Member States, food culture is a particularly well entrenched aspect of national identity. Therefore, this thesis submits that any law which has the effect of constraining the free hand of domestic food culture is likely to encounter opposition. Food is personal. In many respects, should the EU authorities have decided to permit the importation of hormone treated beef into the EU, then the parallels are the same. It is widely agreed that the cultural incentive influences the behaviour of lawmakers, thereby playing a role in dictating the law enacted within a jurisdiction.[18] The cultural context extant within the EU would have resisted any attempt to put hormone treated beef on shop shelves and had that eventuality been foisted upon the EU citizenry, then it is likely that some elements would have expressed significant concern. Therefore, deliberate attempts to change legal culture highlights differences between the legal culture where the adaptation is to take place and that from which the model is taken.[19] In order to fully understand the role of any particular law, attention must also be paid to the context in which the law operates.[20] Therefore, it is contended that the promulgators of international trade laws such as the SPS Agreement must apply an understanding of the cultural background existing in the nations affected. Reference should be had to the socio-cultural variables in understanding the adoption of a given rule.[21]

Many studies on social constructivist analyses of diffusing global legal norms, have opined on the importance of 'cultural-match' in successfully affecting the transfer or implementation of a legal norm that is alien to the target society. Cultural-match has been defined as 'a situation where the prescriptions embodied in an international norm are convergent with domestic norms, as reflected in discourse, the legal system (constitutions, judicial codes,

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[17] D. Nelken & J. Feest (eds), note 11 Chapter 3 above, p.25.
[18] E.A. Feldman, note 31 Chapter 1 above, p.751.
[19] D. Nelken & J. Feest (eds), note 11 Chapter 3 above, p.25.
[20] D. Gerber, "Sculpting the Agenda of Comparative Law: Ernst Rabel and the Facade of Language", in A. Riles (ed), *Rethinking the Masters of Comparative Law* (Oxford: Hart Publishing, 2001) p. 190.
[21] J.Q. Whitman, note 14 Chapter 3 above, p. 1151. James Whittman compared the different privacy rules adopted in Europe and the US, highlighting the different cultural context in which these rules have been created and the influence it had in moulding them.

laws), and bureaucratic agencies (organizational ethos and administrative procedures)'.[22] The concept of cultural-match has been used to explain the mechanisms underpinning the reception of international norms by national states. The expression is intended to denote the correspondence between the content of a legal norm and the values, traditions and institutions present in the society that this norm should resemble. In other words, the legal rule is likely to cause cultural resistance or be refused outright if the adoption of it would threaten the traditional values of the society. Diffusion of legal norms is more possible when 'a cultural-match exists between a systemic norm and a target country, in other words, where it resonates with historically constructed domestic norms'.[23] Therefore, the degree of cultural-match between global norms and domestic practice is key to determining the pattern and degree of successful implementation of those norms.[24] The idea is that a regulation will be adopted into a legal system provided it conforms to the cultural environment characterizing that legal system.[25]

Two different diffusion mechanisms which empower legal norms domestically have been identified - the 'bottom-up' process and the 'top-down' process.[26] The 'bottom-up' process is where a nation's citizenry and private interest groups have a greater ability to influence political decisions and it is more prominent in democratic societies. Societal pressure in the policy arena is possible. It is therefore more difficult is such situations to implement and enforce new regulations in these societies if the cultural-match is not right. No single factor can fully explain something as complex and multi-causal as legal change, and while the interaction of a number of forces are critical, it is evident that a cultural incentive is crucial for a successful transference to occur.[27]

One of the objectives of this thesis is, through the comparative law aspect studying the EU and US food regulatory systems, to identify if differences exist between those food regulatory legal cultures. The analysis to date in this thesis and the subsequent chapters will endeavour to identify whether or not the domestic EU norms (and indeed those of the US) diverge from

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[22] J.T. Checkel, "Norms, Institutions, and National Identity in Contemporary Europe" (1999) *International Studies Quarterly*, Vol. 43, Issue 1, p.87.
[23] *Ibid*, p.86.
[24] *Ibid*, p.86.
[25] E.A. Feldman, note 31 Chapter 1 above, p.743.
[26] J.T. Checkel, note 22 above, p.88. The top-down process is synonymous to regimes where political power is more centralised.
[27] See generally E.A. Feldman, note 31 Chapter 1 above, p.749 - 752.

those instilled under the tenets of the SPS Agreement. In addition, the existence of any cultural-match between the EU food culture and the consumption of beef treated with growth hormones will also be analysed, as a case study specific to identifying the importance of cultural-match in preventing trade disputes. Indeed, food safety regulation is by its very nature an area which often involves the adoption of foreign legal models because states are often required to deal with a new or unprecedented food safety risk. Therefore, culture contributes to the determination of public risk perception and the latter influences the way a legal system regulates given activities. Cultural-match matters. Where a risk is deemed to be high, a new legal norm will be adopted enthusiastically provided the cultural-match is right with the regulatory solution offered. Culture plays a pivotal role in devising the content and format of laws and in their method of application.

3.3 Influence of Culture on Food Safety Regulation

Food is very special to each of us. We are innately protective of it because of its nutritional and organoleptic functions. However, as outlined in Chapter 1, food is also special to us because it is part of our identity; it is anthropological – it helps define who we are. It is as representative of our civilisation as our morals, values, beliefs, customs, or habits. If we think of culture in the broadest sense as the customs, civilisation and achievements of a people, then food is inextricably linked with it. In each geographical location culture is always indigenous and yet it is also in a constant state of flux. As a result, at this thesis argues, because of our desire to protect food as we know it, local influences are always evident in food legislation. Food tradition underpins food safety regulation. The following quote expresses the idea succinctly:-

> It is because they are ordinarily immersed in everyday practice in a material way that foods, abstracted as symbols from this material process can condense in themselves a wealth of ideological meanings, [.....] cultural forces that organize material life.[28]

In addition to seeing the place of food in culture in the broader sense, there is the cultural aspect to how we physically deal with food – 'culinary culture'.

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[28] M.J. Weismantel, *Food, Gender and Poverty in the Ecuadorian Andes* (Illinois: Waveland Press, 1988), p.8.

> 'Culinary culture' is a shorthand term for the ensemble of attitudes and tastes people bring to cooking and eating. Since 'culture' is understood in sociology and anthropology to mean all that is 'learned, shared and transmitted' among groups of human beings from generation to generation, it is not surprising that the idea of culinary culture has been associated with research of an historical-sociological kind aimed at explaining how different social groups – especially different societies or nation-states – came to develop different tastes and attitudes over time.[29]

Therefore, it is not just the issue of the food having some resonance with an individual's ethnicity or religion, but rather it is more pervasive than that. When it comes to the food itself, now more than ever before, consumers are concerned with the quality, taste, appearance, nutritional properties and ethical values of their food. The food should be produced and processed with respect for the environment and for the welfare of the food producing animals. People are concerned about the environmental footprint that the agrifood[30] industry leaves. As a result sustainable methods of food production are more important than ever.[31] The consumer wants to know if some form of esoteric technology was used as an aid to producing or indeed creating the food. To quote the American anthropologist Paul Bohannan:-

> The cultural meanings instilled in human beings standardise their choices [....] People when they are young, learn that some edible substances are food while others are not. They can extend or alter what they define as food by choice or necessity; nevertheless some people will flatly refuse to eat perfectly edible things because they have not previously defined them as food [....] If the policies of government change, we may have to give up a lot of old ways.[32]

In other words, consumers, and consequently countries differ in their sensitivity to certain food practices. It is a divergence resulting from different personal beliefs – biases based on

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[29] S. Mennell, A. Murcott & A. H. van Otterloo, note 1 Chapter 1 above, p.20.
[30] Agrifood encompasses food production activities on farms and the processing of those products into added value food items.
[31] D. Holland, H. Pope, note 14 Chapter 1 above, p.1.
[32] P. Bohannan, *How Culture Works* (New York: Simon & Schuster, 1995), p.9.

historically developed societal values and patterns of behaviour. In short, culture influences measures regulating the production and sale of food. The influence is evident at the national and supranational[33] level, but this influence is even more pronounced when it comes to global trade.

Many erroneously assume that the boundaries of food law are limited to issues relating to the production and marketing of food produce. We think of government agencies and the rules and regulations promulgated by them. However, a true understanding of food law encompasses issues which extend far beyond these narrow confines. It includes, for example, issues relating to national, supranational[34] and international trade, economics, agricultural law, and a host of other provisions pertaining to food and agriculture. Similarly, as a business sector, the food industry is a melange of interest groups, each with their own unique role to play. They are characterised by different and changing interests, cultural attitudes and dimensions. It is an industry comprised of farmers, suppliers, manufacturers, packagers, transporters, exporters, wholesalers, retailers and consumers. It is an industry transformed by improvements in seed, cultivation, fertilisers, pesticides, preservation, methods of storage and transportation.[35] Only a sophisticated food regulatory system can understand and manage these complexities.

3.4 Interplay of Culture and Science in Risk Regulation

Any particular culture can be seen as a set of shared values and supporting social institutions. It is therefore only natural that such a system will be biased towards certain risks while downplaying others.[36] These shared values should play a vital role alongside scientific knowledge, in informing regulatory approaches to risk. In respect of food law, this thesis argues that an over-reliance on science as a basis for legal reasoning will divest a legal system of other attributes, such as benefitting from cultural influences.

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[33] In this thesis, rather than denoting a specific legal definition, the term 'supranational' is used loosely to describe a union of individual states /jurisdictions, where each state's political and legal system is somewhat autonomous from the federal government ; such as that found in the European Union, the United States, and the Australian States/Territories.

[34] Supranational - for example, trade between individual EU Member States or between the individual US States.

[35] C. Counihan, P. Van Esterick, note 8 Chapter 1 above, p.12.

[36] A. Wildavsky & M. Douglas, note 3 Chapter 1 above, p. 194.

Some commentators note that while laws are very often reflective of culture, sometimes they differ from it.[37] It is evident from the historical development of food law that the majority of new developments in this area of law result from advances in science and not upon new legal insight. The history of the development of food regulation is the history of science.[38] Science has been described as 'a cornerstone of modernity',[39] the 'archetype' of all knowledge, privileged over both God and tradition in modern Western culture.[40] Indeed, it has been argued that requiring food safety regulatory agencies to bring the best science available to bear when developing or revising food safety law, has been central to the high level of success achieved by US food safety policies.[41] In order to understand the complex interactions between different determinants and the impact that they have on health, it is necessary to use science. This use of science also assists in identifying the correct policy measures. Science is used to monitor the impact of decisions that have already been taken, to assess the success rate and to identify the corrections needed on a case by case basis.[42]

This thesis contends that if there is an over reliance on science as the criterion for deciding the legitimacy of any food sanitary measures, then the existing international food regulatory framework can never successfully achieve its primary goal of facilitating free trade, while at the same time promoting international harmonisation of food standards and thereby minimising the incidence of trade-disputes. The *Beef Hormones Dispute*[43] is not merely a dispute concerning the risk posed to human health by the use of growth hormones in beef-production. It represents a much broader issue – the interplay between science and culture in food regulation which came to the fore in the 1990s.[44] This thesis argues that the ongoing differences between the EU and the US regarding the use of growth hormones in cattle, emanate from a deep-rooted cultural divide rather than from scientific disagreement alone.[45]

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[37] A.M. Cohler, B.C. Miller & H.S. Stone (eds), *Montesquieu: The Spirit of Laws* (Cambridge: Cambridge University Press, 1989), p.314.
[38] P.B. Hutt, note 24 Chapter 2 above, p.9.
[39] K.T. Litfin, *Ozone Discourses: Science and Politics in Global Environmental Cooperation* (New York: Columbia University Press, 1994), p.8.
[40] M. Davies, *Asking the Law Question: The Dissolution of Legal Theory* (Sydney: Lawbook Co., 2002), p.115.
[41] R. L. Buchanan, "The Development of Science-Based Food Safety Regulations in the United States", (2000) *Irish Journal of Agricultural and Food Research*, Vol. 39, No. 2, p. 332.
[42] See generally, V. Silano, note 55 Chapter 2 above, p.400.
[43] The *Beef Hormones Dispute* is examined in detail later in this thesis.
[44] J. Peel, *Science and Risk Regulation in International Law*, (Cambridge: Cambridge University Press, 2010), p.1.
[45] P. B. Hutt, note 24 Chapter 2 above, p.2.

Under EU food law, the use of animal growth hormones is banned. Commercialisation, the direct involvement of big business in food production and expansion of agricultural biotechnology continues unabated in the US. In stark contrast to the EU ban, animal growth hormones[46] are used extensively in beef production in the US and have been approved for use there since the 1950s. In the US, growth hormones are now believed to be used on approximately two-thirds of all beef cattle and on about 90 per cent of the beef cattle in feedlots.[47] In the massive concentrated animal feeding operations or CAFOs,[48] the use of synthetic growth hormones approaches 100 per cent.[49] All in all, a staggering 67-90 per cent of US beef is produced using growth hormones.[50] This in itself represents a stark cultural difference regarding each nation's attitude towards animal growth hormones. Later, this thesis will analyse the *Beef Hormones Dispute* in order to decipher if cultural divergences between the parties involved combined with the use of science in international risk regulation, played a role in the disagreement.[51]

3.4.1 Fallibility of Science as Absolutism

Scholars have noted that regulatory outcomes cannot be inferred solely on the basis of scientific data alone, because many regulations respond either implicitly or explicitly to social, economic, or political contexts.[52] Scientific analysis can certainly provide assistance in fulfilling a public health goal, but the goal itself is strongly influenced by societal values and there science can provide little, if any, guidance.[53] Essentially, science can inform the

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[46] Synthetic growth hormones reduce fat, increase food conversion efficiency, increase lean tissue growth, on less feed, and thereby reduce production costs.

[47] Since approximately 36 million cattle are produced in the US each year, that is 24 million and 32.4 million head of cattle respectively whose beef contains growth promotant residues. See, J. Raloff, "Hormones: Here's the Beef", (2002) *Science News*, Vol. 161, No. 1, P.10.

[48] See note 167, Chapter 2 above regarding the unhygienic and harsh conditions in the CAFOs.

[49] R. Johnson & C.E. Hanrahan, note 175 Chapter 2 above.

[50] Therefore, 67-90 per cent of all US beef contains growth promotant residues. J. Raloff, note 47 above, P.10.

[51] The Beef Hormone Dispute arose in the 1990s, in the midst of the mad cow disease crisis. The EU banned the import of meat that contained artificial beef hormones. WTO rules permit such bans, but only where a signatory presents scientific evidence proving that the ban is a valid health and safety measure under the terms of the SPS Agreement. Canada and the United States opposed the EU ban.

[52] D.A. Wirth, "Role of Science in the Uruguay Round and NAFTA Trade Disciplines", (1994) *Cornell International Law Journal*, Issue 27, p. 817.

[53] Sometimes to the dismay of those involved. When, in 1985, it was decided that a complete ban would be placed on hormones in the EU, Professor Lamming (who was Chair of the EC Lamming Committee researching hormones safety) stated that 'the ban taken by EU agriculture Ministers on December 19th [1985], flies in the face of scientific evidence requested by the Ministers themselves'. David McBeath, head of pharmaceutical company (and hormone manufacturer) Hoechst's animal research division said 'why should any major company

regulatory process but it cannot by itself determine the end result.[54] The fundamental proposition of this school of thought is that health goals are determined by a society and it is only afterwards that science plays a role.[55] In this context, it is important to note that under the EU's General Food Law, there is a clear division between the scientific risk assessment function, and the risk management stage where societal demands can be entertained. Recital 19 of the preamble to the General Food Law provides that scientific risk assessment does not provide all the information and that other factors should be taken into account including societal, economic, traditional, ethical and environmental considerations. In addition, Article 3.10 of the General Food Law acknowledges a clear division between the constituent parts of risk analysis and identifies them as risk assessment, risk management and risk communication. Article 3.12 of the General Food Law describes risk management as a process 'distinct' from risk assessment of 'weighing policy alternatives' and considering 'other legitimate factors'. This definitive division between risk assessment and risk management facilitates the inclusion of other issues besides purely scientific considerations in setting food safety standards. As we shall also see, in that respect, operationally it differs from the more autocratic US food safety construct.

The EU operates a mediative food safety policy regime, combining strong democratic norms with scepticism towards the authority of science. As far as the EU is concerned, allowing its citizens a voice in matters of scientific question is an important aspect of its political system.[56] Consequently, what transpires in the EU is a food safety regime which is based mainly on a process of consensus building across state and civil society actors. It therefore differs from the US food safety style and this culminates in transatlantic tensions.[57] This is because it is the different attitudes between EU and US consumers, towards the perceived ability of science to resolve food safety issues, which underpins the EU and the US food regulatory models. To a far greater degree than Europeans, Americans are prepared to defer to the authority of 'experts'. This transatlantic chasm in approach to how best to regulate food

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invest millions to develop and licence new generation products when the views of a small but highly vociferous consumer lobby in Europe can sweep away that research overnight? Perhaps we should skip scientific evaluation and let the politicians make the decisions.' See R. Wright, "EC Bans 'Safe' Animal Hormones" (2nd January, 1986) *New Scientist*, p.9.

[54] D.A. Wirth, note 52 above, p. 817.

[55] M. D. Carter, note 149 Chapter 2 above, p.652.

[56] *Ibid*, p.652.

[57] G. Skogstad, "Regulating Food Safety Risk in the European Union: A Comparative Perspective" in C. Ansell and D. Vogel (eds), *What's the Beef? The Contested Governance of European Food Safety* (Massachusetts: The MIT Press, 2006), p.214.

safety, would seem to have originated at least in part from the distinctive experiences of Europeans and North Americans to various food safety crises.[58] In the EU, consumer confidence in the expert governance of food safety was shattered by the various food crises. In that context, it is important to note that the BSE crisis in the 1990s preceded the enactment of the General Food Law which was adopted on 28 January 2002.[59] The BSE crisis 'marked a year zero' for the food authorities by forcing them to accept that shortcomings existed in the EU approach to food safety issues.[60]

The same food safety crises did not occur in the US. It has been argued that Americans possess a 'well known preference for according science a central role in public decision-making'[61] and that US regulators are 'generally ... more inclined to justify their actions with appeals to objective knowledge than their European counterparts'.[62] By contrast, the diffident attitude of EU citizens towards science as a basis for the formulation of comprehensive food safety policies can be seen in the importance attached to the precautionary principle.[63] EU consumers appear to have less faith in science than their North American counterparts and they are reluctant to rely on science to provide the basis for policy solutions. In addition, it has been shown that EU citizen's conflict of faith with science has over time undergone a diminution, manifested in a preponderant view among EU citizen's that science and technology are not 'a panacea' and should be subject to 'social control'.[64] EU governments wrongly insisted for years that the beef supply tainted by mad cow disease was safe.[65] EU consumers no longer trust science and demand higher levels of protection in the form of product bans or labelling disclosing all critical information about the food product.[66]

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[58] *Ibid*, p.14.

[59] The BSE crisis resulted in significant acrimony within the EU, not least of all by events such as the EU banning exports of British beef with effect from March 1996. The ban was a severe blow to British agrifood sector and it lasted for 10 years and was only finally lifted in May 2006.

[60] D. Chalmers, "Food for Thought: Reconciling European Ways of Risk and Traditional Ways of Life" (2003) 66 *Modern Law Review*, Issue 4, p.534.

[61] S. Jasanoff, "Product, process, or programme: three cultures and the regulation of biotechnology," in M. Bauer (ed.), *Resistance to New Technology* (Cambridge: Cambridge University Press, 1995), p. 311.

[62] *Ibid*, p. 311.

[63] S. Schlacke, "Foodstuffs Law and the Precautionary Principle: Normative Bases, Secondary Law and Institutional Tendencies" in C. Joerges and E. Vos, (ed's) *EU Committees: Social Regulation, Law and Politics*, (Oxford: Hart Publishing, 1999), p. 169.

[64] Eurobarometer. 2001. Europeans, Science and Technology. Issue 55:2. Brussels: Director-General for Research.

[65] C. Carlane, note 1 Chapter 2 above, p.318.

[66] *Ibid*, p.305.

Technocratic regulation based on science presupposes a belief in its ability to solve not just the mundane regulatory problems, but also those posed by the risks associated with new technologies. Likewise, the same presupposition pertains for private interest governance as the rationale for advocating self-regulation must be based on the private sector's possession of requisite technical expertise. It seems that in general, North Americans possess such a faith in science and they regard science as being capable of affording the universal and objective facts necessary for the accurate execution of impartial regulatory decisions.[67]

The more commercialised any sector of food production becomes, food safety is required to deal with a more complex matrix where personal judgments regarding food are often seen as of secondary importance. Commercial interests are keen that it is science which is used, both for food technology and as the arbiter of food safety.

3.4.2 Place of Culture in Food Safety Regulation

While scientific advice is of primary importance under EU food law, recital 22 of the preamble to the General Food Law[68] expresses the belief that 'food safety and the protection of consumer's interests is of increasing concern to the general public'. Article 1 of the General Food Law provides for the consideration of consumer interests while even more significantly the Article acknowledges the importance of 'tradition'. Article 1 provides:

> This Regulation provides the basis for the assurance of a high level of protection of human health and consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products, whilst ensuring the effective functioning of the internal market.

When legislating to deal with concerns regarding the safety of the food supply at the national or supranational level, governments must take care not to stifle the creative expression achieved through food or to destroy the heritage of its citizens. This creative expression is the core characteristic of tradition as accommodated under the EU's General Food Law. By

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[67] G. E. Isaac, "*Agricultural Biotechnology and Transatlantic Trade: Regulatory Barriers to GM Crops*", (New York: CABI Publishing, 2002), p.128.
[68] European Parliament and Council Regulation (EC) No 178/2002, note 72 Chapter 2 above.

acknowledging a place for tradition along with consumer interests in the food supply, General Food Law, albeit not explicitly, entertains a place for culture in EU food safety law. This can be viewed as an example of where the substantive EU food law enacted to date espouses traditional food production and processing methods which are still commonplace in a number of EU Member States.[69]

Therefore, under existing EU food law, science becomes only one of the factors relied upon where scientific evaluation does not allow the risk to be determined with sufficient certainty.[70] In the same context, Article 5.1 of the General Food Law also provides that one of the goals of EU food law is the 'protection of consumers' interests' while Article 8 again reiterates the importance of the 'protection of the interests of consumers and providing consumers with the ability 'to make informed choices in relation to the foods they consume'.

The EU may well be correct in this food regulatory approach because as outlined at the beginning of this Chapter, there is an intimate association between food regulation and society - founded on personal beliefs – biases based on historically developed societal values and patterns of behaviour. The ongoing differences between the EU and the US regarding the use of growth hormones in cattle and also the European distrust of GMOs in the food supply, emanate from a deep-rooted cultural divide rather than from scientific disagreement alone.[71]

3.4.3 Culture, the WTO and Free Trade

Until relatively modern times, the economies of many developed countries, including the EU Member States and the US, had a long history of misguided agricultural policies and rampant industrialisation. This was a twin malaise that damaged the trust between producer and consumer. It was not just a fight to save market share, but a fight for the survival of indigenous culture, ecology, and resources. Nowadays, we see economies that have invested heavily in their agricultural sector. Accordingly it is no wonder that they are now keen to protect and indeed promote that investment and those achievements.

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[69] Whereas by contrast the US has been more receptive to food technology and somewhat sceptical of traditional methods and in turn, US regulations reflect this.
[70] B.M.J. van der Meulen, note 148 Chapter 2 above, p.65.
[71] P. B. Hutt, note 24 Chapter 2 above, p.2.

In order to meet these challenges and safeguard their agrifood sector, more and more countries are enacting domestic food safety laws and establishing food inspection and control agencies. It is in this context that the concept of food-sovereignty arises - the idea that food security is combined with the requisite element of national decision-making.[72] Sovereignty denotes that an emphasis has been placed on the centrality of national decision-making authorities in determining food and agricultural policy. It is a nationalistic strategy that places the responsibility for international trade with national governments rather than relinquishing that power to international or foreign bodies.[73] It is the strategy most likely to personify cultural regulatory divergences between nations. Therefore, national food sovereignty results in divergences between countries and supranational economic areas, when it comes to food safety legislation. These divergences are then oftentimes carried through and expressed at the international level as trade disputes.

The problem here is that differences in culture have caused an oftentimes perverse divergence between countries, in regulatory measures. In addition to the resultant divergence in regulatory measures, conflict is also caused by an uneven distribution and recognition of production processes and food related technologies across world economies. A cultural bias results from the national and regional authorities' preconceptions of the effect that certain technologies have on our health. Very often these are technologies that enhance produce yields – technologies that promise greater profits to the producer, such as growth hormones, the use of pesticides, and biotechnology. To the individual producer/farmer[74] who uses these technologies, and to his country's government, it is all too difficult to differentiate these foreign consumer preferences from protectionism – protecting the domestically produced food items from inexpensive imported produce. Nonetheless, the disparities have the effect of personifying the consumer's preconceptions and misconceptions about certain foods.

The GATT recognises that it may be necessary to create some exceptions to these goals and certain of these exceptions are contained in the SPS Agreement.[75] To this end, the SPS Agreement acknowledges that its Members must have freedom to take measures necessary

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[72] See, G. Tansey & T. Rajotte (eds), note 29 Chapter 1 above, p. 177.

[73] Therefore, to some extent, food sovereignty is antithetical to the whole concept of the WTO and its Agreements especially the SPS Agreement.

[74] Indeed, in the US, as this thesis argues, it is mainly corporate entities that benefit from technology/science and it is this realisation that encourages corporate lobbying and meddling in the political/administrative sphere of food regulation.

[75] B.M.J. van der Meulen, note 148 Chapter 2 above , p.61.

for the protection of life and health of people, animals and plants. Under the SPS Agreement, the WTO Members must ensure that sanitary measures are applied only to the extent as is necessary to protect the life and health of people, animals and plants from the potential risk.[76] However, the issue then becomes one of deciding how a Member can evidence the legitimacy of, and justify the sanitary measure enacted. If the Member is only allowed to apply a scientific reasoning, then it is submitted that there is rarely an instance where science based evidence in food safety can be said to be conclusive. In addition, it is never possible to test for all possible health risks. At best, the scientific consensus is only as good as the research and the statistical processes underlying it.

Even if the national or supranational SPS risk regulations are non-discriminatory in nature, if they depart from the standards of recognised international bodies such as the Codex Alimentarius and if they are found to be trade restrictive,[77] then it is necessary to decide what it is that should be the arbiters of WTO-compatibility.[78] The SPS Agreement can be viewed as an effort at reaching a compromise that permits the trading nations involved to take the measures they deem necessary for the protection of public health within their borders provided this is done in such a way as to restrict trade as little as possible.

However, from a cultural perspective, it has been said that any subject that ignores culture is arbitrary and self-defeating.[79] Does the SPS Agreement limit the ability of a country to apply local or indigenous food safety norms? While this may be important to the goal of creating a global food law, it is also likely to be contentious because sometimes it displaces indigenous attitudes towards food safety that are centuries old. In the end, it is cultural disagreement over trade in the products of modem science – of which food is one such product - that is the latest and one of the most volatile areas of modern US-EU economic conflict.[80]

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[76] The language of 'risk' is used in discussing these issues because in many cases available information is inadequate or incomplete. Enough is known to suspect or predict that a threat exists, but the full outcomes for human health and the environment, including for future generations may not be well understood. See, J. Peel, note 44 above, p.1.

[77] J. Peel, note 44 above, p.171.

[78] J. Pauwelyn, "The WTO Agreement on Sanitary and Phytosanitary (SPS) Measures as applied in the First Three SPS Disputes: EC – Hormones, Australia – Salmon, and Japan – Varietals", *Journal of International and Economic Law*, Vol.2, Issue 4, 1999, p.644 at J. Peel, note 44 above, p.171.

[79] A. Wildavsky & M. Douglas, note 3 Chapter 1 above, p. 194.

[80] C. Carlane, note 1 Chapter 2 above, p.304.

3.5 Clash between European Food Tradition and Technology

When considering what constitutes a food safety risk in the comparative context, the starting point in contrasting EU and US attitudes is traditional production methods in the EU versus modern technological processes in the US. As can be seen with the divergent approaches to the legitimisation of growth hormone use, it appears that these perceptions are carried through into the respective legislative provisions of each jurisdiction. EU food law enacted to date espouses traditional food production and processing methods whereas by contrast the US has been more receptive to food technology and somewhat sceptical of traditional methods. While under EU food law, scientific advice is of primary importance, the law also recognises that consumer concerns and national traditions in food must also be taken into consideration during the decision-making process.[81]

Article 1 of the General Food Law acknowledges that the accommodation of tradition in the food supply and consumer interests must not get in the way of the effective functioning of the internal market. This reference to the internal market can be seen as an acknowledgement of the importance still attaching to the free movement of goods within the EU. It is an acknowledgment that traditional or cultural divergences exist and that if they are not dealt with properly that they could act as a barrier to trade thereby jeopardising the effective functioning of the internal market.

As noted earlier in this thesis, throughout history individual European nations have established their own unique requirements regarding the food supply. Consequently, it is not surprising that despite the creation of the EU, some disparities in food regulation still exist at the individual Member State level. The position is somewhat similar in the US where food law was originally a matter of city, county, and state jurisdiction. Federal food laws were enacted in relatively recent times and consequently disparities still exist between federal and state food requirements. In the EU, the divergence between nations is exemplified, for example, by the BSE[82] crisis. During the crisis, France banned the importation of British

[81] Article 1 of the General Food Law assures the 'protection of human health and consumers' interest in relation to food' whilst taking into account 'the diversity in the supply of food including traditional products'.
[82] For a definition and details of BSE please see note 89 Chapter 2 above..

beef, ostensibly because it could have been infected with CJD. Immediately, there was a new appreciation of the tension between market integration and public-health in EU regulation.[83]

In addition to the aforementioned provisions of the General Food Law dealing with traditional products and consumer interests, there are of course many special legislative provisions, dedicated where necessary to governing individual food practices unique to certain EU Member States. As mentioned in the introductory Chapter, one example is the provisions legitimising the marketing of raw-milk cheeses on an EU-wide basis.[84] The controversy that surrounded raw-milk cheeses, described in greater detail later in this Chapter, provides a good illustration of disparities in food safety regulation. It also illustrates that food safety and cultural sovereignty are intertwined, both nationally between EU Member States and also internationally between the EU and the US. It elucidates the clash between small traditional producers and large science advocating corporate producers.

Unpasteurized milk, often called 'raw milk', is prized by many cheesemakers who claim that it adds a special richness of flavour. France fought against any EU requirement for mandatory pasteurization of cheese or an equivalent sanitising measure. Sweden on the other hand was not in favour of regulations that permitted an EU-wide sale of unpasteurized or 'raw-milk' cheeses. Swedish domestic law required that all cheese produced and sold in Sweden be made from pasteurized milk. However, as an EU Member, EU regulations take precedence over the national provisions and Sweden could not ban the import into Sweden of raw milk cheese produced in other EU Member States.[85] This was the domestic or EU aspect to the dispute. Tensions such as these extend beyond the relatively prosaic consideration of public health concerns to the realization that certain foods are emblematic of national culture.[86]

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[83] A. Alemanno, "Food Safety and the Single European Market" in C. Ansell and D. Vogel (eds), *What's the Beef? The Contested Governance of European Food Safety* (Massachusetts: The MIT Press, 2006), p.239.

[84] Council Directive 92/46/EEC and Council Directive 92/47/EEC, note 16 Chapter 1 above.

[85] In the early 90s, the EU was persuaded that raw-milk cheese constituted an important economic niche in which its producers enjoyed a competitive advantage internationally. The EU legislated for the issue with the controlled legalisation of raw-milk cheeses under Council Directive 92/46/EEC of 16 June 1992 and Council Directive 92/47/EEC of 16 June 1992, note 16 Chapter 1 above.

[86] In the context of the *Beef Hormones Dispute* which this thesis analyses, it is interesting to note that some commentators have suggested that inter-state friction such as this over the harmonization of food standards created by the European integration process, which were seen as disputes over cultural sovereignty, had the effect of pre-programming EU public opinion to the controversy over beef hormones and GMOs. See, F. van Waarden, "Taste, Traditions, and Transactions: The Public and Private Regulation of Food" in C. Ansell and D. Vogel (eds), *What's the Beef? The Contested Governance of European Food Safety* (Massachusetts: The MIT Press, 2006), p.38.

As outlined in Chapter 1 of this thesis, at the international level, since 1949,[87] US law has banned the sale of cheese made from unpasteurized milk unless the cheese has been aged for at least 60 days.[88] A number of EU cheeses are traditionally made with raw milk and are aged for less than 60 days. As a result, unpasteurized versions[89] of these products cannot be sold in the US. In 1998, a trade group representing US industrial cheesemakers began actively lobbying the FDA to require that all cheese produced and marketed in the US be pasteurized. In addition, corporate cheesemakers also lobbied the EU to ban raw-milk cheese production.[90] Therefore, the campaign against unpasteurized cheese had also taken on an international perspective.

This is also emblematic of the clash between big business and traditional farming – a conflict which so often characterises the showdown between science and culture. The economic reality was that even if they wished to acquire it, few raw-milk cheesemakers could afford to purchase the large-scale pasteurization equipment required. These small-scale producers might be forced to sell their business to a multinational conglomerate. Alternatively, in order to offset the costs of such an investment, producers would have to amalgamate or expand, thereby in the process effectively becoming industrial producers with the attendant loss of tradition.[91]

The importance attaching to culture and tradition in the food supply is nowhere more evident than in the importance attaching to 'community', 'generic' and 'geographical' food names within the EU. The various types of food used in the Community were defined by the Advocate General in *Canadane*.[92] Community names refer to what the Advocate General termed 'eurofoods' (such as honey and chocolate) and they are regulated by Community secondary law which defines the products characteristics and methods of production for the entire Community. Generic names are common names used for food products such as, for example, yogurt,[93] pasta,[94] beer[95] and edam cheese.[96] Generic names can in principle be used

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[87] 21 C.F.R., S.133.
[88] See note 18 Chapter 1 above.
[89] See note 20 Chapter 1 above.
[90] See generally H.G. West, "Food Fears and Raw Milk Cheese", (2008) *Science Direct*, Vol.51, Issue.1, p.25.
[91] *Ibid*, p.25.
[92] Opinion of Advocate General Ruiz-Jarabo Colomer in Case C-317/1995, *Canadane Cheese Trading AMBA and Adelfi G Kouri Anonymous Emoriki Kai Viomichaniki Etaireia v Hellenic Republic* [1997] ECR I-4681.
[93] Case 298/1987, *Proceedings for compulsory reconstruction against Smanor SA* [1988] ECR-4489.
[94] Case 407/1985, *Glocken GmbH and Kritzinger v USL Centro-Sud and Provincia autonoma di Bolzano* [1988] ECR 4233.

by any producer because they 'form part of the general cultural and gastronomic stock'.[97] Some Member States have on occasion enacted national measures requiring a specific product to meet certain conditions of production before it could use a generic name.[98] Again, this is an example of cultural divergences in food regulation between individual EU Member States. Geographical names derive from the location in which they are traditionally produced.[99]

The consideration in EU food law of divergences between Member States based on food tradition and the inclusion of consumer interests and concerns evidences a fundamental difference in approach between EU and US food law. US food safety legislation at the federal level does not accommodate consumers in that manner. However, this does not prevent individual US states from having their own ordinances governing food practices unique to their jurisdiction, provided they do not contravene the federal provisions relating to interstate commerce.

It has been argued that a reverence for tradition has slowed the EU's broader food regulatory process and resulted in the conservative stance taken by domestic food authorities when it comes to approval of esoteric food processes.[100] The EU has tightened and harmonised regulatory standards in the area of biotechnology. The US willingness to embrace many of the emerging new technologies fosters a more flexible regulatory system than that existing in the EU not least of all because fewer food practices are proscribed. It has also encouraged innovation in the area of food technology. The 'precautionary principle' epitomises the cautious approach taken by the EU.

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[95] Case 178/1984, *Commission v Germany* (bier) [1987] ECR 1227.
[96] Case 286/1986, *Ministère public v Gérard Deserbais* [1988] ECR 4907.
[97] C. MacMaolain, note 58 Chapter 2 above, p.91.
[98] This was likely to be a breach of Article 34 of the Treaty on the Functioning of the European Union (Article 28 EC Treaty) unless it came under certain exceptions. See, Case 286/1986, *Ministère public v Gérard Deserbais* [1988] ECR 4907.
[99] However, a name which represents a place-name may also be generic, or it may simply have become so over time. As a result, it can no longer be considered entitled to a geographical indication or a protected designation of origin and may lose the protection given to such names under Community law. On the economic importance of protected designations of origin, see Case C-388/1995, *Belgium v Spain* [2000] ECR 3123. Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs, O.J. L93/12, contains provisions for the protection of geographical indications and designations of origin. It represents an updated version of the pre-existing legislation having been amended to include third countries comply with WTO Decision in *EC – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, WTO/DS/174 and DS/290.
[100] See generally, G. Skogstad, note 57 Chapter 3 above, p.213.

In the EU, the arrival of the food corporation followed by various food health scares warranted a consumer desire for more sophisticated food safety regulation, while it is arguable that in the US a greater degree of either consumer naivety or indifference exists.[101] Of course, the most fundamental cultural divergence of all between the EU and the US may well be the fact that US consumers are simply unaware that much of their food already contains either growth hormone or genetically modified ingredients.[102] As a result they are not aware of the potential negative effects of this reality. This can be contrasted with EU consumers, where it was found that 94.6 per cent of the EU citizenry 'want to have the right to choose' when it comes to food products containing new technologies such as genetic modification.[103] The indifference shown by US consumers also makes it easier for big business emanating from the more industrialised US food sector, to successfully lobby US food regulatory authorities.[104]

Of course there is another reason why US consumers are simply unaware – 'labelling'. In the US, 'roughly 75 percent of US processed foods - boxed cereals, other grain products, frozen dinners, cooking oils, etc. - contain some genetically modified, or GM, ingredients' and there is no mandatory labelling requirement for any of these products.[105] Likewise, there is no requirement to label beef as having been produced using growth hormones. The only means by which a conscientious US consumer can discern if their beef is hormone free is in effect by a process of elimination, involving purchasing more expensive beef labelled as either 'bio'

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[101] See generally, Marion Nestle, note 35 Chapter 2 above, p.21

[102] C. Carlane, note 1 Chapter 2 above, p.319.

[103] European Union Directorate General for Press and Communication, Eurobarometer 55.2: Europeans, Science and Technology 40 (2001).

[104] This is in stark contrast to the more informed European consumer of food produce – a trait recognised under European law, where the Court of Justice regards the 'average consumer' as being 'reasonably well informed and reasonably observant and circumspect'. See, Case C-239/2002, Douwe Egberts NV v Westrom Pharma NC and Christophe Souranis [2004] ECR I-7007, para 46; Case C-315/1992, Verband Sozialer Wettbewerb eV v Clinique Laboratoires SNC et Estée Lauder Cosmetics GmbH [1994] ECR I-317; Case C-210/1996, Gut Springenheide GmbH and Rudolf Tusky v Oberkreisdirektor des Kreises Steinfurt – Amt für Lebensmittelüberwachung [1998] ECR I-4657; Case C-470/1993, Verein gegen Unwesen in Handel und Gewerbe Köln eV v Mars GmbH [1995] ECR I-1923; Case C-238/1989, Pall Corp v Dahlhausen & Co [1990] ECR I-4827.

[105] C. Carlane, note 1 Chapter 2 above, p.314. As an aid to understanding the importance of labelling and advertising in safeguarding consumer health (in the area of obesity), see A. Garde, "Food Advertising and Obesity Prevention: What Role for the European Union" (2008) *Journal of Consumer Policy*, Vol. 31, Issue 1, p25.

or 'organic'.[106] Consequently, US consumers are not made aware of the presence of either growth hormone residues or GM products in their food.

The US resist labelling of beef as containing growth hormone residues because they see it as likely to raise doubts in the minds of consumers when the level of risk to human health has been deemed acceptable by their scientific community.[107] This is the position often espoused by FDA. FDA is extremely wary of undermining the credibility of science as the sole arbiter informing regulation in this area. For example FDA states that 'if the scientific basis of health and safety standards is perceived to be invalid ... there will be distrust by the public of the regulatory actions that are based on those standards'.[108]

Protagonists, such as the main players in the US food arena, see biotechnology as the way to feed the world and save lives. The US believes that biotechnology will generate enormous economic and social benefits with very few risks. Antagonists, as exemplified by the EU's position on genetic engineering of food produce, see biotechnology as a social and environmental Pandora's box, a calamity that will do more harm than good. By contrast, commercialisation and expansion of agricultural biotechnology continues unabated in the US. According to one report, between 1995 and 2001, the share of US soybean, corn and cotton acreage, planted with GM varieties, increased from a negligible amount to over 70 per cent for soya beans, 56 per cent for cotton and 26 per cent for corn.[109]

Aside from disputes which have as their genesis the use of indigenous and traditional food production methods, for the greater part it is the opposite end of the food production spectrum which leads to trade disputes and cultural clashes over food policy. Science and technological breakthroughs in the food industry have led to political tensions, economic conflict, and a clash of cultures leading to trade wars at a national and supranational level. The long-term

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[106] However, in some States beef, for example, some producers labelled their beef as 'no supplemental hormones used', or 'raised without supplemental hormones', or 'no added hormones', or 'the livestock has never received supplemental hormones from birth to harvest'. If either of these statements is present on the label, then growth promotants were not used. However, such labelling is not mandatory and it is the exception rather than the norm.

[107] W.A. Kerr & J.E. Hobbs, note 164 Chapter 2 above, p. 295.

[108] See, FDA: "Beef Hormone Trade Dispute". Available at: http://www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/ucm092839.htm [Accessed: 12 August, 2012]

[109] See USDA National Agricultural Statistics Board annual report, June 30, 2010 at http://usda.mannlib.cornell.edu/usda/current/Acre/Acre-06-30-2010.pdf [Accessed June 20, 2011].

manner in which governments deal with these new technologies is central to not just global governance of the food industry, but global governance in general.

Genetic modification has advanced rapidly since recombinant DNA (rDNA)[110] technology was discovered in the early 1970s.[111] The colloquial term for the use of rDNA technology is 'genetic engineering'. A genetically modified organism (GMO) or genetically engineered organism (GEO) is an organism whose genetic material has been altered using these genetic engineering techniques. These rDNA techniques, use DNA molecules from different sources, which are combined into one molecule to create a new set of genes. The DNA is then transferred into an organism, giving it modified or novel genes. Transgenic organisms (a subset of GMOs) are organisms into which DNA has been inserted that originated in a different species.

A number of applications of rDNA are now found in agriculture.[112] However, serious reservations remain about some organisms with rDNA, particularly when those organisms leave the laboratory and are introduced into the environment and/or the food chain. These concerns regarding the use of rDNA biotechnology are to the forefront in the controversial debates regarding GMOs.

Most of this food technology originated in the US and ever since, US industrial interests have sought to export it. In the realm of agriculture, rDNA[113] biotechnology promises increased crop production and modified plants and animals. Plants can have built-in insect and disease resistance, and greater tolerance to frost and heat. Meat produced using growth hormones will be low in fat and low in cholesterol. Opposing views regarding the merits and shortcomings of biotechnology continue to separate the activists as well as policy makers. It is a source of and domestic confrontation and international tension.

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[110] rDNA molecules are DNA sequences that result from the use of laboratory methods (molecular cloning) to bring together genetic material from multiple sources, creating sequences that would not otherwise be found in biological organisms, in nature. Recombinant DNA is possible because DNA molecules from all organisms share the same chemical structure; they differ only in the sequence of nucleotides within that identical overall structure.

[111] A patent was awarded in 1980 to the inventors, Stanley N. Cohen and Herbert W. Boyer of Stanford University.

[112] Using rDNA, varieties of certain agricultural crops (such as soy, maize, alfalfa and cotton) have been developed which incorporate a recombinant gene that results in resistance to the herbicide *Roundup*. This allows the use of *Roundup* as a pre-emergence herbicide. However, the downside is a suspicion that resistance may also be occurring in some weed species. Another example of rDNA in food production is insect-resistant crops which produce a protein with insecticidal properties.

[113] See the definition of rDNA at note 110 above.

FDA propounds that due to the rigorous approval process that GMOs must undergo before being released, their effects are neither unknown nor deleterious. According to the US, GMOs approved in the US are as healthy and safe for consumers as traditional products. However, science can never be 100 per cent certain that such foods are not deleterious to human health. In dramatic contrast, the EU sees this as a technology which is inherently dangerous to both animal and human health and as a potential contributor to environmental disaster. Opponents to GMOs within the EU would point to the recognised potential hazards such as food safety, the effect on natural ecosystems, greater reliance on the use of chemicals in agriculture, gene flow into non GM crops, moral/religious concerns, and the economic and social problems associated with corporate control of the food supply. Consequently, the EU has tightened and harmonised regulatory standards in this area of agricultural biotechnology.

EU legislation in this area, such as the 2003 Labelling and Traceability Regulation[114] has deep cultural roots that are difficult for the US agricultural community to understand.[115] The Regulation requires that all food/feed containing or derived from GMOs be labelled so as to inform the consumer that genetic modification has been involved in creating the product.[116] In addition, it is an EU requirement that all genetically modified foods and ingredients can be traced at all stages of the food production process.

3.5.1 EFSA v. FDA: Different Cultures – Different Regulatory Authorities

Cultures not only differ in their tastes for food itself but also in their 'tastes' for the type of institutions entrusted with ensuring them that they will get what they want.[117] Indeed, the manner in which food safety authority enforcement powers and penalties evolve and their

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[114] Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and amending Directive 2001/18/EC [2003] O.J. L268/24.

[115] Strong cultural divergences between regions are also evident, for example, in the feta cheese cases. See, Joined Cases C-289/1996, and C-293/1996 and C-299/1996, *Denmark, Germany and France v Commission* [1999] ECR I-1541

[116] In the context of cultural divergences between EU Member States and harmonisation of food standards, See also, Case C-312/1998, *Schutzverband gegen Unwesen in der Wirtschaft eV v Warsteiner Brauerei Haus Cramer GmbH & C. KG* [2000] ECR I-9187; Case C-47/1990, *Établissements Delhaize frères et Compagnie Le Lion SA v Promalvin SA and AGE Bodegas Unidas SA* [1992] ECR I-3669; Case C-3/1991, *Exportur SA v LOR SA and Confiserie du Tech SA* [1992] ECR I-5529; Joined cases C-321/1994, C-322/1994, C-323/1994 and C-324/1994, *Criminal proceedings against Jacques Pistre, Michèle Barthes, Yves Milhau and Didier Oberti* [1997] ECR I-2343.

[117] F. van Waarden, note 11 Chapter 1 above, p.36.

eventual application can often reveal a lot about the social mores operating in any particular jurisdiction. It also provides insights into effective compliance through enforcement. Under the EU and the US food law regimes, the administrative agency responsible for implementing the law utilises both formal enforcement powers (as provided for by statute) and informal compliance mechanisms (not statutorily based). In the US, in the early years of its administration during the first half of the twentieth century, FDA relied almost exclusively upon formal enforcement powers. It relied more on informal compliance mechanisms during the second half of the century. In contrast, before the development of the EU there was ad-hoc enforcement in individual European countries and it is only now that there is more rigorous enforcement in the EU similar to that of FDA.[118] Unlike the US, EU food law does not prescribe the enforcement mechanisms or the penalties. Instead EU Member States are left to devise these in accordance with their national legal systems.[119]

As discussed earlier in this thesis, there is a diversity of institutional logic – between EFSA (and between the EU Member States) and FDA (and between individual US States) - by which the EU and the US regulates food. The Europeanization and then the internationalization of food can sometimes bring the differing institutional logics into conflict with one another. Worldwide, most societies have created a variety of institutions, either public or private in nature, to reduce the risk and uncertainties implicit in food transactions. Nevertheless, there is an underlying trend across nations whereby the state choreographs the setting of minimum food safety and quality standards which mirror national cultural preferences.

It is immediately apparent that EFSA's resources and powers are dwarfed by those that make FDA a gargantuan administrative agency, armed with both risk assessment and risk management powers. However, in reaching an unbiased appraisal of EFSA, one must keep in mind that EFSA and FDA pursue different missions. Indeed, this is the fundamental difference between the two agencies. By ongoing monitoring of the safety and effectiveness of products, and by enforcing the Food and Drug Act against those who are in breach of its provisions, FDA protects the health of US citizens – it has both regulatory and enforcement

[118] P. B. Hutt, note 24 Chapter 2 above, p.8.
[119] R. Malcolm & J. Pointing, "Food law--EU v UK?" (2005) *The New Law Journal*, Vol. 155, Issue 7184, p. 1034.

powers. In a number of important ways, the sphere in which FDA operates, differs from EFSA's. These are as follows:

(i) FDA's substantive powers cover both functions of risk assessment and risk management - FDA is in charge of both;

(ii) because FDA is required to rely exclusively on scientific evidence and is not required to also consider the sort of social factors resonant in the General Food Law (and the many individual EU legislative provisions specific to traditional products), FDA decisions are more science-based than those adopted within the EU;

(iii) FDA's massive organizational size, with approximately 9,000 general employees (monitoring the manufacture, import, transport, storage and sale of a broad range of products) and 2,100 scientists working in 40 laboratories throughout the US; and

(iv) FDA derives its powers from the formidable Food, Drug and Cosmetic Act[120] augmented with numerous highly descriptive ancillary Federal Regulations which puts FDA in a much stronger position that EFSA under the General Food Law which by comparison merely lays down general principles and requirements of EU food law.

Although for the first time in EU food law, the General Food Law provides for a common model risk analysis applicable to both the EU and its Member States, certain aspects of General Food Law also exemplifies the limited role of EFSA. This watering down of potential EFSA powers is clearly evident from:

(i) Article 6.3 of the General Food Law which provides that in addition to the opinion of EFSA, risk management shall take into account "... other factors legitimate to the matter under consideration [.....] in order to achieve the general objectives of food law...";

(ii) Article 14.7 provides that "[F]ood that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned", and

[120] Federal Food, Drug, and Cosmetic Act, 21 USC.

(iii) Article 14.9 which provides that "[w]here there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed ....".

As noted in Chapter 2, when the concept of an EU wide food safety authority was first conceived, it was promoted as a 'European FDA'.[121] However, the reality now is that EFSA is merely a scientific advisory body that provides advice on food safety issues associated with the food chain. The role of EFSA appears to be even limited within its own area of risk assessment, since the current EU food law regime does not empower EFSA to impose its scientific opinions on the individual EU Member States' competent authorities in the event of diverging opinions.[122] EFSA is the risk assessor, performing risk assessment on behalf of the EU institutions, while the European Commission is the risk manager deciding whether or not to adopt the decisions. Both EFSA and the Commission operate in conformity with the risk analysis framework prescribed in the General Food Law,[123] which in addition to the scientific opinions allows the Commission to take into account 'other factors legitimate to the matter under consideration'[124] and the precautionary principle. The divergences of approach between the two institutions are stark and it is evident that culture and tradition play a silent but crucial role in their rules and processes.[125]

There is no guarantee that a Member State's food agency will not overrule EFSA's opinions and recommendations. There is no provision which prevents the possibility of turf war type disputes emerging between these various agencies.[126] EFSA represents one of the components of an entirely new strategy for EU food law adopted by the EU under the General Food Law. While EFSA's role is pivotal to the functioning of the new food safety regime, EFSA has not been vested with any regulatory power in the matter. Those powers remain with the Commission and the Member States. However, it has been argued that EFSA

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[121] A. Alemanno, note 83 above, p.238.

[122] A. Alemanno, "The Evolution of European Food Regulation - Why the European Food Safety Authority is Not an EU-Style FDA?" in C. Ansell and D. Vogel (eds), *What's the Beef? The Contested Governance of European Food Safety* (Massachusetts: The MIT Press, 2006); Bocconi Legal Studies Research Paper No. 1007451, p.28. Available at SSRN: http://ssrn.com/abstract=1007451 [Accessed: 28 April, 2011]

[123] European Parliament and Council Regulation (EC) No 178/2002, note 72 Chapter 2 above.

[124] Art. 6(3) of Regulation (EC) No 178/2002.

[125] A. Alemanno, note 28 Chapter 1 above, p. 221.

[126] See generally, R. O' Rourke, "Europe adopts new approach to food safety" (2000) *New Law Journal*, Issue 150, p.230

opinions are likely to acquire a de-facto legally binding value for both the EU and the Member State authorities when passing legislation.[127]

The question has arisen as to what party may refer questions to EFSA with regard to scientific opinions. In the case of *HLH Warenvertriebs*,[128] a German court asked the European Court of Justice to clarify whether or not a national judge may refer questions on the classification of a product to EFSA. The Court's decision was that this is not possible. Neither the General Food Law, nor Regulation 1304/2003[129] (on EFSA's procedure in relation to requests for scientific opinions) include national courts among the applicants authorised to ask EFSA for a scientific opinion.

However, in this cultural context, it is important to appreciate the divide between scientific risk assessment and the political step of risk management under EU food safety regulation. Under the General Food Law, risk assessment is confined to a hazard defined as 'a biological, chemical or physical agent in, or condition of, food or feed, with the potential to cause an adverse health effect'.[130] Therefore, aside from natural science, risk assessment does not take other factors such as cultural, economic, religious or ethical issues into account. These 'other factors' may come into play during the risk management stage. The General Food Law does not however provide any indication of how 'other factors' should be incorporated in the decision making process, nor does it prescribe the extent to which measures based on 'other factors' can deviate from the results of the scientific risk assessment step in the food safety process.[131]

EFSA is a stand-alone agency in its sphere of risk assessment. Indeed, EFSA is a somewhat peculiar European agency because of its independence from European decision makers and the EU Member State National Food Safety Authorities. Member State representatives are not permitted on the Management Board of EFSA. In addition, the scientific experts[132] are

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[127] A Alemanno, "European Food Safety Authority at Five" (2008) *European Food & Feed Law Review 2,* p.2.
[128] Joined cases C-211/03, *HLH Warenvertriebs GmbH v Bundesrepublik Deutschland,* and C-299/03, C-316/03 to C-318/03, *Orthica BV v Bundesrepublik Deutschland* [2005] E.C.R. I-05141.
[129] Commission Regulation (EC) No.1304/2003 of 11 July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it, [2003] O.J. L185/6.
[130] Art. 3(14) of Regulation (EC) No 178/2002.
[131] See generally, O. Hospes and I. Hadiprayitno (eds), *Governing Food Security: Law, Politics and the Right to Food (European Institute for Food Law Series)*, (Wageningen, The Netherlands: Wageningen Academic Publishers, 2002) p. 211.
[132] Either on the Scientific Committee or any one of the ten Panels.

not selected either by EU Member States or the European Commission. The selection of EFSA experts is based predominantly on scientific ability and experience. Before being appointed scientific experts have to declare any conflicts of interest. Therefore, the independence of EU risk assessors is strictly safeguarded.[133]

3.5.2 Cultural Administrative Divergences and their Wider Impact

In the US, arguably all local food differences have been obliterated,[134] whereas in the EU deep-rooted culinary traditions symbolizing strong national and local identity values still exist. Therefore, unlike in the US, in the EU when EFSA claims that a certain food product is unsafe, it must back this up with not only scientific evidence, but there must also be a willingness by the Member State to accept that the risk is too great in continuing a certain local tradition. Therefore, conflicts about food safety within the EU inevitably involve tension between an EU-wide or universal vision, and a centric-national or local vision, of both the safety aspect of that food and also the socio-cultural perception of the food.[135] Of course, if it were politically possible to move us closer to a more autocratic style Authority similar to FDA, then by giving the Authority the last word in all scientific contentious matters, we are likely to obliterate local traditions.[136]

While EFSA's aforementioned lack of authoritative power in scientific matters can be seen as a shortcoming of EFSA set against Member State political intervention, this is really the physical manifestation of an EU wide cultural expression of dislike for any standardization of the food supply coupled with strong Member State willingness to defend their indigenous perception of risk.[137] In summary, it is up to the European Courts to resolve any conflicts arising between Member State interests and EFSA scientific opinions. Therefore, EU Courts must perform a balancing exercise between local and supranational attitudes towards risk.

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[133] See, V. Silano, note 55 Chapter 2 above, p.405.
[134] E. Schlosser, note 9 Chapter 1 above, p.5.
[135] D. Chalmers, note 60 Chapter 3 above, p.533.
[136] A. Alemanno, note 122 above.
[137] C. Testori, *Speaking Notes at the Conference on Risk Perception: Science, Public Debate and Policy Making, Brussels*, (2003). European Commission Food Safety Consultations - DG Health & Consumer Protection. Available at: http://ec.europa.eu/food/risk_perception/speech_presentations_en.print.htm [Last Accessed: 28 April, 2011]

This curtailment of EFSA is in stark contrast to the comparative free hand that FDA has in such matters.

A prime example of the nature of this responsibility placed on the EU Courts, where the Courts must act as arbiter between local and EU wide concerns was evident during the BSE[138] Crisis and the BSE associated dispute with France. The dispute arose pursuant to the adoption by the Commission of Decision 96/239/EC.[139] This Decision prohibited the UK from exporting beef to other Member States and third countries.[140] The ban was subsequently lifted subject to strict conditions based on various factors including the eligibility and traceability of the origins of the beef. After the ban was lifted France continued to refuse to allow the importation of British beef, ostensibly on public health grounds. These public health concerns were raised mainly by France's own domestic food safety authority - the French Food Standards Agency (AFSSA). As a response to the French stance, the Commission successfully brought Article 226[141] proceedings against France requiring France to comply with the EU-wide lifting of the ban.[142] France still persisted in its refusal to allow the importation of British Beef. In order to have a fine imposed on France for its continued obstinacy, the Commission took further proceedings against France under Article 228.[143] In or around the same time, the British National Farmer's Union (BNFU) also initiated domestic proceedings in the French courts in an effort to enforce the EU right to free movement of goods. Eventually, on 2 October 2002, over three years after the ban on the export of British

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[138]BSE (bovine spongiform encephalopathy) is a disease found only in cattle which belongs to the family of prion diseases known as transmissible spongiform encephalopathies (TSEs). They are a family of rare progressive neurodegenerative disorders that affect both humans and animals. The most common form in humans is Creutzfeldt-Jakob Disease (CJD) - a rare and fatal form of dementia that can present in individuals between the ages of 40 and 80. Therefore, CJD is not a new disease. However, in 1996 scientists discovered a new strain of CJD (variant CJD, vCJD or new variant CJD, nvCJD) and scientific research has shown that the most likely origin of vCJD is human exposure to the BSE prion or protein by eating food containing traces of the brain, spinal cord or digestive tract of BSE infected carcasses. As with BSE in cattle, vCJD is always fatal in humans.

[139] [1996] OJ L78/47.

[140] This Decision was adopted following the discovery of a probable link between Creutzfeldt-Jakob disease (CJD), a disease affecting human beings, and bovine spongiform encephalopathy (BSE) which was prevalent in the UK.

[141] Under Article 226 of The Treaty Establishing the Economic Community (EC) (1957); now Article 258 of The Treaty on the Functioning of the European Union [2007] OJ C306/01 ('TFEU'), the ECJ can bring enforcement proceedings against a defaulting state who has failed to comply with a Treaty obligation. Firstly, the Commission must deliver a reasoned opinion on the matter after giving the State concerned the opportunity to submit its observations, and then if the State concerned does not comply with the opinion within the period laid down by the Commission, the Commission may bring the matter before the European Court of Justice.

[142] Case C-1/00 *Commission v. France* [2001] ECR I-3493.

beef had been lifted, France finally agreed to lift its ban on the import of British beef.[144] The Commission withdrew its enforcement proceedings relating to the imposition of a fine.[145] The ECJ[146] gave judgement in the BNFU case,[147] where it again confirmed that France could not prevent the resumption of beef imports from the UK. In this context it is also interesting to note the reaction of the British farmers, when the BNFU President Ben Gill said that 'the French have cynically exploited false consumer protection in a shameless attempt to protect their own beef producers'[148] and that it was unacceptable that France could 'walk away from this disgraceful situation at the last possible moment before fines are imposed'.[149]

Disputes such as this evidence a stark difference between the EU and the US when it comes to food safety, namely, that strong national food identities exist in the EU, each with their own perception of risk. However, as we shall see later in this thesis, the accusation made by the British farmers that France was merely protecting national economic interests is not dissimilar to the accusations levelled against the EU when it introduced the ban on the importation into the EU of foreign beef produced with the aid of growth hormones.

This dispute with France offers a prime example of the ECJ's role as arbiter between local and EU wide attitudes towards food and perceptions of risk. In order to further elucidate the role of the ECJ in these matters, it is also important to note that in its judgement the ECJ recognized that traceability of UK Beef was not guaranteed at the time of the Commission decision of 23 July 1999 lifting the ban, in particular as regards meat and products which had been cut, processed or rewrapped. Guaranteed traceability to the point of sale was essential if it was going to be possible for a consignment not fulfilling the conditions of EU law to be recalled. This shows how EU Courts are confronted with reconciling the value of domestic measures to the local population as against the damage done to the EU wide interests, especially free trade. As part of this process the Court is usually confronted with conflicting

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[143] Article 228 of the Treaty Establishing the Economic Community (EC) (1957); now Article 260 of the Treaty on the Functioning of the European Union [2007] OJ C306/01 ('TFEU').

[144] The French lifting of their ban followed an AFSSA report which concluded than British beef imports posed a 'negligible risk' of causing variant CJD.

[145] IP/02/1671, 13 Nov. 2002.

[146] The ECJ was now dealing with this case as it had been referred to the European Court of Justice by the French domestic court.

[147] Case C-241/01 *NFU v. Secretariat general du gouvernement* [2002] ECR I – 9070.

[148] R. Graham, M. Mann and J. Mason, '*France heads off sanctions and lifts embargo on British Beef*', Financial Times, 3 Oct. 2002, p. 1.

[149] J. Henley, '*France lifts ban on British beef after six-year dispute*', Guardian, 3 Oct. 2002, p.6.

scientific opinions from EFSA safety assessors set against the opinions of the national food safety authority of the Member State concerned.

This mechanism whereby the EU Courts are required to intervene and strike a balance between national and EU concerns, has the effect of condensing cultural differences between Member States without creating any kind of generic objective standard for safety which would also have had the result of enabling trade liberalisation across the Union.[150] Somewhat ironically, there is a presumption of safety when the food product is found to be in compliance with EU law, or if relevant EU provisions do not exist, then foods conforming to the national food laws of the Member States shall be deemed to be in compliance. This dispute with France evidences this, because in the event of diverging opinions it has not been empowered to impose its scientific opinion on the individual EU Member State food safety authority – in this case the French Food Standards Agency (AFSSA). The EU Courts must decide on the matter, with the burden of proof resting on the party claiming the product is unsafe. The fact that the Courts have to decide the matter and not EFSA, is also symptomatic of the greater divergences and resulting lack of trust at play between EU Member States as against FDA's more substantive position of power over individual US States.

Therefore, in conclusion, EFSA has a substantially different role than that of FDA in implementing food safety regulation. As outlined above, this is due to the authorities' different missions, diverging regulatory spheres of operation, and more interestingly due to respective divergences in citizen/consumer perceptions of risk based on cultural attitudes. Although likely to result in inter-state conflict, the EU Member States would not stand for EFSA having the last word on all food safety matters as they want to preserve the right of their national food authorities to express their unique perception of risk based on culture and tradition. Internationally, on a political level, this may also be viewed as an honourable attempt by the EU to defend its culinary richness and tradition from obliteration by the forces of mass production and globalisation at the hands of multinationals.

Any danger of over-involvement of the EU courts in deciding between the diverging opinions of EFSA and the Member State authorities can be allayed if EFSA establishes a robust network with the national food agencies so as to try and resolve conflicts over scientific

[150] A. Alemanno, note 122 above, p.30.

opinions before they reach the Courts. The proper operation of this network will help ensure that EU citizens have a high level of confidence in the food that they eat. EFSA is a completely different institution to FDA and it operates in a substantially different societal and regulatory sphere, but this should not prevent it from one day achieving a degree of prominence akin to that of FDA.

3.6 Big Business, Corporate Lobbying and Food Safety Regulation

A number of popular paperbacks have recently shone the spotlight on many of the more undesirable aspects of modern food production methods.[151] For example, in the American documentary '*Food Inc.*', in relation to beef in US supermarkets, the narrator pointedly states:-

> There is this deliberate veil, this curtain that's dropped between us and where our food is coming from ... The industry doesn't want you to know the truth about what you are eating, because if you knew, you might not want to eat it. If you follow the food chain back from those shrink-wrapped packages of meat, you find a very different reality, not a farm, a factory, that's the reality. That meat has been processed by huge multinational corporations that have very little to do with farmers and ranches. Now, our meat is coming from enormous assembly lines where the animals and the workers are being abused and the food is becoming much more dangerous in ways that are deliberately hidden from us.[152]

This quote paints an appalling vista of a US food system that has been hijacked by capitalism and corporate indifference to the sanctity of our food supply. It seems to almost affirm Marxist legal theory's assertion that law functions as part of the ideological superstructure of the capitalist system. The consumer has internalised the myth that the legal system will

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[151] E. Schlosser, *Fast Food Nation: What The All-American Meal is Doing to the World* (New York:Penguin, 2002), F. Lawrence, *Not On the Label: What Really Goes into the Food on Your Plate* (London: Penguin, 2004), J. Blythman, *Bad Food Britain: How a Nation Ruined its Appetite* (London: Harper Collins, 2006), The 2008 American documentary '*Food Inc.*' and accompanying text - K. Webber (ed), *Food Inc.: A Participant Guide - How Industrial Food is Making Us Sicker, Fatter, and Poorer and What You Can Do About it* (Philadelphia: PublicAffairs, 2009), and P. Roberts, *The End of Food* (London: Bloomsbury, 2008).

[152] K. Webber (ed), *Food Inc.: A Participant Guide - How Industrial Food is Making Us Sicker, Fatter, and Poorer and What You Can Do About it* (Philadelphia: Public Affairs, 2009), p.19.

preserve a just social order.[153] At the microeconomic level, cultural food preferences are affected by insidious forces. In order to maintain or expand market-share, food companies are constantly finding new ways to influence what we eat. Their obvious methods are advertising and public relations. However, some businesses aggressively strive to convince government officials, nutrition professionals and the media that certain of their products possess health enhancing powers or at least do no harm. It is a problem that is exacerbated by large food producers and distributors merging into larger and larger units, especially when their interests transgress national borders.[154] Corporate lobbying is a part of contemporary food culture, albeit oftentimes a virtually invisible component.

It is through the consumer that cultural biases towards the food supply are expressed and enforced. However, it is believed that producers possess the ability to exert more influence on an economies regulatory process than consumers, because industrial interests are more concentrated and easier to mobilise.[155] This is especially so in the more industrialised US food sector. As a result, cultural interests lose traction. In addition, these powerful industrial lobbies are a by-product of some greater entity organised for a different purpose – for example, the beef-industry lobby is a by-product of the beef industry which employs many US citizens and contributes significantly to national income. Added to this, in the US many cattle-rearing operations are owned by large corporations.[156] These corporations control the whole beef production process, right from the rearing of the cattle to the packaging of the final product. As a result, in the US, the power and interests of corporate producers tend to shape regulations.[157] In the US, the business community has by far the largest number of lobbies working on its behalf.[158] Indeed, it has been suggested that 'the power wielded by business in American politics may puzzle the person of democratic predilection; a comparatively small minority exercises enormous power'.[159] However, if democracy is to thrive, there must be an active role for minority points of view in public discourse and this

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[153] R. A. Falk, "The Relations of Law to Culture, Power, and Justice" (1961) *Ethics*, Vol. 72, No. 1, p.18.

[154] And as this thesis outlined in the introductory Chapter, domestic regulation becomes less effective when governing food imports as it is less able to govern the policies of foreign producers. See F. van Warden, note 11 Chapter 1 above, p.37.

[155] M. Olson, note 24 Chapter 1 above, p. 141.

[156] This is a dramatic cultural difference with European countries where farms are much smaller and still in the main privately owned by individual farmers.

[157] G.J. Stigler, "The Theory of Economic Regulation", (1971) *Bell Journal of Economics and Management Science*, Vol.2, No.1, p. 3.

[158] See, M. Olson, note 24 Chapter 1 above, p. 142.

[159] V.O. Key, *Politics, Parties and Pressure Groups* (New York: Crowell, 1958), p.96 as cited in M. Olson, note 24 Chapter 1 above, p. 142.

includes the socio-cultural domain.[160] There are cultural consequences for an un-moderated market, whether that market relates to food or some other merchandise such as art. Serious critical debate on urgent social questions does not contribute to the maximisation of profit, and therefore, increasingly in the US, this debate does not take place.[161]

Unlike EFSA, FDA is a powerful stand alone agency, influenced minimally by consumers. It has the power to influence its own political destiny. It has been alleged on a number of occasions that in the US this industrialized food sector 'maintains a revolving door of employment for government regulators and legislators to protect its power to set those conditions'.[162] The documentaries go on to make extraordinary accusations such as that 'for years during the Bush Administration, the Chief of Staff of the USDA was the former chief lobbyist to the beef industry in Washington', that 'the head of the FDA was a former Executive Vice President of the National Food Processors Association'.[163] In respect of Monsanto, it is alleged that there 'has been this revolving door between Monsanto's corporate offices and the various regulatory and judicial bodies that made the key decisions'. For example:-

(i) Clarence Thomas was an attorney with Monsanto (1976 – 1979) and then the same Clarence Thomas is now a Supreme Court Justice (1991 – present). Clarence Thomas wrote the majority decision in a case that granted corporations such as Monsanto the power to prevent farmers from saving their own seed;[164]

(ii) Margaret Miller was Chemical Lab Supervisor with Monsanto (1985 – 1989) and then the same Margaret Miller is FDA Branch Chief (1989 - present);[165]

(iii) Linda Fisher was Vice President, Government and Public Affairs, (1995 – 2000) with Monsanto and Linda Fisher is subsequently EPA Deputy Administrator, (2001 - 2003);[166] and

(iv) Michael Taylor was a lawyer with King & Spaulding Law Firm (1984 – 1991). During that time one of his main clients was Monsanto. During that time he

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[160] C. Gordon, "Culture and the European Union in a Global Context" (2007) *The Journal of Arts Management, Law, and Society*, Vol.37, No.1, p. 21.
[161] J. Smiers, *Arts under pressure: Promoting Cultural Diversity in the Age of Globalisation* (London: Zed Books, 2003) p. 136.
[162] See the 2008 American documentary '*Food Inc.*'
[163] *Ibid.*
[164] *Ibid.*
[165] *Ibid.*
[166] *Ibid.*

> advised Monsanto on labelling of genetically modified foods. Later, Michael Taylor was Deputy Commissioner for Policy at the FDA (1994 – 1994). During his time with FDA, he oversaw the FDA decision not to label genetically modified foods. Then, subsequently, Michael Taylor was Vice President for Public Policy (1998 - 2000).[167]

According to Eric Schlosser, these US 'regulatory agencies are being controlled by the very companies they're supposed to be scrutinizing'.[168] Over time, the influence wielded by big industry has an extraordinary effect on the manner in which the food consumed by the US public is produced. More specifically, corporate interests dictate the nature of US food safety policy.

Although US citizens are not always as concerned about the products of modern agriculture as EU citizens, they are becoming more sceptical of a regulatory framework that approves the safety of products solely on the basis of scientific analysis, oftentimes doing so without disclosing the full facts. When it comes to the legacy of controversial technologies such as novel foods and food additives, US critics of science are becoming more vociferous in arguing that other criteria should have a legitimate role in food safety regulation.[169] To date, in the US it may not be politically salient to include the full panoply of social, economic, and ethical considerations, but a shift towards their inclusion could be a catalyst towards a more EU like regulatory framework, cognizant of non-industry interests and not based solely on science.[170]

Traditional political theory teaches us that industrial interests are better at organizing themselves than consumer groups. Obviously, there are fewer corporations than individual consumers, corporations are more homogeneous in their goals and preferences, and corporations have more financial clout, greater access to information and technical ability when it comes to successfully lobbying politicians. Therefore, considering the influence of big-business in this area of US agriculture, it really comes as no surprise that the use of hormones for enhancing animal growth is legalised there. However, there is little or no

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[167] *Ibid.*
[168] Eric Schlosser, author of *Fast Food Nation: What The All-American Meal is Doing to the World* (New York:Penguin, 2002) speaking on the 2008 American documentary '*Food Inc.*'
[169] G. Skogstad, note 57 Chapter 3 above, p.235.
[170] *Ibid*, p.235.

tradition in the EU of large corporate entities owning cattle rearing operations. This is not just significant in the context of corporate lobbying, but also in the consumer context, because in the EU, the division between the farmer (and by association the consumer) and corporate interests has remained wider. Corporate power and by association science and technology, has not permeated down to the grass-roots of the food production process. The influence of science on food production is not as prevalent in the EU and this cultural trait is closely connected with the fact that EU farming is not industry centred.

This cultural difference is then augmented by a political landscape where private individuals (organized via consumer groups) have more institutional access to or a greater ability to influence the EU regulatory process. An organized consumer lobby can affect decisive political influence. It is public pressure made effective through the EU privilege of institutional access to the European Parliament. It is widely believed that it was a suspected oestrogen contamination of an uncontrolled supply of poultry and beef in Italy in 1977 that ignited consideration at official EU level of a Community-wide ban on growth hormones. The contamination caused hormonal irregularities in school-going children.[171] Then there was the discovery in 1980 of 30,000 jars of baby food in Italy containing dethylstilboestrol (DES).[172] These food safety scares had created a consumer climate in Europe in the early 1980s that was concerned over the potentially harmful health effects of using hormones in livestock production.[173]

At least in part due to lobbying by the EU pharmaceutical industry, the initial EU growth hormone ban in 1981 was only a partial ban.[174] It had been suggested that Commission Directorate VI (agriculture) was primarily sympathetic to industrial agricultural interests.[175] It was also believed that the pharmaceutical industry had a strong relationship with the Commission and that this was why it was successful in its demands for further scientific inquiries before any total ban was entertained.[176] However, due to institutional access and a

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[171] G.M. Fara, G. Del Corvo, S. Bernuzzi, A. Bigatello, C. Di Pietro, S., Scaglioni, G., Chiumello, "Epidemic of breast enlargement in an Italian school", (1979) *Lancet*, Issue. 314, p. 295.

[172] DES was used as a growth hormone in the beef and poultry industry. It was later found to cause cancer and was phased out. From time to time, mainly in the US, allegations surface that some producers continue to use it. See, A.I. Marcus, note 186 Chapter 2 above.

[173] T. Josling, D. Roberts, & A. Hassan, note 188 Chapter 2 above.

[174] Council Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action, [1981] O.J. L222/32.

[175] E. Millstone, "Analysing Biotechnology's Traumas", (2000) *New Genetics and Society*, Issue 19, p.117.

[176] L. Caduff, note 189 Chapter 2 above, p.9.

greater ability to influence the EU regulatory process, EU consumer groups eventually succeeded in attaining the complete ban.[177] Again, in 1984 the Commission made its best efforts to have only a partial ban instituted,[178] but the European Parliament, the EC Economic and Social Committee and the EC Council of Ministers rejected this proposal from the Commission.[179]

Widespread public aversion to a clearly identifiable risk, improves consumer group collective action potential.[180] European consumer groups were therefore successful in influencing the relevant institutional EU bodies to adopt stringent regulations governing growth hormones, despite lobbying by industry interest groups and the fact that scientific evidence supporting the alleged health risks associated with the use of growth hormones was thin at best.

The EU ban on growth hormone use in cattle, introduced throughout the 1980s and 1990s, banned the importation of meat and meat products treated with six specific growth hormones.[181] In the EU, industry or corporate interests which opposed a move towards more restrictive regulations, were unable to shape the EU regulatory outcome.[182] Fundamentally, this occurred because they failed in their efforts to influence EU consumer risk perceptions sufficiently in addition to their insufficient ability to obtain the necessary EU institutional access. Unlike with the regulation of growth hormones in the EU, in the US it is industry that usually dominates the battle for influence in the political regulatory process.

As already outlined, for the most part US consumers are simply unaware that their beef may contain growth hormone residues.[183] As a result they are not aware of the potential negative

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[177] Council Directive 85/649/EEC of 31 December 1985 prohibiting the use in livestock farming of certain substances having a hormonal action, [1985] O.J. L382/228.

[178] On June 12, 1984, the Commission published a proposal (COM(84)295 final) for a Council Directive amending Directive 81/602/EEC. This proposal envisaged the controlled use of the three natural hormones and a re-examination of the ban on the two synthetic hormones.

[179] A. Passantino, "Steroid Hormones in Food Producing Animals: Regulatory Situation in Europe" in C. C. Perez-Marin (ed), *A Birds Eye View of Veterinary Medicine* (Rijeka, Croatia: InTech, February, 2012), p.40.

[180] E. Meins, "Up or Down? Explaining the Stringency of Consumer Protection" in "Debate: Consumer Protection in a Global Market" (2000) *Swiss Political Science Review,* Vol.6, Issue No.2, p.94.

[181] However, it must be noted that the majority of the main international scientific bodies together with two major EU initiatives, have not found any scientifically verifiable evidence of health risks from the use of synthetic growth hormones, with the possible exception of one of the six hormones - oestradiol 17β – which may be a 'complete carcinogen'.

[182] See the comments of Mr. David McBeath, head of pharmaceutical company Hoechst's animal research division (a growth promotant manufacturer) at R. Wright, note 53 Chapter 2 above, p.9.

[183] C. Carlane, note 1 Chapter 2 above, p.319.

effects of this reality. US consumer organizations have never broadly campaigned against the use of hormones and one of the main reasons for this is simply because US consumers assume that the hormones pose no risk to human health – a stark cultural divergence away from the attitude of EU consumers. Consumers in the EU are uncertain about the efficacy of the scientific evidence supporting the safety of hormones. Therefore, we are not merely dealing with a protectionist issue. Even if an element of protectionism were involved, EU citizens do genuinely fear growth hormone residues in beef. One can ask the question as to whether or not the EU could maintain such a protectionist stance without popular support for the ban? The answer would appear to be 'no'. Therefore, in the EU, there is popular support for the ban on growth hormone use.[184] As evidenced in this thesis, this support can be traced to various historical experiences, especially food health scares, and the resultant cultural values imbued. It is these events that have caused most EU consumers to fear the use of growth hormones in cattle. Therefore, it is disingenuous of US officials to dismiss the ban as merely a form of EU protectionism over its food sector.

3.6.1 Independence of the Regulatory Agencies

However, contrary to Eric Schlosser's assertion of complicity between the FDA and vested commercial interests, an investigation of the current FDA leadership does not uncover any prior associations with private sector commercial interests. For example, previous roles held by the current head of the FDA, Commissioner Dr. Margaret A. Hamburg, included working as a researcher at Rockefeller University, a senior scientist at an institute dedicated to neutralising the threat of nuclear weapons, as assistant secretary for policy and evaluation at the U.S. Department of Health and Human Services, and as a commissioner of the New York City Department of Health. The Deputy Commissioner for Foods & Veterinary Medicine, Michael R. Taylor J.D., formerly worked as a research professor at the George Washington University. He also worked as an administrator of USDA's Food Safety and Inspection Service (FSIS) and acting under secretary for food safety at USDA. Howard Sklamberg, the current Deputy Commissioner for Global Regulatory Operations previously worked as a Director of the FDA Office of Compliance, as FDA Deputy Associate Commissioner for Regulatory Affairs and as a federal prosecutor. A similar investigation of the majority of

[184] B. Silverglade, "The WTO Agreement on Sanitary and Phytosanitary Measures: Weakening Food Safety Regulation to Facilitate Trade?" in "Debate: Consumer Protection in a Global Market" (2000) 6 *Swiss Political Science Review*, Issue No.2, p.85.

other executives currently working at the FDA does not disclose any former association between these officials and big-business.

It must also be noted that the Commissioner, Dr. Margaret A. Hamburg, launched FDA's Transparency Initiative in June 2009. This initiative continues to allay any concerns that the U.S. public may have regarding the independence of the FDA. On April 22, 2014, FDA released a report recommending ways to further enhance the transparency and public accessibility of the Agency's compliance and enforcement data.

The FDA uses fifty committees and panels to provide it with independent expert advice. The FDA Food Advisory Committee consists of 17 standing members including the Chair. The two members selected on the basis of industry interests do not have the right to vote on proposals. In addition, FDA's advisory committee program is governed by a number of Federal laws and regulations which set standards for convening the advisory committees and reviewing any potential conflicts of interest. As an additional safeguard, in order to ensure that no conflict of interest arises for an Advisory Committee member, the FDA operates its "Guidance for the Public, FDA Advisory Committee Members, and FDA Staff on Procedures for Determining Conflict of Interest and Eligibility for Participation in FDA Advisory Committees". This document sets-out the procedures which must be followed regarding the disclosure of any vested interests that an Advisory Committee member might have. A similar investigation of the current management at the U.S. Department of Agriculture does not disclose any vested interests.

In relation to Eric Schlosser's aforementioned observation regarding the decision by U.S. Supreme Court Justice Clarence Thomas, effecting the right of farmers to save their own seed, it should be noted that although Justice Thomas wrote the majority opinion, five justices voted with him - it was a 6:2 verdict.[185]

3.6.2 Big Business and the Annihilation of Tradition

As already outlined, the direct involvement of big business in food production and expansion of agricultural biotechnology, continues unabated in the US. US beef production is controlled by a handful of giant corporations. This is a dramatic cultural difference with EU Member

[185] See the judgement of the U.S. Supreme Court in *J. E. M. AG Supply, Inc. v. Pioneer Hi-Bred International, Inc.* 534 Supreme Court 124, 200 F.3d 1374 (2001).

States where farms are much smaller and still in the main privately owned by individual farmers.

This all amounts to one thing – a powerful indictment of US industrial food production methods and the powerful and well funded US government agencies charged with their regulation. These narratives maintain that theirs is an accurate representation of the situation. At their core is the belief that food is becoming industrialized in the same way as fast food.

Over time, big business has had the effect of changing the whole way that ground beef is produced in the US.[186] In other words, at the very least, you are still eating beef that is produced by 'the system' even if you are conscientious enough not to eat at a fast food restaurant. Indeed, this is an industrial food system which began with fast food in the 1930s and can probably be traced back to when the McDonald Brothers basically brought the factory system to the back of their fast food kitchen. However, as announced in Food Inc., this 'mentality of uniformity, conformity and cheapness, applied widely and on a large scale, has all kinds of unintended consequences' – for example, the manner in which chickens are raised. Chickens are raised and slaughtered in approximately half the time it took fifty years ago and they're also substantially larger. They've even 'redesigned' the chicken so that it grows a larger amount of breast meat. As one US farmer states – 'the chicken industry helped this whole community out ... it's all a science. They got it figured out. ... If you got a chicken you can grow in 49 days, why would you want one you can grow in 3 months? More money in your pocket.'[187] However, it's even more far-reaching than that. In order to maximise profit, it has even changed the farmer. For many US farmers, if they want to partake in supplying the corporate food processing giants, then they have to borrow hundreds of thousands of dollars in order to meet corporate requirements for efficient facilities. However, in return they can earn as little as $18,000 per year. As is evident from Food Inc., these powerful corporations are not shy about using their economic clout in order to discourage farmers from showing elements of the media around their operations or speaking-out about their experiences in the world of US corporate farming.

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[186] In the US beef industry, during the 1970s the top five beef packers controlled about 25 per cent of the US market. Today the top four control over than 80 per cent of that market with the US corporate giant 'Tyson' being the biggest meat-packing company in the world.

[187] Kentucky 'Chicken-Grower for Tyson Meats', Vince Edwards, as interviewed on Food Inc.

One farmer was so upset by the industrial animal raising practices on her farm that she defied potential retaliation from the corporation which she supplied, and agreed to allow the media to see what was happening.[188] She wanted the world to see what antibiotics, high-tech breeding and overcrowding were doing to the chickens. She stated that:-

> [t]he chickens never see sunlight, they're pretty much in the dark all the time. Its nasty in here, there's dust flying everywhere, its dirty, ... mass production ... They go from a chick to a five and a half-pound chicken in seven weeks, their bones and their internal organs can't keep up with the rapid growth. The chickens can only take a few steps and then they flop down, its because they can't keep up with all the weight that they are carrying. There are antibiotics that they put into the chickens and now the bacteria has built up a resistance, so the antibiotics don't work [on me] anymore.

This industrialization of the food supply as sensationalized in the popular media depicts a world populated by increasing numbers of sick animals, environmental degradation, adulterated and unhealthy food, and human health issues such as obesity and diabetes.

3.7 Cultural Background to the *Beef Hormones Dispute*

As already confirmed, the *Beef Hormones Dispute* arose in the 1990s in the midst of the mad cow disease crisis. It was feelings of distrust which led EU consumers to pressurise the EU authorities to ban the use of growth hormones and importation of beef produced with the aid of growth hormones.[189] WTO rules permit such bans, but only where a Member presents evidence proving that the ban is a valid health and safety measure under the terms of the SPS Agreement. The US and Canada opposed the EU ban and took the EU to the WTO Dispute Settlement Body.[190]

As previously outlined in this thesis, across the EU consumer confidence in the expert governance of food safety was shattered by the various food safety crises. For example, EU

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[188] Maryland chicken-farmer for the Perdue Corporation, Carole Morison, as interviewed on Food Inc.
[189] C. Carlane, note 1 Chapter 2 above, p.305.
[190] US and Canadian beef producers believed that a broad scientific consensus existed that beef produced with the use of hormones was safe. The EU asserted that it was not safe.

Member State governments had wrongly insisted for years that the beef supply which was tainted by mad cow disease was safe.[191] As a result, EU consumers appear to have less faith in scientific risk analysis than their North American counterparts and they are reluctant to rely on science to provide the basis for policy solutions. They also demand higher levels of protection in the form of product bans or labelling disclosing all critical information about the food product.[192] It is not surprising that EU consumers are uncertain about the efficacy of the scientific evidence supporting the safety of hormones. Therefore, we are not merely dealing with a potential protectionist issue. EU citizens do genuinely fear growth hormone residues in beef.

This can be contrasted with the use of animal growth hormones in the US. As already outlined, US beef production is controlled by a handful of giant corporations. They breed, slaughter and process the animals.[193] Big business is keen to utilise agricultural biotechnology in the commercialisation of the food sector.[194] All in all, a staggering 67 – 90 per cent of US beef is produced using growth hormones.[195] This industrialisation of US beef production is acknowledged by the US regulatory authorities. For example, the United States Department of Agriculture Food Safety and Inspection Service (FSIS) states that since the Federal meat inspection program began at the turn of the twentieth century, the US meat and poultry industries have grown and changed significantly. The FSIS states that in the early 1900s most meat came from small local slaughtering plants and the meat was also consumed locally. Additional processing was limited to relatively simple products such as sausages. However, nowadays, the animals are slaughtered and processed in large, sophisticated, high-volume processing plants. Then, the meat is often shipped great distances to reach consumers. FSIS notes that in those earlier days of food safety, animal diseases were the primary concern of FSIS inspectors and they relied almost exclusively on visual inspection. However,

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[191] C. Carlane, note 1 Chapter 2 above, p.318.
[192] *Ibid*, p.305.
[193] This is a dramatic cultural difference with European countries where farms are much smaller and still in the main, privately owned by individual farmers. In the EU, the beef processing end of the production process remains a separate enterprise. See, C.S. Houston, note 166 Chapter 2 above, p. 269.
[194] As already outlined, growth promotants are used on more than two-thirds of all cattle in the US. Since approximately 36 million cattle are produced in the US each year, that is 24 million and 32.4 million cattle respectively whose beef contains growth promotant residues. See J. Raloff, note 47 Chapter 3 above, P.10.
[195] Therefore, 67-90 per cent of all US beef contains growth promotant residues. J. Raloff, *Ibid*, P.10.

nowadays FSIS inspectors are concerned more with the unseen hazards such as microbiological and chemical contamination.[196]

As this thesis argues, for the greater part it is scientific and technological breakthroughs that lead to trade disputes and cultural clashes over food policy. Moreover, due to the stark cultural difference existent in the US with the use of a technology such as growth hormones, a majority of US consumers perceived little or no risk in consuming meat produced with growth hormones. In fact, many US consumers would be more ready to cite the benefits, as they see it, from using growth hormones in their beef production. As a result, US consumer groups could not succeed in lobbying for higher levels of consumer protection. Corporate power and certain US administrative authorities have actually succeeded in creating a food consumerism favourable to the application of technology in the food supply.

The EU's possibly inadvertent attempt during the *Beef Hormones Dispute* at using the SPS Agreement as a mechanism to obtain protection for what was really a consumer issue, has resulted in a degree of misdirection of focus since this question should be centered on the WTO as a whole and not just on the efficacy of the SPS Agreement. The question really is, how would the WTO deal with issues not concerning 'producers', when those issues are also sources of protection? In this regard it would have been preferable had there been some producer protectionist cases before the WTO prior to the beef-hormone case arising, as this would have preemptively verified the robustness of the SPS Agreement as a dispute resolution mechanism.[197]

3.8 Conclusion

As confirmed by the analysis in this Chapter, our diet is now determined for us by a complex interplay of social, economic and technological forces. When this reality is combined with the fact that some economic regions specialise in large scale mass production while others specialise in high-quality niches, it becomes evident that food standards develop differently.

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[196] For example, over use of antibiotics or growth-promotants having been administered in a manner that breaches the regulations. See, Food Safety and Inspection Service, Inspection & Grading of Meat and Poultry: What Are the Differences? Available at: http://www.fsis.usda.gov/Factsheets/Inspection&Grading/index.asp [Accessed: 15 July 2012].

[197] W.A. Kerr & J.E. Hobbs, note 164 Chapter 2 above, p. 284.

In addition, predominantly, food is no longer produced locally and as a result information asymmetries have arisen that have contributed to consumer mistrust. This has been exacerbated by a number of recent well publicised health scares including bovine spongiform encephalopathy (BSE) in beef, foot-and-mouth disease, *e.coli* poisoning and avian influenza.

In addition to these direct health concerns, differences of opinion have also arisen due to the advent of biotechnological processes or scientific advances in food production. In particular, in Europe there is concern over genetic modification (GMOs) and the use of growth hormones in beef production. Conversely, there are many ardent advocates of biotechnology located in the US, who argue that food products created using these processes are safe to eat and that we can all look forward to the benefits of productivity and a more certain food supply.

These factors can work to augment the consumer bias existent in Europe favouring a more traditional approach to food which in itself is reinforced by the portent of EU food law and the nature of EU food regulatory authorities.[198] The culture of food extant in Europe tends to indicate that European citizens favour traditional foods with minimal processing while being sceptical of new technologies. For example, certain EU Member States such as France pride themselves in the production of raw-milk products such as rocquefort cheese.[199] The EU-wide sale of these raw-milk products is permitted under EU law.[200] In stark contrast, the US food regulatory authorities view raw milk cheese as a 'dangerous microorganisms that can pose serious health risks'.[201] FDA states that as a 'science-based' public health regulatory agency, FDA strongly supports pasteurization in order to protect the safety of the food supply and maintain public confidence in a staple of the diet, namely milk.[202]

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[198] This also supports this thesis' assertion that a nation's food culture is oftentimes reflected in the essence of the food regulations enacted.

[199] Unpasteurized milk or 'raw milk' has not been heated or pasteurized in order to kill harmful bacteria. Instead, aging allows time for the natural acids and salt in cheese to destroy harmful bacteria. Raw milk is prized by some cheesemakers who claim that it adds a special richness of flavour.

[200] The EU has a number of measures which permit the survival of raw-milk cheese production while simultaneously regulating the process in order to try and ensure consumer safety. Certain conditions must be met. See Council Directive 92/46/EEC of 16 June 1992 laying down the health rules for the production and placing on the market of raw milk, heat-treated milk and milk-based products, [1992] O.J. L.268/1.

[201] In the US in 1987, FDA issued a regulation prohibiting the interstate sale of raw milk intended for human consumption – unless the raw milk products had been aged for at least 60 days. However, some states do permit the intrastate (within the borders) sale of raw milk. Many EU raw milk products are aged for a maximum of 30 days.

[202] See, *FDA. The Dangers of Raw Milk*, note 22 Chapter 1 above. In stark contrast, the corporate led US agrifood sector has no qualms in utilising modern technologies such as animal growth hormones in the food production process.

Raw milk produce is just one area of food production where a clear divergence in regulatory approach between the EU and the US is evident.[203] However, there are many others specific enactments which protect tradition and individuality in the European food supply, such as the protection of food tradition inherent in geographical indications and designations of origin ('PGO'[204] and 'PDI'[205]), and traditional speciality guaranteed ('TSG'[206]). In addition, as the investigations in this thesis will evidence, this cultural divide between the EU and the US is nowhere more apparent than in the divergent regulatory approaches surrounding the GMO and animal growth hormone controversies.

Unlike the US, under EU food law we have a clear division between risk assessment (i.e. scientific risk-analysis) and risk management built into the legislation itself and this enables the inclusion of a social factor in the formulation of food safety measures.[207] As outlined, the General Food Law caters for consumer interests and tradition. Health goals should be determined by a society and only then should science play a role. In addition, EFSA is not empowered to enforce its opinions on EU consumers, and individual EU Member States still possess a lot of autonomy in these matters.

The US represents a far more industrialised agrifood sector where tradition in food production has been almost obliterated. US consumers are simply less aware of the dominant role played by technology in creating their food and are thereby less concerned with the potential deleterious ramifications for human health. Corporate might is keen to utilise

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[203] Where such provisions such as these in the EU which protect tradition exist in the US, usually they only exist at State level. The produce concerned can only be marketed across state borders ('interstate commerce') provided it does not breach any applicable federal provisions. In most cases it could not be allowed into interstate commerce. For example, this is the position with raw-milk cheese in the US Therefore, this is also a stark cultural divergence of regulatory approach, because as we have seen with trade disputes within the EU, generally, when a foodstuff is lawfully marketable in one Member State it must be lawfully marketable in all – *Cassis de Dijon* - Case 120/1978, *Rewe-Zentral AG v Bundesmonopolverwaltung fur Branntwein* [1979] ECR 649.

[204] Protected Geographical Indication.

[205] Protected Designation of Origin.

[206] See Council Regulation (EC) No 509/2006 of 20 March 2006 on agricultural products and foodstuffs as traditional specialities guaranteed, [2006] O.J. L93/1, Commission Regulation (EC) No 1216/2007 of 18 October 2007 laying down detailed rules for the implementation of Council Regulation (EC) No 509/2006 on agricultural products and foodstuffs as traditional specialities guaranteed, [2006] O.J. L275/3.

[207] Paragraph 19 of the Preamble to the General Food Law provides that 'scientific risk assessment alone cannot ... provide all the information ... and that other factors ... should ... be taken into account including societal, economic, traditional, ethical and environmental factors ...' In addition, Articles 3.10 and 3.12 of the General Food Law substantiate this approach.

science in order to legitimise its use of food technology in boosting profits. The predominantly science-based food law and more autocratic food safety governance structure extant in the US, perpetuates these powerful industrial interests.

In the next Chapter, we shall examine the merits of science and the extent to which it is utilised as the arbiter of risk analysis in international food safety law. Subsequent to the analysis contained in the next Chapter, at that stage, this thesis will have served to inform an understanding of why the *Beef Hormones Dispute* was not merely a dispute concerning a potential risk posed by food to human health, but the broader issue of a sometimes acrimonious interplay between culture and science in food safety regulation. Subsequent Chapters will expand upon this theme, to show how risk is dealt with under the SPS Agreement, and how these matters were interpreted by the WTO Dispute Settlement Body during the *Beef Hormones Dispute*.

CHAPTER 4

MODERN FOOD PRODUCTION AND REGULATION: A DUAL ROLE FOR SCIENCE

4.1 Introduction

As already outlined in the introductory Chapter, the references in this thesis to science refer to both science as a factor in the creation of food, and also science as the arbiter of risk analysis regulating the safety of food prior to human consumption. Therefore, science plays a significant role at both ends of the food spectrum. As part of the risk assessment process, food safety analysis is usually either wholly science based or at least predominantly science based by utilizing some element of scientific risk analysis as a method of gauging the likely risk, if any, posed to human health by the food. There is a proportionate diminution of other factors such as culture in the food safety measures enacted depending upon the extent to which science is incorporated into the food safety risk analysis process. If decisions are taken purely on the basis of scientific empirical findings, then there is no room for cultural considerations. It is in this context that somewhat unusually for a subject of legal discourse, commentators have noted that the majority of new developments in the historical development of food law result from advances in science and not upon new legal insight. The history of the development of food regulation is the history of science.[1]

Because of the technological aspect to modern food, science is also closely associated with the food processor or manufacturer, especially when that party is a corporate entity. This represents the utilisation of science for commercial purposes. The typical examples are where the application of science allows economies in production costs, or the preservation or shelf-life extension of a product, or the creation of a patent or market niche. In addition, the food item itself is sometimes intrinsically imbued with a science element, for example, the

[1] P.B. Hutt, note 24 Chapter 2 above, p.9.

pasteurization of milk or the genetic modification of vegetables.[2] In particular, the more industrialised food sectors extol the virtues of science because it is due to the technical sophistication of their food production methods that they have succeeded. Large food companies are synonymous with the application of science in food as it through advances in food processing techniques that they compete with their rivals and increase profitability. They often see cultural considerations as something that can only restrain their capitalist agenda.

Therefore, in effect, culture interacts with science on two separate but interconnected fronts – (a) science based food safety risk analysis and (b) science in the form of food technology/commerce. Therefore, in this thesis, the aphorism 'food as science' is used an umbrella term for the role played by science in each of these contexts. Irrespective, to whatever guise science takes, it is antithetical to the concept of food as culture. However, in reality, some element of both is always present and oftentimes necessary.[3]

In respect of food law, this thesis argues that an over-reliance on science as a basis for legal reasoning will divest a legal system of other attributes. In addition, there is rarely an instance where science based evidence in food safety can be said to be conclusive. It is never possible to test for all possible health risks and the resultant scientific consensus is only as good as the research and the statistical processes underlying it.[4]

On the other hand, science has been described as 'a cornerstone of modernity',[5] the 'archtype' of all knowledge, privileged over both God and tradition in modern Western culture.[6] Indeed, it has been argued that requiring food safety regulatory agencies to bring the best science available to bear when developing or revising food safety law, has been central

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[2] GM or GMOs refers to genetically modified organisms. The EU legal definition for a GMO is 'any life form, with the exceptions of human beings, in which the genetic material has been altered in a way that does not occur by natural reproduction' - Article 2(2) of Directive 2001/18/EC of the of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

[3] The analysis of the *Beef Hormones Dispute* later in this thesis will serve to exemplify these arguments.

[4] Typically in situations where science is used to identify hazards, the burden of proof is on authorities, whereas, where science is used to exclude hazards, the burden of proof (or at least the provision of the necessary scientific data) is on the business wanting to bring a product to market, See B. M. J. van der Meulen, note 67 Chapter 2 above, p. 338.

[5] K.T. Litfin, note 39 Chapter 3 above, p.8.

[6] M. Davies, note 40 Chapter 3 above, p.115.

to the high level of success, for example, achieved by US food safety policies.[7] It is indisputable that in order to understand the complex interactions between different determinants and the impact that they have on health, it is necessary to use science. This use of science also assists in identifying the correct policy measures. Science is used to monitor the impact of decisions that have already been taken - to assess the success rate and to identify the corrections needed on a case by case basis.[8]

The WTO Agreements – General Agreement on Tariffs and Trade (GATT) and the Agreement on the Application of Sanitary and Phytosanitary Measures[9] (SPS Agreement), set the global stage for science based food law and they have as their main goal the liberalisation of international trade.[10] When it comes to the liberalisation of international trade, the traditional involvement of the state in matters cultural, is called into question. The relationship between culture and trade is oftentimes cast as a conflict between protectionism and liberalisation. In order to advance the goal of international trade liberalisation, GATT uses the standard of non-discrimination between the trading partners. Indeed, all of the WTO Agreements reflect the goal of trade liberalisation as a means to achieving broader social and economic objectives.[11] WTO Members, such as the EU and the US, must show compliance with the SPS Agreement and consequently their food regulatory measures must comply with it.

Any definition of food or a specific food product will usually involve reference to two components – matter and human motivation. Examination of the composition of food involves physical and biological science. Examination of the human motivation aspect involves psychology, sociology and cultural studies. This thesis contends it is for this reason that there is always a need to take account of non-scientific factors. Based merely on the one

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[7] R. L. Buchanan, note 41 Chapter 3 above, p. 332.

[8] See generally, V. Silano, note 55 Chapter 2 above, p.400.

[9] During the GATT Uruguay Round of multilateral trade negotiations, the GATT member nations established The SPS Agreement and also the Agreement on Technical Barriers to Trade (TBT) Agreement, in an effort to address the emerging debate over the use of standards in international trade. The Agreement on the Application of Sanitary and Phytosanitary Measures entered into force with the establishment of the World Trade Organization on 1 January 1995. It concerns the application of food safety, and animal & plant health regulations. Generally, the SPS and TBT Agreements can be interpreted as an attempt at balancing the competing spheres of domestic regulatory autonomy as against global harmonization of product standards. At the same time, the agreements are also intended to prevent standards from becoming a protectionist device.

[10] The SPS Agreement was negotiated during the Uruguay Round of trade-talks which also led to the establishment of the WTO.

[11] T. Voon, *Cultural Products and The World Trade Organisation* (Cambridge: Cambridge University Press, 2007), p.4.

dimensional perspective of food science alone, it would be foolhardy to attempt to persuade consumers that they should behave is a specific manner towards a particular food item.[12]

It has been said that any subject that ignores culture is arbitrary and self-defeating.[13] The more science oriented a food safety regime is, by definition the most it must limit the influence of culture. Therefore, depending on how science is dealt with under the SPS Agreement will dictate the ability of a country to apply local or indigenous food safety norms. This thesis argues that the WTO objective of creating a global food law, thereby removing discriminatory food standards which act as a non-tariff barrier to trade, will by default displace indigenous attitudes towards food safety that are centuries old.

This Chapter examines the extent to which science dominates food regulation – an analysis which will be completed by the Chapter examining the SPS Agreement. Further lessons which will augment this examination will be gleaned, later in this thesis, from the study of the *Beef Hormones Dispute*.[14] The *Beef Hormones Dispute* arose in the 1990s between the European Union and the United States/Canada, over the use of growth hormones in beef production. The *Beef Hormones Dispute* was the first ruling to interpret the WTO SPS Agreement. The analysis of the Dispute will provide invaluable insights into the workings of the SPS Agreement. It will also elucidate the role played by science in the SPS Agreement, thereby highlighting the role, potentially, which culture could play.

4.2 Harmonisation of Food Standards and a Role for Science in EU Food Law

Until the arrival of the General Food Law,[15] EU food legislation had come about through the gradual harmonisation of national rules necessary to ensure the free movement of foodstuffs[16]

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[12] P. Belton & T. Belton (eds), note 9 Chapter 2 above, p.1.
[13] A. Wildavsky & M. Douglas, note 3 Chapter 1 above, p. 194.
[14] *EC Measures Concerning Meat and Meat Products ('EC-Hormones')* WT/DS26, and *United States – Continued Suspension of Obligations in the EC – Hormones Dispute ('US-Continued Suspension')* WT/DS320.
[15] The General Food Law Regulation entered into force on the 21 February 2002. European Parliament and Council Regulation (EC) No 178/2002, note 72 Chapter 2 above.
[16] The fundamental EU principle of the Free Movement of Goods, applies to food. The free movement of goods is aimed at the abolition of all individual Member State commercial and tariff barriers to intra-EU trade - Articles 23-31 EC.

and prevent anti-competitive practices in the establishment of the single market.[17] The primary influences on the development of EU food law were the program for the realisation of the internal market and to a lesser extent the Common Agricultural Policy (CAP).[18] Therefore, it was economic rather than consumer or safety concerns that originally informed the legislative framework of EU food law.

Therefore, from the early 1960s until the BSE crisis erupted in the mid-1990s, EU food law was principally informed by matters pertaining to the creation of an internal market for food products in the EU. This market-oriented phase can be divided into two episodes, firstly, an emphasis was on harmonisation through vertical directives which ended with case law of which the *Cassis de Dijon*[19] judgment is the most famous, and secondly, a period where the emphasis shifted to harmonisation through horizontal directives.[20]

One of the most significant aspects of the free movement of goods principle in EU law, as far as national food legislation is concerned, is the prohibition imposed by Article 34 TFEU[21] on measures having effect equivalent to qualitative restrictions on imports from other Member States.[22] The *Cassin de Dijon*[23] case involved a situation where the German Federal Monopoly Administration for Spirits prohibited the importation of a French liqueur (cassis

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[17] A. Alemanno, note 83 Chapter 3 above, p. 239.

[18] Begun in post-war 1950s Europe, the Common Agricultural Policy (CAP) is a system of EU agricultural subsidies and programmes aimed at supporting farmer standards of living, support the production of quality food at fair prices and the preserve rural heritage. Some people have criticized CAP for not taking food quality, safety and environmental concerns into consideration. These criticisms increased with the mad cow disease crisis and therefore the question of quality has been incorporated into CAP as an incentive to production. See, M.A. Recuerda, "Food Safety: Science, Politics and the Law" (2006) *European Food and Feed Law Review*, Issue 1, p. 3. Therefore, in order to assist in food safety assurance and animal health and welfare standards, the CAP offers some financial supports in these areas under the scope of Rural Development. See, M. Lugt, "Enforcing European and National Food Law in the Netherlands and England", (The Hague: Koninklijke Vermande, 1999) as cited in C. Ansell and D. Vogel (eds), *What's the Beef? The Contested Governance of European Food Safety* (Massachusetts: The MIT Press, 2006), p. 239.

[19] Case 120/70, *Rewa-Zentral AG v Bundesmonopolverwaltung für Branntwein* [1979] ECR 649.

[20] B. M. J. van der Meulen, note 67 Chapter 2 above, p. 313.

[21] Article 34 TFEU (formerly Article 28 EC) sets out a general obligation on Member States to ensure that 'quantitative restrictions on imports and all measures having equivalent effect shall ... be prohibited between Member States'. This wide-ranging responsibility received further elaboration and clarification in Commission Directive 70/50/EEC of 22 December 1969 based on the provisions of Article 33 (7), on the abolition of measures which have an effect equivalent to quantitative restrictions on imports and are not covered by other provisions adopted in pursuance of the EEC Treaty, [1970] O.J. L13/29. Until the *Cassin de Dijon* judgment by the European Court of Justice (ECJ) in 1979, it was assumed that the Article 20 prohibition was confined to measures that discriminated against imports. However, the *Cassin de Dijon* judgment made it clear that the prohibition does in fact extend to any measure applying to imports and also home products as well, if it restricts imports of products lawfully produced and marketed in another Member State.

[22] For example, a 'quality label' for national products was declared illegal in Case C-325/00 *Commission v Germany* [2002] ECR I-9977.

[23] Case 120/70, *Rewa-Zentral AG v Bundesmonopolverwaltung für Branntwein* [1979] ECR 649.

from Dijon), because the liqueur did not meet German regulations governing alcohol content. The importer brought a lawsuit against the relevant German authority and won the case. The ECJ stated that the limitation of the free movement of goods could only be permitted in exceptional cases - if it can be shown that the measure is necessary in order to satisfy a compelling public interest requirement (a 'mandatory requirement') such as the protection of public health, the fairness of commercial transaction, or the defence of the consumer. In order for the measure to be justified on one of these grounds, the measure must be proportionate to its objective.[24] The decision in *Cassis* stipulates that Member States mutually recognise their respective regulations in this context.[25] Each Member State now has to presume, unless it can prove otherwise, that the system in each Member State is appropriately thorough to protect consumers in respect of their health or general well-being or in relation to the possibility that the consumer will unwittingly purchase a foodstuff believing it to be a certain type of product when it is in fact another.[26] In ruling against the national rules, the ECJ effectively created a system whereby national standards for a product must always correspond to the lowest level acceptable in any one of the Member States in order to comply with the interpretation of Article 34 TFEU. The Court stated that the 'simple matter' of ensuring that the consumer receives appropriate information on the label[27] would always be sufficient to ensure the consumer's protection from unfair commercial practices.[28] Accordingly, where goods have been legally manufactured and marketed in one Member State, they may as a matter of principle, also be sold in all other Member States without additional controls.[29]

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[24] For example, in a judgment in 1987, the ECJ took the view that it was unnecessary for consumer protection and it was therefore illegal, to impose a national beer standard on imports – for that purpose compulsory labelling outlining the position in accordance with the nature of the product would have been sufficient - Case 178/84 *EC Commission v Germany* [1987] ECR 1227.

[25] The Commission now states that, to make the mutual recognition principle fully operational, the European Parliament and the Council adopted Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC, [2008] O.J. L218/21.

[26] Moreover, the Member States obligation is not only confined to acceptance of adequately labelled products that have been lawfully manufactured in the EU, they must likewise normally accept third country products that have been put in free circulation in that Member State. Article 23.2 EC deals with 'free circulation' and see case 41/76 *Criel (nee Donckerwolke)* [1976] ECR 1921.

[27] In the EU, a number of Court of Justice decisions have laid down stipulations regarding labelling language. For example, see Cases C-369/1989, *Piageme and others v BVBA Peeters* [1991] ECR I-2971, C-385/1996, *Criminal proceedings against Hermann Josef Goerres* [1998] ECR I-4431, C-366/1998, *Criminal proceedings against Yannick Geffroy and Casino France SNC* [2000] ECR I-6579, C-144/1993, *Pfanni Werke Otto Eckart KG v Landeshauptstadt München* [1994] ECR I-4605 and C-51/1994, *Commission v Germany* (sauces and pastries) [1995] ECR I-3599.

[28] See, C. MacMaolain, note 58 Chapter 2 above, p.23.

[29] Since 1979 the Cassis de Dijon doctrine (of which the extended interpretation of Article 34 TFEU (ex Art. 28 EC) and the public interest derogation from it are sometimes respectively called the 'mutual recognition principle' and the 'rule of reason') has been applied in numerous ECJ cases and is now well established. The

Then, predominantly in the 1990s, a number of high-profile food safety crises, aroused EU consumer concern about their food, its method of manufacture, its safety and concerns regarding the impact on their health.[30] After the food health scares, it became clear within the EU that the free movement of goods could no longer be the driving force underlying EU food law.[31] Food safety was now also necessary as a buttress to the proper functioning of the internal market.[32] The BSE crisis had 'marked a Year Zero for the European Union food regime by forcing both Member States and the Community to acknowledge the shortcomings of the existing European approach to food safety issues'.[33] In due course, this impetus led to the creation in the EU of Regulation 178/2002,[34] commonly referred to as the General Food Law,[35] which laid down the general principles and requirements of food law, established the European Food Safety Authority, and laid down procedures in matters of food safety. The General Food Law articulates the general concepts and principles that serve as the foundation of contemporary EU food law.

As is evident from the historical narrative of EU food law outlined above, originally the imperative was Community trade liberalisation via the harmonisation of individual Member State food regulatory measures. There is a strong similarity between this historical EU approach and the existing core WTO objective of enabling global free trade. However, as shown by the arrival of the General Food Law, eventually in Europe there was a realisation that this in itself was not enough.

4.2.1 Sound Science and Risk Analysis under the General Food Law

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principles which have arisen out of the Court of Justice decision in *Cassis* have been further developed in subsequent case law, especially the decision in Case 178/1984, *Commission v Germany* (bier) [1987] ECR 1227. In relation to the use of additives in foodstuffs and mutual recognition, see for example Cases C-344/1990, *Commission v France* (cheese nitrate) [1992] ECR I-4719 and Case C-24/2000, *Commission v France* (fortified foods – 'Red Bull') [2004] ECR I-1277.

[30] See generally, C. MacMaolain, note 58 Chapter 2 above, p.175

[31] A. Alemanno, note 83 Chapter 3 above, p. 243.

[32] Although, Article 4(2) of the General Food Law still provides that "Food law shall aim to achieve the free movement in the Community of food and feed manufactured or marketed according to the general principles and requirements in this Chapter".

[33] D. Chalmers, note 60 Chapter 3 above, p.534.

[34] European Parliament and Council Regulation (EC) No 178/2002, note 72 Chapter 2 above.

[35] The General Food Law Regulation entered into force on the 21 February 2002.

Now, the most fundamental norm of EU food law is that food may not be placed on the market if it is unsafe.[36] Risk analysis,[37] risk assessment[38] and risk management[39] are utilised to ensure that the food is safe. Almost every paragraph of the preamble to the General Food Law reiterates the science based character of the Regulation. Article 6.1 of the General Food Law provides that 'in order to achieve the general objective of a high level of protection of human health and life, food law shall be based on risk analysis ...'[40] Indeed, Article 1 states that the General Food Law enables the means to 'provide a strong science base' for food safety regulation. In other words EU food law protecting human health is largely science based. In the context of the *Beef Hormones Dispute*, some commentators have noted that it is likely that this EU decision to make food law (more) science-based was influenced to some extent by discussions within the WTO on the EU approach to dealing with animal growth hormones and genetically modified foods.[41]

When dealing with scientific risk assessment, it is important to note the difference between 'hazard' and 'risk' in food science. The term 'hazard' refers to the *source* that has caused or could cause an adverse health effect, while 'risk' refers to the *probability* of that effect and its severity. The General Food Law defines risk as 'a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard'.[42] The Codex Alimentarius defines risk as 'a function of the probability of an adverse health effect ... consequential to a hazard(s) in food'.[43] Therefore, for example, if dioxins are detected in

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[36] Article 14 of European Parliament and Council Regulation (EC) No 178/2002, note 72 Chapter 2 above. Generally, it is left to food businesses to scientifically determine if their produce is either safe or unsafe. However, by making provision for toxicological and other scientific tests, legislation sets specific limits distinguishing what is considered safe and unsafe. For example, "acceptable daily intake" (ADI). A common example would be the residue remaining of a pesticide or veterinary drug. For products requiring pre-market approval, such as pesticides and veterinary drugs, the concept of good agricultural practices (GAP) is used to quantify that level of residue remaining when the product is used in accordance with good practices. If the GAP is higher than the ADI the product is not approved for use. If the GAP is lower than the ADI, then this lower level represents the maximum residue level (MRL). See generally B.M.J. van der Meulen, note 148 Chapter 2 above, p.64.

[37] Article 6(1) of the General Food Law.

[38] *Ibid*, Article 6(2).

[39] *Ibid*, Article 6(3).

[40] In practice, under the EU food safety system, scientific risk assessment is the responsibility of EFSA. Therefore risk assessment is carried out independently (as the Commission cannot tell EFSA what to do) from risk management (by the Commission, which includes, for example, market authorisation) and ultimately it is the European Commission that decides whether or not to authorise a certain product.

[41] B. M. J. van der Meulen, note 67 Chapter 2 above, p. 322.

[42] Article 3(9).

[43] Codex in its *Procedural Manual, 17th ed.*, p.44.

foods, we know that dioxins are a hazard, but in miniscule quantities they do not pose a (health) risk.[44]

As is evident from a reading of Article 6 of the General Food Law,[45] EU food law is to be based on risk analysis. Article 6.1 ends with the ambiguous exception that risk analysis shall not be necessary 'where this is not appropriate to the circumstances or the nature of the measure'. Unfortunately, whether it is due to a misunderstanding of the Article 6.1 exception or not, in practice it appears that risk analysis is not always of paramount consideration to EU legislators. For example, one would now expect that based on Article 6, DG Sanco would ask for a scientific opinion from the European Food Safety Authority (EFSA) each time new food safety legislation is proposed. From the available evidence it appears that DG Sanco never asks EFSA for an opinion on general provisions on food legislation.[46] An examination of the opinions available on EFSA's website, confirms that virtually all of their opinions refer to specific substances or food products. They are merely case specific opinions. Therefore it is submitted that these are not general EFSA opinions which would guide the legislators of EU food law on the risks posed by certain classes or categories of food produce. Effectively, the laws eventually enacted do not have a risk analysis seal of approval.[47] Accordingly, this does not appear to be the role of EFSA envisaged in Article 6.3[48] of the General Food Law. It also represents a cultural regulatory divergence when set against the US approach.

The practical ramification of this approach by DG Sanco and EFSA is that EFSA scientific advice need only be part of the procedure when preparing decisions on the marketability of specific substances or products.[49] In turn, when one considers the EU obligations in the global arena, then one can see the practicality of this approach. WTO Members such as the EU must seek to avoid unnecessary barriers to trade and trade barriers usually relate only to specific products. Therefore, by obtaining scientific opinions on certain specific products the

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[44] M.A. Recuerda, note 18 above, p. 6.
[45] European Parliament and Council Regulation (EC) No 178/2002, note 72 Chapter 2 above.
[46] In the preambles of the legislation there is no evidence that such advice was sought. See, B.M.J. van der Meulen, note 148 Chapter 2 above, p.60.
[47] B.M.J. van der Meulen, note 148 Chapter 2 above, p.61.
[48] Article 6 of the General Food Law governs 'Risk Analysis' and Article 6(3) provides that "Risk management shall take into account the results of risk assessment, and in particular, the opinions of the Authority [...], other factors legitimate to the matter under consideration and the precautionary principle where the conditions laid down in Article 7(1) are relevant [...]." Article 7(1) stipulates that in where the possibility of harmful effects on health are identified but there is scientific uncertainty, then provisional risk management measures can be taken pending further scientific information.
[49] See generally, B.M.J. van der Meulen, note 148 Chapter 2 above, p.61.

promulgators of EU food law have done as much as is required in order to ensure that a dispute external to the EU itself does not ensue.[50] Therefore, the concept of an EU-wide, broad spectrum scientific food risk analysis, which the General Food Law seemed to promise, has been significantly watered down in the process.[51]

4.3 Precautionary Principle: Caution in the Face of Uncertainty

This whole approach dovetails neatly with the EU mediative food safety policy regime, combining strong democratic norms with scepticism towards the authority of science.[52] EU consumers appear to have less faith in science than their North American counterparts and they are reluctant to rely on science to provide the basis for policy solutions. The diffident attitude of EU citizens towards science as a basis for the formulation of comprehensive food-safety policies can be seen in the importance attached to the precautionary principle.[53]

As outlined above, Modern EU food safety regulation under the General Food Law is science based. However, in what represents a pronounced cultural regulatory divergence with the US, in situations of scientific uncertainty, the precautionary principle applies. The precautionary principle exemplifies the idea of caution in the face of risk. It has been suggested that 'precaution is nowhere of greater salience than in the field of food safety...'[54] It is in this spirit that some consumer groups strongly advocate a 'better safe than sorry approach', arguing that food safety is something which by its very nature warrants a more strict precautionary approach.[55]

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[50] *Ibid*, p.61.

[51] In relation to the safety of a food product introduced to the EU market, it can be said that EU food law now follows two approval streams – what some German scholars term the 'abuse principle' and the 'prohibition principle'.[51] Under the concept of the 'abuse principle', individual food producers or businesses must judge if their produce is safe before bringing it to market. For potential hazards posed by some products, on the basis of scientific risk assessment the legislator has defined acceptable levels, thereby distinguishing safe foods from unsafe foods. In that instance, safety must be proven beforehand. A zero tolerance may apply for ingredients/products that have not been approved, or for which no lowest safety level can be established. To these foods the 'prohibition principle' applies. See, M. Will and D. Guenther, *Food Quality and Safety Standards, as Required by EU Law and the Private Industry - A Practitioners' Reference Book*, 2nd edn. (Eschborn, Germany: GTZ, 2007), p.7.

[52] S. Schlacke, note 63 Chapter 3 above, p. 169.

[53] *Ibid*, p. 169.

[54] A. Stirling et al., "A Framework for the Precautionary Governance of Food Safety: Integrating Science and Participation in the Social Apprisal of Risk", in E. Fisher, J. Jones & R. Von Schomberg (eds), *Implementing the Precautionary Principle: Perspectives and Prospects* (Massachusetts: Edward Elgar Pub, 2006), p.284.

[55] See, B. Krissoff, M. Bohman & J. Caswell (eds), *Global Food Trade and Consumer Demand for Quality*, (New York: Kluwer Academic, 2002), p. 6.

Article 7 of the General Food Law, entitled 'Precautionary Principle', provides:-

> [...] where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection [...] may be adopted, pending further scientific information for a more comprehensive risk assessment.
>
> Measures adopted [...] shall be proportionate and no more restrictive of trade than is required to achieve the high level of health protection chosen in the Community [...].[56]

The precautionary principle acts as a constraint on the free reign of science. The principle has firmly established the idea that scientific uncertainty about a risk should not be an obstacle to the adoption of precautionary measures when there is a probability that the risk will result in grave and irreparable damage.[57] Therefore, in accordance with the precautionary principle, when there are scientific reasons to suspect a food safety risk but the risk assessment is inconclusive, public authorities can effectively base their protective measures on a worst case scenario outcome.[58] Aside from a purely scientific approach to food safety, the precautionary approach to food safety presupposes an assumption that expert scientific advice alone can only provide a partial identification of potential hazards and it gives credence to the opinions of lay citizens. This creates a regulatory approach in which science is not absolute. Instead science is only one factor relied upon by political officials when taking risk management decisions.[59] In this context, advocates of the precautionary principle would say that it is

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[56] The text of Article 7 seems an accurate summary of the relevant case law here as it has developed in the EU. *See*, B.M.J. van der Meulen, note 148 Chapter 2 above, p.60. In practice this provision means that where scientific analysis shows that a reason may exist to fear a risk to public health, even if actual proof is not available, this can still legitimize the taking of trade restrictive measures, especially temporary ones.

[57] M.A. Recuerda, "Dangerous Interpretations of the Precautionary Principle and the Foundational Values of European Union Food Law: Risk versus Risk", (2008) *Journal of Food Law and Policy*, Vol.4, Issue 1, p.2.

[58] However, as detailed in the Chapter dealing with the SPS Agreement, this use of the precautionary principle by the EU may also be subject to limitations. Nonetheless, one observer noted that, because of the similarities this Article 7 of the General Food Law bears with Article 5(7) of the SPS Agreement, there seems little doubt that this Article 5(7) served the EU legislature as a template. B.M.J. van der Meulen, note 148 Chapter 2 above, p.61.

[59] For example, when it was decided that an EU-wide ban on all growth promotants would be introduced in the EU, it was noted that the European Parliament as 'the main focus of political opposition to hormones had

invaluable as a means of dealing with the question of how to proceed with risk management if after the first step of risk assessment, the findings on safety are still inconclusive.[60]

Since avoiding risk is the main concern, then this idea that scientific uncertainty about the risk must not be invoked and thereby paralyze decision-making, is at the principle's core. Essentially, in the EU, when a product or procedure could pose potential detrimental consequences for the safety of food, then where some scientific evidence is presented to support the action, the principle enables the EU institutions to restrict the use of that product or procedure. The data available must be sufficient, but it does not have to be either undisputed or conclusive.[61] It is an acknowledgement that science can never be 100 per cent certain.

There is of course a direct link between science and the precautionary principle. The precautionary principle cannot be divorced from science, because 'a scientific view of the risk is an essential component of the evaluation of risk that the principle anticipates'.[62] Therefore, some element of scientific risk analysis is always present. Yet, the growing popularity of the precautionary principle within the EU is evidence of the belief that scientific knowledge alone is an inadequate guide to regulatory policy.[63] The food crises[64] also had the effect of increasing EU scepticism towards the ability of science to deal with risk.[65] This was manifested in a preponderant view among the EU citizenry that science and technology are not 'a panacea' and should be subject to 'social control'.[66] In particular, the BSE crisis[67]

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included the issue of hormones as part of its wider assault on the issue of Europe's farming surpluses'. See R. Wright, note 52 Chapter 3 above, p.9.

[60] B.M.J. van der Meulen, note 148 Chapter 2 above, p.58.

[61] C. MacMaolain, note 58 Chapter 2 above, p.195.

[62] J. Cameron, note 55 Chapter 2 above, p. 292.

[63] D. Vogel, "The Hare and the Tortoise Revisited: The New Politics of Consumer and Environmental Regulation in Europe" (2003) *British Journal of Political Science*, Vol.33, Issue.4, p. 566.

[64] 'From the mid-1980s onwards, listeria in cheese, salmonella in eggs and chocolate, bovine spongiform encephalopathy (BSE) in beef, genetically modified vegetables and soya, the use of hormones in meat production, toxins, foot-and-mouth disease, avian influenza, and *e.coli* poisoning have all, at one time or another, given rise to particular cause for concern' – See, C. MacMaolain, note 58 Chapter 2 above, p.1.

[65] G. Skogstad, note 57 Chapter 3 above, p.221.

[66] Eurobarometer. 2001. Europeans, Science and Technology. Issue 55:2. Brussels: Director-General for Research.

[67] BSE (bovine spongiform encephalopathy) is a disease found only in cattle which belongs to the family of prion diseases known as transmissible spongiform encephalopathies (TSEs). They are a family of rare progressive neurodegenerative disorders that affect both humans and animals. The most common form in humans is Creutzfeldt-Jakob Disease (CJD) - a rare and fatal form of dementia that can present in individuals between the ages of 40 and 80. Therefore, CJD is not a new disease. However, in 1996 scientists discovered a new strain of CJD (variant CJD, vCJD or new variant CJD, nvCJD) and scientific research has shown that the most likely origin of vCJD is human exposure to the BSE prion or protein by eating food containing traces of

undermined the idea of scientists as 'objective' and 'independent'.[68] The scientific experts who advised the Commission on BSE, were blamed for having a role in playing down the severity of the crisis, and government was seen as a party to this duplicity.[69] The BSE crisis was seen as a failure by the government regulators and their scientific advisers to protect the public health.[70] It has been argued that the precautionary principle is a concept derived from new social perceptions regarding the appropriate role of science, economics, politics, and the law in protecting the environment and that this genre is now being applied in a variety of contexts.[71] It was the BSE crisis that gave rise to one of the most influential consequences for food safety with the extension of what is known as the precautionary principle from environmental law into measures taken to protect human health.[72]

Regulatory failures in the EU which have created or exacerbated environmental disasters, resulted in a dramatic shift in public attitudes towards the efficacy of science.[73] In recent times, a significant shift occurred in the pattern of divergence between consumer and environmental protection policies in the EU and the US. From the 1960s, through to the mid 1980s, US regulatory standards were inclined to be more stringent, comprehensive and innovative than those found in Europe.[74] However, since around 1990 the reverse has been the case with many important EU consumer and environmental regulations now being more precautionary than their US equivalents. This modern politics of consumer and environmental regulation in Europe is attributable to three inter-related factors. Firstly, a series of regulatory failures which occurred within Europe,[75] secondly, greater political support for better

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the brain, spinal cord or digestive tract of BSE infected carcasses. As with BSE in cattle, vCJD is always fatal in humans.

[68] C. Joerges & J. Neyer, "Transforming Strategic Interaction into Deliberative Problem Solving: European Comitology in the Foodstuffs Sector", (1997) *Journal of European Public Policy*, Vol.4, Issue 4, p.612.

[69] D. Chalmers, "The BSE Crisis and the European Parliament" in C. Joerges and E. Vos, (ed's) *EU Committees: Social Regulation, Law and Politics*, (Oxford: Hart Publishing, 1997), pp.5-106.

[70] Discovery from time to time of BSE-infected cattle in a number of European countries contributed further to elevating public concern about the effectiveness of the scientific methods used, in ensuring that beef was not a threat to human health.

[71] T. O'Riordan, J. Cameron & A. Jordan (eds), note 57 Chapter 2 above, p.9.

[72] C. MacMaolain, note 58 Chapter 2 above, p.195.

[73] In other parts of the worlds, there have been several recent environmental disasters where regulatory failures have played a significant role such as the BP oil spill in the Gulf of Mexico, where weak regulation contributed to a massive spill, and also the reactor melt-down and radioactive releases that occurred after the recent Japanese tsunami.

[74] D. Vogel, note 63 above, p. 557.

[75] Aside from the food crises, there were the death of workers on various oil and deepwater drilling rigs, conservation issues such as over-fishing, nuclear reactor problems such as Ireland's complaints about Sellafield, 'killer fogs' caused by air pollution including the recent cases of legionnaires disease in Edinburgh, and climate regulation such as devastating heat waves in Europe which killed thousands of people and were most likely caused by climate change.

regulatory standards within the EU and thirdly, growth in EU regulatory competence.[76] Consequently, EU regulatory policies since the 1990s are more emblematic of those found in the US during the 1970s.[77] Thus health, safety and environmental politics and policies in the US are no longer as distinctive as many scholars have portrayed them.[78]

As a result an EU risk society has developed which is characterized by a loss of faith in scientists and their advice when it comes to formulating the policies required in allaying the hazards that are the by-products of modern industrial society.[79] In conclusion, some of these are actual regulatory failures while others are perceived regulatory failures.[80] However, both have had the effect of a public loss of confidence both at national and EU level in the legitimacy of technocratic styles of regulatory policymaking.[81]

Therefore, there have been different transatlantic experiences of regulatory risk management.[82] Because of cultural differences especially the aforementioned food crises, EU citizens and Americans have divergent perceptions of risk.[83] Consequently, at a time when the US appeared to be moving away from reliance on the precautionary principle, it was only at that stage that the EU enacted an effectual constitutional endorsement of the precautionary principle.[84] This in itself evidences a different view of science in risk management as between the EU and the US.[85] Therefore, underpinning the EU and the US food regulatory models are consumer's different attitudes towards the perceived ability of science to resolve food safety issues that are normative as well as empirical in nature.

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[76] D. Vogel, note 63 above, p. 557.
[77] *Ibid*, p. 557.
[78] *Ibid*, p. 557.
[79] U. Beck, *Risk Society: Towards a new Modernity* (London: Sage Publications, 1992), p.29.
[80] As investigated in Chapter 8 dealing with the *Beef Hormones Dispute*, it has also been suggested that the EU ban on growth hormones emanated at least in part from the European reaction to the dethylstilboestrol (DES) scare in the 1970s. The oestrogen drug DES was used in veal production for baby food in France and concerns arose over a possible link to cases of hormonal irregularities in Italian adolescents. While BSE crises was unrelated to the use of hormones, many EU beef producers were fearful of using hormones as that might give consumers another disincentive to buy meat. See T. Josling, D. Roberts, & A. Hassan, note 188 Chapter 2 above, p.3.
[81] G. Skogstad, note 57 Chapter 3 above, p.221.
[82] *Ibid*, p.221.
[83] A. Alemanno, note 83 Chapter 3 above, p. 256.
[84] In the Treaty of Amsterdam [1997] OJ C340, subsequently enshrined in EU food safety by Article 7 of European Parliament and Council Regulation (EC) No 178/2002, note 72 Chapter 2 above.
[85] D. Vogel, note 63 above, p. 579.

Differences in perceptions of risks can influence how those charged with food safety respond to identifiable risks and the risk analysis methods employed. Scientists and non-scientists see differing degrees of risk. One could say, that the scientific approach rationally deals with science based studies and probabilities, whereas others are guided by their 'values' and are more likely to behave purely based on perceptions rather than relying on facts alone.[86]

Therefore, in taking social considerations into account in its risk analysis, it appears that the EU is more agreeable than the FDA to address this dichotomy between the perceptions of scientists and non-scientists.[87] The precautionary principle is one means of achieving this. Of course, the danger is that this will attract accusations of risk management cloaked as protectionism. However, if history tells us anything, it is that what we now regard as a scientific 'truth' could actually be only a partial understanding of the issue.[88] This also applies to risks associated with food.

4.3.1 Precautionary Principle and Accusations of Protectionism

The precautionary principle is a 'culturally framed concept that takes its cue from changing social conceptions about the appropriate roles of science, economics, ethics, politics and law in anticipatory environmental protection and management'.[89] Some would see the precautionary principle as a significant exception to the claim that EU food law is science based. The alternative viewpoint is that the precautionary principle merely addresses the question of how to apply science when faced with an exceptional situation.[90] In this regard, the precautionary principle does not impose a mandatory line of action but provides the discretion to decide on it.[91] In this context, it is also important to note that the General Food Law separates the scientific requirement from the precautionary principle.[92]

As outlined above, essentially, in the EU when a product or procedure could pose potential detrimental consequences for the safety of food, then where some scientific evidence is presented to support the action, the precautionary principle enables the EU institutions to

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[86] R. Coleman, "Communicating Risk to Consumers", Address to the Interim Scientific Advisory Forum, Brussels, October 30, 2001.
[87] A. Alemanno, note 83 Chapter 3 above, p. 256.
[88] *Ibid*, p. 256.
[89] T. O'Riordan, and J. Cameron, note 59 Chapter 2 above, p.12.
[90] B.M.J. van der Meulen, note 148 Chapter 2 above, p.58.
[91] *Ibid*, p.65.
[92] *Ibid*, p.60.

restrict the use of that product or procedure. The data available must be sufficient, but it does not have to be either undisputed or conclusive.[93] Where scientific analysis shows that a reason may exist to fear a risk to public health, even if actual proof is not available, this can still legitimize the taking of trade restrictive measures.[94] However, insofar as there exists only a beginning of proof of a risk, then the trade restrictive measures could only be provisional and further scientific research will be required.[95] Official US policy would be critical of this procedure, seeing it as permitting the creation of sanitary measures which do not have a sufficient scientific basis and which act a non-tariff barrier to free trade. However, the motivation is not a protectionist one and what gives the precautionary principle its raison d'être is that in some cases the risks are uncertain and perhaps even catastrophic.[96]

In the US and indeed in other jurisdictions the precautionary principle is a somewhat elusive and ambiguous legal concept. However, as we have seen, due to the enactment of Article 7 of the General Food Law, this is not the case in the EU. Nonetheless, Article 7 does not impose a specific line of action on the decision-makers or politicians, but instead, as part of the risk management process provides discretion to decide on it.

In this context, it is useful to note that before the entry into force of the General Food Law, in its 2000 Communication on the Precautionary Principle,[97] the European Commission declared an interesting stance on matters pertaining to the burden of proof. The Commission stated that along with those of many third countries, Community rules enshrined the principle of prior approval ('positive list') of certain products such as drugs, pesticides or food additives, before they are placed on the market.[98] These would be substances deemed 'a priori' hazardous or which would be potentially hazardous at a particular level of absorption. The Commission effectively went on to identify two scenarios:-

> [...] the legislator, by way of precaution, has clearly reversed the burden of proof by requiring that the substances be deemed hazardous until proven

[93] C. MacMaolain, note 58 Chapter 2 above, p.195.
[94] Article 7 of the General Food Law stipulates that the precautionary principle allows the adoption of provisional risk management measures pending further scientific information. However, the measures cannot be more restrictive of trade than is required to achieve the level of health protection which the Community has chosen.
[95] B.M.J. van der Meulen, note 148 Chapter 2 above, p.62.
[96] M.A. Recuerda, note 57 above, p. 7.
[97] Communication from the Commission on the Precautionary Principle, COM(2000) 1.
[98] *Ibid*, p. 20.

> otherwise. Hence it is up to the business community to carry out the scientific work needed to evaluate the risk.[99] As long as the human health risk cannot be evaluated with sufficient certainty, the legislator is not legally entitled to authorise use of the substance, unless exceptionally for test purposes. In other cases, where such a prior approval procedure does not exist, it may be for the user, a private individual, a consumer association, citizens or the public authorities to demonstrate the nature of a danger and the level of risk posed by a product or process.[100]

The Commission views a system of pre-market approval as an application of the precautionary principle, albeit one which shifts the responsibility for producing the scientific evidence onto the party which ultimately benefits from the marketing and sale of the product in question.

In the cautious approach to a potential food health risk, taken in either of the scenarios above, science must be included as a factor, which is inevitable in this area. However, one of the interesting ramifications is the issue of which of the two scenarios would be more desirable in the interests of lay citizens? The second scenario whereby citizens themselves can perform the scientific test appears to be the more interesting proposition but the likelihood of private organizations funding this and the logistics involved, may prove prohibitive.

4.3.2 Conclusion: Precautionary Principle

Under EU law, the precautionary principle has grown in importance to such an extent that it has been introduced into EU primary legislation. It is to be found in many EU regulations and has been recognized by the Court of First Instance as a general principle of law.[101] A general principle of law is by its nature abstract insofar as it does not set out the legal consequences that automatically result. A rule of law is concrete because of its obvious specificity and

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[99] The Commission suggested that a provision reversing the burden of proof and placing it on the producer, manufacturer or importer, could not be systematically entertained as a general principle and should instead be examined on a case-by-case basis.

[100] Communication from the Commission on the Precautionary Principle, COM(2000) 1, pp. 20- 21.

[101] *See* Joined Cases T-74/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00, T- 137/00, & T-141/00, *Artegodan GmbH v. Commission of the European Communities*, 2002 E.C.R. 114945.

concrete character which allows it the inherent characteristic to stipulate answers.[102] Nonetheless, general principles of law are of course applied by the courts in interpreting the rules and as a means of filling in gaps that exist in the written law.[103]

In contrast, US law does not see the precautionary principle as a principle of law, but as an approach.[104] Indeed, American opinion is skeptical of the precautionary principle.[105] A stark diametric in approach is the tendency of EU authorities to adopt stringent sanitary measures without incontrovertible evidence of risk, even at times going against the scientific opinions of its scientific bodies. Chapter 8 will elucidate as to how this was dealt with in the *Beef Hormones Dispute*[106] and this issue also arose in a legal dispute involving the use of virginiamicyn[107] as a growth promoter in livestock.[108]

What transpires in the EU is a food safety regime which is based mainly on a process of consensus building across state and civil society actors. In contrast, it has been argued that Americans possess a 'well known preference for according science a central role in public decision-making'[109] and that US regulators are 'generally ... more inclined to justify their actions with appeals to objective knowledge than their EU counterparts'.[110] This cultural regulatory divergence between EU and US food safety styles culminates in transatlantic (trade) tensions.[111]

4.4 Legitimate Exceptions to Compliance with WTO Rules

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[102] M.A. Recuerda, note 57 above, p.3.
[103] *See*, T. Tridimas, *The General Principles of EU Law* (Oxford, OUP, 2nd Ed., 2006), p.4.
[104] M.A. Recuerda, note 57 above, p.6.
[105] *See* C. Button, *The Power to Protect: Trade, Health and Uncertainty in the WTO* (Portland, Oregon: Hart Publishing, 2004), p. 125-129.
[106] *See* Dispute Settlement, US -Continued Suppression of Obligations in the EC-Hormones Dispute, WT/DS321/12 (June 2, 2008); Dispute Settlement, Canada-Continued Suppression of Obligations in the EC-Hormones Dispute, WT/DS321/12 (June 2, 2008).
[107] *See* Case T-13/99, *Pfizer Animal Health SA v. Council of the European Union*, 2002 E.C.R. 3305.
[108] M.A. Recuerda, note 57 above, p.6.
[109] S. Jasanoff, note 61 Chapter 3 above, p. 311.
[110] *Ibid*, p. 311.
[111] G. Skogstad, note 57 Chapter 3 above, p.214.

The global arena for science based food law is represented by the WTO Agreements - GATT[112] and the SPS Agreement.[113] The WTO Agreements are signed by representatives of Member governments and ratified by their parliaments. Where possible, as a confederation of WTO Members, EU food law must conform to WTO obligations.[114] The same obligation applies to US food law. The SPS Agreement heralded the arrival for the first time in international trade of an agreement which provides that any restrictions on food products imposed with the objective of protecting human or animal health or the environment should be non-discriminatory, and based on the prescribed form of risk analysis. The Chapter on the *Beef Hormones Dispute* will evidence that these obligation can have far-reaching implications affecting a WTO member's right to set its preferred levels of regulatory protection.[115]

GATT does not preclude members from taking measures necessary for the protection of life and health of people, animals and plants.[116] In turn, this exception has been elaborated on, in the SPS Agreement.[117] Article 2 of the SPS Agreement gives Members the freedom 'to take sanitary and phytosanitary measures[118] necessary for the protection of human, animal or plant health', provided those measures are not inconsistent with the provisions of the SPS Agreement. Article 2 further explains that Members must ensure that any sanitary measure taken 'is applied only to the extent necessary to protect human, animal or plant life or

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[112] The WTO has replaced GATT as an international organization. However, the General Agreement still exists (as updated by the Uruguay Round negotiations) as the WTO umbrella treaty for trade in goods. GATT 1994 is the updated version and at the heart of that Agreement is the original GATT 1947.

[113] The SPS Agreement (opened for signature 15 April 1994, 1867 UNTS 493), was negotiated during the Uruguay Round of trade talks which also led to the establishment of the WTO. The Agreement entered into force with the establishment of the World Trade Organization on 1 January 1995. It concerns the application of food safety, and animal & plant health regulations. "Sanitary" regulations can be defined as general food safety and animal health regulations which restrict or prohibit the importation or marketing of certain food items. "Phytosanitary" regulations are regulations that restrict or prohibit the importation and marketing of certain plant species, or food products manufactured with those plants, so as to prevent contamination by any plant pests or pathogens that the plants may be carrying.

[114] C. MacMaolain, note 58 Chapter 2 above, p.149.

[115] M. Bronckers & R. Soopramanien, note 131 Chapter 2 above, p.361.

[116] GATT Article XX(b)

[117] B.M.J. van der Meulen, note 148 Chapter 2 above, p.61.

[118] Annex A to the SPS Agreement defines a "sanitary or phytosanitary measure" as any measure applied to "protect human or animal life or health .... from risks arising from additives, contaminants, toxins, or disease causing organisms in foods, beverages or feedstuffs." The term 'measure' covers "all relevant laws, decrees, regulations, requirements and procedures ... and methods of risk assessment ... directly related to food safety".

health'.[119] Each Member is allowed to choose the 'appropriate' level of protection, provided the Member considers 'the objective of minimizing negative trade effects'.[120]

Article 3.1 of the SPS Agreement provides that in order 'to harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations'. Then, definition 3(a) of Annex A to the SPS Agreement defines 'international standards, guidelines and recommendations' in respect of food safety as, 'the standards, guidelines and recommendations established by the Codex Alimentarius Commission[121] relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice'.

Therefore, the burden of proof of compliance with the standard set by Article 2 of the SPS Agreement is alleviated for measures which conform to international standards, guidelines or recommendations. Such measures would then be deemed to be necessary to protect human, animal or plant life or health and are automatically presumed to be consistent with the relevant provisions of the SPS Agreement and of GATT 1994.[122]

The requirement that Members base their SPS measures on recognised 'international standards, guidelines or recommendations', does not imply that the Codex standards are mandatory on Members of the WTO.[123] In particular, under Article 3.3 of the SPS Agreement, a Member can decide to adopt divergent regulatory measures 'which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations' but only 'if

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[119] Because of the similarities that Article 7 (the Precautionary Principle) of the General Food Law bears with this Article 5(7) of the SPS Agreement, there seems little doubt that this Article 5(7) served the EU legislature as a template. See, B.M.J. van der Meulen, note 148 Chapter 2 above, p.61.

[120] Article 5(4).

[121] The Codex Alimentarius Commission ('Codex') is run under the aegis of the United Nations Food and Agricultural Organization (FAO) and the World Health Organization (WHO). Codex was formed in 1962 in order to facilitate the development of trade in foodstuffs. As part of this initiative it has developed a set of international indicative standards, recommendations and guidelines aimed at food safety and fair trade.

[122] B.M.J. van der Meulen, note 148 Chapter 2 above, p.61.

[123] Codex standards also have strong persuasive value. On occasion, when an EU Member State wants to prohibit the sale of product based on a certain name or label, the Court of Justice defers to Codex Alimentarius standards in assessing if there is any any significant difference between the composition of that product and similar products which are commonly known by that name. See for example, Case 298/1987, *Proceedings for compulsory reconstruction against Smanor SA* [1988] ECR 4489.

there is a scientific justification'.[124] Therefore, a WTO Member can set its own maximum acceptable level of health risk. Then, without discriminating based on product origin, the Member concerned can insist that all food products must at a minimum meet these standards. However, because these regulatory measures are not based on Codex, then the Member may be challenged to provide scientific evidence of the measures effectiveness based on a risk assessment.[125]

There is a further alleviation of the requirement for scientific substantiation as required under Article 2 of the SPS Agreement, contained in Article 5.7, which provides that members may impose 'provisional measures' in cases where scientific data is 'insufficient' to justify regulations based solely on current scientific knowledge. Members are obligated to discover any available additional scientific evidence and to then re-evaluate their health measures. In the context of any role that might be played by culture, these measures will be investigated in greater detail in the Chapter covering the SPS Agreement.

In addition, the Member may adopt measures more stringent than those based on relevant international standards,[126] guidelines or recommendations, so long as those measures have a 'scientific justification'.[127] As already outlined above, the SPS Agreement goes on to explain that 'there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of ... protection'.[128]

These exceptions evidence the potential for an alleviation of any over reliance on science as the sole arbiter of sanitary measure legitimacy under the WTO global construct. This adoption of international standards such as Codex by Members is a significant part of WTO efforts at achieving the harmonization of global and regional food standards in order to better

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[124] 'or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5'. This will be elaborated on, further, in the Chapter dealing with the SPS Agreement.

[125] M.A. Pollack & G.C. Shaffer, *When Cooperation Fails: The International Law and Politics of Genetically Modified Foods* (Oxford: Oxford University Press, 2009), p.151.

[126] Again, it is important to note that any national measures which conform to international standards, such as the Codex Alimentarius Commission, are presumptively valid. See D.A. Wirth, note 52 Chapter 3 above, p. 817.

[127] Article 3(3).

[128] *Ibid.*

ensure the protection of consumer health and especially to facilitate further liberalisation of international trade.

In the EU, Article 5.3 of the General Food Law[129] provides that international standards shall be taken into consideration in the development or adaptation of EU food law except where the international standard would be an ineffective or inappropriate means of fulfilling the legitimate objectives of EU food law, or if there is a scientific justification not to use the international standard, or if the international standard would result in a different level of protection from the one determined as appropriate in the Community.

4.5 Codex Standards and Science

Codex standards are explicitly based on scientific risk analysis, especially the health and safety aspects.[130] Precaution is incorporated as an inherent element of the risk analysis and in situations of scientific uncertainty, as a rule no Codex standard should be adopted. In effect, this aspect of the issue is left open which is in keeping with Codex's non-binding role as an over-arching template for national legislation.[131] Codex states that 'the food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence ... in order that the standards assure the quality and safety of the food supply'.[132]

The manner in which Codex operates is that if Codex has evidence that a risk to human health exists but the scientific data to back that up is insufficient, then Codex will not proceed to set a standard but will specify a suggested code of practice supported by the available scientific evidence. Codex goes on to provide that precaution is an inherent element of their

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[129] European Parliament and Council Regulation (EC) No 178/2002, note 72 Chapter 2 above.

[130] As stated by Codex in its *Procedural Manual, 17th ed.*, p.194. National sanitary and phytosanitary measures which conform to international standards, such as the Codex Alimentarius Commission, are presumptively valid under the terms of the WTO SPS Agreement. In the EU, Article 5(3) of the General Food Law prescribes that international standards shall be taken into consideration in the development or adaptation of EU food law - the Codex Alimentarius being the most important of these international food standards. Codex standards are used by the World Trade Organization as a barometer of international scientific consensus in trade cases involving food safety issues.

[131] B.M.J. van der Meulen, note 148 Chapter 2 above, p.61.

[132] Codex Alimentarius Commission's *Procedural Manual, 17th ed.*, p.194. However, when deciding upon food standards Codex Alimentarius will also have regard to 'other legitimate factors' relevant for the health protection of consumers and for the promotion of fair practices in the food trade.

risk analysis as many sources of 'uncertainty' exist in the process of risk assessment and risk management of hazards[133] associated with food. Therefore, in the context of this thesis, importantly, Codex does acknowledge that a degree of uncertainty and variability in scientific information exists and this must be considered in the risk analysis.[134]

Most of the output of Codex is suitable to be based on scientific considerations.[135] This is evident from the fact that as of July 2011 the Codex had over 200 product standards, some 50 hygiene codes, about 60 guidelines and over 1,000 assessments of food additives and contaminants, along with more than 3,200 maximum residue limits (MRLs) for pesticides and veterinary drugs. Food additives and contaminants and maximum residue limits for pesticides and veterinary drugs comprise over 90 per cent of Codex Alimentarius products in numbers of texts.[136] These two categories are product specific and outline numbers regarding exposure, toxicity, etc. In this regard Codex standards resemble the product specific decisions taken by EFSA.[137] In other words, this thesis notes that the Codex standards based on scientific analysis are too narrowly defined and not of much assistance when legislators are formulating legislation governing whole categories or classes of food products.

As outlined previously in this thesis, the SPS Agreement provides that the 'international standards, guidelines and recommendations' to be applied by WTO Members are those established by the Codex Alimentarius Commission.[138] With the advent of the WTO in 1995, the Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement)[139] came into being. For some time prior to 1995, because of the added importance its standards would now have, Codex began to consider its new role. At its international food standards conference in 1991, Codex examined its procedures in order to determine what changes if any were needed to be taken into account due to the new recognition given to Codex standards.[140] Due to the importance which Codex attaches to the

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[133] 'Hazard' is the *source* that can cause an adverse health effect, while 'risk' is the *probability* of that effect and its severity. M.A. Recuerda, note 18 Chapter 4 above, p. 6.
[134] Codex Alimentarius Commission's *Procedural Manual, 17th ed.*, para's 10 & 11, p.113.
[135] B.M.J. van der Meulen, note 148 Chapter 2 above, p.62.
[136] *Ibid*, p.62.
[137] *Ibid*, p.62.
[138] Article 3.1 of the SPS Agreement provides that any sanitary measure which conform to international standards, guidelines or recommendations shall be deemed legitimate and then Annex A paragraph 3 of the SPS Agreement defines those international standards, guidelines or recommendations as those established by Codex.
[139] Agreement on the Application of Sanitary and Phytosanitary Measures, opened for signature 15 April 1994, 1867 UNTS 493 (entered into force 1 January 1995).
[140] D. Jukes, "The Role of Science in International Food Standards", (2000) *Food Control*, Vol.11, No.3, p.182.

role of science, the Conference recommended 'establishing an early review programme to examine all Codex standards as to their current relevance and sound scientific basis, with a view to facilitating international trade',[141] and requested 'all Codex Committees, as well as JECFA[142] and JMPR,[143] to continue to base their evaluations on suitable scientific principles'.[144] Of course, because of the obligation on countries to base their food safety measures 'on scientific principles', now for the first time Codex were required to consider in more detail the methods it used to develop and adopt those same standards. The principles used by Codex in setting standards were ill-defined and oftentimes subject to different interpretation and application from meeting to meeting.[145]

4.5.1 Codex Alimentarius and Animal Growth Hormones

Generally, there is little dispute as to the importance of science in many areas of Codex' work, especially in establishing Codex standards. It has formed the basis for many discussions and decisions. However, two issues caused major difficulty for Codex and both related to the use of hormones as veterinary substances, namely, growth promoting hormones used in beef cattle and 'production aids' (such as recombinant Bovine Somatotropin, 'rBST') used to increase milk production in cows.[146] This is important to this thesis because subsequent Chapters will deal with growth hormones in beef and the associated *Beef Hormones Dispute*.

Within Codex, approval for the use of veterinary drugs (including animal growth hormones) is by the adoption of a maximum residue limit (MRL). The recommendation for an MRL comes from JECFA[147] and is formulated based on a number of factors including toxicological

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[141] Report of the FAO/WHO Conference on Food Standards, Chemicals in Food and Food Trade (March, 1991), FAO/WHO, 1991a.

[142] The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an international expert scientific committee administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). JECFA serves as an independent scientific committee which performs risk assessments and provides advice to FAO, WHO and the member countries of both organizations.

[143] The Joint FAO/WHO Meetings on Pesticide Residues provide independent scientific expert advice to the Codex Commission and its specialist Committee on Pesticide Residues.

[144] Report of the FAO/WHO Conference on Food Standards, note 140 above.

[145] D. Jukes, note 140 above, p.182.

[146] *Ibid*, p.183.

[147] The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an international expert scientific committee administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). JECFA serves as an independent scientific committee which performs risk assessments and provides advice to FAO, WHO and the member countries of both organizations.

and radiolabel residue studies, the bioavailability of residues, the existence of a residue marker for determining compliance with safe residue limits, residue data from use of the veterinary drug according to good practice in the use of veterinary drugs, withdrawal periods for adequate residue depletion, and practical analytical methods for residue analysis.[148]

The toxicological data is then assessed in order to establish the appropriate Acceptable Daily Intake (ADI) for the drug.[149] JECFA then allows the incorporation of the other data so as to establish a 'recommended MRL' which meets the required criteria.[150] The MRL can be either set at a quantified level or if the drug is regarded as basically not harmful at all to human health the MRL is termed 'not specified' which indicates that 'the presence of residues in the named animal product does not represent a health concern and there is no need to specify a numerical MRL'.[151]

Because of the controversy surrounding the *Beef Hormones Dispute*, an attempt has been made to define more precisely the role of science in Codex decisions. The result has been the development of certain 'Statements of Principle', a development which is dealt with in the following section of this Chapter.[152]

4.5.2 Science versus 'Other Factors' and the History of Growth Hormones at Codex

As confirmed on a number of occasions in this thesis, the science based Codex standards are of strong persuasive value in many food related legal disputes. Their importance is such that they also play a crucial role in the SPS Agreement. Article 3.1 of the SPS Agreement provides that any sanitary measure which conform to international standards, guidelines or recommendations shall be deemed legitimate and then Annex A paragraph 3 of the SPS Agreement defines those international standards, guidelines or recommendations as those established by Codex. However, the following narrative on the adoption of MRLs for animal

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[148] Evaluation of certain veterinary drug residues in food (Thirty-sixth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 799, 1990, p.8.
[149] The concept of good agricultural practices (GAP) is used to quantify that expected level of residue remaining provided the product is used in accordance with recognised good practices. If the GAP is higher than the acceptable daily intake ('ADI'), then the product is not approved for use. If the GAP is lower than the ADI, then this lower level represents the maximum residue level (MRL).
[150] Thirty-sixth report of the Joint FAO/WHO Expert Committee on Food Additives, note 147 above, p.8.
[151] D. Jukes, note 140 above, p.183.
[152] *Ibid*, p.183.

growth hormones serves to illustrate the political controversy often underlying the formulation of Codex standards. It is evidence that the standard setting process within Codex is a subjective process and that it is also open to political manipulation.

The use of the growth hormones in beef production was examined by the Joint Expert Committee on Food Additives (JECFA) in 1987 and JECFA adopted an ADI of 'not specified'.[153] Subsequently it was proposed that this ADI would be adopted as the Codex maximum residue limit (MRL) for growth hormones. The Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF) agreed that the MRLs would be adopted at the 19th Session of the Codex Commission in 1991.

However, at the 19th Codex Session, positions had become entrenched with the EU position being expressed by the delegation from the Netherlands. Whilst 'not objecting to the evaluation of JECFA', the Dutch (i.e. representing the EU) had the following reservations:[154]

(i) concerns about the different aspects of the use of hormones;
(ii) concerns about the practical possibilities to enforce and control the prescribed administration of growth hormones independent of these concerns;
(iii) the need to take into account the clear concerns of EU consumers on the safety of meat produced with growth hormones; and
(iv) the opposition to the use of hormones for growth promoting purposes as expressed on repeated occasions by the European Parliament as well as consumer organizations within the EU.

The opposing view expressed by parties such as the US who were fully in agreement with the JECFA findings and the proposal to adopt the MRLs, was that the evaluation was based on 'sound science'.[155] As recorded in the Codex Report:

> Other delegations noted that the work of Codex was consistently based on sound scientific principles and that the JECFA evaluation confirmed that

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[153] Thirty-second report of the Joint FAO/WHO Expert Committee on Food Additives, note 147 above.
[154] Report of the Nineteenth Session of the Joint FAO/WHO Codex Alimentarius Commission, Rome, 1 - 10 July 1991, CAC19, ALINORM 91/40, *http://www.codexalimentarius.org/meetings-reports/en/?sortingDate=011991* [Accessed: June 14, 2012]
[155] *Ibid.*

> health issues in relation to residues of these substances in food were not a cause for concern. It was stated that consumers were often unaware of the scientific validity and logic supporting the use of these compounds, and that regulatory control procedures for their use were similar to those for the application of any chemical substance.

At the end of the Session, the proposal to adopt the MRLs as Codex standards was put to a vote and 12 countries voted in favour with 27 against. The MRLs were therefore not adopted. The non-adoption of the MRLs was then discussed at the Sixth Session of the CCRVDF[156] in October 1991. The US Secretariat to Codex had prepared a paper setting out the questions which they believed merited further attention. As noted in the Report of this Meeting, the US Secretariat stated the following:[157]

> The principle problem was not with the safety of the substances and their residues, but in the public perception of their safety ... It was clear that the governments represented at the Commission had acted in the light of their national situations, and that the Commission decision clearly reflected this. The Secretariat further stated that it would be preferable to consider the Commission decision as an isolated incident and not as a precedent for future considerations.

The US discussion paper was considered at a number of subsequent Codex Sessions and at the Tenth Session of the Codex Committee in September 1992 the US stated that 'Codex should demonstrate that it was a genuinely neutral intergovernmental body and that it must show that its standards, guidelines and other recommendations rested on a sound scientific basis'.[158] As evidenced by the Report for the Tenth Codex Session, the US (backed by Canada and New Zealand) asked that a modification of procedures for the Codex process be considered.[159] However, in response, whilst expressing support for 'the principle that Codex recommendations should be based on the best scientific opinion available', delegations from

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[156] The Codex Committee on Residues of Veterinary Drugs in Food.

[157] Report of the Sixth Session of the Codex Committee on Residues on Veterinary Drugs in Foods, Washington, D.C., 22–25 October 1991, CCRVDF6, ALINROM 93/31 *http://www.codexalimentarius.org/meetings-reports/en/?sortingDate=011993* [Accessed, June 14, 2012]

[158] Report of the Tenth Session of the Codex Committee of General Principles, Paris, France, 7 – 11 September 1992, CCGP10, ALINROM 93/33, *http://www.codexalimentarius.org/meetings-reports/en/?sortingDate=011993* [Accessed, June 14, 2012]

[159] *Ibid.*

other Member countries submitted observations that 'other non-scientific criteria, such as economic factors or consumer concerns, which needed to be taken into account in arriving at Codex recommendations' should also be included as part of the Codex standards setting process for drugs such as animal growth hormones.[160]

The matter was finally resolved at the Twenty-First Commission Meeting in July 1995. There was a lengthy debate on the issue, in particular centred on whether or not to base a final decision to adopt the MRLs on current available scientific evidence or the taking into account of other factors such as health concerns. The EU lost a motion for adjournment and a secret ballot on the adoption of the MRLs was then held. The result of the secret ballot was 33 votes in favour, 29 votes against with 7 abstentions. As a result the Codex Commission adopted the controversial MRLs.[161] That was the end of what was a rather protracted debate. The JECFA MRLs would henceforth be used in any dispute brought to the WTO Dispute Settlement Body under the SPS Agreement.

This history of the adoption of MRLs for animal growth hormones illustrates the difficulty with basing sanitary regulatory standards on science alone as a basis for risk analysis. It also highlights the divergent positions taken globally by various countries on the issue of how best to formulate sanitary measures.

4.5.3 Codex Adopts Other Legitimate Factors

Arising from the controversy with the growth hormone MRLs outlined above, in July 1993 at the Twentieth Codex Commission meeting, the Codex Commission asked the Codex Committee on General Principles to consider the integration into the Codex decision making process of guidance on how 'other factors' could be included, although science would still remain preeminent.[162] These other factors would potentially allow the inclusion in risk analysis of issues such as legitimate consumer concerns, animal welfare, labelling and ethical

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[160] *Ibid.*

[161] Report of the Twenty First Session of the Joint FAO/WHO Codex Alimentarius Commission, Rome, 3 – 8 July 1995, CAC21, ALINORM 95/37, *http://www.codexalimentarius.org/meetings-reports/en/?sortingDate=011995* [Accessed, June 14, 2012]

[162] Report of the Twentieth Session of the Joint FAO/WHO Codex Alimentarius Commission, Geneva, 28 June - 7 July 1993, CAC20, ALINORM 93/40, http://www.codexalimentarius.org/meetings-reports/en/?sortingDate=011993 [Accessed, June 14, 2012]

and cultural considerations. These other factors were eventually incorporated into the Codex Process using the terminology 'other legitimate factors' and included in the four 'Statements of Principle'[163] adopted at the Twenty First Codex Commission meeting in July 1995 and are now contained in an Annex attached to the Codex Procedural Manual.[164]

4.5.3.1 Defining Other Legitimate Factors

Article 1 of the Statues of Codex Alimentarius provides that the Codex Commission is responsible for all matters pertaining to the implementation of the joint FAO/WHO Food Standards Programme and that the purposes of the Programme includes 'the protection of the health of consumers and ensuring fair practices in the food trade'.[165] However, it is apparent that the fundamental approach to the development of international food standards is often based on one or two major issues when in fact there are many other scientific, technical and cultural aspects involved.[166] In an attempt to remedy this, the phrase 'other legitimate factors' was coined with the creation of the four Statements of Principle outlined above. Other legitimate factors has to be seen in the context of science providing the key factor used in establishing standards but that in addition, 'other legitimate factors' (OLFs) can be considered.

Therefore, the second Codex Statement of Principle provides that 'when elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade'. Importantly, the fourth Statement of Principle reaffirms the separation between scientific risk analysis and risk management by providing that 'consideration of other factors should not affect the scientific basis of risk analysis'.

4.5.3.2 Specific OLFs Identified by the Codex Secretariat

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[163] 'Statements of Principle Concerning the Role of Science in the Codex Decision Making Process and The Extent to Which Other Factors are Taken Into Account'. See, Codex Alimentarius Commission's *Procedural Manual, 17th ed.*, (Rome: FAO, 2007) p.194.
[164] Codex Alimentarius Commission's *Procedural Manual, 17th ed.*, (Rome: FAO, 2007) p.194.
[165] *Ibid*, p.3.
[166] See D. Jukes, note 140 above, p.189.

The minutes of a number of Codex meetings evidence the divergence of approach to other legitimate factors as between EU Members of Codex and the US. For example, at the fourteenth session of the Codex Committee on General Principles, the Netherlands emphasised the importance of including other legitimate factors.[167] In stark contrast, the US Delegation to Codex expressed the view that it is the scientific basis of risk assessment which is essential in the Codex decision process and that the introduction of other factors, more appropriately considered at the national level, was not appropriate in Codex.[168] The French delegate to Codex reiterated the importance of risk analysis in taking decisions on food safety and that such decisions should consider other factors. The French delegate stated that food safety decisions should take other factors into account such as the concerns of consumers, animal health or socio-economic consequences. The French delegate expressed the view that standards should be adopted on the basis of the largest consensus possible. Obtaining such a consensus at the level of the Codex Committees or the Commission would facilitate the harmonization of national standards and the development of international trade.[169] Various Codex papers and discussion documents have identified possible OLFs.[170] The following 'other legitimate factors' identified by Codex, are the ones most relevant to the analysis contained in this thesis.

4.5.3.3 Safety Factors

In formulating numerical values for the ADI of an additive, contaminant or residue, JECFA[171] developed the concept of a 'safety factor'. The safety factor acknowledges that the application of scientific principles alone may not have led to a wholly accurate result. Therefore the safety factor is formulated based on an acknowledgement that other issues may have affected the result. Typical issues might be the age or diet of the consumer or variations in an individual's metabolic rate.

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[167] Report of the Fourteenth Session of the Codex Committee on General Principles, Paris, 19 – 23 April, 1999, CX4/10, ALINORM 99/33A, p.9.
[168] *Ibid*, p.9.
[169] Mme. Marian Guillou speaking on behalf of the French Department of Agriculture as quoted in the Report of the Fourteenth Session of the Codex Committee on General Principles, note 166 above, p.1.
[170] Note 166 above.
[171] Joint Expert Committee on Food Additives

4.5.3.4 Consumer Concerns as Other Legitimate Factor

The October 1991 Report of the CCRVDF[172] dealt with the issue of consumer concerns and in the context of growth hormones stated that 'the principle problem was not with the safety of the substance and their residues, but in the public perception of their safety'.[173] As previously confirmed in this thesis, consumer concerns were heightened, predominantly in the 1990s, by various food safety scares, especially BSE. This was followed by concerns over genetically modified foods. As a result it is not surprising that politicians were reluctant to express approval of new technologies including hormones.[174]

In considering the precautionary principle, the Codex Committee on General Principles (CCGP) acknowledged that there will on occasion be a lack of scientific evidence.[175] However, the CCGP believes that the precautionary principle should only apply when the science base is still being developed – in other words, that there comes a point when science sufficiently clarifies the issue of any hazard posed by the process under consideration. This means that the precautionary principle comes into play in the first Statement of Principle governing the use of science rather than the second Statement of Principle dealing with the consideration of other legitimate factors. Again, this appears to correlate with the separation of risk analysis from risk management.

The other pertinent issue is using labelling to provide consumers with adequate information at the time of purchase. This is dealt with by the third Statement of Principle.[176] The wording of this Statement of Principle would appear to indicate that labelling can be considered as constituting an 'other legitimate factor'.[177] The issue of labelling and science based risk regulation appears to revolve around the consideration of what it is consumers need to know. This debate has received contributions from both consumer and industry interests.

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[172] The Codex Committee on Residues of Veterinary Drugs in Food.

[173] Paragraph 15 of the Report of the Twentieth Session of the Joint FAO/WHO Food Standards Programme. Codex Alimentarius Commission, Twentieth Session incorporating the Report of the Sixth Session of the Codex Committee on Residues of Veterinary Drugs in Food. Washington D.C., 22 – 25 October, 1991, CX4,60.2, ALINORM 93/31.

[174] D. Jukes, note 140 above, p.189.

[175] Report of the Fourteenth Session of the Codex Committee on General Principles, note 166 above, p.4.

[176] The third Statement of Principle provides that 'In this regard it is noted that food labelling plays an important role in furthering both of these objectives' – the two objectives being that food standards, guidelines and recommendations of Codex shall be based on the principle of sound scientific analysis and that Codex will have regard to other legitimate factors.

[177] D. Jukes, note 140 above, p.189.

An industry submission to the CCGP draws a distinction between a consumer's need to know, and a consumer's right or desire to know. The argument here is that a consumer's need to know specific information about a product so as to ensure food safety or satisfy health concerns is an appropriate Codex consideration. However, a consumer's mere desire to know or right to choose should be outside of Codex's purview because Codex standards deal with protecting consumer health.[178]

However, it appears that consumers would reject the idea that in the absence of a clear risk to health, labelling cannot be justified.[179] Similarly, labelling for the purpose of informing consumers of a food containing or created using a new technological ingredient such as hormones, should not be seen as an illegitimate sanitary measure acting as a barrier to trade. Consumers argue that they have a fundamental right to decide which risks and which social impacts of products are acceptable to them.[180] Ultimately, the precise meaning and use of the term 'other legitimate factors' is still uncertain.

4.5.4 Is the Inclusion of Other Legitimate Factors Necessary?

The application of science to the evaluation of animal growth hormones would at first consideration appear to be straightforward. In other words, it is merely a matter of conducting a science based safety assessment and based on the result, set acceptable residue levels. However, those who advocate the inclusion of other considerations in addition to science will argue that there is an over-reliance on insufficient scientific data and this creates a food safety risk. Governments are there to protect consumers. It is acknowledged that it is difficult to define the level of risk, but when substances involved confer little direct benefit to the consumer, then even a low risk is considered unacceptable. Among consumer groups there is a suspicion that anyone who promotes the use of hormones in the face of consumer opposition is merely motivated by avarice and commercial objectives.[181]

The industry is accused of manipulating the scientific evaluation process and consumer activists are accused of manipulating the media by publicising scare stories in an attempt to

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[178] Report of the Fourteenth Session of the Codex Committee on General Principles, note 166 above.
[179] A paper submitted to Codex by Consumer's International relating to the consideration of other legitimate factors in the case of BST hormone in Milk. See generally, D. Jukes, note 140 above, p.189.
[180] D. Jukes, note 140 above, p.189.
[181] *Ibid*, p.189.

influence consumer opinion. Both views are likely to have an element of truth.[182] Some nations and industry sectors assert that the use of labelling places an excessive burden on them. However, labelling undoubtedly does enable consumers to express a choice.

As we shall see in the following Chapters, the issue of growth hormones in beef is difficult and complex. When disputes over these issues arise, is it better for Codex to recognise that the issue is simply too contentious and avoid adopting a standard? To US interests, such an approach would apparently have 'profound, far-reaching and possibly fatal consequences'.[183] However, it is revealing that such substantial division and ambivalence was evident when the same Codex standards that were key to the WTO ruling in the *Beef Hormones Dispute* were originally adopted. The standards were only adopted by a vote of 33 to 29 with 7 abstentions.[184]

On a practical level it is genuinely difficult to see how the European Parliament and national parliaments in the EU can simply allow unimpeded marketing of hormone treated beef. As already outlined in this thesis, in the EU there is a clear resistance to these esoteric technological advances in the food supply. The political representatives must reassure their constituents. It is clear that science is only one of several factors to be considered in formulating international food standards. There should be some appreciation of the fact that society is willing to accept that science plays an invaluable role in that process but that other factors are relevant.[185]

4.6 US Science Based Food Law, Other Factors, and the Precautionary Principle

US food law espouses a firm belief that science should take precedence as the arbiter in food safety matters. For example, the FDA approach to food safety analysis is so predominantly science based that they have coined the term 'regulatory science', which it defines as 'the science of developing new tools, standards, and approaches to assess the safety, efficacy,

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[182] *Ibid*, p.189.
[183] D. Jukes, note 140 above, p.189.
[184] S. Charnovitz, "The World Trade Organisation, Meat Hormones, and Food Safety, (1997) *International Trade Reporter*, Issue 41, p.1786.
[185] D. Jukes, note 140 above, p.189.

quality, and performance of FDA-regulated products'.[186] Those charged with food safety in the US have generally opposed use of the precautionary principle as it is understood in the EU, because they regard its application as unscientific and arbitrary. Instead, the approach taken is to approve the food product using scientific risk analysis, provide information to the consumer regarding the product, and then allow the consumer the opportunity to apply a precautionary approach if he/she so wishes. Any element of precaution and consideration of other factors is conveniently shifted away from the US food regulatory administration and onto the consumer.[187]

Typically, US commentators are forthright in their views regarding, as they see it, the unscientific nature of the precautionary principle and EU use of it. The entrenched US position is succinctly exemplified by the following quote:

> No quantitative or objective standard or definition for the precautionary principle exists. Lack of a definition lends itself to wide variations in interpretation and levels of precaution [and] also allows exploitation by those who would impose trade barriers disguised as precautions ... EU Directive 178/2002 requires that precautionary restrictions should not be more trade restrictive than required to meet the desired level of health protection. The EU ban on US-approved GE crops is largely based on public opinion and fear rather than protection of a concrete public health risk ... While restrictions may be created to respond to a country's fears and public perceptions, generalised or vague fears are insufficient. Food safety measures must be based on scientific risk assessments.[188]

However, almost immediately this commentator goes on to acknowledge that 'proving 100 per cent safety is impossible to achieve, even with conventional foods'. The US position is that proving absolute safety is unachievable for most innovative food products such as growth hormones or GE foods. Therefore, they advance the notion of 'comparable safety' as

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[186] See FDA – "Strengthen Social and Behavioural Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products" Available at: http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm268150.htm [Accessed: 22 July 2012]

[187] A good example of this is FDA's policy emphasis on consumer behaviour. See FDA – "Strengthen Social and Behavioural Science", note 185 above.

[188] N. D. Fortin JD, note 23 Chapter 2 above, p.651.

the standard to be applied. Comparable safety is a form of scientific risk analysis where comparative studies are conducted on the chemical composition, nutritional quality, and any potentially toxic components of both the engineered and conventional food product or ingredient. The belief is that by applying established methods of analytical, nutritional, and toxicological research using the natural food as a barometer, this approach will provide an adequate means of quantifying any increased health hazards in the new food. Proponents in the US would argue that this is a prudential approach which balances risks against benefits.[189] However, one could also argue that there is an over-emphasis on any potential 'benefits' and that this balancing of risks against benefits is an excuse for giving the benefit of the doubt in risk-analysis to commercial interests.

Of course, the precautionary principle does arise in US law. The most famous example is the Delaney Clause,[190] a 1958 amendment to the US Food, Drug and Cosmetic Act, which sets a zero risk standard against any suspected carcinogenic food and colour additives. The Delaney Clause provides that 'the Secretary of the Food and Drug Administration shall not approve for use in food any chemical additive found to induce cancer in man, or, after tests, found to induce cancer in animals'. Therefore, the Food, Drug and Cosmetic Act approach to the approval of new drugs and new food additives is precautionary to that extent.

Nonetheless, US scholars see application of the principle as problematic. They point to the fact that use of the precautionary principle can cause unnecessary delay in new drug approvals when people may be desperately in need of those life saving drugs. Therefore, adversaries of the precautionary principle in the US would argue that applying the Precautionary Principle and choosing inaction does not guarantee 'zero risk'. Therefore, while it provides a benefit, there is also a cost associated with precaution. When endeavouring to decide what is 'safe', it can be very difficult to decide what level of precaution is appropriate and it is at best subjective.[191]

From an EU perspective, the main difference appears to be that under US law, precaution is targeted at either specific risks or categories of foods or drugs, whereas the precautionary

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[189] *Ibid*, p.652.

[190] The Clause was proposed by New York Congressman James Delaney. The 1960 Colour Additive Amendment to the Food, Drug and Cosmetic Act 1938 is another example of a Delaney Clause, where manufacturers are required to establish the safety of colour additives in food, drugs and cosmetics and prohibits the approval of any colour additive shown to induce cancer in humans or animals.

[191] See generally, N. D. Fortin JD, note 23 Chapter 2 above, p.648.

principle as espoused by Article 7 of the General Food Law[192] is more expansive, therefore affecting every aspect of potential risk assessment across the whole of EU food law. Article 7 uses terminology such as 'the possibility of harmful effects on health' and 'pending further scientific information for a more comprehensive risk assessment'.

4.7 Science as Commerce: Industrialisation of Agriculture

There is often a marked difference in farm size between countries. American farms are large, whereas by contrast, EU farms are small. Similar to that of the EU, early 20th century agriculture in the US was labour intensive. There were a large number of small, diversified rural farms. In the US, these farms employed close to half of the US workforce.[193] However, since then, a dramatic change has taken place and the US agricultural sector of the 21st century is concentrated on a small number of large, mechanized and specialized farms employing only a tiny share of US workers.[194] In the US, since 1900, the number of farms has fallen by 63 per cent, while the average farm size has risen by 67 per cent.[195] These changes were brought about by 'rising productivity, driven by the rapid adoption of mechanical and chemical technology'.[196] By 1948, 18 per cent of the US population lived on the farm. Approximately, 61 per cent of the total land area was in farmland.[197] By 1995, less than 50 per cent of the total land area was in farmland.[198] Now, because of the large size of US farms and their level of sophistication, less than 1 per cent of the US population claim farming as an occupation.[199] As farming became more industrialised, it became more of a business than a way of life. As a result a large part of the cultural element was removed from food production.

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[192] European Parliament and Council Regulation (EC) No 178/2002, note 72 Chapter 2 above.
[193] C. Dimitri, A. Effland, and N. Conklin, *The Twentieth Century Transformation of US Agriculture and Farm Policy*, (United States Department of Agriculture – Economic Information Bulletin No.3, June 2005), p.2.
[194] *Ibid*, p.2.
[195] *Ibid*, p.2.
[196] *Ibid*, p.2.
[197] United States Department of Agriculture, Agricultural Statistics 1953, Tables 639 and 661.
[198] United States Department of Agriculture, Agricultural Statistics 1997, Tables 9-2 and 9-7.
[199] United States Environmental Protection Agency – Demographies. Available at: http://www.epa.gov/oecaagct/ag101/demographics.html [Accessed: 12 August, 2012] As we shall see later in this thesis, there is a close correlation between this concentration of US farming and the legalisation of growth-promotant use. In the US growth-promotants are now believed to be used on approximately two-thirds of all cattle and in the massive industrial concentrated animal feeding operations (CAFOs), their use approaches 100 per cent.

From 1900 onwards, globally, through advances in science the amount of manpower required to produce food plummeted. Accordingly, the relative cost of food dropped impressively. Nowhere has this change been more apparent than in the US. According to the Federal Reserve Bank of Dallas, in 1901, 46.4 per cent of US household income went on food. By 1995, incredibly, that percentage had dropped to 14 per cent.[200] While the main cause of the decrease has resulted from a decrease in total personal income, cost-savings brought about by new food technologies such as the use of growth hormones in beef have played no small part.

In stark contrast, even as recently as 2005, half of all the farms in the 25 Member States comprising the EU had an area of less than 5 hectares, whereas farms with an area over 30 hectares accounted for little more than 16 per cent of all EU farms.[201] In 2007, in the 27 EU Member States, there were 13.7 million agricultural holdings with an average farm size of 13 hectares of utilised agricultural area (i.e. the proportion of national land available for agricultural use).[202] The dramatic increase in farm size occurred earlier in the US. It is only now that EU farms are going through the same process with *Eurostat* recently commenting that 'the drop in the number of agricultural holdings can be linked to the technical developments of the agricultural sector ... as well as the ageing of the holders, often leading to the disappearance of the smaller holdings. This general tendency of abandonment of the smaller units is followed by an increase in the number of the larger holdings'.[203]

The EU public scepticism of science is a cultural trait more associated with individual perception and traditional farming methods. EU farming is not as corporate centred as US agriculture. In the US many cattle-rearing operations are owned by large corporations. In contrast, there is little or no tradition in the EU of large corporate entities owning cattle rearing operations. This agricultural cultural divergence is then augmented by a political landscape in the EU where private individuals (organized via consumer groups) have more institutional access to or a greater ability to influence the EU regulatory process.[204]

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[200] J.W. Plunkett, *Plunkett's Food Industry Almanac 2006*, (Houston, Texas: Plunkett Research Limited, 2006), p.7.
[201] Eurostat Pocketbooks, 2007 Edition – Agricultural Statistics: Data 1995-2005, p.35.
[202] European Commission, EU Agricultural Economic Briefs – Generational Renewal in EU Agriculture: Statistical Background, Brief No. 6, June 2012.
[203] Eurostat - Statistics Explained Archive: Agriculture, Environment, Energy and Transport Statistics, Vol.4, May 2012, p.96.
[204] L. Caduff, note 189 Chapter 2 above, p.3.

Instead, industrial interests are given greater countenance in the US as can be seen from FDA mission statement which while focusing on the interests of consumers, also explicitly includes the encouragement of innovation by industry. In its mission statement FDA outlines that in addition to being responsible for protecting the public health, FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable.[205] This can be contrasted with the emphasis in Article 5.1 of the General Food Law on the protection of consumer interests.

Commercialisation and expansion of agricultural biotechnology continues unabated in the US. According to one report, between 1995 and 2001, the share of US soybean, corn and cotton acreage, planted with GM varieties, increased from a negligible amount to over 70 per cent for soya beans, 56 per cent for cotton and 26 per cent for corn.[206] The US willingness to embrace many of the emerging new technologies fosters a more flexible regulatory system than that existing in the EU. Consequently, the EU has tightened and harmonised regulatory standards in the area of agricultural biotechnology. As this thesis argues, for the greater part it is scientific and technological breakthroughs that lead to trade disputes and cultural clashes over food policy.

Antagonists, as exemplified by the EU position on genetic engineering of food produce, see biotechnology as a social and environmental Pandora's box, a calamity that will do more harm than good. As discussed in greater detail in Chapter 7, growth hormones[207] are used extensively in many countries around the world to enhance beef cattle production. In particular, growth hormones are used widely in beef production in the US and have been approved for use there since the 1950s. In the US, growth hormones are now believed to be used on approximately two-thirds of all cattle and on about 90 per cent of the cattle in feedlots. In the massive concentrated animal feeding operations or CAFOs,[208] the use of synthetic growth hormones approaches 100 per cent.

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[205] US Food and Drug Administration, *About FDA – What we Do.* Available at: http://www.fda.gov/AboutFDA/WhatWeDo/default.htm [Accessed: 12 June, 2012].

[206] See USDA National Agricultural Statistics Board annual report, June 30, 2010 at http://usda.mannlib.cornell.edu/usda/current/Acre/Acre-06-30-2010.pdf [Accessed June 20, 2011].

[207] Synthetic growth hormones reduce fat, increase food conversion efficiency, increase lean tissue growth, on less feed, and thereby reduce production costs.

[208] Aside from the concerns surrounding hormones, United States beef from their CAFO raised cattle can have up to 500 per cent more saturated fat than that of grass-fed cattle – the producers feed a diet that will produce a more marbled meat. Because the cattle are raised in appalling overcrowded conditions, their skin is often

Throughout the 1980s and 1990s, the EU introduced a number of provisions that banned the use of certain hormones in beef production. More importantly the measures banned the importation of meat and meat products treated with six specific growth hormones.[209] The EU stated that it would justify its ban on the needs and demands of EU consumers. It was consumer concerns regarding the safety of growth hormones that encouraged the public campaign leading to the hormone ban.[210] But the question remains as to how significant a role consumer concern should play in a country's decision to impose a ban that restricts international trade. Of course, for the US, the answer to this question is obvious – such a ban cannot be upheld unless it is based on scientific evidence.[211] By contrast, the EU places a stronger emphasis on the preferences and needs of its consumers and it caters for such concerns by allowing them to play a key role in health regulations. As far as the EU is concerned, allowing its citizens a voice in matters of scientific question is an important aspect of its political system.[212]

For example, with the *Beef Hormones Dispute*, industry or corporate interests in the EU which opposed a move towards more restrictive regulations were unable to shape the EU regulatory outcome. Fundamentally, this occurred because they failed in their efforts to influence public risk perceptions sufficiently in addition to their insufficient ability to obtain the necessary EU institutional access.[213] By contrast, in the lead-up to the US approval of growth hormones, a well-organized alignment of export-oriented industrial farming interests prevailed over traditional farming. Moreover, US consumer groups were not particularly vociferous in lobbying for restrictions apparently because rather than seeing risk in consuming meat produced with growth hormones, the majority of US consumers saw it as beneficial.[214]

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covered in faecal matter and bacteria which can be a breeding ground for e.coli. As a result, after slaughter, their meat is sometimes cleaned with chlorine.

[209] However, it must be noted that the majority of the main international scientific bodies together with two major EU initiatives, have not found any evidence of health risks from the use of synthetic growth hormones.

[210] M. D. Carter, note 149 Chapter 2 above, p.652.

[211] First Submission of the United States (Public Version), WTO Dispute Settlement Panel, European Communities - Measures Concerning Meat and Meat Products, (Aug. 28, 1996).

[212] M. D. Carter, note 149 Chapter 2 above, p.652.

[213] L. Caduff, note 189 Chapter 2 above, p.6.

[214] *Ibid*, p.6.

It is believed that producers possess the ability to exert more influence on an economies regulatory process than consumers, because industrial interests are more concentrated and easier to mobilise.[215] In addition, these powerful lobbies are a by-product of some greater entity organised for a different purpose – for example, the beef-industry lobby is a by-product of the beef industry which employs many US citizens and contributes significantly to national income. In the US the business community has by far the largest number of lobbies working on its behalf.[216] Indeed, it has been suggested that 'the power wielded by business in American politics may puzzle the person of democratic predilection; a comparatively small minority exercises enormous power'.[217] As a result, the power and interests of producers tend to shape regulations.[218]

Traditional political theory teaches us that industrial interests are better at organizing themselves than consumer groups. Obviously, there are fewer corporations than individual consumers, corporations are more homogeneous in their goals, they have greater financial clout and greater access to information and technical ability when it comes to successfully lobbying politicians. Consequently, when it comes to winning authorisation for a controversial new food, in the US it is industry that usually dominates the battle for influence in the political regulatory process. Technocratic regulation based on science presupposes a belief in its ability to solve not just the mundane regulatory problems, but also those posed by the risks associated with new technologies.[219]

4.7.1 Science as Commerce: Popular Criticism of US Food Production

A number of popular paperbacks have recently shone the spotlight on many of the more undesirable practices operative in the US food sector.[220] Food safety is inextricably connected with the interests of this powerful industry which is ruthless in maximizing profits. It is an industry which grapples with a paradox where on the one hand it proclaims that public health

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[215] M. Olson, note 24 Chapter 1 above, p. 141.
[216] *Ibid*, p. 142.
[217] V.O. Key, note 159 Chapter 3, p. 142.
[218] G.J. Stigler, note 157 Chapter 3 above, p. 3.
[219] G. E. Isaac, note 67 Chapter 3 above, p.128.
[220] E. Schlosser, *Fast Food Nation: What The All-American Meal is Doing to the World* (New York:Penguin, 2002), F. Lawrence, *Not On the Label: What Really Goes into the Food on Your Plate* (London: Penguin, 2004), J. Blythman, *Bad Food Britain: How a Nation Ruined its Appetite* (London: Harper Collins, 2006), The 2008 American documentary '*Food Inc.*' and accompanying text - K. Webber (ed), *Food Inc.: A Participant Guide - How Industrial Food is Making Us Sicker, Fatter, and Poorer and What You Can Do About it* (Philadelphia: Public Affairs, 2009), and P. Roberts, *The End of Food* (London: Bloomsbury, 2008).

is its priority while knowing at the same time that profits will increase the more people eat. The irony is that if the population begins to eat in a healthier manner, some sectors of the industry will benefit but other sectors will suffer the consequences. Business always protects its own interests.[221]

Culture and tradition are not as ascendant in countries with highly industrialised food sectors. The US industrial food system began with fast food in the 1930s. and can probably be traced back to when the McDonald Brothers brought the factory system to the back of their fast food kitchen. However, as announced in Food Inc., this 'mentality of uniformity, conformity and cheapness, applied widely and on a large scale, has all kinds of unintended consequences'.[222] For example, over time, this had the effect of changing the whole way that ground beef is produced in the US.[223] In other words, at the very least, you are still eating beef that is produced by 'the system' even if you are conscientious enough not to eat at a fast food restaurant. In the US, the 1960s saw the arrival of 'the march of agricultural science in full stride. Agriculture was changing from a way of living to a way of making a living ... from a business of arts and crafts to a business undergirded with large amounts of science and technology'.[224]

Industrial intensification profoundly changed the manner in which animals were raised. Chickens, for example, are now raised and slaughtered in approximately half the time it took fifty years ago, but they're also substantially larger. They've even 'redesigned' the chicken so that it grows a larger amount of breast meat. As one US farmer states – 'it's all a science. They got it figured out. ... If you got a chicken you can grow in 49 days, why would you want one you can grow in 3 months?'[225] Its even more far-reaching than that. In order to maximise profit, it has even changed the farmer. For many US farmers, if they want to partake in supplying the corporate food processing giants, then they have to borrow hundreds of thousands of dollars in order to meet corporate requirements for efficient facilities. However, in return they can earn as little as $18,000 per year. As is evident from Food Inc.,

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[221] M.A. Recuerda, note 18 Chapter 4 above, p. 3.
[222] See the 2008 American documentary '*Food Inc.*'
[223] In the US beef industry, during the 1970s the top five beef packers controlled about 25 per cent of the US market. Today the top four control over 80 per cent of that market with the US corporate giant 'Tyson' being the biggest meat-packing company in the world.
[224] E.L. Butz, "Agribusiness in the Machine Age" in *Yearbook of Agriculture 1960* (Washington, D.C.: United States Department of Agriculture, 1960), p.380.
[225] Kentucky 'Chicken-Grower for Tyson Meats', Vince Edwards, as interviewed on *Food Inc.*

these powerful corporations are not shy about using their economic clout in order to discourage farmers from showing elements of the media around their operations or speaking-out about their experience in the era of US corporate led farming.

This industrialization of the food supply as sensationalized in the popular media, depicts a world populated by increasing numbers of sick animals, environmental degradation, adulterated and unhealthy food, and the resultant human health issues such as obesity and diabetes. In the American documentary '*Food Inc.*', in relation to beef in US supermarkets, the narrator pointedly states:-

> There is this deliberate veil ... dropped between us and where our food is coming from ... The industry doesn't want you to know the truth ... If you follow the food chain back ... you find a very different reality, not a farm, a factory, that's the reality. That meat has been processed by huge multinational corporations. Now, our meat is coming from enormous assembly lines where the animals and the workers are being abused and the food is becoming much more dangerous in ways that are deliberately hidden from us.[226]

In addition to criticism of the food productions processes, unscrupulous political activities are also alleged. There are accusations that the industry 'maintains a revolving door of employment for government regulators and legislators to protect its power to set those conditions'.[227] The documentaries go on to observe that 'for years during the Bush Administration, the Chief of Staff of the USDA was the former chief lobbyist to the beef industry in Washington', that 'the head of the FDA was a former Executive Vice President of the National Food Processors Association'.[228] In respect of Monsanto, it is alleged that there 'has been this revolving door between Monsanto's corporate offices and the various regulatory and judicial bodies that made the key decisions'.[229] According to Eric Schlosser,

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[226] K. Webber (ed), note 152 Chapter 3, p.19.
[227] See the 2008 American documentary '*Food Inc.*'
[228] *Ibid.*
[229] For example *Food Inc.* makes the following observations: that Clarance Thomas was an attorney with Monsanto (1976 – 1979) and the same Clarence Thomas is now a Supreme Court Justice (1991 – present). Clarence Thomas wrote the majority decision in a case that granted corporations such as Monsanto the power to prevent farmers from saving their own seed. There are other examples - Margaret Miller was Chemical Lab Supervisor with Monsanto (1985 – 1989) and then the same Margaret Miller is FDA Branch Chief (1989 - present). Michael Taylor was a lawyer with King & Spaulding Law Firm (1984 – 1991). During that time one of his main clients was Monsanto. During that time he advised Monsanto on labelling of genetically modified

these US 'regulatory agencies are being controlled by the very companies they're supposed to be scrutinizing'.[230] These narratives maintain that theirs is an accurate representation of the situation. At their core is the belief that wholesome food is becoming industrialized in the same way as fast food. If the aforementioned commentators can substantiate any of these claims further, then this all amounts to one thing – a powerful indictment of US industrial food production methods and the powerful and well funded US government agencies charged with their regulation.

All of these factors combine to create different regulatory environments. In conclusion, the following quote from the WTO Panel Report[231] in *EC-Hormones*[232] provides an apt summary of the differences of approach between the EU and the US in this context and the resultant regulatory divergences:

> This difference in degree of regulation was a reflection of the different levels of consumer protection adopted by the European Communities and the United States. The European Communities took a precautionary approach, placing the attainment of a high level of consumer protection before the commercial interests of farmers and pharmaceutical companies ... Where there existed a doubt over the safety of a product, the European Communities gave the benefit of doubt to the consumer ... The United States had, in the case of growth hormones, given it to the producer. The ... difference in degree of regulation ... was due to the greater attachment of the European Communities to the precautionary principle. Such an approach was required to avoid situations as those portrayed by many cases of health hazards which only became apparent long after substances or products had been assumed to be safe, such as Thalidomide and DES. Two cases of recent interest in the European Communities illustrated the desirability of taking a precautionary approach to consumer protection: *E. Coli* and BSE.[233]

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foods. Later, Michael Taylor was Deputy Commissioner for Policy at the FDA (1994 – 1994). During his time with FDA, he oversaw FDA's decision not to label genetically modified foods. Then, subsequently, Michael Taylor was Vice President at Monsanto for Public Policy (1998 - 2000).

[230] Eric Schlosser, author *Fast Food Nation: What The All-American Meal is Doing to the World* (New York:Penguin, 2002) speaking on the 2008 American documentary '*Food Inc.*'

[231] Panel Report WT/DS26/R and WT/DS48/R.

[232] *EC-Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26 and WT/DS48.

[233] Page 86 of Panel Report WT/DS26/R in *EC-Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26. Before the WTO Panel, the EU explained that *E. Coli* was a bacterium which inhabited the intestines

Here, we can see the WTO Panel summarise the divergent positions put forward by the EU and the US. The cultural regulatory divergences attaching to the consumer, industry and precaution in the face of a new sanitary risk, are all evident in the above passage.

4.8 Conclusion

As outlined in this Chapter, the more science oriented a food safety regime is, by definition the more it must limit the influence of culture. Any particular culture can be seen as a set of shared values and supporting social institutions. It is therefore only natural that such a system will be biased towards certain risks and downplaying others.[234] These shared values should play a vital role alongside scientific knowledge, in informing regulatory approaches to risk.

Unfortunately, oftentimes at the international level, these considerations have not limited the appeal of science as a resource for risk decision making where international institutions employing global regulatory constructs seek the acceptance of their determinations as neutral and universally valid.[235] The US food regulatory system and the WTO food regulatory construct as implemented through the SPS Agreement are science based. The US food regulatory administration maintains close ties with the US agrifood sector which has undergone profound intensification – focused on the role of science in innovation and technology. US food law espouses a firm belief that science should take precedence as the arbiter in food safety matters.

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of all animals. In the early days of food bacteriology it had been assumed to be ubiquitous and harmless. When in 1964, the EU had adopted its first rules on meat hygiene, it had taken a precautionary approach, requiring hygienic facilities, handling procedures and equipment. This approach had been strongly criticised at the time by the US Subsequently, several large *E. Coli* outbreaks in which children had died, had persuaded the US to review and propose radical changes to its meat hygiene rules.
With regard to *Bovine Spongiform Encephalopathy* (BSE), the EU noted that this was a new disease of cattle. As there was no evidence of a danger to human health from eating meat from scrapie-affected sheep, it had been assumed in some quarters that there would similarly be no danger to humans from BSE. In this case, it was fortunate that the EU took a precautionary approach at an early stage, despite the generally held view that any risk to humans was uncertain or extremely small. At the time, this action was criticised in some quarters as an over-reaction but it now appeared to have been far-sighted. See footnote 130 at page 86 of Panel Report WT/DS26/R in *EC-Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26 and WT/DS48.

[234] A. Wildavsky & M. Douglas, note 3 Chapter 1 above, p. 194.

[235] V. Walker, note 34 Chapter 1 above, p. 197- 8.

As highlighted by the analysis contained in this Chapter, the enactment of the General Food Law evidences that Europe has learned that the pursuit of trade liberalisation alone is insufficient without the support of a proper comprehensive system of food safety. Originally, the European imperative was Community trade liberalisation via the harmonisation of individual Member State food regulatory measures. Now, the most fundamental norm of EU food law is that food may not be placed on the market if it is unsafe.

While the General Food Law is science based, it makes provision for the use of the precautionary principle in cases of scientific uncertainty, placing a high level of consumer protection above commercial interests. In addition, 'other legitimate factors' have been accommodated in the General Food Law. In stark divergence with the US approach, this enables culture to be included at the risk management stage of food safety risk analysis. In contrast, US law does not see the precautionary principle as a principle of law, but as an approach. American opinion is skeptical of the precautionary principle.

Scholars have noted that regulatory outcomes cannot be inferred solely on the basis of scientific data alone, because many regulations respond either implicitly or explicitly to social, economic, or political contexts.[236] Consequently, this thesis notes that it is for this reason that other legitimate factors have a fundamental role to play in sanitary measure formulation. This Chapter outlined the political wrangling at Codex that surrounded the formulation of an MRL for growth hormones and the eventual acceptance of a role at Codex for other legitimate factors. In effect, even at Codex, science alone proved insufficient to affect acceptance of the proposed safety standards.

Scientific analysis can certainly provide assistance in fulfilling a public health goal, but the goal itself is strongly influenced by societal values and there science can provide little, if any, guidance. Essentially, science can inform the regulatory process but it cannot by itself determine the end result.[237] The fundamental proposition of this school of thought is that health goals should be determined by society and it is only afterwards that science plays a role.[238]

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[236] D.A. Wirth, note 52 Chapter 3 above, p. 817.
[237] *Ibid*, p. 817.
[238] M. D. Carter, note 149 Chapter 2 above, p.652.

CHAPTER 5

THE CULTURAL ASPECT TO THE IDENTIFICATION AND ASSESSMENT OF RISK IN FOOD SAFETY REGULATION

5.1 Introduction

EU citizens and Americans have differing perceptions of risk which align with each society's prevailing cultural norms regarding food safety.[1] In other words, the public perceives risk through its own cultural model.[2] Risk constitutes a cultural outlook.[3] This outlook is then communicated to government. In democratic societies, consumer sentiment and public opinion has a bearing on the official food safety policy adopted. However, public opinion regarding the benefits or dangers inherent in any particular food is informed mainly by the populations perception of the risk associated with that food – what this thesis refers to as 'public risk perception'. If the public didn't perceive a risk, then they wouldn't feel the need to voice any opinion one way or the other or lobby their political representatives. The WTO system itself has been undermined by intractable disputes[4] precipitated by high levels of public concern about potential health risks associated with imported produce.[5] A fundamental aspect of the *Beef Hormones Dispute* concerned how people felt about eating beef that might contain residues from animal growth hormones, where those residues could increase, even minimally, the chances of cancer in the population.[6] It is this precise cultural difference between the public perception of the existence of a 'risk' associated with consuming beef

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[1] A. Alemanno, "Food Safety and the Single European Market" in C. Ansell and D. Vogel (eds), *What's the Beef? The Contested Governance of European Food Safety* (Massachusetts: The MIT Press, 2006), p.256.
[2] A. Alemanno, note 122 Chapter 3 above, p.31.
[3] See W.A. McIntosh, *Sociologies of Food and Nutrition*, (New York: Plenum Press, 1996), p.42. The idea that risk is a cultural outlook is accredited by McIntosh to both Ulrich Beck and Anthony Giddens. U. Beck, *Risk Society: Towards a New Modernity* (London: Sage Publications, 1992). A. Giddens, *Modernity and Self-Identity: Self and Society in the Late Modern Age* (Cambridge: Polity, 1991).
[4] For example, the *Beef Hormone Dispute* (WT/DS26 & WT/DS320) and the *Marketing of Biotech Products* cases (WT/DS291, WT/DS292 & WT/DS293).
[5] C.E. Foster, "Public Opinion and the Interpretation of the World Trade Organisations Agreement on Sanitary and Phytosanitary Measures", (2008) *Journal of International Economic Law*, Vol. 11, No.2, p.427.
[6] *Ibid*, p.429.

containing growth hormone residue which exists in the EU, and does not exist in the US, that has helped create the divergent regulatory environments which exist on each side of the Atlantic. By acknowledging cultural regulatory divergences such as the nature of public risk perception we become aware of the relevance of the distinctive cultural quality and social structure underpinning any given legal system. It is this awareness that allows us to better understand a legal system.[7]

Major food safety scares in recent years have culminated in lasting changes to consumer perceptions and food purchasing patterns.[8] Certain well publicised health scares, especially in the EU in the 1990s, raised questions over the safety of food and elevated the importance of food safety in the minds of consumers. The food chain withstood attack from various sources including foot-and-mouth disease, *e.coli* poisoning, avian influenza, and dioxin contamination. Serious incidents such as these highlighted the vulnerability of consumers as they went about the very normal activity of purchasing food. These incidents caused consumers to become even more concerned about their food, its method of manufacture, its safety and concerns regarding the impact on their health increased.[9] Much of this unease was fuelled by such crises as bovine spongiform encephalopathy (BSE)[10] in meat, and other food technology based developments such as the use of GMOs in food manufacture. Calls for deregulation in the food sector were silenced by the BSE crisis for some time. Instead the question became how to test the safety of food and how to deal with ambiguous results.[11]

As outlined in Chapter 1 of this thesis, the way we eat has changed more in the last sixty years than it did in the previous ten thousand years. Technological change and globalisation

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[7] R. A. Falk, "The Relations of Law to Culture, Power, and Justice" (1961) *Ethics*, Vol. 72, No. 1, p. 26.

[8] A. Regmi & M. Gehlhar, "Consumer Preferences and Concerns Shape Global Food Trade" (2001) *Food Review: Global Food Trade*, Vol.24, No.3, p. 4.

[9] See generally, C. MacMaolain, note 58 Chapter 2 above, p.175

[10] BSE (bovine spongiform encephalopathy) is a disease found only in cattle which belongs to the family of prion diseases known as transmissible spongiform encephalopathies (TSEs). They are a family of rare progressive neurodegenerative disorders that affect both humans and animals. The most common form in humans is Creutzfeldt-Jakob Disease (CJD) - a rare and fatal form of dementia that can present in individuals between the ages of 40 and 80. Therefore, CJD is not a new disease. However, in 1996 scientists discovered a new strain of CJD (variant CJD, vCJD or new variant CJD, nvCJD) and scientific research has shown that the most likely origin of vCJD is human exposure to the BSE prion or protein by eating food containing traces of the brain, spinal cord or digestive tract of BSE infected carcasses. As with BSE in cattle, vCJD is always fatal in humans.

[11] These concerns precipitated the publication in May 1997 of the Commission's Green Paper on the General Principles of Food Law in the European Union[11] (EC, 1997) which formed the basis for the subsequent White Paper with the adoption of the precautionary principle as one of its guiding principles. This in turn led to the enactment of the General Food Law.

are reshaping how our food is produced, marketed, and distributed. Due to globalisation and the increased diversity of foods in the marketplace, people are now exposed to pathogens native to other parts of the world.[12] Differences of opinion have arisen due to the advent of biotechnological processes, in particular genetic modification. On one side of the debate the ardent advocates of biotechnology, who are predominantly located in the US, argue that food products created using these processes are good and wholesome to eat. On the other side the consumer associations/interest groups, especially in the EU, voice their fears of the long term health and environmental effects of eating genetically modified foods.

Because of this internationalisation of food, consumer confidence has been undermined.[13] Consumers are no longer purchasing food locally which has been produced by local farmers. More generally, due to the complexity of modern production methods and food supply chains, information asymmetries have increased and the consumer's sense of uncertainty has been heightened. Consumers are anxious because due to the speed at which advances in agricultural, industrial and food production practices are taking place, the safety of the products generated through such mechanisms cannot be established.[14] Due to globalisation of the food supply, there has been a decline in the capacity of government and national authorities to meet public demand for food safety standards, and yet ironically they are faced with increasing public demand for those standards. The consequences of industrial and scientific development are a set of risks and hazards, the likes of which we have never seen before.[15]

When considering what constitutes a food safety risk in the comparative context, the starting point in contrasting EU and US attitudes is traditional production methods in the EU versus modern technological processes in the US. EU reverence for more traditional food production methods creates a risk perception that is wary of foods produced with the aid of technologies

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[12] Some illnesses have been associated with internationally distributed foods. For example, an outbreak of cholera in consumers living in Maryland, US was caused by coconut milk imported from Thailand. See S.F. Altekruse, M.L. Cohen & D.L. Swerdlow, "Emerging Foodborne Diseases" (1997) *Emerging Infectuous Diseases*, Vol.3, No.3.

[13] In this context, it is interesting to note that the Court of Justice has defined the average European consumer as being 'reasonably well informed and reasonably observant and circumspect' – See, for example, Cases C-239/2002, *Douwe Egberts NV v Westrom Pharma NC and Christophe Souranis* [2004] ECR I-7007, para 146; Joined cases C-421/2000, C-426/2000 and C-16/2001, *Renate Sterbenz and Paul Dieter Haug* [2003] ECR I-1065, para 43; Case C-465/1998, *Verein gegen Unwesen in Handel und Gewerbe Köln eV v Adolf Darbo AG* [2000] ECR I-2297, para 20.

[14] T. O'Riordan, J. Cameron and A. Jordan, "The Evolution of the Precautionary Principle" in T. O'Riordan and J. Cameron (eds), note 59 Chapter 2 above, p.9.

[15] U. Beck, note 79 Chapter 4 above, p.2.

such as GMOs or beef containing growth hormone residues. It appears that these cultural perceptions of risk and precaution are carried through into the food safety provisions enacted.[16]

The empirical research shows that there is significant cross-border diversity of regulatory standards.[17] This diversity causes tensions within regional and bilateral trading arrangements. Depending on the economic sector or goods involved, in the event of a trade embargo the country with the more lax consumer regulations accuses the country with more stringent consumer regulations of instigating illegitimate[18] non-tariff barriers to trade. In such situations, exporting countries have suggested that the regulations be either removed in their entirety or replaced by other less trade-restrictive measures, such as a system of mutual recognition, and/or a system of certification with labelling.[19]

5.2 Risk Communication: Culture and Science

Food safety regulations can be defined as mandatory controls designed to govern the quality attributes of a final product in order to minimise the potential detrimental effect on human health by food handling, preparation, or consumption.[20] In this context, it is important to note the difference between 'hazard' and 'risk' in food science. The term 'hazard' refers to the source that has caused or could cause an adverse health effect. 'Risk' refers to the probability of that effect and its severity. As outlined previously in Chapter 4, in the EU, the General Food Law defines risk as 'a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard'.[21] The Codex Alimentarius defines risk as 'a function of the probability of an adverse health effect ... consequential to a hazard(s) in food'.[22] Therefore, for example, if dioxins are detected in foods, we know that dioxins are a hazard, but in miniscule quantities they do not pose a (health) risk.[23] The language of 'risk' is used in discussing these issues because in many cases available information is inadequate or incomplete. Enough is known to suspect or predict that a threat exists, but the full outcomes

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[16] C. Carlane, note 1 Chapter 2 above, p.318.
[17] T. Bernauer, note 7 Chapter 2 above, p.81.
[18] Illegitimate in the context of being in breach of the jurisdiction's obligations under the WTO SPS Agreement.
[19] T. Bernauer, note 7 Chapter 2 above, p.82.
[20] N. H. Hooker, note 7 Chapter 1 above, p. 653.
[21] Article 3(9).
[22] Codex in its *Procedural Manual, 17th ed.*, p.44.
[23] M.A. Recuerda, note 18 Chapter 4 above, p. 6.

for human health and the environment, including for future generations, may not be well understood.[24]

There is a widely used triumvirate applied when officially dealing with risk – 'risk analysis', 'risk assessment' and 'risk management'. Codex provides the following definition of each term:[25]

(i) firstly, risk analysis is a process consisting of three components - risk assessment, risk management and risk communication;

(ii) secondly, risk assessment is a scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment and (iv) risk characterization; and

(iii) thirdly, risk management is the process of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and if needed, the selection of appropriate prevention and control options.

Then, in order to evaluate a food health risk it is necessary to apply three criteria to the risk assessment evaluation (1) 'severity', indicating the kind of effect from slight to serious; (2) 'incidence', that indicates the actual or likely number of cases; (3) an 'incubation period', indicating the period of time between exposure and ultimate manifestation of harm.[26]

However, we know that some risks trigger a greater degree of public anxiety than others. In endeavouring to understand why this is so, the 'psychometric approach' to risk analysis examines how different risk attributes affect individual attitudes or public risk perception. There has been a significant amount of research in this area and the results are summarised in the list of 'fright factors' outlined below:[27]

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[24] See, J. Peel, note 44 Chapter 3 above, p.1.

[25] Codex Alimentarius *Procedural Manual, 17th ed.*, p.44.

[26] See, M.A. Recuerda, note 18 Chapter 4 above, p. 6.

[27] See, P. Bennett, K. Calman, S. Curtis, & D. Fischbacher-Smith, "Understanding Public Responses to Risk: Policy and Practice", in P. Bennett, K. Calman, S. Curtis, & D. Fischbacher-Smith (eds), *Risk, Communication and Public Health*, 2nd edn (Oxford: Oxford University Press, 2010) p.8.

The risk is generally more worrying if it is perceived:[28]

(i) to be involuntary (e.g. exposure to pollution) rather than voluntary (e.g. smoking);

(ii) as inequitably distributed (some benefit while others suffer the consequences);

(iii) as inescapable by taking personal precautions;

(iv) to arise from an unfamiliar or novel source (e.g. people tend to overestimate deaths owing to unusual or dramatic causes, while underestimating those due to common killers such as heart disease);

(v) to arise from man-made rather than natural sources;

(vi) to cause hidden and irreversible damage, e.g. through onset of illness many years after exposure;

(vii) to pose some particular danger to small children or pregnant women or more generally to future generations;

(viii) to threaten a form of death (or illness/injury) arousing particular dread;

(ix) to damage identifiable rather than anonymous victims;

(x) to be poorly understood by science; and

(xi) to be subject to contradictory statements from responsible sources (or, even worse, from the same source).

The communication of risk information is important – pressure groups are anxious to attract media attention in their campaigns for safety measures, the food science fraternity complains of media scare-mongering and industry employs 'risk communicators' in an attempt to gain public confidence. Ultimately, the public has a strong preference for the provision of full information in situations where uncertainty arises with regard to food safety. Indeed, many people believe that it is their right to be informed about risk uncertainty associated with

[28] Risks that score highly against these fright factors possess all of the ingredients that are likely to lead to a health 'scare'. The 'fright-factors' signify public 'perceptions' of risk. Therefore, the risk may not actually be 'involuntary' insofar as an individual may actually have control over it, but nonetheless, the individual/group sees it as involuntary.

food.[29] In the EU, Article 3.13 of the General Food Law provides a definition of 'risk communication' and more notably, risk perception among consumers is also included. Article 3.13 defines 'risk communication' as:

> ... the interactive exchange of information and opinions throughout the risk analysis process as regards hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers ... including the explanation of risk assessment findings and the basis of risk management decisions.

Here we see an emphasis on the deference given to the role of the consumer under EU food law. In addition, there is a desire to disclose not just the risk management aspect and any inclusion of 'other factors' but also to disclose the scientific reasoning behind the findings. It may have been a desire to placate public concern and loss of confidence in the regulatory authorities after the various EU food health scares that led to this all inclusive approach. In contrast, FDA adopts a 'science-based approach' to its communication strategy. FDA defines this science based approach to risk communication as a procedure which communicates the product information to the consumer through effective labelling. In other words, the main part of the risk communication begins after the product has been approved – after risk assessment and any element of risk management. Then FDA 'scientifically' tests 'how the public understands information' and assesses 'the impact of the information on public understanding, attitudes, and behaviours'.[30] At the very least, the EU approach appears to have an in-built desire to be as open as possible about the whole approval process. This is important in public risk perception.

In this context, there are some widely used guidelines on good practices for risk communication. The most famous of these is the 'seven cardinal rules of risk communication', which has been widely quoted.[31] The seven cardinal rules are:

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[29] L. Frewer, "Science, Society, ad Public Confidence in Food Risk Management", in P. Belton & T. Belton (eds), note 9 Chapter 2 above, p.64.

[30] See FDA – "Strengthen Social and Behavioural Science", note 185 Chapter 4 above.

[31] See for example, V. T. Covello and F.W. Allen, *EPA's Seven Cardinal Rules Of Risk Communication* (Washington, D.C., US Environmental Protection Agency, 1988) OPA-87-020.

(i) accept and involve the public as a partner: Your goal is to produce an informed public, not to defuse public concerns or replace actions;

(ii) plan carefully and evaluate your efforts: Different goals, audiences, and media require different actions;

(iii) listen to the public's specific concerns: People often care more about trust, credibility, competence, fairness, and empathy than about statistics and details;

(iv) be honest, frank, and open: Trust and credibility are difficult to obtain; once lost, they are almost impossible to regain;

(v) work with other credible sources: Conflicts and disagreements among organizations make communication with the public much more difficult;

(vi) meet the needs of the media: The media are usually more interested in politics than risk, simplicity than complexity, danger than safety; and

(vii) speak clearly and with compassion: Never let your efforts prevent your acknowledging the tragedy of an illness, injury, or death. People can understand risk information, but they may still not agree with you; some people will not be satisfied.

Therefore, the manner in which potential risks are framed by the authorities in charge of food safety has a major effect on consumer risk perception. The joint FAO/WTO Committee concluded that the available data on the identity and concentrations of growth hormone residues in animal tissues indicated that it was possible to sanction a wide margin of safety for consumption of residues in food. However, this was provided that the products were 'used according to good practice in the use of veterinary drugs'. Any consumer can immediately see that these findings are only as good as the regulatory oversight of the use of growth hormones as administered by animal feeding-lot operators. Only if the drugs are administered in the correct manner and in no greater a dosage that the maximum permitted, can they be considered as safe, at least based on the findings of this Report.

Another expert stated that if you assume no threshold, you should continually be taking steps to get down to lower levels, because 'no level is safe', in effect, 'the jury is still out on these

hormones'.[32] Even worse, it is simply not possible to monitor naturally occurring hormones,[33] since it is not possible to separate or tell the difference between the hormones used for treatment from those made by the animal's own body.[34] When EU consumers read these findings, then it raises their sense of risk associated with consuming beef produced with the aid of growth hormones. However, other expert reports may also exist which opine on the safety of eating beef produced using growth hormones. Nonetheless, public risk perception is likely to be more influenced by the more negative expert reports and by the conflicting opinions.

In the *Beef Hormones Dispute*, the EU cited as its main concern, the protection of consumer health and safety in response to 'consumer anxiety' regarding the safety of beef treated with hormones.[35] This anxiety is based on consumer risk perception. It is not difficult to envisage how consumer anxiety is increased in situations where radical new food technologies are foisted upon them without proper public consultation or involvement. There is usually little disagreement over the threat posed to human health by adulterated or contaminated food. However, the situation is far less clear when it comes to modern dangers emanating from the production process rather than the food product itself.[36] There are many examples of concerns arising directly from the production process. For example, some dangers arise from new food technologies such as growth hormones in beef, the genetic modification of foods, animal cloning or nanotechnology. Animal feeding methods have also given rise to contentious issues.[37]

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[32] Professor Jim Bridges, a toxicologist at the University of Surrey and a member of an EU working group on the use of growth hormones as quoted in M. Balter, "Scientific Cross-Claims Fly in Continuing Beef War", (1999) *Science*, Vol. 284, No. 5419, p. 1453.

[33] Three of the six hormones banned in the EU are what are known as 'naturally occurring hormones', that is, certain amounts of the hormones are also present naturally in the animal.

[34] S.S. Epstein, "The Chemical Jungle: Today's Beef Industry", (1990) *International Journal of Health Studies*, Vol.20, No.2, p.277.

[35] First Written Submission of the European Community to the Panel on European Community WTO Dispute Settlement Panel: Measures Concerning Meat and Meat Products (Hormones) (1996) WL807621, p. 146 – 250.

[36] Under the WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), sanitary or phytosanitary measures 'include all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, ... processes and production methods'. In addition, Article 5(2) of the SPS Agreement provides that in 'the assessment of risks, Members shall take into account ... relevant processes and production methods ..'

[37] It was cattle feeding practices that are believed to have led to *Bovine Spongiform Encephalopathy* (BSE) in animals and *Creutzfeldt-Jakob Disease* (CJD) in humans. Gavaging or force-feeding of geese is an example of an aspect of the food production process that has raised animal welfare concerns.

In contrast, FDA says that people are not at risk from eating food from animals treated with these drugs[38] because the amount of additional hormone following drug treatment is very small compared with the amount of natural hormones that are normally found in the meat of untreated animals and that are naturally produced in the human body.[39] The EU interprets its ban on the importation of hormone treated beef as a way of ameliorating public concern regarding the safety of growth hormones in beef and at the same time protecting public health. As we shall see later in this thesis, when the EU introduced its ban on growth hormones in beef production, one of the reasons given was the assuaging of consumer anxieties.[40] In deciding whether or not to impose a ban on growth hormones, it was public pressure derived from the cultural nature of the public risk perception that proved decisive.[41] This was confirmed at the time by EU Agriculture Commissioner Franz Andreissen's statement, that 'in public opinion, this is a very delicate issue'.[42] However, the US would be anxious to know that the ban is not merely protectionism disguised as a sanitary based non-tariff barrier to trade.

As outlined in Chapter 4, the approach taken under US risk assessment is to approve the food product using 'regulatory science', provide information to the consumer regarding the product, and then allow the consumer the opportunity to apply a precautionary approach if he/she so wishes. Any element of precaution and consideration of other factors is conveniently shifted away from the US food regulatory administration and onto the consumer.[43] In furtherance of this goal, in their efforts to 'strengthen social and behavioural science to help consumers and professionals make informed decisions', FDA uses a 'science-based approach' in developing its communication strategy. As also outlined in Chapter 4,

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[38] i.e. any of the six growth hormones banned in the EU.

[39] Of course, FDA's job of risk communication is aided by US consumers simply being unaware of the potential dangers associated with technological advances in food production. In some cases, they were not even aware that the beef they were eating was produced with the aid of growth promotants. See generally, C. Carlane, note 1 Chapter 2 above, p.319.

[40] G. Skogstad, note 57 Chapter 3 above, p.223.

[41] There were many comments evidencing this. When, in 1985, it was decided that a complete ban would be placed on hormones, Professor Lamming (who was Chair of the EC Lamming Committee researching hormones safety) stated that 'the ban taken by EU agriculture Ministers on December 19th [1985], flies in the face of scientific evidence requested by the Ministers themselves'. David McBeath, head of pharmaceutical company Hoechst's animal research division said 'why should any major company invest millions to develop and licence new generation products when the views of a small but highly vociferous consumer lobby in Europe can sweep away that research overnight? Perhaps we should skip scientific evaluation and let the politicians make the decisions.' See R. Wright, note 52 Chapter 3 above.

[42] As quoted by A. Gowers & I. Dawnay, "*Another Shot of Politics for the Beef Farmer; EEC Hormones Ban*", (1986) The Financial Times, January 24, p.15.

[43] A good example of this is FDA policy emphasis on consumer behaviour. See FDA – "Strengthen Social and Behavioural Science", note 185 Chapter 4 above.

FDA defines this science based approach to risk communication as a procedure which communicates the product information to the consumer through effective labelling, then FDA 'scientifically' tests 'how the public understands information, assuring optimal delivery to relevant populations', and assesses 'the impact of the information on public understanding, attitudes, and behaviours'.[44] This is all done in order to 'facilitate the translation of science-based regulatory decisions'. There are a number of cultural regulatory divergences imbued in this approach to risk communication. For example, the US reverence for science in all aspects of risk analysis is again apparent. In addition, this process of science based risk assessment and then permitting the consumer to decide on any remaining risk, corroborates the assertion made in this thesis that the precautionary principle is not a respected part of food safety strategy in the US. The importance of risk communication is acknowledged on both sides of the Atlantic, but the cultural divergences in risk analysis effect the tenor of the risk communicated.

5.3 Public Outrage and the Adoption of Stringent Sanitary Measures

Despite public participation, more stringent food safety regulation can still arise, such as the ban imposed in the EU on growth promoting hormones. In relation to food safety regulations commentators have noted that there are two conditions which increase the likelihood of more stringent consumer protection regulations being adopted.[45] Firstly, the relevant domestic industry as a whole must have an interest in more stringent regulation. The most likely reason for this is if the regulation will shield import-competing domestic industry or firms from foreign competition.

The second condition which is likely to result in more stringent consumer protection regulations is that the issue concerned provokes public outrage based on existing public risk perception.[46] If the public fears a particular risk and in addition concludes that it is insufficiently safeguarded by the existing regulations, then there is an increased incentive to

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[44] See FDA – "Strengthen Social and Behavioural Science", note 185 Chapter 4 above.
[45] E. Meins, note 179 Chapter 3 above, p.97.
[46] Public outrage can have a number of effects on the regulatory process. Firstly, it can result in outcomes that more strongly reflect consumer concerns instead of producer interests. Secondly, if the public is concerned enough, this can significantly raise consumer interest groups' power and they in turn can threaten producers with for example, a boycott of produce. This can coerce producers or industry into changing its position on the issue.

join and support consumer groups. Those consumer groups can then exert powerful influence over the form of regulatory enactments. Economic reality, effecting what can and cannot be imported, must then conform to these regulatory requirements. Public outrage can be defined as fear or anger that the perceived risk induces in a relatively large element of a jurisdictions population. The magnitude of this public outrage can be either independent of the scientifically proven probability of harm or it can be exacerbated by a perception that the risk is unknown.[47] Therefore, public outrage is dependent on existing contextual factors, such as the various food safety crises in the EU concerning BSE, etc.

This thesis argues that public risk perception expressed as public outrage was a major factor in causing the EU beef hormone ban to be instigated. The formation of consumer risk perception can be seen in the years preceding the *Beef Hormones Dispute*. It has been suggested that originally the EU position emanated at least in part from the European reaction to dethylstilboestrol (DES)[48] in the 1970s.[49] When the issue of possible negative health effects of using hormones in livestock production arose, it came as no surprise that consumers were alarmed. The DES scare had created a consumer climate in Europe that was concerned over the potentially harmful health effects of using hormones in livestock production.[50] Similar suspicions resurfaced with the outbreak of BSE[51] during the 1990s. Scientifically established links between BSE and Creutzfeldt-Jakob disease (CJD), the human variant of BSE, compounded consumer distrust about the safety of the meat supply. While BSE is unrelated to the use of hormones, many EU beef producers were fearful of using hormones as that might have given EU consumers another disincentive to buy meat. Unlike

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[47] E. Groth, *Consumer Perceptions of and Responses to Potentially Hazardous Technologies* (Vienna: ICGFI Secretary, 1994): Document no. 18, p. 123 as cited in E. Meins, note 179 Chapter 3 above, p.94.

[48] DES was used as a growth hormone in the beef and poultry industry. It was later found to cause cancer and was phased out.

[49] The oestrogen drug DES was used in veal production in France and concerns arose over a possible link to cases of hormonal irregularities in Italian adolescents. Traces of DES were found in baby food made from veal. As a result, it was suspected that cases of children born with birth defects were caused by the children's exposure to DES.

[50] T. Josling, D. Roberts, & A. Hassan, note 188 Chapter 2 above, p.4.

[51] BSE (bovine spongiform encephalopathy) is a disease found only in cattle which belongs to the family of prion diseases known as transmissible spongiform encephalopathies (TSEs). They are a family of rare progressive neurodegenerative disorders that affect both humans and animals. The most common form in humans is Creutzfeldt-Jakob Disease (CJD), a rare and fatal form of dementia that can present in individuals between the ages of 40 and 80. Therefore, CJD is not a new disease. However, in 1996 scientists discovered a new strain of CJD in humans (variant CJD, vCJD or new variant CJD, nvCJD) and scientific research has shown that the most likely origin of vCJD is human exposure to the BSE prion or protein by eating food containing traces of the brain, spinal cord or digestive tract of BSE infected carcasses. As with BSE in cattle, vCJD is always eventually fatal in humans.

DES, none of the hormones at issue in the *Beef Hormones Dispute*[52] have been unequivocally proven to pose a threat to human or animal health.[53] Similar issues have surfaced in consumer reactions to the introduction of transgenic plants (GMOs) and other forms of biotechnology into the food chain.

There are a number of examples of food safety scenarios which evidence the adoption of more stringent consumer protection regulations. The EU mandatory labelling scheme for food products containing, for example, approved genetically modified soy or corn types.[54] In contrast, labelling is only mandatory in this instance in the US if certain common allergens have been added to the food product using biotechnology. In the US, the label must merely state that a potential allergen has been added to the food and it does not have to state that biotechnology (GMOs) was used in the manufacturing process. Therefore, in comparison to the US, the EU regulation could be seen as a more stringent standard. The regulation of growth hormones in beef, as analysed in this thesis, is an example of where stringent consumer protection regulations were formulated without an accompanying certification scheme such as labelling. Therefore, a certification system, such as labelling, is not a prerequisite when a jurisdiction is establishing more stringent consumer protection regulations. Indeed, it could be argued that any requirement for a system of certification is redundant in the EU because due to the hormone ban the consumer could simply take it in good faith that all meat is in any event growth hormone free. Therefore, economies do not always lose regulatory efficacy due to globalisation. In some instances a more stringent regime of consumer protection has been adopted.[55]

Labelling or providing the consumer with sufficient information on which to base a decision at the time of purchase, is an effective means of assuaging consumer concern regarding risk in food safety. However, according to a recent German survey, when it comes to product

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[52] With the exception of the hormone oestradiol 17β which can be considered a 'complete carcinogen'. See *Opinion of the Scientific Committee on Veterinary Measures relating to Public Health Assessment of potential Risk to Human Health from Hormone Residues in Bovine Meat and Meat Products* (30 APRIL 1999).

[53] M.D. Carter, note 149 Chapter 2 above, p.627.

[54] See, Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed [2003] O.J. L 268/24 and Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and amending Directive 2001/18/EC. [2003] O.J. L 268/24. Again, there was US opposition to the EU decision at the time to adopt compulsory tracing and labelling rules for all food and animal feed containing genetically modified organisms (GMOs). The US was concerned that the tracing and labelling rules would limit EU imports of US crops such as GM soy and corn and that the EU proposal would only erode rather than strengthen consumer confidence.

[55] E. Meins, note 179 Chapter 3 above, p.98.

contents or ingredients, there is a lack of consumer confidence. Half of the participants in the survey were afraid that the labelling and the actual contents of the product did not coincide, or that important ingredients are omitted or not properly indicated.[56] In turn, labelling should be buttressed by a credible system of identity preservation and traceability.[57] This appears to be particularly important in the EU due to the nature of its public risk perception. Harmonisation of these approaches across economic regions would help to neutralise asymmetries in consumer concern that might otherwise lead to trade tensions.

In the EU, the Court of Justice has defined the 'average consumer' as being 'reasonably well informed and reasonably observant and circumspect'.[58] According to the European Commission, consumers want to receive more and clear information about the food they buy. The information should appear on labelling, and in the EU it has been suggested that the information should be understandable and not overly complex.[59] In order that the consumer can make an informed choice, details of the composition, nutritional value and processing of the foodstuffs should be available. The information on the label should be understandable and not overly complex.[60]

5.4 Risk Perception, Public Distrust of Science, and Consumer Groups

When endeavouring to estimate or indeed eradicate risk using science, there is always one fundamental difficulty, namely, that science can only ever confirm that there is no evidence of risk, whereas the consumer is asking for evidence of no risk. It is never possible to

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[56] SGS Institut Fresenius Verbraucherstudie 2010: *Lebensmittelqualität und Verbrauchervertrauen*. See: S. Leible, "Consumer Information beyond Food Law", (2010) *European Food & Feed Law Review*, Vol. 5 Issue 6, p.316.

[57] Identity preservation or IP refers to tracking the produce from origin to customer. Traceability refers to the ability to trace the produce from customer to origin – the application of both techniques together is often termed 'IPT'.

[58] See, for example, Case C-239/2002, *Douwe Egberts NV v Westrom Pharma NC and Christophe Souranis* [2004] ECR I-7007, para 146. On occasion, the Court has found that it was not necessary to organise an expert report or a consumer research exercise in order to ascertain how well informed the consumer is. See Case C-362/1988, *GB-INNO-BM v Confédération du commerce Luxembourgeois* [1990] ECR I-667; Case C-126/1991, *Schutzverband gegen Unwesen in der Wirtschaft eV v Yves Rocher* [1993] ECR I-2361; Case C-456/1993, *Zentrale zur Bekämpfung unlauteren Wettbewerbs eV v Privatkelleriei Franz Wilhelm Langguth Erben GmbH & Co KG* [1995] ECR I-1737; Case C-470/1993, *Verein gegen Unwesen in Handel und Gewerbe Köln eV v Mars GmbH* [1995] ECR I-1923.

[59] *See* Proposal for a Regulation of the European Parliament and of the Council on the provision of food information to consumers, (COM(2008)0040 – C6-0052/2008 – 2008/0028(COD)) (A7-0109/2010). Council agreement was secured at Council Session 3053 on 7 December 2010.

[60] *Ibid.*

guarantee with 100 per cent certainty that there is no risk whatsoever and this principle applies whether its GM foods, beef from animals fed with growth hormones, or for that matter using mobile phones or any other new technology.[61] As a result, consumers want to make their own decisions rather than have solutions thrust upon them by the 'experts'. A number of reasons have been put forward for this loss in consumer confidence:[62]

(i) firstly, scientists and scientific risk analysis is no longer trusted as it once was. Food health scares such as the BSE epidemic has damaged consumer confidence within the EU, especially confidence in the regulatory process;

(ii) secondly, scientists do not always succeed in explaining to the public what is meant by different degrees of risk. In a similar manner as one appreciates that the chances of winning the lottery are very low, one still think 'maybe it will be me'. Similarly, even when the risk to human health posed by a new product is very low, the consumer still fears that as a result of consuming this food, he/she could be the one that develops a serious or deadly disease. This situation is compounded by the fact that the public is largely unaware of the successful modern methods of minimising risk, such as the use of hazard analysis;

(iii) thirdly, the public is confused as it also has to consider the points raised by the many consumer organisations and pressure groups denouncing modern food productions methods; and

(iv) fourthly, consumers assess risks according to their context – people will not tolerate much risk at all when it comes to food.

Why are the standpoints of scientists and the public so diametrically opposed? Scientists and in particular food technologists see the application of novel technologies as logical and they firmly regard all opposition as unreasonable. They simply conclude that the consumer does not understand what it is they do. However, while scientists and food technologists handle uncertainty and risk judgements on a daily basis, the perception of the public is different. People feel that they are losing all control over the provenance of their food. These are modern consumer concerns over high intensity agriculture, modern food production methods, the consolidation of the agrifood business worldwide into a small number of huge corporations, esoteric regulatory processes, and decisions regarding the future of our food

[61] See generally, P. Belton & T. Belton (eds), note 9 Chapter 2 above, p.138.
[62] *Ibid*, p.138.

been taken in the US or Switzerland. Consumers in the EU feel they are losing control of tradition in the food supply. Their food culture is under attack, they know it, and more often than not, they blame technology. When faced with the unknown, public reaction can often be summarised as a combination of outrage,[63] dread and stigma[64].

Therefore, the important conclusion to be drawn from this is that it is not possible by consulting just scientists and food technologists, to predict the way consumers will react to a new food associated risk. Public perception of risk is now of crucial importance and a scientific or technical assessment of risk alone is insufficient when introducing a new technology into the food production process. Indeed, widespread public aversion to a clearly identifiable risk, improves consumer group collective action potential.[65] European consumer groups were therefore successful in influencing the relevant institutional EU bodies to adopt stringent regulations governing animal growth hormones.

In stark contrast, US consumer groups were almost non-existent when it came to lobbying for higher levels of consumer protection through a ban or curtailment of growth hormone use. Moreover, due to the stark cultural difference existent in the US with the use of a technology such as animal growth hormones, a majority of US consumers perceived little or no risk in consuming meat produced with growth hormones. In fact, many US consumers would be more ready to cite the benefits, as they see it, from using growth hormones in their beef production. As a result, US consumer groups were never going to succeed in lobbying for higher levels of consumer protection.

It does not seem surprising that the manner in which risk is perceived will have a significant influence on the way that risk is ultimately managed. A scientific approach to risk is going to be based on fact and will be rational, whereas a person's (and ultimately the consumer's) value driven personal judgment of risk will oftentimes be based on perception only and therefore it may simply be incorrect. Yet, in a democratic society people have the right to require that their food supply accords with their tastes and traditions.

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[63] People react with "how dare they do this to us?" – this reaction has been seen with public reaction in Europe to Monsanto's GM crop trials.
[64] For example, the way some people regard food irradiation
[65] E. Meins, note 179 Chapter 3 above, p.94.

Risk assessment provides risk managers with only one body of information. It does not in itself enable risk regulators to decide what if any food safety measure is required.[66] It is in this spirit that the General Food Law perhaps at the risk of being accused of protectionism, gives cognizance to a social factor in its assessment of risk.[67] Unlike the position with the US system, under the substantive EU food safety law, there is a clear division between risk assessment and risk management built into the legislation itself and this almost ensures the inclusion of a social factor in the formulation of food safety law. The General Food Law caters for consumer interests and tradition.[68] This dichotomy of approach, between culturally influenced food safety regulation as against purely science based food safety regulation is evidenced by for example the EU resistance to GMOs and animal growth hormones. Yet, empirical or science based judgments are only as good as the accuracy of information on which they are based and in addition, science is always evolving. Therefore, there may well be some merit in the inclusion of a cultural element through public risk perception in risk analysis.

Consumer risk perception is oftentimes a force for improvements in food safety. Over the years, consumer demands have resulted in improved food quality.[69] They have also incentivised both public and private sectors to develop and implement quality control procedures and quality assurance schemes.[70] These quality control schemes have changed the way that food products are produced and marketed in the EU and also to some extent in the US.[71] The concept of traceability[72] under EU food law is an example of a public standard. US

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[66] C. Button, note 105 Chapter 4 above, p.102.

[67] For an outline of the important components of risk assessment under EU law as envisaged by The Court of Justice, see Case C-355/1990, *Commission v Spain* (conservation of wild birds) [1993] ECR I-4221.

[68] Article 1 of the General Food Law provides that '[t]his Regulation provides the basis for the ... protection of ... consumers' interest in relation to food, taking into account in particular the diversity in the supply of food including traditional products'.

[69] Aside from the issue of growth-promotants in beef, there are many scenarios extant under EU food safety law which exemplify the importance attaching to consumer safety and consumer demands. For example, the use of additives attracts much consumer attention. The additive cannot present any danger to public health and can only be rejected by an importing Member State if it does not meet any genuine technological need, etc. See for example, Case C-95/1989, *Commission v Italy* (added nitrate) [1992] ECR I-4545; Case 247/1984, *Criminal proceedings against Léon Motte* [1985] ECR 3887, para 25; Case 304/1984, *Criminal proceedings against Claude Muller* [1986] ECR 1511, para 26; Case C-42/1990 *Criminal proceedings against Jean-Claude Bellon* [1990] ECR I-4863, paras 16 and 17; Case 53/1980, *Officier van Justitie v Koninklijke Kaasfabriek Eyssen BV* [1981] ECR 409.

[70] Quality assurance schemes standardize parameters surrounding the production, processing, and transport of food. They may also include environmental standards and management practices.

[71] A. Regmi & M. Gehlhar, note 8 above, p. 4.

[72] Traceability is a risk-management tool that enables food business operators or authorities to withdraw or recall food produce which has been identified as unsafe. It is a cornerstone of EU food safety policy. Under EU law, 'traceability' means the ability to track any food, feed, food-producing animal or substance that will be

quality assurance programs tend to be dissimilar to the EU approach, focusing only on food safety or health standards and rarely covering issues such as animal welfare or environmental issues. The US programs are often limited to on-farm quality assurance rather than the type of 'farm to table'[73] or entire supply chain quality assurance extant under existing EU food law. For example, in the US, the National Cattlemen's Beef Association's Beef Quality Assurance certification which was introduced in 1982, addresses concerns regarding chemical residues in beef.[74]

5.5 Precautionary Principle and Risk under EU Food Law

In particular in the 1990s, EU consumers became even more concerned about their food, its method of manufacture, its safety and concerns regarding the impact on their health increased.[75] Much of this was fuelled by such crises as BSE[76] in meat, and other developments such as the use of GMOs in food manufacture. The question became how to test the safety of food and how to deal with ambiguous results. These concerns precipitated the adoption by the Commission on 12 January 2000, of its White Paper on the General Principles of Food Law in the European Union.[77]

The very first sentence in the 2000 White Paper on Food Safety opens with - 'Assuring that the EU has the highest standards of food safety is a key policy priority for the Commission'. Other sentences announce:- 'A radical new approach is proposed' and 'risk analysis must form the foundation on which food safety policy is based'. In practice, under the EU food

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used for consumption, through all stages of production, processing and distribution. See the Health and Consumer Protection Directorate General '*Food Traceability Factsheet*' (June, 2007).

[73] The EU describes its approach to food safety as an integrated approach aimed at assuring a high level of food safety, animal health, animal welfare and plant health within the European Union through coherent farm-to-table measures and adequate monitoring, while ensuring the effective functioning of the internal market. See, *Food Safety: From the Farm to the Fork*, note 63 Chapter 2 above.

[74] A. Regmi & M. Gehlhar, note 8 above, p. 4.

[75] See generally, C. MacMaolain, note 58 Chapter 2 above, p.175

[76] BSE (bovine spongiform encephalopathy) is a disease found only in cattle which belongs to the family of prion diseases known as transmissible spongiform encephalopathies (TSEs). They are a family of rare progressive neurodegenerative disorders that affect both humans and animals. The most common form in humans is Creutzfeldt-Jakob Disease (CJD) - a rare and fatal form of dementia that can present in individuals between the ages of 40 and 80. Therefore, CJD is not a new disease. However, in 1996 scientists discovered a new strain of CJD (variant CJD, vCJD or new variant CJD, nvCJD) and scientific research has shown that the most likely origin of vCJD is human exposure to the BSE prion or protein by eating food containing traces of the brain, spinal cord or digestive tract of BSE infected carcasses. As with BSE in cattle, vCJD is always fatal in humans.

[77] COM (1999) 719 final, 12 January, 2000.

safety system, scientific risk assessment is the responsibility of EFSA. Therefore risk assessment is carried out independently from risk management and it is the European Commission as part of the risk management function that decides whether or not to authorise a certain product (which would have included market authorisation of beef containing growth hormone residues, had that been permitted).

In the *Beef Hormones Dispute*, the US argued that the EU ban on the importation of beef from cattle raised on growth hormones was an unjustifiable restriction on trade. The US believed that it was not a legitimate SPS measure and that it was merely a cynical effort to protect EU beef farmers from foreign competition. The EU position was that they were entitled to select a risk level of no risk and that, having then chosen that level of risk, they were entitled under the precautionary principle to ban the import of hormone-treated beef because consumers in the EU had the 'perception' that such beef created a significant health risk.[78] It is because this Chapter deals with 'risk' that the following commentary on the precautionary principle is included. If it weren't for risk, whether real or perceived, the precautionary principle would not exist.

In the EU, it was the BSE crisis that gave rise to one of the most influential consequences for food safety with the extension of what is known as the precautionary principle from environmental law into measures taken to protect human health.[79] It has been argued that the precautionary principle is a concept derived from new social perceptions regarding the appropriate role of science, economics, politics, and the law in protecting the environment and that this genre is now being applied in a variety of contexts.[80] Indeed it has been suggested that 'precaution is nowhere of greater salience than in the field of food safety'.[81] Consumers are anxious because due to the speed at which advances in agricultural, industrial and food production practices are taking place, the safety of the products generated through such mechanisms cannot be established.[82] It is in this spirit that consumer groups, especially

[78] K. A. Ambrose, "Science and the WTO", (2000) *Law and Policy in International Business*, Vol.31, p.863.
[79] C. MacMaolain, note 58 Chapter 2 above, p.195.
[80] T. O'Riordan, J. Cameron & A. Jordan (eds), note 70 Chapter 4 above, p.9.
[81] A. Stirling et al., "A Framework for the Precautionary Governance of Food Safety: Integrating Science and Participation in the Social Appraisal of Risk", in E. Fisher, J. Jones & R. Von Schomberg (eds), *Implementing the Precautionary Principle: Perspectives and Prospects* (Massachusetts: Edward Elgar Pub, 2006), p.284.
[82] T. O'Riordan, J. Cameron and A. Jordan, note 14 above, p.9.

in the EU, strongly advocate a 'better safe than sorry approach', arguing that food safety is something which by its very nature warrants a more strict precautionary approach.[83]

The precautionary principle cannot be divorced from scientific risk analysis, because 'a scientific view of the risk is an essential component of the evaluation of risk that the principle anticipates'.[84] However, the precautionary approach to food safety extant in EU food safety regulation, presupposes an assumption that expert scientific advice alone can only provide a partial identification of potential hazards and it gives credence to the opinions of lay citizens.[85] However, it has been argued that the precautionary principle removes science as the ultimate arbiter of the legitimacy of regulatory action.[86] Especially, since the enactment of the General Food Law,[87] a lot of deference has been shown to consumer risk perception and consumer interests under EU food safety regulation.[88] Consumer concern or risk-perception has often appeared as an important consideration in judgements handed down by the European Court of Justice (the Court). In *UK v Commission*,[89] the Court noted that a definitive stance on the transmissibility of BSE to humans was not possible and this continued 'uncertainty' had created 'serious concern among consumers'.[90] In relation to the use of growth hormones in cattle, the issue of consumer considerations arose in *R v The Minister for Agriculture and Fisheries and Food and the Secretary of State for Health*, ex parte: Fedesa & others,[91] - a case which challenged the validity of Directive 88/146/EEC.[92] The importance of the issue of consumer interests under EU law was set out in particularly clear terms when the Court decided that the Council had instigated the ban on growth hormone use in beef in order to ensure that 'all consumers were able to buy the products in

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[83] See, B. Krissoff, M. Bohman & J. Caswell (eds), note 55 Chapter 4 above, p. 6.
[84] J. Cameron, note 55 Chapter 2 above, p. 292.
[85] B.M.J. van der Meulen, note 148 Chapter 2 above, p.65.
[86] D. Vogel, *Ships Passing in the Night: The Changing Policy of Risk Regulation in Europe and the United States*, (San Domenico, Italy, European University Institute 2001), Working Paper No. 2001/16.
[87] European Parliament and Council Regulation (EC) No 178/2002, note 72 Chapter 2 above.
[88] For example, the references and provisions relating to consumer interests and the role played by consumers in Preamble para's 22, 35, 56 and also Article 1.1 of the General Food Law - European Parliament and Council Regulation (EC) No 178/2002, note 72 Chapter 2 above.
[89] Case C-180/1996, *UK v Commission* (BSE) [1998] 4 ECR I-2265.
[90] *Ibid*, para 20. Indeed, the *BSE Case* was the catalyst for the extension of the application of the precautionary principle from environmental law and policy into food safety regulation.
[91] Case C-331/1988, *R v The Minister for Agriculture and Fisheries and Food and the Secretary of State for Health*, ex parte: Fedesa & others [1990] ECR I-4023. The case concerned whether or not the Council had infringed the principle of legal certainty or legitimate expectations of traders by banning the use of growth promotants throughout the EU.
[92] Council Directive 88/146/EEC, note 190 Chapter 2 above.

question under largely identical conditions of supply and that those products corresponded to their anxieties and expectations in the best possible manner'.[93]

The growing popularity of the precautionary principle in the EU is evidence of the belief that scientific knowledge alone is an inadequate guide to regulatory policy.[94] The precautionary principle exemplifies the idea of caution in the face of risk.[95] The principle has firmly established the idea that scientific uncertainty about a risk should not be an obstacle to the adoption of precautionary measures when there is a probability that the risk will result in grave and irreparable damage.[96] Since avoiding risks is the main concern of food safety regulation, then this idea that scientific uncertainty about the risk must not be invoked and thereby paralyze decision-making, is at the principle's core. Science must be only one of the factors relied upon by political officials when taking risk management decisions.

Essentially, in the EU, when a product or procedure could pose potential detrimental consequences for the safety of food, then where some scientific evidence is presented to support the action, or indeed where the public perceives a risk, the precautionary principle enables the EU institutions to restrict the use of that product or procedure. There must be sufficient data available, but it does not have to be either undisputed or conclusive.[97] In this context, advocates of the precautionary principle would say that it is invaluable as a means of dealing with the question of how to proceed with risk management, if after the first step of risk assessment, the findings on safety are still inconclusive.[98]

In this context, it is important to note that in the EU, the General Food Law separates the scientific requirement (i.e. 'risk assessment') from the precautionary principle.[99] Article 6 of the General Food Law, deals with 'risk analysis', and provides that '... food law shall be based on risk analysis except where this is not appropriate to the circumstances or the nature

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[93] Case C-331/1988 *R v The Minister for Agriculture and Fisheries and Food and the Secretary of State for Health*, ex parte: Fedesa & others [1990] ECR I-4023, para 5.
[94] D. Vogel, note 63 Chapter 4 above, p. 566.
[95] It is likely that the EU would see its approach as reasonable in the circumstances. This is similar to the 'reasonable regulator' approach as evidenced under WTO case law. See *US-Preliminary Determinations with respect to Certain Softwood Lumber from Canada* WT/DS236/R. The EU argued for a 'deferential reasonableness standard'. See *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26//AB/R, (n.9), paras 112-13.
[96] M.A. Recuerda, note 57 Chapter 4 above, p.2.
[97] C. MacMaolain, note 58 Chapter 2 above, p.195.
[98] B.M.J. van der Meulen, note 148 Chapter 2 above, p.58.
[99] *Ibid*, p.60.

of the measure'. Article 6 goes on to provide that risk assessment 'shall be based on the available scientific evidence' and risk management 'shall take into account the results of risk assessment ... the opinions of the Authority. ... other factors legitimate to the matter ... and the precautionary principle where the conditions laid down in Article 7.1 are relevant'. The precautionary principle is then dealt with in Article 7 which provides that 'where, following an assessment ... scientific uncertainty persists, provisional risk management measures ... may be adopted, pending further scientific information'. However, in deference to the EU's WTO obligations and liberalisation of trade, Article 7 also prescribes that 'measures adopted ... shall be proportionate and no more restrictive of trade than is required'.[100]

As previously outlined in Chapter 4, in the US and indeed in other jurisdictions the precautionary principle is a somewhat elusive and ambiguous legal concept. This evidences a different view of science in risk management as between the EU and the US.[101] Why has this happened? In response to that question, it must be noted that there have been different transatlantic experiences of regulatory risk management success and this has contributed to a higher level of EU scepticism of science-based risk regulation.[102] Americans on the other hand regard scientific risk analysis alone as being capable of affording the universal and objective facts necessary for the accurate execution of impartial regulatory decisions.[103] To a far greater degree than citizens of the EU, American public risk perception is prepared to defer to the authority of 'experts'. This transatlantic chasm in approach to how best to regulate food safety, would seem to have originated at least in part from the distinctive experiences of Europeans and Americans to various food safety crises.[104] Regulatory failures within the EU which have created or exacerbated environmental disasters, has resulted in a dramatic shift in public attitudes towards the efficacy of science. As a result a risk society has developed with a public risk perception characterized by a loss of faith in scientists and their

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[100] The text of Article 7 seems an accurate summary of the relevant case law here as it has developed in the EU. Because of the similarities this Article 7 of the General Food Law bears with Article 5(7) of the SPS Agreement, there seems little doubt that this Article 5(7) served the EU legislature as a template. *See*, B.M.J. van der Meulen, note 148 Chapter 2 above, p.60.

[101] D. Vogel, note 63 Chapter 4 above, p. 579.

[102] G. Skogstad, note 57 Chapter 3 above, p.221.

[103] G. E. Isaac, note 67 Chapter 3 above, p.128.

[104] G. Skogstad, "Legitimacy, Democracy and Multi-Level Regulatory Governance: The Case of Agricultural Biotechnology", (May 2, 2002) Paper presented at Conference on "*Globalization, Multilevel Governance and Democracy: Continental, Comparative and Global Perspectives*", Queen's University, Kingston, Ontario, Canada, p.14.

advice when it comes to formulating the policies required in allaying the hazards that are the by-products of modern industrial society.[105]

Others point to food safety scares, such as the BSE[106] crisis, which were seen as a failure by the government regulators and their scientific advisers to foresee the risk and protect the public health. In particular, in the eyes of the consumers, the BSE crisis undermined the idea of scientists as 'objective' and 'independent'.[107] The scientific experts who advised the Commission on the BSE risk, were blamed for having a role in playing down the severity of the crisis, and government was seen as a party to this duplicity.[108] Some of these are actual regulatory failures while others are perceived regulatory failures. However, both have had the effect of a public loss of confidence both at national and EU level in the legitimacy of technocratic styles of regulatory risk policymaking.[109] This resulted in a public risk perception which was unfavourable to permitting the importation and sale of the unfamiliar – beef containing growth hormone residues.

New products, especially those created using new technologies, possess both positive and negative traits. The positive aspect is that these products obviously carry with them important benefits, but from a negative perspective they also come with uncertain risks.[110] A good example of these new risks are those posed by genetically modified foods. Aside from the benefits associated with GMOs, there are concerns surrounding their ability to provoke allergenicity, the potential for gene transfer and out-crossing.[111] Choosing GMOs as just one example, we can see that what gives the precautionary principle, or more generally a

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[105] U. Beck, note 79 Chapter 4 above, p.29.

[106] BSE (bovine spongiform encephalopathy) is a disease found only in cattle which belongs to the family of prion diseases known as transmissible spongiform encephalopathies (TSEs). They are a family of rare progressive neurodegenerative disorders that affect both humans and animals. The most common form in humans is Creutzfeldt-Jakob Disease (CJD) - a rare and fatal form of dementia that can present in individuals between the ages of 40 and 80. Therefore, CJD is not a new disease. However, in 1996 scientists discovered a new strain of CJD (variant CJD, vCJD or new variant CJD, nvCJD) and scientific research has shown that the most likely origin of vCJD is human exposure to the BSE prion or protein by eating food containing traces of the brain, spinal cord or digestive tract of BSE infected carcasses. As with BSE in cattle, vCJD is always fatal in humans.

[107] C. Joerges & J. Neyer, note 68 Chapter 4 above, p.612.

[108] D. Chalmers, note 69 Chapter 4 above, p.5-106.

[109] G. Skogstad, note 57 Chapter 3 above, p.221.

[110] M.A. Recuerda, note 57 Chapter 4 above, p.7.

[111] *See*, WHO, Modern Food Biotechnology, Human Health and Development: An Evidence Based Study (2005), p. 16 – 18. Available at: http://www.who.int/foodsafety/biotech/who_study/en/index.html [Accessed: 21 June, 2011]. In relation to national fears concerning food ingredients see Case C-236/2001, *Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others* [2003] ECR I-8105; Case C-192/2001, *Commission v Denmark* (enriched foodstuffs) [2003] ECR I-9693.

precautionary approach to food safety its raison d'être, is that in some cases the risks are uncertain and perhaps even catastrophic.[112]

There have also been a number of other high profile dissimilar reactions from the EU and the US when it comes to assessing the riskiness of traditional foods and their production processes. A famous example is cheese made from unpasteurized milk.[113] This provides a stark illustration of the importance of tradition in EU food legislation as against the practicality of applying scientific evidence in the US. In the EU, this cheese is created in accordance with centuries-old tradition and it is therefore a cultural icon. Therefore the EU agrifood sector extols this product both in quality and safety. In a diametrically opposed position, on health grounds, in most cases the US restricts production and marketing of such cheeses, especially their sale in interstate commerce. A stark diametric in approach is the tendency of EU authorities to adopt stringent sanitary measures without incontrovertible evidence of risk, even at times going against the scientific opinions of its scientific bodies. It has been argued that this is what occurred in the *Beef Hormones Dispute* and in a legal dispute involving the use of virginiamicyn[114] as a growth promoter in livestock.[115] To quote one observer:

> [i]t is simply wrong to say that Europeans are more precautionary than Americans. As an empirical matter, neither is "more precautionary". Europeans are not more averse to risks than Americans. They are more averse to particular risks, such as the risks associated with global warming; but Americans have their own preoccupations as well. In the early twenty-first century, for example, many Americans have been highly "precautionary" about the risks associated with aggressive regulation itself fearing that costly steps, designed to combat global warming and other environmental problems, will lead to unemployment and excessive prices of energy, including gasoline. Whether or not that fear is justified, it is, in its own way, highly precautionary.[116]

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[112] M.A. Recuerda, note 57 Chapter 4 above, p.7.
[113] Oftentimes referred to as 'raw milk cheeses'. A similar example to exemplify the dissimilar reaction from the EU and the US are cured-meats.
[114] *See* Case T-13/99, *Pfizer Animal Health SA v. Council of the European Union*, 2002 E.C.R. 3305.
[115] M.A. Recuerda, note 57 Chapter 4 above, p.6.
[116] C. R. Sunstein, *Laws of Fear: Beyond the Precautionary Principle* (Cambridge: Cambridge University Press, 2005), p.14.

As we have seen, under EU law, the precautionary principle has grown in importance to such an extent that it has been introduced into EU primary legislation. It is to be found in many EU regulations and has been recognized by the Court of First Instance as a general principle of law.[117] As we shall see later in this thesis, in support of its defence in the *Beef Hormones Dispute*, EU submitted that the precautionary principle[118] is, or has become, 'a general customary rule of international law' or at least 'a general principle of law'.[119] In contrast, US law does not see the precautionary principle as a principle of law, but as an approach.[120] Indeed, American opinion is skeptical of the precautionary principle as applied to sanitary risks.[121]

On the global stage and in the context of liberalisation of free trade, opponents of the precautionary principle, particularly US industry groups, would argue that a greater application of the precautionary principle would undermine the SPS Agreement by giving countries an excuse to ignore valid scientific evidence in favour of political justifications to block trade. In contrast, proponents of the precautionary principle have argued that the principle is necessary due to public risk perception - it allays public fear about new technologies and the desire of industry to capitalize on these technologies at all costs in order to maximise profits.[122] This is a clear clash between culture and economics.

As we shall see in Chapter 8 of this thesis which deals with the *Beef Hormones Dispute*, the WTO Appellate Body noted that the precautionary principle had not been written into the SPS Agreement. However, nonetheless, the DSB[123] Panel had to bear in mind that governments were required to act from 'perspectives of prudence and precaution where risks of irreversible damage to human health are concerned'.[124]

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[117] *See* Joined Cases T-74/00, T-76/00, T-83/00, T-84/00, T-85/00, T-132/00, T- 137/00, & T-141/00, *Artegodan GmbH v. Commission of the European Communities*, 2002 E.C.R. 114945. A general principle of law is by its nature abstract insofar as it does not set out the legal consequences that automatically result. A rule of law is concrete because of its obvious specificity and concrete character which allows it the inherent characteristic to stipulate answers. Nonetheless, general principles of law are of course applied by the courts in interpreting the rules and as a means of filling in gaps that exist in the written law. *See*, T. Tridimas, note 103 Chapter 4 above, p.3.

[118] And thereby the taking of a precautionary approach to growth promotant treated beef.

[119] Paragraph 91 of the EU submission to the WTO Appellate Body.

[120] M.A. Recuerda, note 57 Chapter 4 above, p.6.

[121] *See* Button, note 105 Chapter 4 above, p. 125-129.

[122] L.A. Patterson and T. Josling, "Regulating Biotechnology: Comparing EU and US Approaches", in A. Jordan (ed), *Environmental Policy in the EU: Actors, Institutions and Processes*, 2nd edn. (London: Earthscan, 2005), p. 183.

[123] WTO Dispute Settlement Body.

[124] Paragraph 124 of WTO Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.

5.6 Problem with WTO Review of Other Factors and the Precautionary Principle

As outlined in Chapter 8 of this thesis which analyses the *Beef Hormones Dispute*, in *EC-Hormones*,[125] the WTO Panel[126] did not make any definitive finding with regard to the status of the precautionary principle in international law. However, the Panel (and subsequently the Appellate Body) found that the principle would not override the explicit wording of Articles 5.1 and 5.2 of the SPS Agreement,[127] especially since the precautionary principle has been incorporated and given a specific (albeit limited) meaning in Article 5.7 of the SPS Agreement.[128]

As previously outlined in this thesis, the obvious objection to accepting the precautionary principle or indeed 'other factors' as having a central role to play in setting sanitary measures, is that it diminishes the role of science as the ultimate arbiter when deciding at the international level whether or not the regulatory measures taken were legitimate. However, there is also a widely accepted jurisprudential difficulty in applying the precautionary principle. Because of its ability to stifle the role of science, it would have to be complemented by some additional basis of review in order to enable the WTO Panel/Appellate Body to review sanitary measures taken on reliance on the precautionary principle.[129] In other words, the use of the precautionary principle on its own makes it too easy to exploit protectionist opportunities.

The application of the precautionary principle as envisaged by the EU still requires a thorough evaluation of the available scientific information and this would assist in eliminating exploitation.[130] Proportionality is an obvious candidate for the additional basis of review. Proportionality would limit exploitation of the protectionist opportunities offered by the precautionary principle. It would allow a Panel to assess whether the chosen level of

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[125] *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26, WT/DS48, WT/DS26//AB, WT/DS48/AB.
[126] The 'Panel' of experts appointed by the WTO Dispute Settlement Body to arbitrate on the trade dispute.
[127] i.e., basically it would not override the requirement for science based risk analysis.
[128] P. 201 of Panel Report WT/DS26/R and WT/DS48/R and Paragraph 253 of Appellate Body Reports WT/DS26AB/R and WT/DS48/AB/R.
[129] See C. Button, note 105 Chapter 4 above, p.141.
[130] Communication from the Commission on the Precautionary Principle, 2 February 2000. COM (2000) 1.

protection is disproportionate given the risk or the resultant trade effects suffered by the other Members.[131] On a more basic level, it can simply elucidate whether the measure is proportionate to the level of protection sought.

However, the use of proportionality is not readily acceptable because it would require an overly extensive review of national regulatory preferences by the Panel. The Panel would have to weigh-up the entire costs and benefits of regulatory action. As a result, in order to ensure that the Panel does not incur this responsibility or not overly intervene in the independent democratic processes of any Member, a procedural model of review has been developed.[132] Procedural review also ensures that discretionary decision-making is transparent and accountable. This procedural model of review focuses on how the national regulation was formed and not on its substantive content. This procedural review allows a form of review with recourse to the precautionary principle, while preventing its abuse. However, it does not extend the scope of the review in the way that proportionality review would have. As a result, it would require very careful consideration by a Panel.[133] However, case law in the US where procedural review is more widely applied, evidences an inherent shortcoming in its application. While procedural review is supposed to focus on how national regulation was formed and not on its substantive content, unfortunately, jurists find it necessary to stray into the realm of substantive content, thereby effectively applying the proportionality principle and defeating the initial premise on which the procedural review principle was applied.[134]

There are a number of US cases which show that courts have engaged in intrusive reviews of the methodology and data underpinning the studies on which regulations were based.[135] As a result the courts have had to try and construct limits to their decision making powers. One such limitation was the formulation of the 'arbitrary and capricious' standard to ensure that the 'agency [had] considered all the relevant factors and that its decision contained no clear error of judgment'.[136] Arbitrary and capricious review was famously described as 'an inquiry into the facts [which] is to be searching and careful, [but ultimately] the standard of review is

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[131] C. Button, note 105 Chapter 4 above, p.141.
[132] *Ibid*, p.147.
[133] *Ibid*, p.147.
[134] *Ibid*, p.152.
[135] *Ibid*, p.154.
[136] *Pacific Coast Federation of Fishermen's Associations v National Marine Fisheries Service*, 265 F 3d 1028 (US Court of Appeals (9th Cir), 2001).

a narrow one. The court is not empowered to substitute its judgment for that of the agency'.[137] This was subsequently taken by the courts to mean that they could engage in an aggressive review contrary to the spirit of procedural review. The US courts engaged in a 'searching and careful' analysis of the facts in each case.[138] For example, in *South Terminal Corp v EPA*, the court felt that it had to engage in 'searching and careful' review and therefore it had to assure itself that the EPA's technical conclusions were founded on supportable data and methodology.[139] Aside from the arbitrary and capricious standard of procedural review, the other standard applied is the 'substantial evidence' standard. The substantial evidence standard is satisfied where there is evidence such as a reasonable mind might accept as adequate to support a conclusion.[140] Unfortunately, there is also evidence that this form of procedural review had also led to overly intrusive review. For example, in *Gulf South Insulation*, the court found that 'it is not good science to reply on a single experiment, particularly one involving only 240 subjects, to make precise estimates of cancer risk'.[141]

As we shall see in the subsequent Chapters contained in this thesis, the SPS Agreement attempts to do more than eliminate protectionist abuses.[142] It attempts to identify measures which are simply unnecessary irrespective of any protectionist intent being involved. The foregoing passage provides an understanding of the difficulties inherent for any judicial process in reviewing a 'legitimate' application of the precautionary principle. This is one of the main reasons why some of the interested parties in the global food regulatory arena are

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[137] Justice Marshall in *Citizens to Preserve Overton Park Inc v Volpe* 401 US 402, 91 S Ct 814, 28 L Ed 2d 136 (1971), para 416.

[138] *International Harvester Co v Ruckelshaus* 478 F 2d 615 (US Ct of Apps (DC Cir), 1973) – Judge Leventhal promised restraint but then dismantled the assumptions behind the EPA's determination on whether effective technology was available to meet and emissions standard; *Motor Vehicle Manufacturers Association of the US Inc v State Farm Mutual Automobile Insurance Co* 463 US 29, 103 S Ct 2865, 77 L Ed 443 (1983) ('State Farm'); *Ohio v EPA* 784 F 2d 224 (US Court of Appeals (6th Cir), 1986), where it was found that the EPAs failure to validate the accuracy of the air pollution model in the vicinity of the plants was arbitrary; *AFL-CIO v OSHA* 965 F 2d 962 (US Ct of Apps (11th Cir), 1992).

[139] *South Terminal Corp v EPA* 504 F 2d 646 (US Court of Appeals (1st Cir), 1974). The court found that the EPA's conclusions as to carbon monoxide levels were without reliable foundation and were therefore arbitrary and capricious.

[140] See *Consolidated Edison Co v NLRB* 305 US 197, 59 Supreme Court 206, 83 L Ed 126 (1938); *Aqua Slide 'N' Dive v CPSC* 569 F 2d 831 (US Court of Appeals, (5th Cir), 1978).

[141] *Gulf South Insulation v Consumer Product Safety Commission*, 701 F 2d 1137 (US Court of Appeals (5th Cir), 1983). See also *Industrial Union Department, AFL-CIO v American Petroleum Institute* 448 US 607, 100 Supreme Court 2844, 65 L Ed 2d, 1010 (1980); *Corrosion Proof Fittings v EPA* 947 F 2d 1201 (US Court of Appeals (5th Cir), 1991); *Ethyl Corp v EPA* 541 F 2d 1(US Court of Appeals (DC Cir), 1976); *Appalachian Power Co v EPA* 249 F 3d 1032 (US Court of Appeals (DC Cir), 2001); *Custer County Action Association v Garvey* 256 F 3d 1024 (US Court of Appeals (10th Cir), 2001).

[142] C. Button, note 105 Chapter 4 above, p.147.

reluctant to see its use legitimised. It represents another watering down of the role of science as the sole arbiter of sanitary measure legitimacy.

Ultimately, the problem with procedural review is that it does not go further than dealing with the protectionist aspect as it merely focuses on abuse of discretion.[143] As a result, it is unlikely that agreement could be found at the WTO to adopt the application of procedural review. Nonetheless, it seems apparent that in order to prevent its abuse, the precautionary principle should be complemented with additional basis of review. However, that also poses difficulties as it is likely to ultimately cause a WTO Panel to engage in an overly intrusive and prolonged in-depth investigation of the whole landscape behind the sanitary measure being introduced.

5.7 Public Risk Perception and the SPS Agreement

Before the industrial revolution, hazards assaulted the nose or the eyes and were thus perceptible to the senses. However, 'the risks of civilisation today typically escape perception and are localised in the sphere of physical and chemical formulas (e.g. toxins in foodstuff or the nuclear threat)'.[144] Consequently, the public perceive risk in a very different way to experts. It is a disparity that is fundamental to the problem of coping with risk and uncertainty, because when it comes to assessing risk based upon only a 'factual' scientific analysis, there is a problem. For example, if we take a dreaded event such as the meltdown of a nuclear-reactor core at a power station. If we suppose that the expert assessment of the probability of that happening is one in a million reactor-years or once every thousand years for every thousand reactors that exist. Therefore, it is an extremely small probability and most people would agree that such a risk is so small it is not worth worrying over and that more reactors should be constructed. Yet, the 'fear' of a nuclear meltdown disaster is so profound in the US that no nuclear station of any significance has been commissioned there for over twenty years.[145] Clearly, there is a marked disparity between what the public worry about and

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[143] M. Trebilcock and J. Soloway, "International Trade Policy and Domestic Food Safety Regulation: The Case for Substantial Deference by the WTO Dispute Settlement Body under the SPS Agreement" in D.L.M. Kennedy and J.D. Suthwick (eds) *The Political Economy of International Trade Law* (Cambridge: Cambridge University Press, 2002), p.553.

[144] U. Beck, note 79 Chapter 4 above, p.21.

[145] D. Pearse, "The Precautionary Principle and Economic Analysis" in T. O'Riordan and J. Cameron (eds), note 59 Chapter 2 above, p.140.

what the experts calculate as important. This disparity has major implications for regulatory policy in all areas.[146]

Indeed, social scientific investigations into risk have disclosed a close relationship between everyday culture and the nature of the risk perceived.[147] For example, the very nature of a public health problem and its underlying causes, as it exists within a given geographical area, is connected with that areas history and its identity. Therefore, the assessment of the risk and the resultant policies put in place to deal with it must take cognisance of the societal fabrics that are entwined with the problem. In contrast, any failure to address 'the situational context in which risks are generated and to ignore the insights that citizens have on the nature of those risks will prove problematic in trying to implement solutions to the issues'.[148] When intervention is necessary, it is important that implementation does not disenfranchise the very people who were deemed to be 'at risk' in the first place.[149] This contention is also pertinent to global multilateral food safety arrangements.

As we have seen earlier in this thesis, the fundamental difference in situational context exists between the EU and the US.[150] In the more industrialised US beef sector, many cattle-rearing operations are owned by large corporations. As a result, the power and interests of producers tend to shape regulations.[151] This is particularly so in the US where the business community has by far the largest number of lobbies working on its behalf.[152] This has a major effect on the formation of not just food safety regulation but also on the formation of risk perception in American food culture. Due to the greater corporate centred power extant in US beef production, the interested parties are able to influence US public risk perception. This thesis argues that this is possible due to the predominantly science based food safety system which discounts cultural considerations and is administered through FDA. The system is structured to create a public risk perception which is at best indifferent to the use of growth hormones in

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[146] In addition, this 'public risk perception' will only have been exacerbated by the recent nuclear-reactor meltdowns in Japan, similar to the manner in which EU public risk perception towards issues such as growth hormones in beef was exacerbated by various European food safety scares.

[147] D. Fischbacher-Smith, A. Irwin & M. Fischbacher-Smith, "Bringing Light to the Shadows and Shadows to the Light", in P. Bennett, K. Calman, S. Curtis, D. Fischbacher-Smith (eds), *Risk. Communication and Public Health,* 2nd edn (Oxford: Oxford University Press, 2010) p.32.

[148] *Ibid*, p.32.

[149] *Ibid*, p.32.

[150] As previously outlined in this thesis, EU food law enacted to date espouses traditional food production and processing methods whereas by contrast the US has been more receptive to food technology and somewhat sceptical of traditional methods.

[151] G.J. Stigler, note 157 Chapter 3 above, p. 3.

[152] See, M. Olson, note 24 Chapter 1 above, p. 142.

cattle. In contrast, there is little or no tradition in the EU of large corporate entities owning cattle rearing operations and, as outlined in the previous Chapters, our food safety regulatory system takes cognisance of culture and consumer interests. By contrast, the whole area of EU beef production is far less industrialised.

The question of public risk perception about sanitary risks has arisen most directly in the context of dispute settlement.[153] As evidenced by the *Beef Hormones Dispute*, sometimes consumers are adamant that a danger exists even when scientists remain unconcerned. Scientists cannot always predict the long term effect that the incorporation of a new food production technology into the food chain may have on human health. Whether the focus is on the food or the production process, food tradition and culture influences the public perception of risk. Intractable disputes such as the *Beef Hormones Dispute* have been precipitated by high levels of public concern about health risks associated with imported produce.[154] This indicates a systemic problem in the interpretation and application of the SPS Agreement.[155] The democratic approach to finding a solution to this problem would mean that when a WTO Member's population does not want to run a given risk, then that risk should not be enforced on them.[156] A careful consideration of the core SPS Agreement provisions shows that there is considerable scope within the SPS jurisprudence for a greater recognition of public risk perception in administrative decision making about risks to human health.[157] This can be managed in a way that combines both scientific and non-scientific aspects of risk decision-making.[158]

Therefore, in the context of risk perception, when scientific uncertainty arises, should it be possible for a WTO Member to defend its sanitary measures on the basis that its population will not accept the risk as they see it?[159] As the SPS Agreement currently stands, can its

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[153] See, C.E. Foster, note 5 above, p.429.
[154] *Ibid*, p.427.
[155] An agreement which has trade liberalisation as its main goal. C.E. Foster, note 5 above, p.427.
[156] Y. Bonzon, "Institutionalising Public Participation in WTO Decision Making: Some Conceptual Hurdles and Avenues" (2008) *Journal of International Economic Law*, Vol. 11(4), p.755.
[157] C.E. Foster, note 5 above, p.427.
[158] *Ibid*, p.427.
[159] In other words, should it be accepted that this is a valid element of an 'objective' assessment of the risk. A number of WTO cases have provided guidance on the nature of their standards of review a Panel is to apply to see if the Member carried out an objective assessment of the risk. See, *US-Restrictions on Imports of Cotton and Man-Made Fibre Underwear*, WT/DS24/R and *US-Transitional Safeguard Measure on Combed Cotton Yarn from Pakistan*, WT/DS192/AB/R. In *EC-Hormones*, the Appellate Body found that the standard of review applicable to SPS Agreement proceedings, must reflect the balance in that Agreement between the jurisdictional competences conceded by the Members to the WTO and the jurisdictional competences retained by the

provisions be interpreted in a manner that will permit an accommodation of public concern about an uncertain risk? And, in any event, is it not likely that the Panel[160] will form its own 'subjective' view of the risk based on each panellists own personal perception of that risk? For example, in the *EC-Hormones* case, the Panel's appreciation of the risk of developing cancer due to consumption of beef produced using growth hormones may well be different from the EU citizenry's appreciation of the same risk.[161]

As detailed in Chapter 8 of this thesis, to date, risk assessment under the SPS Agreement has been interpreted by the various Panels and Appellate Bodies as a purely scientific activity. *EC-Hormones*[162] was the first case brought under the SPS Agreement. Initially, in this case, the WTO Appellate Body expressed a denial of a distinction between risk assessment and risk management for sanitary measures, but as we shall see in the analysis of the *Beef Hormones Dispute*, this two-stage separation of risk analysis was eventually accepted. However, it appears that in a predominance of the cases decided to date by the WTO Dispute Settlement Body, an acknowledgement of any role for public opinion is regarded as an aspect of risk management.[163] In that context, it is important to note that in disputes brought under the SPS Agreement to date,[164] the approach taken by the WTO Dispute Settlement Body can ostensibly be divided into two sets of core requirements:

(i) the first set of requirements: as one would expect, is the need for SPS measures to have a scientific basis;[165] and

(ii) the second set of requirements: other requirements, such as the requirement that a member instigate only the least trade-restrictive food safety measure possible in order to ensure the level of risk protection demanded.[166]

Members for themselves. *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, (n.9), para 115.

[160] WTO Dispute Settlement Body Panels assembled to settle disputes brought under the WTO SPS Agreement.

[161] See generally, Y. Bonzon, note 156 above, p.762.

[162] *EC Measures Concerning Meat and Meat Products (EC-Hormones)*, WT/DS26/R.

[163] *Ibid*, paras 8.94 – 95.

[164] For example see, *EC-Hormones* case (WT/DS26/R/USA, WT/DS26/AB/R, WT/DS48), the *Australia-Salmon* case (WT/DS18/R, WT/DS18/AB/R), the *Japan-Agricultural Products II* case (WT/DS76/R, WT/DS76/AB/R), the *Japan-Apples* case (WT/DS245/R, WT/DS245/AB/R) and the *EC – Approval and Marketing of Biotech Products* case (WT/DS291/R, WT/DS292/R, WT/DS293/R).

[165] This is where 'risk assessment' comes in. Based on the interpretation evidenced in SPS Judgements handed down to date, these provisions requiring that SPS measures be based on scientific grounds and on risk assessments are comprised in Articles 2.2, 5.1, and 5.7 of the SPS Agreement.

[166] This is where 'risk management' comes into play based on this interpretation. These provisions are comprised in Articles 5.5 and 5.6 of the SPS Agreement. They impose an obligation on a member to avoid

Indeed, if one takes that insight further, in the majority of cases decided to date[167] under the SPS Agreement, the decisions have predominantly been based on the first set of requirements relating to scientific risk assessment.[168] In other words, the second set of requirements listed above do not hold as much significance at the WTO. However, while public risk perception has been acknowledged as having a potential role to play, it has been placed with the second set of requirements - a group of measures which do not in any event influence WTO Panel/Appellate Body decisions.[169]

Consequently, this thesis would argue that it is unfortunate, that the important consideration of public risk perception would not be included as part of the risk-analysis based on the first set of requirements. In other words, as the analysis in this thesis of the *Beef Hormones Dispute* will evidence, such consideration appears to be excluded from the scientific considerations.[170] As we shall see, in the *Beef Hormones Dispute*, under WTO interpretation of the SPS Agreement, the taking into account of public risk perception and with it risk management, is something that would be governed by the second set of requirements.[171]

In relation to risk assessment, basically, Article 2.2 of the SPS Agreement requires that measures be based on scientific principles and not be maintained without sufficient scientific evidence. Then, Article 2.2 refers to Article 5.7, which permits the potential application of SPS measures, based on the information then available, on a temporary or provisional basis when the scientific evidence is insufficient. However, generally, all SPS measures must to be based on a full risk assessment in accordance with Article 5.1[172] of the SPS Agreement,[173]

'arbitrary or unjustifiable distinctions' in the levels of protection that Members consider appropriate in different situations, i.e. when these distinctions result in discrimination or a disguised restriction on imported food items.

[167] For example, *EC-Hormones* case (WT/DS26/R/USA, WT/DS26/AB/R, WT/DS48), the *Australia-Salmon* case (WT/DS18/R, WT/DS18/AB/R), the *Japan-Agricultural Products II* case (WT/DS76/R, WT/DS76/AB/R), the *Japan-Apples* case (WT/DS245/R, WT/DS245/AB/R) and the *EC – Approval and Marketing of Biotech Products* case (WT/DS291/R, WT/DS292/R, WT/DS293/R).

[168] i.e. Articles 2.2, 5.1, and 5.7 of the SPS Agreement, which set out the basic requirements that SPS measures be based on scientific grounds and on risk assessments. See, C.E. Foster, note 5 above, p.430.

[169] As we shall see later in this thesis, this does not necessarily have to be the approach. In the *EC-Hormones* Appeal, when commenting on risk assessment under Article 5.2 of the SPS Agreement, noted that the factors to be taken into account was not necessarily intended to be a closed list and the risk that is to be evaluated in a risk assessment under Article 5.1 is not just risk ascertainable in a science laboratory, but also risk in human societies as they actually exist – the actual potential for damaging human health in the real world. See *EC-Hormones* Appellate Body Report paragraph 187. Therefore, a much wider interpretation of the issues to be included in a risk-assessment may be possible.

[170] See, C.E. Foster, note 5 above, p.430.

[171] *Ibid*, p.430.

[172] Possibly the most influential procedural discipline in the SPS Agreement.

except where Article 5.7 applies, or else where the SPS measures applied conform to international standards.[174] Article 5.7 represents a specific meaning of the precautionary principle.[175] However, for example, the interpretation taken by the WTO Panel in *Varietals*[176] has been rather restrictive.[177]

The second set of SPS Agreement requirements requiring a Member instigate only the least trade-restrictive food safety measures possible, is governed by Articles 5.5 and 5.6. In relation to the levels of protection that Members consider appropriate in different situations, Article 5.5 imposes an obligation to avoid arbitrary or unjustifiable distinctions, where such distinctions would create a disguised restriction on international trade. Article 5.6 requires WTO Members to ensure that their sanitary measures are not any more trade-restrictive than necessary in order to achieve the appropriate level of sanitary protection.

It is under this entitlement to set their own level of protection against a risk, under Articles 5.5 and 5.6 of the Agreement, that a member's capacity to take into account public risk perception has been accommodated. However, this has not been involved in determining the compliance of a Member's measures under Articles 2.2, 5.1, and 5.7 – i.e. since only first the set of provisions have been applied anyway.[178]

In the context of 'risk', this thesis submits that it is this very equivocation in thinking under the SPS Agreement that has given rise to the intractable nature of the *Beef Hormones Dispute* and also the implicit determination by the Panels and Appellate Bodies to regard the first set of requirements under Articles 2.2, 5.1, and 5.7 of the SPS Agreement as excluding any consideration of public risk perception.[179]

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[173] Article 5.1 of the SPS Agreement provides: 'Members shall ensure that their sanitary ... measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations'.

[174] See Article 3.2 of the SPS Agreement. International standards such as Codex standards.

[175] P. 201 of Panel Report WT/DS26/R and WT/DS48/R and Paragraph 253 of Appellate Body Reports WT/DS26AB/R and WT/DS48/AB/R.

[176] *Japan – Measures Affecting Agricultural Products*, WT/DS76 – 'Varietals'. A case which was brought before the WTO Dispute Settlement Body shortly after *EC-Hormones*.

[177] At paragraph 8.46, p.113 of the Panel Report in *Varietals*, the Panels states that '[w]e ... need to examine next whether the varietal testing requirement is a measure meeting the requirements in Article 5.7. If the varietal testing requirement meets these requirements, we cannot find that it violates Article 2.2'. However the Panel found that Japan had failed the second part of Article 5.7 in that they hadn't made the sufficient efforts necessary 'to obtain the additional information necessary for a more objective assessment of risk'. *Japan – Measures Affecting Agricultural Products*, WT/DS76/R, para 8.59, p.116.

[178] See, C.E. Foster, note 5 above, p.431.

[179] *Ibid*, p.431.

The ultimate problem is that an overly rigid interpretation of risk assessment and regulation under the SPS Agreement could actually cause inadequate risk assessments, subject human to undue risk, and undermine the WTO legitimacy. In the next Chapter we will consider the merits and shortcomings of the SPS Agreement in more detail, in order to see if culture and risk-perception can be better accommodated into the WTO Dispute Settlement Process.

5.8 Conclusion

EU citizens perceive the risk associated with consuming hormone produced beef as being at best, unknown, and EU consumers do not trust the unknown.[180] It is this unknown element of the risk that informed EU public opinion and exacerbated or increased the magnitude of public outrage.[181] In Europe, the already existing adverse public risk perception was caused by a number of contextual factors, such as EU reverence for tradition[182] in the food supply and especially, various food health scares not least of all Bovine Spongiform Encephalopathy. Events such as food health scares do not in themselves produce changes in legal arrangements. However, they lead to changes in what people expect from law and this may set off a process which will, in the end, produce legal change. Therefore, it is forces such as these that create a system of law. These forces represent the aggregate demands which flow from the legal culture.[183]

For example, if the public fears a particular risk and in addition concludes that it is insufficiently safeguarded by the existing regulations, then there is an increased incentive to join and support consumer groups. Those consumer groups can then exert powerful influence over the form of regulatory enactments. Widespread public aversion to a clearly identifiable

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[180] U. Kjaernes, A. Dulsrud & C. Poppe, "Contentions Over Food Safety: The Significance of Consumer Trust" in C. Ansell and D. Vogel (eds), *What's the Beef? The Contested Governance of European Food Safety* (Massachusetts: The MIT Press, 2006), p.68. See also, G. Skogstad, "Regulating Food Safety Risks in the European Union: A Comparative Perspective" in C. Ansell and D. Vogel (eds), *What's the Beef? The Contested Governance of European Food Safety* (Massachusetts: The MIT Press, 2006), p.222.

[181] E. Groth, *Consumer Perceptions of and Responses to Potentially Hazardous Technologies* (Vienna: International Consultative Group on Food Irradiation, 1994): Document no. 18, p. 123 as cited in E. Meins, note 180 Chapter 3 above, p.94.

[182] Due to globalisation of the food supply, EU consumers feels alien to the food and its method of production. This lack of familiarity with their food leaves consumers ill at ease. This is especially the case with EU consumers when met with foreign food manufactured with the aid of a new food technology.

[183] L. M. Friedman, note 10 Chapter 1 above, p. 28.

risk, improves consumer group collective action potential.[184] EU consumer groups were therefore successful in influencing the relevant institutional EU bodies to adopt stringent regulations governing animal growth hormones. EU regulatory activity in the area of growth hormones, has served to illuminate how an organized consumer lobby, motivated by their risk perception, can affect decisive political influence. It is simply public pressure made effective through the EU privilege of institutional access to the European Parliament. In contrast, the use of animal growth hormones was already long established in the US – it is a cultural norm there. As a result US consumers perceive the potential risk through their own cultural model and perceived little or no risk in consuming beef produced with growth hormones.

When culturally divergent public risk perceptions collide, they create difficulties for the harmonious operation of international trade arrangements and agreements. As we have seen, the most fundamental norm of EU food safety law is that food may not be placed on the market if it is unsafe.[185] The question that arises is what level of caution should the EU authorities exercise and which method of exercising that caution should they adopt? When science cannot be 100 per cent certain, should it be possible for a WTO Member to defend its sanitary measures on the basis that its population will not accept the risk as they see it? However, the democratic approach to finding a solution to intractable trade disputes such as the *Beef Hormones Dispute* would suggest that when a Member's population does not want to run a given risk (as they 'perceive' it), then that risk should not be enforced on them. New technologies have to be tested over time. In the intervening period, consumers do not want market driven initiatives to dictate government heath policy. Even those that are particularly 'sceptical about the value of popular perceptions of risk in risk management would accept that there are situations in which they ought to find expression'.[186]

As we shall see, in *EC-Hormones* the WTO Panel noted that governments were required to act from 'perspectives of prudence and precaution where risks of irreversible damage to human health are concerned'.[187] As analysed in the next Chapter, the Article 5.7 precautionary provision of the SPS Agreement may yet present the best means for adopting a wait and see

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[184] E. Meins, note 179 Chapter 3 above, p.94.
[185] Article 14 of European Parliament and Council Regulation (EC) No 178/2002, note 72 Chapter 2 above.
[186] J. Scott, *The WTO Agreement on Sanitary and Phytosanitary Measures: A Commentary* (Oxford: Oxford University Press, 2007) p.150.
[187] See Paragraph 124 of WTO Appellate Reports WT/DS26AB/R and WT/DS48/AB/R where the Appellate Body concurred with the Panel's finding in this regard.

approach.[188] It is here that a Member might consider taking public risk perception into account when setting food safety precautions. The analysis of the SPS Agreement contained in the following Chapter will elucidate the matter further before moving on to see what lessons can be learned from how the *Beef Hormones Dispute* was handled by the WTO Dispute Settlement Body.

[188] Article 5.7 of the SPS Agreement provides that 'In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary ... measures on the basis of available pertinent information ...'.

CHAPTER 6

SANITARY MEASURES AND THE SPS AGREEMENT AS ARBITER OF THE LEGITIMACY OF CULTURE AND SCIENCE

6.1 Introduction

Historically, Article XX(b) of the GATT condemned domestic taxes or regulations that discriminated against imported goods and constituted a barrier to trade.[1] Although some constraints had been applied by Article XX(b) of GATT, it was believed that some countries used food safety concerns as a means of justifying the creation and maintenance of food regulations against imported foods, which were a barrier to trade. However, there was no specific provision of the GATT aimed at verifying the justification for the measures, nor was there any other international agreement capable of doing so. Accordingly, where a country asserted a justification of food safety, then that assertion could not be questioned or removed. Consequently, an agreement was needed that would act as a mechanism for dealing with this precise problem.

The most significant development in this area was the creation in 1995 of the World Trade Organization (WTO). This development was particularly significant because unlike the already existing UN organizations such as the World Health Organisation (WHO) or the Food and Agricultural Organization of the United Nations (FAO), the WTO has a binding dispute settlement mechanism reinforced by its ability to impose sanctions. As a result, when

[1] The GATT was the only multilateral instrument governing international trade from 1945 until the establishment of the WTO in 1995. The WTO has replaced GATT as an international organization. However, the General Agreement still exists (as updated by the Uruguay Round negotiations) as the WTO umbrella treaty for trade in goods. There is GATT 1994 which is the updated version and at the heart of that Agreement is the original GATT 1947.

a country fails to follow its rules, that country does so in the knowledge that it could be penalised accordingly.[2]

Attached to the short Marrakesh Agreement establishing the WTO, is a much lengthier set of four annexes[3] which contain the other multilateral international trade agreements[4] together with the rules and procedures governing the operation of the Organization. Annex 1A of the WTO Agreements contains the multilateral agreements[5] on trade in goods such as the Agreement on Agriculture[6] and the SPS Agreement.[7] The SPS Agreement heralded the arrival of an agreement for the first time in international trade, which provides that any restrictions on food products imposed with the objective of protecting human or animal health or the environment should not only be non-discriminatory, but should also be based on sound science and risk analysis. The SPS Agreement created a means by which a country could impose bona-fide health-related measures or, alternatively, prevent a trading partner from imposing measures for purely protectionist reasons.[8]

The science based SPS Agreement imposes strict scientific justification requirements in an effort to eliminate protectionist or unnecessary non-tariff barriers to trade.[9] In respect of food law, this thesis argues that an over reliance on science as a basis for legal reasoning will

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[2] The organization is currently dealing with a trade negotiation called the Doha Development Agenda (or Doha Round), which was launched in 2001. The Doha Round is intended to enhance equitable participation of many poorer countries representing a majority of the world's population. However, to date the negotiations have been stymied by disagreement between exporters of agricultural bulk commodities and countries with large numbers of subsistence farmers, regarding the precise terms of a 'special safeguard measure' to protect those farmers from any surges in imports.

[3] Annex 1A contains the multilateral agreements on trade in goods (containing the substantive trade policy obligations which all WTO members have accepted) such as the Agreement on Agriculture and the SPS Agreement, Annex 1B contains the General Agreement on Trade in Services, Annex 1C contains the Agreement on Trade Related Aspects of International Property Rights, Annex 2 contains the Rules and Procedures Governing the Settlement of Disputes, Annex 3 contains the Trade Policy Review Mechanism, and Annex 4 contains the plurilateral trade agreements such as the International Dairy Agreement and the International Bovine Meat Agreement.

[4] These Agreements comprise the substantive trade policy obligations which all WTO members have accepted.

[5] These Agreements they comprise the substantive trade policy obligations which all WTO members have accepted.

[6] The Agreement on Agriculture caps 'acceptable' agricultural import and export subsidies and it also subjects such subsidies to reduction commitments. Unless the subsidies are explicitly listed in the agreement, they are in principle prohibited.

[7] Agreement on the Application of Sanitary and Phytosanitary Measures, opened for signature 15 April 1994, 1867 UNTS 493 (entered into force 1 January 1995). Since 1995, the SPS Agreement has provided an enforceable set of rules based on science and risk analysis, directed at ensuring that food safety as well as animal and plant health regulations are used for health protection purposes and not as a means of trade protectionism. It is as an attempt at balancing the competing spheres of domestic regulatory autonomy as against global harmonization of product standards.

[8] M.D. Carter, note 149 Chapter 2 above, p.632.

[9] C. Button, note 105 Chapter 4 above, p.103.

divest a legal system of other attributes. However, in order to understand the complex interactions between different determinants and the impact that they have on health, it is necessary to use science. This use of science also assists in identifying the correct policy measures. Science is used to monitor the impact of decisions that have already been taken, to assess the success rate and to identify the corrections needed on a case by case basis.[10]

The WTO Agreement and its Annexes define the rights and the obligations of WTO Members and are designed to direct each Member's polices toward trade liberalisation. In layman terms, what the WTO Members have agreed is that if a fellow Member violates trade rules, the Members will use the WTO multilateral dispute settlement system instead of taking action unilaterally. To do so, they would refer the matter to the WTO Dispute Settlement Body (DSB).[11] Usually, a dispute arises when one country implements a change in their trade policy or commits some act which the other WTO Members regard as a breach of the WTO agreements. The offended Member government (the 'complainant') may take a case against another Member government (the 'defendant') setting out its objections to the trade measures of the defendant government.[12] Insofar as the WTO deals with contentious disputes, it is true to state that food occupies a central role within it. For example, of the 380 or so disputes initiated, between WTO inception in 1995, and 2008, over a third involved food. In this regard, except for 'metals', no other product category came close.[13] Indeed, cultural disagreement over trade in the products of modem science is the latest and one of the most volatile areas of modern EU-US economic conflict.[14]

Where possible, EU food law must conform to these WTO obligations.[15] However, except for the *Beef Hormones Dispute* which is examined in detail later in this thesis, few other circumstances have yet arisen that would allow important provisions of the SPS Agreement agreements effecting food to be fully addressed by the WTO DSB Panels and Appellate Bodies. Notwithstanding this, the domestic regulation disputes that have arisen to date have

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[10] See generally, V. Silano, note 55 Chapter 2 above, p.400.
[11] The Dispute Settlement Body (which is effectively the General Council in another guise) consists of all WTO members.
[12] In addition, a third group of countries can declare that they have an interest in the case, by notifying the WTO and confirming that they have a 'substantial interest' in the case.
[13] M. Bronckers & R. Soopramanien, note 131 Chapter 2 above, p.361.
[14] C. Carlane, note 1 Chapter 2 above, p.304.
[15] C. MacMaolain, note 58 Chapter 2 above, p.149.

revealed that the SPS Agreement has far-reaching implications affecting a Member's right to set its preferred levels of regulatory protection.[16]

The use of WTO dispute settlement procedures[17] as a means of resolving trade disputes caused by sanitary measures can be viewed as an indication of the effectiveness of the SPS Agreement. However, while a number of trade problems have been resolved at the bilateral level, without recourse to a Dispute Settlement Panel, the same cannot be said of the *Beef-Hormones Dispute*. US consumer organisations have never broadly campaigned against the use of hormones and one of the main reasons for this is simply because US consumers assume that the hormones pose no risk to human health – a stark cultural divergence from the attitude of EU consumers. Consumers in the EU are uncertain about the efficacy of the scientific evidence supporting the safety of hormones. Therefore, we are not merely dealing with a protectionist issue. What if EU citizens do genuinely fear growth hormone residues in beef? One can ask the question as to whether or not the EU could maintain such a protectionist stance without popular support for the ban? The answer would appear to be 'no'. Therefore, in the EU, there is popular support for the ban on growth hormone use.[18] As outlined in Chapter 4 of this thesis, this support can be traced to various historical experiences, especially food health scares, and the resultant cultural values imbued. It is these events that have caused most EU consumers to fear the use of growth hormones in cattle. Therefore, this thesis argues that it is disingenuous of US officials to dismiss the ban as merely a form of EU protectionism over its food sector.

6.2 Culture, Trade Conflict and the SPS Agreement

Worldwide, 2.5 billion people are still directly dependent on agriculture, yet access to food is severely inequitable. There is massive over production and over consumption with approximately one billion people overweight.[19] Yet, conversely, a multitude experience

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[16] M. Bronckers & R. Soopramanien, note 131 Chapter 2 above, p.361.

[17] The Dispute Settlement Understanding of the WTO outlines the procedures for resolving conflict between Members, including a fourteen month timetable within which DSU proceedings are to be completed. Article 11 of the SPS Agreement provides that 'the provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the WTO Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement'.

[18] See B. Silverglade, note 184 Chapter 3 above, p.85.

[19] Approximately 300 million people are officially obese. *See* WHO '*Obesity & Overweight*' Fact-sheet No.311, February 2011.

scarcity and hunger with approximately 850 million people being currently undernourished.[20] This global imbalance in the food supply is one of the issues that we are concerned with insofar as it is related to trade in food - issues such as whether or not a particular country can export certain food produce, or the regulations that the food item must comply with before it can be exported. In an exceptionally competitive market, the actors in this food system vie for control over production and supply, seeking to minimise the risks they face and maximise the gains which inure for their benefit.

Unfortunately, the disparate development of food laws and standards around the world, result in different sets of standards operating in individual counties and territories. Disparate sanitary measures oftentimes act as a barrier to trade especially where the importing nation operates a more onerous set of sanitary measures concerning the goods in question. By providing a common lexicon for both food quality as well as safety, food laws can assist in facilitating the free movement of goods within economic confederations such as the EU and the US, and also internationally between trading nations.

When it comes to the liberalisation of international trade, the traditional involvement of the state in matters cultural is called into question. The relationship between culture and trade is oftentimes cast as a conflict between protectionism and liberalisation.[21] The GATT has the liberalisation of international trade as its main objective and its standard is non-discrimination between the trading partners. Indeed, all of the WTO Agreements reflect the goal of trade liberalisation as a means to achieve broader social and economic objectives.[22] This is the core objective of all these Agreements including the SPS Agreement. As noted by the FAO,[23] both the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the

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[20] There were approximately 960 million people malnourished in the world, in 1970. Today, at 850 million malnourished, the figure has dropped by only 100 million. This is despite governments over the last forty years or so having made commitments to end hunger – most recently at the World Food Summit in Rome in 1996. See FAO, www.fao.org/faostat/foodsecurity/index_en.htm

[21] When a Member feels that embargos are implemented for protectionist reasons, they will seek redress under the SPS Agreement. One of the most recent cases to come before the WTO is the United State's Request for Consultations of 8 March 2012 in '*India – Measures Concerning the Importation of Certain Agricultural Products from the United States*' WT/DS430/1. This dispute has arisen because of prohibitions imposed by India on the importation of various agricultural products from the United States purportedly because of concerns related to Avian Influenza.

[22] T. Voon, note 11 Chapter 4 above, p.4.

[23] See FAO and WHO, "The Codex system: the Codex Alimentarius Commission and How it Works", note 12 Chapter 2 above.

Technical Barriers to Trade (TBT) Agreement,[24] encourage the international harmonisation of food standards.[25]

As outlined above, trade in food is central to several of the WTO Agreements, in particular the Agreement on Agriculture, the Agreement on Technical Barriers to Trade (TBT),[26] the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) and the Agreement on Sanitary and Phytosanitary Measures (SPS). In the context of this thesis, we are concerned with whether or not issues other than science and especially cultural interests are safeguarded under the terms of the SPS Agreement. This is central to the *Beef Hormones Dispute* between the EU and the US which is analysed in greater detail later in this thesis.[27] The WTO agreements have a significant influence over the manner in which any region regulates its food sector. Indeed, the WTO agreements may be the main external threat to EU autonomy in the manner in which the EU regulates its indigenous food industry.[28]

Unfortunately, the relationship between culture and trade is oftentimes synonymous with the two contradictory tenets of protectionism and liberalisation. This also leads to an ideological debate. For many, culture is an expression of national identity, part of a nation's soul and as such is not up for negotiation. There must be regulatory measures in place to defend the national interest. As a result, disputes involving goods which are imbued with some cultural element are more likely to invoke protectionist norms with greater intervention by national government. Conversely, many see goods purely in economic terms. For them, trade liberalisation is paramount and free-market economics strives for the creation of a level playing field, a place where goods can intermingle and compete subject to market forces without government intervention.

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[24] Agreement on Technical Barriers to Trade (1868 U.N.T.S. 120)

[25] The SPS Agreement exclusively covers food related measures dealing with public or animal health, while the Technical Barriers to Trade ('TBT') Agreement essentially addresses regulatory measures taken in furtherance of objectives other than those of the SPS Agreement.

[26] The SPS Agreement exclusively covers food related measures dealing with public or animal health, while the TBT Agreement essentially addresses regulatory measures taken in furtherance of objectives other than those of the SPS Agreement.

[27] The *Beef Hormones Dispute* has major ramifications for international trade and not just in beef, because in retaliation, the exporting country may impose tariffs on other goods as a result. For example, this is clear from the comments made by Dr. Harcharick at Page 1 of the Fiftieth Report of the joint FAO/WTO Expert Committee on Food Additives, when he stated that the beef hormone dispute clearly emphasized the importance and possible impact of the Committees work, on international trade. See the Fiftieth Report of the joint FAO/WTO Expert Committee on Food Additives, WTO Technical Report Series 888, (Geneva, 1999), Available at: http://whqlibdoc.who.int/trs/WHO_TRS_888.pdf [Accessed: 20 March, 2012].

[28] C. MacMaolain, note 58 Chapter 2 above, p.134.

Under the SPS Agreement, non-tariff barriers to trade are not allowed unless there is scientific evidence to suggest that a product is unsafe. However, despite what some would regard as a lack of solid scientific evidence to show that beef treated with growth hormones is unsafe for human consumption, the EU claims that public health concerns constitute a valid basis for their implementation of trade restrictions. The US maintains that the EU import ban on hormone treated beef protects domestic agricultural prices by limiting international competition. When it comes to any attempt at an assessment of EU consumer sentiment towards hormone treated beef, it must be noted that the stance taken by the EU towards growth hormones may in itself have exacerbated consumer concerns, which are now cited as the motivation and justification for the trade barrier.[29]

This thesis posits that one of the main reasons there has been minimal integration of global food laws, is due to a failure to acknowledge the place of culture. Open trade oftentimes culminates in trade-conflict between nations. As this thesis argues, trade conflict is usually caused by distinctive cultural attitudes towards food. Aside from the obvious food proclivities based on ethnicity, these distinctive attitudes exist both at the national and supranational level. These divergences in attitude towards food eventually transpose into cultural regulatory divergences. The disparities in transatlantic food regulation can therefore be ascribed to distinctive European and American food cultures.

Global free trade has been lauded as a mechanism that ensures an efficient allocation of resources, an increase in the variety of goods available to consumers, a lowering of the prices of those goods and the general promotion of better world citizenship through peaceful cooperation and exchange. As a result, it is necessary to encourage the international harmonisation of the regulations that impinge upon trade, not least of all food regulation. SPS acknowledges that its members must have freedom to take measures necessary for the protection of life and health of people, animals and plants.[30] Yet, the SPS Agreement is designed to deal with situations where standards are not harmonised and a trade dispute erupts. However, it order to maintain public confidence in food safety and support for free trade, this international harmonisation of food standards must occur in an upward direction.[31]

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[29] J. L. Lusk, J. Roosen & J. A. Fox, "Demand for Beef from Cattle Administered Growth Hormones or Fed Genetically Modified Corn: A Comparison of Consumers in France, Germany, the United Kingdom, and the United States" (2003) *American Journal of Agricultural Economics*, Vol.85, Issue 1, p.16.

[30] Article 2.1 of the SPS Agreement.

[31] B. Silverglade, note 184 Chapter 3 above, p.83.

Globalisation and trade liberalisation can promote more stringent standards of consumer protection by acting as a medium for the dispersal of the prevailing policy preferences of large markets.[32] Sometimes, the trading partners of the more powerful nations are forced to choose between meeting the higher (food safety) standards or risk losing access to an important export market.

6.2.1 Influence of WTO Rules on Domestic Food Safety Regulations

Where possible, EU food law must conform to WTO obligations.[33] However, it is still early days for the various WTO tribunals in clarifying the full scope of the rights and obligations contained in the WTO agreements affecting food. Notwithstanding that, the trade disputes that have arisen to date have revealed that the SPS and TBT Agreements have far-reaching implications affecting a Member's right to set its preferred levels of regulatory protection.[34]

The very existence of the WTO rules and EU deference as a WTO Member, can affect the nature of EU food laws. On occasion, this may even influence the EU to amend already enacted regulations. If one consider for example Regulation 2081/1992[35] which established a system for the protection of geographical food indications. It was found that a situation existed which amounted to a curtailment of access to the EU registration system for applicants from third countries and as a result the legislation had to be ameliorated. In circumstances such as this, where there is an emphasis on prompt compliance with the findings of WTO Panel reports, the dispute resolution process can be deemed a success. However, such situations can be contrasted with the delays that took place in reaching a decision on the EU moratorium on the approval and use of GMOs.[36] The procrastination or obfuscation in that instance only serves to diminish the impact of a ruling once it ultimately arrives.

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[32] See generally, D. Vogel, *Trading Up - Consumer and Environmental Regulation in a Global Economy* (Cambridge, MA: Harvard University Press, 1995).
[33] C. MacMaolain, note 58 Chapter 2 above, p.149.
[34] M. Bronckers & R. Soopramanien, note 131 Chapter 2 above, p.361.
[35] These provisions are now contained in Council Regulation 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs. [2006] O.J. L93/12.
[36] C. MacMaolain, note 58 Chapter 2 above, p.150.

With regard to the situation regarding GMOs, the EU actions were initiated in the late 1990s, but the WTO Panel Report[37] did not issue until late 2006.[38] This was nearly a decade after the trade inhibiting actions of the EU had first been implemented. By September 2006, EU public concern over the use of GMOs in food production had already died down.[39] The EU has established a legal framework regulating genetically modified (GM) food and feed in the EU.[40] The Regulation is supplemented by Regulation (EC) 1830/2003[41] which ensures traceability and labelling of GMOs placed on the market.[42]

6.2.2 SPS Agreement and the Codex Alimentarius

As already outlined in this thesis, due to globalisation of the food supply, there has been a decline in the capacity of government and national authorities to meet public demand for standards, and yet ironically they are faced with increasing public demand for those standards. While the most obvious solution to this problem is a single set of international food standards to which every trading nation adheres. However, this is likely to be highly contested in practice due to the international diversity between cultures, oftentimes displaying diametrically opposed ideas and interests when it comes to food.

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[37] Reports of the World Trade Organisation Dispute Settlement Panel in, *European Communities — Measures Affecting the Approval and Marketing of Biotech Products;* United States (WT/DS291/R), Canada (WT/DS292/R), and Argentina (WT/DS293/R), (29 September, 2006).

[38] On 29 September 2006, a World Trade Organisation Dispute Panel circulated its final report in the international trade dispute over the European Communities' implementation of rules and procedures for approving the growing of genetically modified crops and the sale of GM food. The dispute had been initiated by the United States, Canada and Argentina.

[39] GM crops continue to create problems. In a recent case, the Court of Justice has ruled that honey containing traces of GM products, even if they exist unintentionally, 'must always be regarded as food produced from a GMO'. The case arose out of an action brought by a German beekeeper who demanded compensation due to having been prevented from selling his honey because it was found to contain minute traces of GM pollen. The ruling may give rise to compensation claims by food producers against biotech companies such as Monsanto or governments which authorise test fields, in the event that cross-contamination occurs. See, Case C-442/2009, *Karl Heinz Bablok and Others v Freistaat Bayern* O.J. C311/7.

[40] Regulation (EC) 1829/2003 of the European Parliament and of the Council of 22 September 2003on genetically modified food and feed, [2003] O.J. L268/1. The framework pursues the global objective of ensuring a high level of protection of human life and health and welfare, environment and consumer interests, whilst ensuring that the internal market works effectively.

[41] Regulation (EC) 1830/2003concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, [2003] O.J. L268/24.

[42] Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, O.J. L106/1.

True and complete harmonisation of food standards can only be achieved when all trading nations adopt the same standards. The Codex Alimentarius (Codex)[43] is the most important international standard.[44] Codex standards can be fully accepted, accepted with minor deviations, or accepted by 'free distribution' by the Member Countries of Codex. In practice, it can be difficult for some countries to include the Codex standards in their statutory code, because differing legal systems, political concerns and sometimes the influence of national attitudes and concepts of sovereign rights impede the progress of harmonisation and deter the acceptance of Codex standards.[45] Notwithstanding this, the process of harmonisation still maintains a certain impetus due to the overriding international imperative of facilitating trade. As a result, countries continue to align either part (especially those relating to safety) or all of their national food standards and sanitary measures with those of Codex. According to the FAO, this is particularly so in the case of the 'invisibles', namely, additives, contaminants and residues.[46]

If Codex standards can achieve the intended level of consumer protection, then the SPS Agreement commits WTO Member governments to using Codex standards for their domestic sanitary regulations. Article 3.1 of the SPS Agreement requires Members to base their SPS measures on recognised 'international standards, guidelines or recommendations'.[47] Definition 3(a) of Annex A to the SPS Agreement defines 'international standards, guidelines and recommendations' in respect of food safety as, 'the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice'. Therefore, even if the national or supranational SPS risk regulations are non-discriminatory in nature, if they depart from the

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[43] The Codex Alimentarius Commission is often simply referred to as 'Codex'. Codex was formed in 1962 to facilitate the development of trade in foodstuffs. It is run under the aegis of the United Nations Food and Agricultural Organization (FAO) and the World Health Organization (WHO).

[44] The Codex Alimentarius is a collection of internationally recognized standards, codes of practice, guidelines and recommendations relating to foods, food production and food safety. The World Trade Organization utilizes the Codex Alimentarius as an international reference point for the resolution of disputes concerning food safety and consumer protection. Because virtually all states of the world are represented in the Codex Alimentarius Commission, the Codex is very useful as a benchmark in comparative food law. See, B. M. J. van der Meulen, note 67 Chapter 2 above, p.323.

[45] See FAO and WHO, "The Codex system: the Codex Alimentarius Commission and How it Works" note 12 Chapter 2 above.

[46] *Ibid.*

[47] A point often overlooked, which is particularly relevant in the realm of private standards, is that there 'must be sufficient government involvement' for the SPS Agreement to apply. See *Japan–Measures Affecting Consumer Photographic Film and Paper*, WT/DS44/R, para 10.56. In addition, the measure must be 'dependent on government action or intervention'. See *Japan – Trade in Semi-Conductors* (GATT Panel, L/6309-35S/116)

standards of recognised international bodies such as the Codex Alimentarius and if they are found to be trade restrictive,[48] then it is scientific evidence and risk assessment that are the arbiters of WTO-compatibility.[49]

However, this does not imply that the Codex standards are mandatory on WTO Members. The major qualification is that contained in Article 3.3 of the SPS Agreement which states that:

> [m]embers may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary ... protection than would be achieved by measures based on the relevant international standards ... if there is a scientific justification, or as a consequence of the level of sanitary ... protection a Member determines to be appropriate in accordance with the relevant provisions ...

Linked to this permission is a footnote designed to clarify the operation of the term 'scientific justification'. The footnote states:

> ... there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards ... are not sufficient to achieve its appropriate level of sanitary ... protection.[50]

6.3 Difficulty with Science Based Risk Regulation

The GATT and the SPS Agreement set the global stage for science based food law.[51] The WTO Agreements recognise that it may be necessary to create some exceptions to these goals

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[48] J. Peel, note 44 Chapter 3 above, p.171.

[49] J. Pauwelyn, "The WTO Agreement on Sanitary and Phytosanitary (SPS) Measures as applied in the First Three SPS Disputes: EC – Hormones, Australia – Salmon, and Japan – Varietals", *Journal of International Economic Law*, Vol.2, Issue 4, 1999, p.644. at J. Peel, note 44 Chapter 3 above, p.171.

[50] Note 2 to the SPS Agreement.

[51] The SPS Agreement was negotiated during the Uruguay Round of trade-talks which also led to the establishment of the WTO.

and certain of these exceptions are contained in SPS.[52] To this end, SPS acknowledges that its Members must have freedom to take measures necessary for the protection of life and health of people, animals and plants.[53] Under the SPS Agreement, the WTO Members must ensure that sanitary measures are applied only to the extent as is necessary to protect the life and health of people, animals and plants, and that any such measures are based on scientific principles and are not maintained unless there is sufficient scientific evidence.[54] This thesis argues that, from a cultural perspective, a food safety regulatory mechanism that is predominantly science orientated must by definition limit the influence of culture. Cultural values should play a vital role alongside scientific knowledge, in informing regulatory approaches to risk. Unfortunately, oftentimes at the international level, these considerations have not limited the appeal of science as a resource for risk decision making where international institutions employing global regulatory constructs seek the acceptance of their determinations as neutral and universally valid.[55] Because it is predominantly science based, the SPS Agreement limits the ability of a country to apply only local or indigenous food safety norms. While this can be justified through the prism of creating a global food law, it can also be criticised because it displaces indigenous attitudes towards food safety that are centuries old.

However, as already stated, this thesis argues that there is rarely an instance where science based evidence in food safety can be said to be conclusive. In addition, it is never possible to test for all possible health risks. At best, the scientific consensus is only as good as the research and the statistical processes underlying it. Science can only ever confirm that there is no evidence of risk, whereas the consumer is asking for evidence of no risk.[56] However, the scientific evidence criteria, is one of the pillars of the SPS Agreement.[57] Therefore, in the context of this thesis, the issue is whether or not this exception is overly reliant on science as a basis for risk assessment? The analysis of the WTO Dispute Settlement Body's decision on the *Beef Hormones Dispute* contained in Chapter 8 of this thesis, will elucidate the answer to this question.

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[52] B.M.J. van der Meulen, note 148 Chapter 2 above, p.61.
[53] Article 2.1.
[54] Article 2.2.
[55] V. Walker, note 34 Chapter 1 above, p. 197-8.
[56] See generally, P. Belton & T. Belton (eds), note 9 Chapter 2 above, p.138.
[57] W.A. Kerr & J.E. Hobbs, note 164 Chapter 2 above, p. 285.

Unfortunately, because the SPS Agreement appears to be robust in preventing the abuse of sanitary measures as a means of providing domestic producers with protection (which is what was intended), it also inadvertently prevents the protection of cultural interests and consumer concerns. Indeed, the SPS Agreement does not specify the extent to which consumer preferences (including, for example, pubic risk perception) may be taken into account in the domestic food regulatory measures of WTO Members.[58] Ironically, as the EU would argue in the *Beef Hormones Dispute*, it was not producers that it wanted to protect, but rather consumers (legitimate protectionism). Therefore, the *Beef Hormones Dispute* does indicate a weakness of the SPS Agreement, insofar as it only recognises producers as a source of (illegitimate) protectionism.[59]

These problems result from a number of factors, not least of all because the SPS Agreement is best understood as a business arrangement made between trading nations with the main objective of promoting free trade, but also because there is a predominant emphasis on science as the arbiter of the legitimacy of sanitary measures. In short, the SPS was not designed to have the protection of public health as it core objective.[60] Therefore, this thesis argues that in the event cultural considerations are not included, then decisions taken under it could undermine consumer interests not just in the EU but also in the US and other nations.

In summary, global food regulatory authorities are faced with several challenges. As this thesis will evidence, science alone is rarely sufficient as a basis for credible and legitimate risk decision-making under international law. Scientific analysis can certainly provide assistance in fulfilling a public health goal, but the goal itself is strongly influenced by societal values and there science can provide little, if any, guidance. Essentially, science should inform the regulatory process but it cannot by itself determine the end result.[61] The appropriate role of science in global food safety regulation requires that the parties involved strike a delicate balance between their desire for credibility in the sphere of risk governance

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[58] However, scientific focus of the Agreement suggests that a priority will be placed on rational, scientifically driven regulation. See, C. Button, note 105 Chapter 4 above, p.103.

[59] N. Perdikis, W.A. Kerr & J.E. Hobbs, "Can the WTO/GATT Agreements on Sanitary and Phyto-Sanitary Measures and Technical Barriers to Trade Be Renegotiated to Accommodate Agricultural Biotechnology?" in W.H. Lesser (ed), *Transitions in Agbiotech: Economics of Strategy and Policy* (Connecticut: University of Connecticut, 2000), p. 696.

[60] B. Silverglade, note 184 Chapter 3 above, p.84.

[61] D.A. Wirth, note 52 Chapter 3 above, p. 817. The fundamental proposition of this school of thought is that health goals are determined by a society and it is only afterwards that science plays a role. See, M. D. Carter, note 149 Chapter 2 above, p.652.

while simultaneously acknowledging and utilising the politico-cultural concerns instilled in regional legislation.

6.4 SPS Agreement: Main Provisions

In examining the provisions of the SPS Agreement, it is important to keep in mind that the *Beef Hormones Dispute* raised, in the context of dispute settlement under the SPS Agreement, the question of public opinion about sanitary risks. The risk was one of food safety. It centred around high levels of public concern about the safety of certain food products which were going to be imported into the EU. In practical terms, it raised the issue of how consumers in the EU feel about meat possibly containing residues from growth promoting hormones, where those residues could have deleterious health consequences such as increasing (no matter how minimally) the incidence of cancer in the population.

In order to attain maximum benefit from the analysis of how the WTO Dispute Settlement Body dealt with the *Beef Hormones Dispute*, but more especially to understand how they dealt with considerations more extraneous to risk analysis such as the inclusion of cultural considerations or other legitimate factors, it is necessary to outline the analysis of the various provisions of the SPS Agreement contained in the following narrative.

6.4.1 Requirement for Scientific Substantiation

The salient aspects of the SPS Agreement begin with Article 2. Article 2 gives Members the freedom 'to take sanitary ... measures necessary for the protection of human, animal or plant health', provided those measures are not inconsistent with the provisions of the SPS Agreement. Article 2.2 further explains that Members must ensure that any sanitary measure taken 'is applied only to the extent necessary[62] to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence'. The burden of proof of compliance with this standard is alleviated for measures

[62] In order to be 'necessary', the measure does not need to be 'indispensable' but must at least be capable of making a contribution to the objective in question. *Korea – Measures Affecting the Importation of Fresh, Chilled and Frozen Beef*, WT/DS169/AB/R, para 161.

which conform to international standards, guidelines or recommendations. Such measures would then be deemed to be necessary to protect human, animal or plant life or health and are automatically presumed to be consistent with the relevant provisions of the SPS Agreement.[63] As far as food law is concerned, the international standard is the Codex Alimentarius.[64] As outlined below, there is a further alleviation of this requirement of scientific substantiation contained in Article 5.7.

Article 2 goes on to prohibit Members from applying a sanitary measure in any manner 'which would constitute a disguised restriction on international trade'. In this context, Article 8 of the Agreement requires that any sanitary measure which has the effect of creating a trade barrier must pass a stricter level of scrutiny before being allowed to impose such barriers.

Annex A to the SPS Agreement defines a sanitary measure as any measure applied to 'protect human or animal life or health .... from risks arising from additives, contaminants, toxins, or disease causing organisms in foods, beverages or feedstuffs'. The term 'measure' covers:

> all relevant laws, decrees, regulations, requirements and procedures including, *inter alia*, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.[65]

The additional alleviation of the requirement for scientific substantiation contained in Article 2 is where Article 5.7 allows Members to impose 'provisional measures' in cases where scientific data is 'insufficient' to justify regulations based solely on current scientific knowledge.[66] However, Members are obligated to discover any available additional scientific

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[63] B.M.J. van der Meulen, note 148 Chapter 2 above, p.61.

[64] Article 3.1 of the SPS Agreement provides that any sanitary measure which conform to international standards, guidelines or recommendations shall be deemed legitimate and then Annex A paragraph 3 of the SPS Agreement defines those international standards as those established by Codex.

[65] Annex A to the SPS Agreement .

[66] B.M.J. van der Meulen, note 148 Chapter 2 above, p.61.

evidence and to then re-evaluate their health measures.[67] As already outlined in this thesis, this provision contained in Article 5.7 is where the precautionary principle is given meaning, albeit limited, within the SPS Agreement. In addition, it may provide a means for a Member to legitimately include cultural considerations and 'other factors' such as public risk perception within the domestic sanitary measures enacted.

6.4.2 Risk Assessment under the SPS Agreement

In relation to 'risk assessment' the SPS Agreement requires Members to evaluate the likelihood of health risks as related to the proposed sanitary measure to be applied.[68] 'Risk assessment' is defined as:

> [t]he evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary... measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives ... in food.[69]

After evaluating the risk, the Member is required to choose the level of protection it deems necessary. While on a practical level this will involve the application of 'risk management' procedures, it is important to note as a concept, 'risk management' is not mentioned in the SPS Agreement. Therefore the concept cannot be used to sustain a more restrictive interpretation of 'risk assessment' than is justified by the terms of Article 5.2,[70] Article 8[71] and Annex C[72] of the

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[67] Because of the similarities that Article 7 (the Precautionary Principle) of the General Food Law bears with this Article 5(7) of the SPS Agreement, there seems little doubt that this Article 5(7) served the EU legislature as a template. See, B.M.J. van der Meulen, note 148 Chapter 2 above, p.61.

[68] M.D. Carter, note 149 Chapter 2 above, p.633.

[69] Annex A, paragraph No.4.

[70] Article 5.2 of the SPS Agreement provides 'that in the assessment of risks, Members shall take into account 'available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment'.

[71] Article 8 of the SPS Agreement provides that Members shall 'observe the provisions of Annex C in the operation of control, inspection and approval procedures ... in foods, beverages or feedstuffs, and otherwise ensure that their procedures are not inconsistent with the provisions of this Agreement'

[72] ANNEX C sets out various stipulations regarding 'control, inspection and approval procedures' such as that 'procedures are undertaken and completed without undue delay and in no less favourable manner for imported products than for like domestic products' and that 'any requirements for control, inspection and approval of individual specimens of a product are limited to what is reasonable and necessary', etc.

SPS Agreement.[73] Of course, this creates a dilemma for legitimately effecting the inclusion of cultural considerations because as we have already seen in this thesis, such matters must predominantly fall within the realm of risk management.

Nonetheless, the SPS Agreement does permit each Member to choose its own level of sanitary protection or 'acceptable level of risk'. It defines the appropriate level of protection as 'the level of protection deemed appropriate by the Member establishing a sanitary ... measure to protect human, animal or plant life within its territory'.[74] Each Member is allowed to choose the 'appropriate' level of protection, provided the Member considers 'the objective of minimizing negative trade effects'.[75]

In order for a Member's sanitary measures to stand up to international scrutiny, or for the measures to be objectively justifiable to those with whom the Member trades in the affected products, in addition to Members ensuring that any measures taken are based on an appropriate assessment of the risks to human, animal or plant life or health, the Member must also take into account the risk assessment techniques developed by the relevant international organisations such as Codex.[76]

Article 5.5 of the SPS Agreement allows the Member to impose levels of protection higher than the 'appropriate levels', but establishes that in creating the higher levels 'the objective of obtaining consistency in the application of... appropriate level[s] of sanitary or phytosanitary protection' must be followed. Under Article 5.5 the Member must avoid 'arbitrary or unjustifiable distinctions in the levels it considers to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction on international trade'.

The Member may adopt measures more stringent than those based on relevant international standards, guidelines or recommendations, so long as those measures have a 'scientific justification'.[77] The SPS Agreement goes on to explain that 'there is a scientific justification

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[73] See the *Beef Hormones Dispute* and paragraph 206 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.
[74] Annex A, paragraph No.5.
[75] Article 5(4).
[76] The objectives of the risk assessment are also a factor is deciding the nature of the risk assessment upon which the measure must be based. There are types of risk assessment defined in Annex A(4) of the SPS Agreement. See Panel Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/R, paras 8.31 – 8.37.
[77] Article 3(3).

if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards ... are not sufficient to achieve its appropriate level of ... protection'.[78] As previously confirmed, it is important to note that any national measures which conform to international standards, such as Codex, are presumptively valid.[79]

In developing the implementation guidelines, Members must co-operate with the Committee on Sanitary and Phytosanitary Measures, while taking into account 'all relevant factors, including the exceptional character of human health risks to which people voluntarily expose themselves'.[80] Therefore, a Member should not simply tailor sanitary regulations purely to accommodate selfish goals unrelated to health, such as trade protectionism.

6.5 Other Legitimate Factors and Codex Alimentarius

Science based regulation represents a necessary constraint on protectionist non-tariff barriers. However, it can go too far and constrain any flexibility that WTO Members may have to implement sanitary measures which satisfy national concerns regarding culture. The vexed question of the role of 'other factors' in risk regulation attempts to deal with this very concern.[81] Article 1 of the Statues of Codex Alimentarius provides that the Codex Commission is responsible for all matters pertaining to the implementation of the joint FAO/WHO Food Standards Programme and that the purposes of the Programme includes 'the protection of the health of consumers and ensuring fair practices in the food trade'.[82] However, it is apparent that the fundamental approach to the development of international food standards is often based on one or two major issues when in fact there are many other scientific, technical and cultural aspects involved.[83] In an attempt to remedy this, the phrase 'other legitimate factors'[84] was coined with the creation by Codex of its four Statements of

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[78] Article 3(3).
[79] See D.A. Wirth, note 52 Chapter 3 above, p. 817.
[80] Article 5(5).
[81] C. Button, note 105 Chapter 4 above, p.117.
[82] Codex Alimentarius Commission's *Procedural Manual, 17th ed.*, (Rome: FAO, 2007) p.3.
[83] See D. Jukes, note 140 Chapter 4 above, p.189.
[84] Usually, either referred to as 'other factors' or 'other legitimate factors'. The phrase 'other legitimate factors' is the one used in the Codex Alimentarius' 2nd Statement of Principle and that phrase is used in this thesis.

Principle.[85] 'Other legitimate factors' has to be seen in the context of science providing the key factor used in establishing standards, except that in addition, 'other legitimate factors' (OLFs) can be considered.

Therefore, the second Codex Statement of Principle provides that 'when elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to "other legitimate factors" relevant for the health protection of consumers and for the promotion of fair practices in food trade'. However, the fourth Statement of Principle reaffirms the separation between scientific risk analysis and risk management by providing that 'consideration of other factors should not affect the scientific basis of risk analysis'.[86] In relation to the criteria for the consideration of the other factors referred to in the Second Statement of Principle, Codex goes on to provide that:

(i) 'other legitimate factors' relevant for health protection and fair trade practices may be identified in the risk management process ... ;

(ii) consideration of 'other factors' should not affect the scientific basis of risk analysis; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment;

(iii) it should be recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant worldwide;

(iv) only those 'other factors' which can be accepted on a worldwide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex;

(v) ...

(vi) ...

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[85] Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which other Factors are Taken into Account.

[86] Statements of Principle Concerning the Role of Science in the Codex Decision-Making Process and the Extent to which other Factors are Taken into Account. The Four Statements of Principle provide: (a) '[t]he food standards, guidelines and other recommendations of Codex ... shall be based on the principle of sound scientific analysis ... involving a thorough review of all relevant information', (b) 'When ... deciding upon food standards Codex ... will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers ..., (c) 'In this regard it is noted that food labelling plays an important role in furthering both of these objectives', and (d) 'When ... members of Codex agree on the ... level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex'.

(vii) the integration of 'other legitimate factors' in risk management should not create unjustified barriers to trade ...

6.5.1 Specific OLFs Identified by the Codex Secretariat

The minutes of a number of Codex meetings evidence the cultural divergence of approach to OLFs as between EU Members of Codex and the US. For example, at the fourteenth session of the Codex Committee on General Principles, the Netherlands emphasised the importance of including other legitimate factors linked to the production process such as animal welfare, biotechnology and the use of growth hormones and that when setting standards, Codex should include recommendations made on these issues at the international level.[87] In stark contrast, the US Delegation to Codex expressed the view that it is the scientific basis of risk assessment which is essential in the Codex decision process and that the introduction of other factors, more appropriately considered at the national level, was not appropriate in Codex.[88] The French delegate to Codex reiterated the importance of risk analysis in taking decisions on food safety and that such decisions should consider other factors. The French delegate stated:

> [b]ut such decisions [should take] into account 'other factors', such as the concerns of consumers, animal health or socio-economic consequences ... It was essential that such standards took into account all of the concerns expressed, including those that did not relate directly to food safety and that they should be adopted on the basis of the largest consensus possible. Obtaining such a consensus at the level of the Codex Committees or the Commission would facilitate the harmonization of national standards and the development of international trade.[89]

Various Codex papers and discussion documents have identified possible OLFs and a number of these have been detailed in previous Chapters in this thesis.[90] The OLFs identified by Codex which are most relevant to this thesis are as follows:[91]

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[87] Report of the Fourteenth Session of the Codex Committee on General Principles, note 166 Chapter 4 above, p.9.
[88] *Ibid.*
[89] Mme. Marian Guillou speaking on behalf of the French Department of Agriculture as quoted in the Report of the Fourteenth Session of the Codex Committee on General Principles, note 166 Chapter 4 above, p.1.
[90] Report of the Fourteenth Session of the Codex Committee on General Principles, note 166 Chapter 4 above.
[91] In order to clarify any potential confusion, the outline of potential OLFs contained in previous Chapters of this thesis, dealt with OLFs as enunciated by various decisions taken by the WTO Panel/Appellate Bodies in

6.5.1.1 Safety Factors

In formulating numerical values for the ADI of an additive, contaminant or residue, JECFA[92] developed the concept of a 'safety factor'. The safety factor acknowledges that the application of scientific principles alone may not have led to a wholly accurate result. Therefore the safety factor is formulated based on an acknowledgement that other issues may have effected the result. Typical issues might be the age or diet of the consumer or variations in an individual's metabolic rate.

6.5.1.2 Consumer Concerns as Other Legitimate Factor

The October 1991 Report of the CCRVDF[93] dealt with the issue of consumer concerns (such as public risk perception) and in the context of growth hormones stated that 'the principle problem was not with the safety of the substance and their residues, but in the public perception of their safety'.[94] Consumer concerns were heightened, predominantly in the 1990s, by various food safety scares, especially BSE. This was followed by concerns over genetically modified foods. As a result it is not surprising that politicians were reluctant to express approval of new technologies including hormones.[95]

6.5.1.3 Precautionary Principle

In considering the precautionary principle, the Codex Committee on General Principles (CCGP) acknowledged that there will on occasion be a lack of scientific evidence.[96] However, the CCGP believes that the precautionary principle should only apply when the science base is still being developed – in other words, that there comes a point when science

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various trade dispute. However, it is also important to understand the OLFs listed here in order to verify the potential for including cultural considerations.

[92] Joint Expert Committee on Food Additives

[93] The Codex Committee on Residues of Veterinary Drugs in Food.

[94] Paragraph 15 of the Report of the Twentieth Session of the Joint FAO/WHO Food Standards Programme. Codex Alimentarius Commission, Twentieth Session incorporating the Report of the Sixth Session of the Codex Committee on Residues of Veterinary Drugs in Food. Washington D.C., 22 – 25 October, 1991, CX4,60.2, ALINORM 93/31.

[95] D. Jukes, note 140 Chapter 4 above, p.189.

[96] Report of the Fourteenth Session of the Codex Committee on General Principles, note 166 Chapter 4 above, p.4.

sufficiently clarifies the issue of any hazard posed by the process under consideration. This means that the precautionary principle comes into play in the first Statement of Principle governing the use of science rather than the second Statement of Principle dealing with the consideration of OLFs. Again, this appears to correlate with the separation of risk analysis from risk management. Unfortunately, in theory at least, this limits the use of the precautionary principle as it cannot be applied in the risk management process where issues such as cultural considerations and public risk perception arise. It is also in keeping with the rather restrictive meaning given to the precautionary principle in Article 5.7 of the SPS Agreement.

6.5.1.4 Labelling

The other pertinent issue is using labelling to provide consumers with adequate information at the time of purchase. This is dealt with by the third Statement of Principle.[97] The wording of this Statement of Principle would appear to indicate that labelling can be considered as constituting an OLF.[98] The issue of labelling and science based risk regulation appears to revolve around the consideration of what it is consumers need to know. This debate has received contributions from both consumer and industry interests.

An industry submission to the CCGP draws a distinction between a consumer's need to know, and a consumer's right or desire to know. The argument here is that a consumer's need to know specific information about a product so as to ensure food safety or satisfy health concerns is an appropriate Codex consideration. However, a consumer's mere desire to know or right to choose should be outside of Codex's purview because Codex standards deal with protecting consumer health.[99] This approach would appear to conveniently negate any need for Codex to decide on the issue of labelling acting as an OLF to solve the issue of consumer outrage over a potential health risk.

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[97] The third Statement of Principle provides that 'In this regard it is noted that food labelling plays an important role in furthering both of these objectives' – the two objectives being that food standards, guidelines and recommendations of Codex shall be based on the principle of sound scientific analysis and that Codex will have regard to other legitimate factors.

[98] D. Jukes, note 140 Chapter 4 above, p.189.

[99] Report of the Fourteenth Session of the Codex Committee on General Principles, note 166 Chapter 4 above.

However, consumers reject the idea that in the absence of a clear risk to health, labelling cannot be justified.[100] Similarly, labelling for the purpose of informing consumers of a food containing or created using a new technological ingredient such as hormones, should not be seen as a barrier to trade. Consumers argue that they have a fundamental right to decide which risks and which social impacts of products are acceptable to them.[101]

Ultimately, in Codex, as with the meaning given to OLFs by the various WTO Panel/Appellate Body decisions handed down to date, the precise meaning and use of the term 'other legitimate factors' is still uncertain.

6.6 Other Legitimate Factors under the SPS Agreement

Potentially, there are three provisions of the SPS Agreement which may permit a consideration of OLFs:

(i) Article 5.1 stipulates that Member's must ensure that their SPS Measures are 'based on' a risk assessment. Several questions arise with Article 5.1 in this context. Firstly, what does 'based on' mean? Secondly, since the SPS measure only has to be 'based on' a risk assessment, to what extent, if any, can OLFs be included?;

(ii) Article 5.2 specifies that WTO Members must, in their risk assessments, take into account a list of factors. As we shall see in Chapter 8 of this thesis, given that the Appellate Body has found that the list of factors in Article 5.2 is not closed,[102] to what extent can recourse be had to 'other factors' as part of a risk assessment under the SPS Agreement?; and

(iii) Article 5.5 requires WTO Members to avoid 'arbitrary or unjustifiable distinctions' in the levels of sanitary protection they consider appropriate in different situations. Therefore, if a Member's population regards a particular food production practice as representing an especially serious health risk and sanitary

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[100] A paper submitted to Codex by Consumer's International relating to the consideration of other legitimate factors in the case of BST hormone in Milk. See generally, D. Jukes, note 140 Chapter 4 above, p.189.
[101] D. Jukes, note 140 Chapter 4 above, p.189.
[102] *EC Measures Concerning Meat and Meat Products (Hormones)* WT/DS26AB/R, WT/DS48/AB/R AB Report adopted 13 February, 1998 ('*EC-Hormones*'), para 187.

measures are introduced accordingly, can the Member defend its position on the basis of cultural preferences or public risk perception?

6.6.1 SPS Measures be 'based on' a Risk Assessment and Other Legitimate Factors

For an Article 5.1 SPS measure to be 'based on' a risk assessment, it is not necessary for the Member in question to show that risk assessment immediately preceded the adoption of the measure. If necessary, the Member can rely on an existing risk assessment that was carried out by a third party.[103] Instead, the important criteria for 'based on' is that the risk assessment 'sufficiently supported or reasonably warranted' the measure.[104] Therefore, the measure adopted cannot contradict the risk assessment and there must be a clear relationship or connection between the measure implemented and the risk assessment used to support it.

In formulating the final regulatory measure, in the context of the accommodation of OLFs, to what extent can OLFs be included (in risk management) before they have the effect of no longer having the final sanitary measure 'based on' the risk assessment? This is particularly important to the EU from a procedural perspective, because under EU law, science (risk assessment) is there to inform risk management decisions. From a reading of the General Food Law it appears clear that EFSA and its scientific opinions (i.e. science) are there to inform the food safety regulatory process.[105]

As already detailed in this thesis, there is the clear division between risk assessment and risk management throughout the General Food Law.[106] In addition, the role of science is explicitly balanced by the references to 'societal, economic, traditional, ethical and environmental factors'[107] and indeed by specific reference to the significance of 'other factors'.[108] All of this can be interpreted as an acknowledgement of a role for 'non-scientific factors' or OLFs in informing the formulation of sanitary measures under EU food law. This role for other

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[103] *Ibid*, para 190.
[104] *Ibid*, para 186.
[105] Preamble para. 34, Art. 22.5 and Art. 22.7 of European Parliament and Council Regulation (EC) No 178/2002, note 72 Chapter 2 above.
[106] European Parliament and Council Regulation (EC) No 178/2002, note 72 Chapter 2 above.
[107] Preamble para.19 of the General Food Law. References to consumer interest and the role played by consumers in Preamble para's 22, 35, 56 and also Article 1.1. The reference to the importance of tradition in the food supply in Preamble para.22 and in Article 1.1.
[108] Preamble para.19, Art. 6.3 and Art. 7 of the General Food Law.

legitimate factors is a *de facto* acknowledgment that in certain situations the eventual food safety measure enacted may not be 'based on' the results of the risk assessment in any material sense.[109] Therefore, this is a cultural regulatory divergence which is problematic when it comes to the formulation of sanitary measures that are 'legitimate' under the terms of the SPS Agreement.

As outlined in Chapter 5 of this thesis in the context of 'risk', in food science, the term 'hazard'[110] refers to the source that has caused or could cause an adverse health effect. 'Risk' refers to the probability of that effect and its severity. The strength of the connection between the hazard and the risk varies depending on how clear the relationship is. There may be a great deal of incontrovertible evidence proving that the risk emanating from the perceived hazard is real and significant. Alternatively, there may be little evidence proving the risk one way or the other. In situations where cause and effect between hazard and risk is strong public risk perception will play little or no role in deciding upon the required sanitary measure. In situations where the relationship between the hazard and the risk is less clear, based on an acceptance of a role for OLFs, public risk perception would have an important role to play. This variance between the probabilities of risk only serves to highlight the importance of the role of 'other factors' in shaping regulatory outcomes.[111] In other words, as this thesis argues, society cannot always rely on science alone to provide a clear-cut definitive answer.

In situations where it is not abundantly clear that the measure is 'based on' the risk assessment, WTO Panels[112] are likely to be influenced by their own perception of the additional considerations (i.e. by the OLFs) which caused the Member to enact the measure. For example, a Panel which appreciates the value of public risk perception in risk regulation is more likely to find a link between the measure and the risk assessment underlying it.[113]

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[109] C. Button, note 105 Chapter 4 above, p.105.

[110] Art.3.14 of the General Food Law defines 'hazard' as a 'biological, chemical or physical agent in, or condition of, food or feed with the potential to cause an adverse health effect'.

[111] M. McGarvin, "Science, Precaution, Facts and Values" in T. O'Riordan and J. Cameron (eds), *Reinterpreting the Precautionary Principle*, (London: Cameron May, 2002), p.41.

[112] The WTO Dispute Settlement Body Panels of experts, formed to adjudicate on disputes between Members.

[113] i.e. that the measure is 'based on' the risk assessment. See C. Button, note 105 Chapter 4 above, p.105.

6.6.2 Other Legitimate Factors within Risk Assessment

The foregoing analysis of the measure being 'based on' a risk assessment presupposes that other legitimate factors would form part of risk management. However, there is no explicit distinction in the terminology of the SPS Agreement separating risk assessment from risk management.[114] In addition, Chapter 8 of this thesis will outline how the Appellate Body has found that the list of factors that can be included in Article 5.2 is not closed.[115] Therefore, it is open to a WTO Member to argue that OLFs should be considered as a valid part of risk assessment under Article 5.2?

However, generally, it is felt that any attempt to legitimise 'other factors' in risk analysis by arguing that they come under Article 5.2 of the SPS Agreement is counterproductive. Firstly, it is not clear that they would be subject to review by WTO Panels in the event that they are claimed to come under Article 5.1, but bringing them under Article 5.2 would make them subject to review. In addition, defining other legitimate factors as forming part of risk assessment would undermine the work that Codex has done. As previously outlined, the Second Codex Statement of Principle confirms that Codex 'will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade'.[116] The Codex criteria define OLFs as coming in under the risk management process.[117] Codex also prescribes that OLFs should 'not affect the scientific basis of risk analysis and that the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment'.[118]

Therefore, it appears that Codex are of the view that OLFs would come into play at the risk management stage and that it would not be appropriate that they be considered as part of risk

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[114] Para. 181 *EC-Hormones*. The Appellate Body noted that 'Article 5 and Annex A of the *SPS Agreement* speak of 'risk assessment' only and that the term 'risk management' is not to be found ... in ... the *SPS Agreement*. Thus, the Panel's distinction [between risk assessment and risk management] ... has no textual basis'.

[115] *EC Measures Concerning Meat and Meat Products (Hormones)* WT/DS26AB/R, WT/DS48/AB/R AB Report adopted 13 February, 1998 ('*EC-Hormones*'), para 187.

[116] Codex Alimentarius Commission's *Procedural Manual, 17th ed.*, (Rome: FAO, 2007) p.194.

[117] In their Statements of Principle, Codex state that 'other legitimate factors ... may be identified in the risk management process' and 'Food safety risk assessment should be soundly based on science'. Codex Alimentarius Commission's *Procedural Manual, 17th ed.*, (Rome: FAO, 2007) p.194.

[118] See Codex Alimentarius *Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle* (Decision of the 24th Session of the Commission, 2001 ALINORM 01/41).

assessment. More generally, if OLFs were to form part of risk assessment, then the scientific integrity of risk assessment would be compromised – risk assessment could no longer be considered untainted by politics. In that case the innate value of scientific risk-evaluation would be tarnished along with the whole risk analysis process.[119]

6.7 Difficulty with Public Risk Perception as Other Legitimate Factor

In considering the extent to which Members can allow public risk perception to influence food safety regulation and not breach the terms of the SPS Agreement, it is necessary to consider the nature of the perception – the extent to which the public fear the potential risk. For example, where the public fear some aspect of the food supply and that hazard has also been scientifically verified as having a deleterious effect on human health (no matter how miniscule), then the issue is not as potentially contentious. However, where the public fear that something is harmful to human health and there is no scientific evidence to support that fear, then that is a different issue.

Nonetheless, when Members signed-up to the SPS Agreement they agreed to only use trade limiting regulatory barriers in respect of scientifically-verified risks. They did not commit themselves to the formulation of sanitary measures without any reference at all to public risk perception. However, reference to completely unsubstantiated public fears would undermine the SPS Agreement because in that scenario there can be no place for the scientific justification rationale in justifying trader restrictive sanitary measures.[120] It would be almost impossible to eliminate non-tariff barriers to trade disguised as food safety measures.

In addition, it must be noted that in democratic societies, along with other private interest groups, media is often one of the main drivers behind public risk perception.[121] Therefore, sometimes public risk perception is fickle and is in any event largely outside of governmental control. For many lay citizens, issues such as 'distrust of controllability' and knowledge-related characteristics such as whether the risk is 'observable, known and new' have a strong

[119] C. Button, note 105 Chapter 4 above, p.107.
[120] *Ibid*, p.111.
[121] *Ibid*, p.111.

impact on the severity of public fear regarding the hazard.[122] Therefore, it may be necessary to consider more abstruse solutions such as educating the public about food associated risk with national regulatory authorities implementing trust-building exercises. Irrespective of the magnitude or nature of the public fear, the problem of finding a methodological basis for valuing public risk perception also arises. One solution might be to ask WTO Members to adduce a scientific basis for the level of public risk perception in the same manner as they adduce evidence of the scientific basis for a risk (under the SPS Agreement).[123]

6.7.1 Public Risk Perception framed as 'Uncertainty'

When faced with a public risk perception that demands the enactment of restrictive regulatory measures, government must endeavour to find a justification for both the risk perception and the measure. Ideally, it is possible to buttress the stance taken by providing a scientific basis for the regulatory measure. In the event that scientific evidence proving the validity of a serious risk to human health does not exist, then the best that government can do is to argue 'uncertainty' regarding the safety of the food practice concerned.[124]

As previously outlined, Article 2.2 of the SPS Agreement stipulates that SPS measures must be based on scientific principles and not maintained without sufficient scientific evidence. Article 5.1 requires that SPS measures must be based on a risk assessment and Article 5.2 requires that the risk assessment shall take available scientific evidence into account. In both *EC-Hormones*[125] and *Agricultural Products,*[126] the WTO Appellate Body decided that the scientific justification principle outlined in Article 2.2 is to be read together with the risk assessment discipline contained in Article 5.1. Article 5.7 of the SPS Agreement permits a

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[122] European Commission *Final Report on Setting the Scientific Framework for the Inclusion of New Quality of Life Concerns in the Risk Assessment Process* (adopted by the Scientific Steering Committee at its Meeting on 10-11 April, 2003), p.11.

[123] See, J. Scott and E. Vos, "The Juridification of Uncertainty: Observations on the Ambivalence of the Precautionary Principle with the EU and the WTO", in C. Joerges and R. Dehousse (eds), *Good Governance in Europe's Integrated Market*, (Oxford: Oxford University Press, 2002) p.279.

[124] Oftentimes consumers are anxious because they are uncertain regarding the safety of consuming a particular food. They are uncertain because due to the speed at which advances in agricultural, industrial and food production practices are taking place, they know that sometimes the safety of the products generated through such mechanisms cannot be established. See, T. O'Riordan, J. Cameron and A. Jordan, note 14 Chapter 5 above, p.9.

[125] *EC Measures Concerning Meat and Meat Products (Hormones)* WT/DS26AB/R, WT/DS48/AB/R AB Report adopted 13 February, 1998 ('*EC-Hormones*'), para 193.

[126] *Japan-Measures Affecting Agricultural Products* WT/DS76/AB/R, AB Report adopted 19 March,1999, para 76.

Member to provisionally adopt measures where the available scientific evidence is insufficient provided that: (a) the measures are adopted on the basis of available pertinent information;[127] (b) the Member continues to seek the additional information necessary for a more objective assessment of risk; and (c) the measure is accordingly reviewed within a reasonable period of time.[128] Therefore, basically, Article 5.2 and Article 5.7 cover two sets of SPS measures: (a) firstly, final measures which have been based on applicable scientific evidence and a risk assessment as required by Article 5.1, and (b) secondly, temporary measures where there was insufficient scientific information to allow a qualifying risk assessment as required by Article 5.1. This neat demarcation of the two groups is somewhat ambiguous because, in practice, there is always some element of uncertainty involved even in scientific risk assessment.[129] Instead, it is best described as a spectrum of knowledge.[130]

Risk assessment is a method of 'systematically organising scientific and technical information and its associated uncertainties'. In fact, it requires 'explicit recognition of uncertainties' and acknowledgement that 'alternative interpretations of the available data may be scientifically plausible'.[131] However, these risk assessments satisfy Articles 5.1 and 5.2 requirements because of the acknowledged limits governing mainstream science. Uncertainty in itself does not prevent a measure from being based on a scientific assessment of risk, nor by implication that it is being sustained without sufficient scientific information.[132] Whether it is the uncertainty surrounding the deleterious effect on human health of growth hormones residues or genetically engineered foods, as one of the expert Panel advisers, Dr. Ritter,[133] in *EC-Hormones* put it, 'it would be silly for any scientist to presume that the day will ever come, on this issue or on any other, where we could say we know enough and that there is no

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[127] Where a provisional measure is based on available pertinent information, it follows that there must be a strong relationship between that measure and the existing international standard. *EC –Trade Description of Sardines*, WT/DS231/AB/R, para 245.

[128] Article 5.7 is a 'qualified exemption' rather than an exception to Article 2.2. See J. Scott, note 186 Chapter 5 above, p.111. However, there is uncertainty as to whether or not it grants an exemption to all three of Article 2.2' constituent parts. *EC-Conditions for the Granting of Tariff Preferences to Developing Countries*, WT/DS246.R, Para 7.2969.

[129] In *Australia-Certain Measures Affecting the Importation of Fresh Fruit and Vegetables*, WT/DS270/R, it was found that Australia could not rely on Article 5.7 simply because it was delayed or constrained by the resources available and other priorities.

[130] C. Button, note 105 Chapter 4 above, p.114.

[131] Joint FAO/WHO Expert Consultation Application of Risk Analysis to Food Standards Issues (WHO/FNU/FOS/95.3 Geneva 1995), p.12.

[132] R. Howse, "Democracy, Science and Free Trade: Risk Regulation on Trail at the World Trade Organisation", (2000) *Michigan Law Review*, Vol. 98, Issue.7, p. 2342.

[133] Dr. Leonard Ritter, Executive Director of the Canadian Network of Toxicology Centers and Professor of Toxicology in the School of Environmental Sciences at the University of Guelph, Guelph, Ontario, Canada. He was one of six expert advisors to the Panel in *EC-Hormones*.

need to do any further work'.[134] However, the shifting sands of science and the existence of a spectrum of knowledge is not explicitly acknowledged anywhere in the SPS Agreement. There is a further dilemma connected with this insofar as Article 5.7 requires that provisional measures must be based on available pertinent information and yet it is unlikely that the WTO Panel would allow a Member to base a sanitary measure on mere unsubstantiated claims about possible detrimental health concerns – such as wholly unfounded pubic risk perception. However, how does one define available pertinent information and what if this information is simply not (scientifically) ascertainable? It may very well be the prospect of this dilemma which prompted the EU not to rely on Article 5.7 in the *EC-Hormones* case as it would mean that they would have conceded that sufficient information was not available and that their measures would merely be 'provisional'.[135]

6.8 Conclusion

The global food regulatory construct must resolve the issue of disparate sanitary measures caused by cultural regulatory divergences acting as non-tariff barriers to free trade, in order to mitigate against the incidence of discriminatory food standards and the resultant trade disputes. Underpinning the EU and the US food regulatory models are consumer's different attitudes towards the perceived ability of science and the SPS Agreement to deal with this issue. As confirmed by the analysis in the foregoing Chapters in this thesis, to a far greater degree than citizens of the EU, Americans are prepared to defer to the authority of 'experts'. This transatlantic chasm in approach to how best to regulate food safety, would seem to have originated at least in part from the distinctive experiences of EU citizens and North Americans to various food safety crises.[136]

The more science based the SPS Agreement is, the more it will limit the role of culture. As confirmed by the analysis, in particular contained in Chapters 3 and 4 of this thesis, science alone is unlikely to be an adequate arbiter of sanitary measure legitimacy in most situations, and a failure to acknowledge a role for culture will be problematic. The analysis in this Chapter uncovered that the SPS Agreement is science based. As outlined in this Chapter,

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[134] *EC Measures Concerning Meat and Meat Products (Hormones)* WT/DS26AB/R, WT/DS48/AB/R AB Report adopted 13 February, 1998 ('*EC-Hormones*'): Annex: Transcript of the Joint Meeting with Experts, para 423..
[135] C. Button, note 105 Chapter 4 above, p.116.
[136] G. Skogstad, note 104 Chapter 5 above, p.14.

while the SPS Agreement is predominantly science based, provided they do not contravene the terms of the SPS Agreement, signatories to the SPS Agreement are allowed to set their own level of sanitary protection and indeed compliance with Codex standards is not mandatory under the SPS Agreement.

As outlined in this Chapter, some important exceptions to the science basis do exist. Indeed, even Codex reluctantly had to make a role for the inclusion of cultural considerations under its Statements of Principle covering Other Legitimate Factors. Therefore, in the context of this thesis, the important question now is to what extent do these exceptions permit in risk management the inclusion of 'other factors' such as culture, in all its forms including public risk perception? The analysis of the *Beef Hormones Dispute,* augmented by some additional Dispute Settlement Body SPS Agreement decisions, contained in Chapter 8 of this thesis, will assist in answering this remaining question.

CHAPTER 7

ANIMAL GROWTH HORMONES AND THEIR REGULATION

7.1 Introduction

The *Beef Hormones Dispute* arose in the 1990s in the midst of the mad cow disease crisis in Europe when the EU banned the use of animal growth hormones and the importation of meat from animals which had been given growth promoting hormones.[1] The *Beef Hormones Dispute* was the first ruling to interpret the WTO SPS Agreement.[2] As outlined in Chapters 5 and 6 of this thesis, WTO Members such as the EU and the US must show compliance with the SPS Agreement. With trade liberalisation as its core objective, the SPS Agreement endeavours to ensure that the sanitary measures enacted by Members do not act as disguised restrictions on international trade.[3] WTO rules permit the adoption of sanitary measures such as the ban on animal growth hormones, but only where the Member presents scientific evidence proving that the ban is a valid health and safety measure under the terms of the SPS Agreement.[4] The US opposed the EU ban and took the EU to the WTO Dispute Settlement Body (DSB).[5]

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[1] *EC Measures Concerning Meat and Meat Products ('EC-Hormones')* WT/DS26, and *United States – Continued Suspension of Obligations in the EC – Hormones Dispute ('US-Continued Suspension')* WT/DS320. The *Beef Hormones Dispute* also set the stage for the debate between the US and the EU over trade in GMOs. See, C. Carlane, note 1 Chapter 2 above, p.308. The EU provisions instituting the ban were: Council Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action, [1981] O.J. L222/32; Council Directive 88/146/EEC prohibiting the use in livestock farming of certain substances having a hormonal action, [1988] O.J. L70/16; Council Directive 88/299/EEC on trade in animals treated with certain substances having a hormonal action and their meat, as referred to in Article 7 of Directive 88/146/EEC, [1988] O.J. L128/36; Council Directive 96/22/EC concerning the prohibition on the use in stock-farming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC, [1996] O.J. L 125/03.

[2] As confirmed by the investigations in the previous Chapters of this thesis, the SPS Agreement is science based and any food regulatory measures enacted by a WTO Member aimed at protecting human health must be based on sound science and risk analysis. The SPS Agreement was drafted without explicit reference to cultural considerations.

[3] The first round of retaliatory tariffs alone, imposed at the end of 1987 by President Reagan, imposed a tariff of 100 per cent ad valorem duty, worth about $100 million, on EU imports. The *Beef Hormones Dispute* continued at huge monetary cost to the European Union.

[4] This thesis argues that it is not possible by consulting just scientists and food technologists, to predict the way consumers will react to a new food associated risk. While scientists and food technologists handle uncertainty

This thesis posits that cultural influences are evident in the sanitary measures enacted by each Member. As confirmed by the investigations carried out in the preceding Chapters of this thesis, there is a fundamental difference between the EU and the US food safety regimes. As supported by the analysis so far in this thesis, generally it can be said that EU food production espouses traditional food production and processing methods whereas by contrast the US has been more receptive to food technology and somewhat sceptical of traditional methods. In addition, unlike US consumers, EU consumers possess a public risk perception which is considerably more alert to, and wary of, the use of modern technologies such as genetic modification and growth hormones in food production.[6]

These cultural differences feed into the formulation of food standards and as a result cultural regulatory divergences are evident in the domestic sanitary measures adopted. These cultural regulatory divergences can lead to international trade conflict. This occurs when these sovereign idiosyncrasies in the domestic regulations have the effect of acting as a non-tariff barrier to trade.[7] In addition, the distinctive experiences of EU citizens and North Americans with various food safety crises has created a transatlantic chasm in approach as to how best to regulate food safety.[8] To a far greater degree than the EU citizenry, Americans are prepared to defer to the authority of 'experts'. As analysed in Chapter 6, the more science based any regulatory procedure is, the more it will limit the role of culture. As confirmed by the analysis in Chapters 3 and 4 in particular, science alone is unlikely to be an adequate arbiter of sanitary measure legitimacy in most situations, and a failure to acknowledge a role for culture will be problematic. The analysis in Chapter 6 uncovered that the SPS Agreement is science based.

Consequently, the *Beef Hormones Dispute* is not merely a dispute concerning the risk posed to human health by the use of growth hormones in beef production. It represents a much

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and risk judgements on a daily basis, the perception of the public is different. At the international level, public risk perception should be of crucial importance for policy makers.

[5] The Dispute Settlement Body (which is effectively the WTO General Council in another guise) consists of all WTO members and they will then arbitrate on the matter.

[6] This was confirmed by the analysis in Chapter 5.

[7] Where the exporting party wants to either sell a technologically-advanced or novel food product in an economic area that is subject to different cultural norms and a different regulatory system.

[8] G. Skogstad, note 104 Chapter 5, p.14.

broader issue – the conflict between science and culture in food regulation.[9] It presents a dilemma concerning the preservation of individual consumer preferences through national or regional food regulatory autonomy, while at the same time promoting global trade liberalisation and economic integration in foodstuffs.[10] It seems apparent from the protracted nature of the *Beef Hormones Dispute* that the current WTO dispute resolution mechanisms were inadequate to deal with the anomalies caused by an inability to properly handle what this thesis terms – 'cultural regulatory divergences'. The analysis in this thesis of the *Beef Hormones Dispute* in the next Chapter provides a window through which we can view the WTO framework and particularly the SPS Agreement in action. In order to create a proper analysis and understanding of the how the WTO Dispute Settlement Body handled the *Beef Hormones Dispute*, it is necessary in this Chapter to understand what animal growth hormones are, and the nature of their regulation in the EU and in the US.

7.1.1 Animal Growth Hormones Explained

Before examining the *Beef Hormones Dispute* in detail, it is necessary to understand the issue in dispute, namely, the use of growth hormones as an aid to enhance lean tissue growth in cattle. An understanding of growth hormone use in cattle is necessary in order to properly investigate and analyse the Dispute. It is also necessary in order to fully understand the inter-connectivity between animal growth hormones and their treatment under the terms of the SPS Agreement.

Scientific or technological breakthrough has resulted in the creation of hormone supplements which can be given to animals in order to assist the growth of lean meat tissue. Growth promoting hormones are used extensively in many countries around the world to enhance beef cattle production. In particular, the large cattle-producing regions of Australia, New Zealand, and Argentina sanction the production of beef using growth hormones.[11] Growth hormones are used widely in beef production in the US and have been approved for use there since the 1950s. In the US, animal growth hormones are now believed to be used on

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[9] Science espoused as the basis for risk analysis in the SPS Agreement and culture in the form of regulatory biases in national or supranational sanitary measures enacted.

[10] Indeed, while in pursuit of further trade liberalisation, WTO Members have sometimes failed in global trade talks because the proposed trade liberalisation touched upon fundamental societal values enshrined in longstanding and robust domestic regulations. See T. Bernauer, note 7 Chapter 2 above, p.79.

[11] W.A. Kerr & J.E. Hobbs, note 164 Chapter 2 above, p. 285.

approximately two-thirds of all cattle and on about 90 per cent of the cattle in feedlots. In the massive concentrated animal feeding operations (CAFOs),[12] their use approaches 100 per cent.

The economic benefits are substantial. Apparently, growth hormones used in cattle typically increase lean tissue by between 8 – 20 per cent over the cattle-raising cycle.[13] One US study has found that through improving cattle growth rates and feed conversion efficiency, growth hormones have increased annual US beef production by more than 700 million pounds while saving more than 6 billion pounds of feed. In addition, if US beef production practices from 1955 were applied today, an additional 165 million acres of land (an area almost the size of Texas) would be required in order to equal modern growth hormone assisted beef production in the US.[14]

FDA says that people are not at risk from eating food from animals treated with these drugs.[15] In a diametrically opposed move, when before the WTO Dispute Settlement Body in the *Beef Hormones Dispute*, one of the arguments put forward by the EU was that there was insufficient scientific data supporting the safety of growth hormones.[16] In stark contrast with the US approach, as of March 1988,[17] the use of all growth hormones for fattening purposes had been banned in the EU. In particular, the six specific growth hormones in dispute with the US[18] had been banned including a ban on the importation into the EU of meat or live cattle treated with any of the growth hormones.

Growth hormones are used because they have the effect of reducing fat deposition in animals and since fat is so energy dense, food conversion efficiency is increased. Lean tissue growth

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[12] Aside from the concerns surrounding hormones, United States beef from their CAFO raised cattle can have up to 500 per cent more saturated fat than that of grass-fed cattle – the producers feed a diet that will produce a more marbled meat. Because the cattle are raised in appalling overcrowded conditions, their skin is often covered in faecal matter and bacteria which can be a breeding ground for the bacteria *e-coli*. As a result, after slaughter, their meat is sometimes washed with chlorine in order to prevent an outbreak of *e-coli* infection.

[13] See generally C.S. Houston, note 166 Chapter 2 above, p. 269.

[14] J. Kelzer, note 175 Chapter 2 above.

[15] See "Steroid Hormone Implants Used for Growth in Food-Producing Animals", Available at: http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm055436.htm [Accessed: 18 March 2012]

[16] Paragraph 200 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.

[17] Council Directive 88/146/EEC, note 190 Chapter 2 above.

[18] The six specific growth promotants are oestradiol 17β, testosterone, progesterone, trenbolone acetate (TBA), zeranol, and melengestrol acetate (MGA). While all such animal growth hormones are banned in the EU, it is these six in particular that were in dispute with the US, as it is these six hormones which have been legitimised for use under US law.

is also increased. This allows the animals to grow larger, more quickly, on less feed and fewer other inputs, thereby reducing production costs. In addition, the resultant leaner carcass is more in line with consumer preferences for lean meat and also for diets with reduced fat and cholesterol.[19] Recent years has seen research into the effect of growth hormone treatment on the eating quality of beef. Apparently, 'the balanced view on hormone treatments, especially repeat implantations, is that they lead to small reductions in tenderness and eating quality' of the beef.[20]

Apparently, the most important implant in terms of 'improving performance' and reducing costs is the last growth hormone implant used prior to selling the animal. This is colloquially called the 'terminal implant'. Therefore, as it gets closer to the sale of the cattle, it is important for the feedlot manager to choose the optimum implant strategy depending on the objective. The more 'aggressive' form of implant programs (high potency combination implants given early and re-implanted) yield maximum performance and lowest cost for the gain achieved, but they increase the risk of lower quality beef. Therefore, this aggressive implant strategy suits a lower quality market that demands a leaner less tasty beef and a greater quantity of it. High quality markets demand a more tender, marbled[21] beef and this usually correlates with a smaller animal. Therefore, these markets demand a less aggressive implant strategy or else longer feeding periods to achieve those heavier weights. Therefore, in those situations a moderate growth hormone dosage combination implant is used. This allows improved carcass quality without giving up a large performance response.[22]

The hormones in growth promoting implants include estrogens[23] (estradiol and zeranol), androgens[24] (testosterone and trenbolone acetate or TBA) and progestins[25] (progesterone and melengestrol acetate or MGA). The group of six hormones banned by the EU and sanctioned

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[19] See generally, R. Johnson & C.E. Hanrahan, note 175 Chapter 2 above.

[20] See, New South Wales, Department of Primary Industries, *Understanding Hormonal Growth Promotants*, note 172 Chapter 2 above.

[21] In the US, the Unites States Department of Agriculture Food Safety and Inspection Service (FSIS) uses 'marbling' as the factor governing beef quality. Marbling or intramuscular fat is the intermingling or dispersion of fat within the lean beef. Graders evaluate the amount and distribution of marbling after the carcass has been ribbed between the 12th and 13th ribs. Prime-cut would have marbling described as 'abundant' whereas standard-cut would have marbling classed as 'trace'. This system correlates quite accurately with the length of time it took to raise the cattle versus the amount of growth promotant used.

[22] See, D. Loy, *Growth Promotants in Cattle*, (Iowa: Iowa Beef Center – Iowa State University, 2008) p.4.

[23] Female sex hormone.

[24] Male sex hormones.

[25] A progestin is a synthetic progestogen that has progestinic effects similar to the female hormone progesterone.

for use by the US (and Canada) are comprised of three 'natural hormones'[26] (that also occur naturally in the animal) and three 'synthetic hormones'. The three natural hormones are oestradiol-17β (responsible for female characteristics), testosterone (responsible for male characteristics), and progesterone (responsible for maintaining pregnancy). The three synthetic hormones are zeranol, trenbolone acetate (TBA),[27] and melengestrol acetate (MGA).

Hormones derived from one sex, when used in the opposite sex, produce additional growth in that animal. Oestrogen is the female sex hormone and there are two oestrogen hormones: oestradiol 17β and oestradiol benzoate. 'Androgen' is the term used to refer to a male sex hormone such as testosterone.[28] Androgens are not as decisive a growth hormone as oestrogens. Comprehensive worldwide research has identified oestrogens as the major class of growth promoting hormones and therefore oestrogens are regarded as the most important growth hormone in beef cattle.[29] Consequently, oestrogens are the base hormone in most growth hormone implants registered for use in the US and other countries where the use of growth hormones in beef production is permitted.

Most growth hormones come in the form of small pellets that are implanted under the skin at the back of the animal's ear. The pellet slowly releases a gradual hormone dosage over a certain period of time - usually 100 to 200 days, depending on the product used. A minority of growth hormones also come in either powder or liquid form and are administered by mixing the product with the animal's feed.

A number of trials have been carried out with combined preparations of implants containing two hormones. The combination of an oestrogen with an anabolic steroid, or with progesterone, has met with the greatest responses. Indeed, the most marked effects for highly significant positive effects on the growth rate and feed conversion efficiency ('FCE') in cattle is provoked by implants combining an oestrogen with an androgen of high anabolic activity.[30]

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[26] Often referred to as 'naturally occurring' hormones.

[27] Zeranol and trenbolone acetate hormones are implanted behind one of the animal's ears as a time-release implant, releasing hormones during key growth stages. The hormones provide a substantial cost saving to the cattle-producer as they may eliminate as much as twenty days feeding equivalent each time they are used.

[28] See generally, W. Velle, "The Use of Hormones in Animal Production" – *Paper 31 of selected papers presented to the joint FAO/WHO Expert Committee on Food Additives, Geneva, 23 March - 1 April 1981* (Rome: Food & Agriculture Organisation of the United Nations, 1982).

[29] *Ibid.*

[30] *Ibid.*

The two oestrogen hormones oestradiol 17β and oestradiol benzoate have the same activity and are therefore used either individually or in combination with a progesterone or androgen hormone, in implants.[31]

It has been found that 'repeat implantation of hormone is not likely to produce the benefits obtained from its initial use, since a second dramatic change in the endocrine balance of the animal is not likely to occur. In addition, double implantation increases the possibility of exceeding the optimum dose rate and the chance of deleterious side effects occurring'.[32]

It is also important to note that the US consumer is not prevented entirely from buying hormone-free beef. Hormone-free beef is available in many US foodstores. However, it is significantly more expensive. There are two kinds of hormone-free beef – 'naturally raised' and 'organic'. Beef packaged with the 'naturally raised' label must come from cattle raised without growth hormones and it must have been verified as such via a United State's Department of Agriculture (USDA) verification program.[33] Beef marketed as organic must have been raised without hormones and must adhere to strict organic guidelines especially the feeding of the cattle with only organically-grown feed.[34] Research has shown that Americans are gradually transitioning to a reliance on organic meat and this may imply a rejection of beef produced with the aid of growth hormones.[35]

7.2 EU and US Cultural Divergences in the Approval of Drug Safety

The Federal Food, Drug, and Cosmetic Act, 1938, which governs the regulation of new animal drugs in the US, was substantially revised by the enactment of the Animal Drug Amendments in 1962.[36] Although the amendments made in 1962 purported to simply expand

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[31] *Ibid* - see generally.
[32] G.E. Lamming, "1958 - Recent developments in the use of growth stimulants in farm animals" (1958) *Journal Royal Agricultural Society of England*, Issue 119, p. 45.
[33] In addition, these cattle cannot have been fed antibiotics or any food originating from an animal by-product.
[34] See, D. Loy, *Understanding Hormone Use in Beef Cattle*, (Iowa: Iowa Beef Center – Iowa State University, 2008).
[35] See A. Ziehl, D. Thilmany, and W. Umberger, "A Cluster Analysis of Natural Beef Product Consumers by Shopping Behavior, Importance of Production Attributes, and Demographics" (2005) 31 *Journal of Food Distribution Research*, p1.
[36] See, P. Barton Hutt & R.A. Merrill, *Food and Drug Law: Cases and Materials, 2nd edn.*, (Westbury, N.Y.: Foundation Press, 1991), p.13.

the new-drug approval system, they in fact transformed it.[37] It is a requirement of the Federal Food, Drug, and Cosmetic Act, 1938 ('Food and Drug Act') that any potential new animal drug must obtain FDA approval for use, prior to being put on the market. In addition, the amendments of 1962 provided that the FDA carry out a review of effectiveness as well as safety for any new drug.[38] What had been in effect a premarket notification system had now been converted into a premarket approval system.[39]

The United States Food and Drug Administration (FDA) has authority over substances added to animal feed and over animal drugs falls within two areas of the Food and Drug Act – (a) food additives, and (b) new animal drugs. A food additive is any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of food.[40] S.510.3(g) Title 21 of the Code of Federal Regulations (CFR),[41] defines 'new animal drug' as 'any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed'.

Under US food and drug law, the definition of food additive is so broad that it covers most substances capable of being becoming a constituent part of any food item. If the applicant does not want a substance to be classified as a food additive, then evidence must be provided that the substance does not become a component of food for human consumption, or if it does, then it must be shown that it is generally recognized as safe (GRAS). Under US food law, since 1958,[42] 'food additives' and 'dietary supplements'[43] require pre-market approval from FDA unless they are GRAS.

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[37] R.A. Merrill, "Regulation of Drugs and Devices: An Evolution", (1994) 13 *Health Affairs*, 13, No.3, p.50

[38] The 1962 *Drug Amendments* were passed in response to the thalidomide scandal. Thalidomide was marketed to assist with relief for pregnant women from morning sickness in but it was later found to cause birth deformities in babies. As a result of the 1962 Amendments, drug companies were required, prior to market release, to establish that drugs were both safe *and* effective and the FDA was granted greater authority to oversee clinical trials for new drugs. Prior to the amendments of 1962, the 1938 Act had only required proof of safety.

[39] R.A. Merrill, note 37 above, p.50

[40] 21 USC 321(s). Note: The United States Code (USC.) is the compilation and codification of the general and permanent federal laws of the United States. It is composed of 51 Titles. Basically, it takes each Act of Congress or Statute (as amended) and then accumulates all of these on the basis of subject areas, so that it is not necessary to trawl through a multitude of enactments in order find all of the substantive law on any particular topic.

[41] The Code of Federal Regulations being the 'administrative law' which spells out in greater detail the substantive law contained in the 'enabling statute'. The enabling statute in this case being the Food and Drug Act.

[42] Amendments made in 1958 to the Federal Food, Drug and Cosmetic Act 1938, 21 USC. S.321 *et seq*

[43] Examples of dietary supplements are vitamins, minerals, herbs, etc.

However, the Food and Drug Act expressly excludes 'new animal drugs' from the definition of 'food additive' and they are regulated separately.[44] In effect, new animal drugs are treated in the same way as new drugs intended for human application. The six growth hormones which are the subject of the *Beef Hormones Dispute*, are classified as new animal drugs - listed as such at S.522 'Implantation or Injectable Dosage Form New Animal Drugs' - Title 21[45] CFR.

An application to market a new animal drug must include the applicant's details; the proposed trade name and chemical name; the drug's chemical structure; details of the dosage and quantitative composition; the scientific and clinical purpose of the drug; detail of any significant pharmacological or toxicological findings when laboratory studies were carried out; an outline of the new drug's major attributes of effectiveness and safety; copies of the labelling; details of usage as appears on the label; details of the ingredients used in the production of the new animal drug; and a description of the manufacturing, processing, and packing methods.[46] In particular, the application for approval of the drug must be accompanied by 'full reports of investigations which have been made to show whether or not such drug is safe and effective for use'. Otherwise the application for drug approval will be refused. [47] These investigations must be based on the opinions of experts, qualified by scientific training and experience to evaluate the safety of such drugs.[48]

The Delaney Clause is a 1958 Amendment to the Food and Drug Act, which provides that 'the Secretary of the Food and Drug Administration shall not approve for use in food any chemical additive found to induce cancer in man, or, after tests, found to induce cancer in animals'. Both the approval of food additives and new animal drugs are subject to a form of Delaney Clause which means that if they are shown to be in any way carcinogenic, then they will not be authorised for use.

In the process for approving a new animal drug, if after the appropriate tests have been carried out and it is shown that the 'drug induces cancer when ingested by man or animal'

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[44] 21 USC 321(s)(5).
[45] 'Subchapter E' of Title 21, covers animal drugs, feeds, and related products.
[46] See, 21 CFR, S.514.1 (b).
[47] 21 USC 360(b).
[48] 21 USC 360(b)(d)(2)(C).

then an order shall be issued to refuse the application. However, quite incredibly, this order for refusal shall not be issued if it is found that:

> under the conditions of use specified in the proposed labelling and reasonably certain to be followed in practice (i) such drug will not adversely affect the animals for which it is intended, and (ii) no residue of such drug will be found ... in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animals.[49]

Therefore, this is in effect, an exception to the Delany Clause requirement. While there is an exception to this requirement for new animal drugs 'given to animals for production' in the circumstances outlined above, there is no such exception for any food additive. Therefore, since as we shall see, questions have been raised about the potential carcinogenic effects of some growth hormones, manufacturers of growth promoting hormones were keen to ensure that their products came under the new animal drug head of regulation.

Additional criticisms can also be levelled at the scientific nature of the exception. For example, how does one ensure a definition of 'residue' that is safe to human health? It would be based on estimated tolerance levels, but again, there is an element of subjectivity involved there also. In relation to the inedible 'portion of such animals after slaughter', where do those portions go? Are they used as an input for animal feed and then re-fed to animals which are used for human consumption? No doubt these issues are likely to be also regulated. However, this all evidences the difficulty in striving to base effective food or drug approvals on scientific risk assessment alone.

It is evident from the process described here, that it is a purely science driven mechanism for approving 'new animal drugs'. The reliance on scientific risk analysis is palpable in the wording of these drug safety regulations. It is a purely methodical process with no provision for the inclusion of issues such as 'other legitimate factors' at any time, until the drug has been approved for use. It is a system which favours technological innovation, but it also favours industry and commerce.

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[49] 21 USC 360(b)(d)(1)(I).

This can be contrasted with the more consumer orientated and tradition favouring position under EU food law. As we have seen, the most fundamental norm of EU food safety law is that food may not be placed on the market if it is unsafe.[50] Under EU law such all encompassing terms as the definition of food additive in US law, are not as prevalent. Instead, in the EU, it is on a one by one basis that certain foods and categories of foods have been brought under approval requirements.

In its 2000 Communication on the Precautionary Principle,[51] the European Commission declared it stance on the burden of proof when it comes to risks to the health of EU citizens. The Commission stated that along with those of many third countries, Community rules enshrined the principle of prior approval. This idea of prior approval would apply to substances deemed 'a priori' hazardous or which would be potentially hazardous at a certain level of adsorption. The substances would be deemed hazardous until proven otherwise and the legislator would not authorize use of the substance. This effectively means the creation of 'positive lists' of potentially hazardous substances.[52] These lists would contain certain proscribed products such as drugs, pesticides or food additives, and therefore pre-market approval would be necessary before a manufacturer could place these on the open market.[53] The Commission views this system of pre-market approval as an application of the precautionary principle. However, most items are covered by positive lists which list all of the approved components, for example all of the approved flavourings that may be used in food. Therefore, application would have to be made and after risk analysis, the list can be amended to include a new flavouring which has been authorised for use.[54]

In addition, the division between risk assessment and risk management extant under EU food safety regulation, identified by the analysis in the preceding Chapters of this thesis, will allow the inclusion of cultural considerations at the risk management stage before any product approval is granted. Overall, regulatory divergences are clearly evident here between the EU

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[50] Article 14 of European Parliament and Council Regulation (EC) No 178/2002, note 72 Chapter 2 above.
[51] Communication from the Commission on the Precautionary Principle, COM(2000) 1.
[52] See, B.M.J. van der Meulen, note 148 Chapter 2 above, p.58.
[53] Communication from the Commission on the Precautionary Principle, COM(2000) 1, p. 20.
[54] See for example, Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC, [2008] O.J. L354/34.

approach applying the precautionary principle and allowing other legitimate factors, and the US predominantly science based approach.

7.3 Six Animal Growth Hormones Banned in the EU

Throughout the 1980s and 1990s, the EU introduced a number of provisions that banned the use of growth hormones in beef production throughout the EU.[55] As of March 1988,[56] the use of all growth hormones for fattening purposes had been banned in the EU.[57] In particular, the six specific hormones in dispute with the US[58] had been banned including a ban on the importation into the EU of meat or live cattle, treated with any of the growth hormones. The ban is still in place. It has been noted that serious critical debate on urgent social questions does not contribute to the maximisation of profit, and therefore, increasingly in the US, this debate does not take place.[59] In the US, the question of the safety or otherwise of the six growth hormones never entered the political agenda.

The fear in the EU was that a growth hormone residue would remain in the meat after the animals were slaughtered and that the ingestion of these residues would pose a threat to human health. In the US,[60] FDA had what was for them a routine decision as to whether or not to approve the growth hormones. Their culture allows for the accepted exclusive reliance

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[55] The legislative measures introduced were: Council Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action, [1981] O.J. L222/32; Council Directive 88/146/EEC prohibiting the use in livestock farming of certain substances having a hormonal action, [1988] O.J. L70/16; Council Directive 88/299/EEC on trade in animals treated with certain substances having a hormonal action and their meat, as referred to in Article 7 of Directive 88/146/EEC, [1988] O.J. L128/36; Council Directive 96/22/EC concerning the prohibition on the use in stock-farming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC, [1996] O.J. L 125/03.

[56] Council Directive 88/146/EEC, note 190 Chapter 2 above.

[57] A number of the controversial EU provisions banning growth promotants were enacted before the coming into existence of the SPS Agreement in 1995. However, in *EC-Hormones*, the Appellate Body agreed with the Panel's findings and concluded that 'the SPS Agreement, and in particular Articles 5.1 and 5.5 thereof, applies to measures that were enacted before the entry into force of the WTO Agreement, but that remain in force thereafter'. Paragraph 253(d) of Appellate Body Reports WT/DS26AB/R and WT/DS48/AB/R

[58] The six specific growth promotants are oestradiol 17β, testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate. These six growth promotants are used widely in the US In the US, it is legally permissible to administer these six growth promotants (or combinations thereof) to animals, under certain conditions, for growth promotion or fattening purposes.

[59] J. Smiers, *Arts under pressure: Promoting Cultural Diversity in the Age of Globalisation* (London: Zed Books, 2003) p. 136.

[60] And similarly with Health Canada – the food safety authority in Canada.

on scientific data as a basis for regulatory approval.[61] By relying, only on the available scientific evidence, the Americans approved the use of the hormones. The taking of the US decision was depoliticised by a system which keeps the information on which the approval or disapproval of veterinary drugs is based, confidential. In addition, more specifically, during this approval process, the application or testing carried out by the developer of the hormones was kept confidential.[62] On the contrary, this thesis notes that this approach would have been impossible in the EU due to the existence of a more politicised and less technocratic regulatory style which accommodates cultural considerations and consumer concerns under the risk management function.

7.4 Regulation of Animal Growth Hormones in the United States

The relevant Sections of the Food and Drug Act as codified in the US Code of Federal Regulations (CFR), details the permissible growth hormones.[63] Each Section of the CFR containing the details and dosage for an approved use of a New Animal Drug begins with a clause which specifies the relevant section of the CFR containing a list of the approved applicants or sponsors for that drug. The company (also called applicant or sponsor) that submits an application to FDA for approval to market a drug product in the US is referred to either as the applicant or the sponsor. Next, the section of the CFR containing the details and dosage for an approved use of a New Animal Drug, lists a reference to the relevant section of the CFR which contains the specified allowable tolerances for the drug. The section then moves on to outline the 'conditions of use' for the specific hormones or combination of hormones – i.e. the dosage amount or quantity, method of application and uses.

Rather than outline the complete text authorising each of the six growth hormones, the following summary contains the complete details for the natural hormone estradiol, along with the complete details for the synthetic hormone zeranol, as provided in the relevant US legislation. While also based on the relevant US legislation, only a basic description of the other four growth hormones will be provided as this will be more appropriate for the purposes of this thesis.

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[61] In addition, this use of the administrative principle of delegated agency responsibility has the effect of producing a technocratic regulatory policy style. See generally, G. Skogstad, note 57 Chapter 3 above, p.222.
[62] *Ibid*, p.222.
[63] See generally C.S. Houston, note 166 Chapter 2 above, p. 269.

7.4.1 Six Specific Growth Hormones:

7.4.1.1 Three Natural Hormones:

(a) Estradiol

Estradiol[64] is one of the hormones prohibited in the EU. Estradiol can be administered in the US in the form of silicone implants in either 25.7 or 43.9 milligram doses.[65] Implantation[66] with estradiol is permitted in steers and heifers only.[67] The legislation specifies that one 25.7 milligram implant can be used every 200 days, or one 43.9 milligram implant every 400 days.[68] The estradiol implant has the effect of increasing weight gain in suckling and pastured growing steers, improves feed efficiency, and increases the rate of weight gain in confined steers and heifers.[69] A second such implant was expressly permitted. However in November 2004 the language authorizing such use was removed from the regulation.[70]

Section 522.841 Title 21 CFR permits the use of estradiol benzoate in stockfarming.[71] It is permitted to administer it by subcutaneous injection[72] in the ear, for growth enhancement purposes.[73] Ten milligrams of estradiol benzoate may be administered to suckling beef calves,[74] and twenty milligrams for steers and heifers fed in confinement for slaughter.[75] The

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[64] Estradiol is also known as E2, 17β-estradiol, or oestradiol.
[65] 21 CFR, S.522.840(a).
[66] Due to rapid metabolic transformation in the liver, these natural hormones have low bioavailability when administered orally. As a result they are therefore administered by subcutaneous implantation. Subcutaneous implantation, usually at the base of the ear, eliminates the risk that residues of the implantation site will be present in edible tissue.
[67] See 21 CFR, S.522.840(d)(3).
[68] 21 CFR, S.522.840(d)(1).
[69] *See* 21 CFR, S.522.840(d)(2).
[70] *See* 21 CFR, S.522.840(c)(3).
[71] *See* 21 CFR, S.522.841.
[72] Due to rapid metabolic transformation in the liver, these natural hormones have low bioavailability when administered orally. As a result they are therefore administered by subcutaneous implantation or injection. Subcutaneous implantation, usually at the base of the ear, eliminates the risk that residues of the implantation site will be present in edible tissue.
[73] 21 CFR, S.522.841(d)(1)(iii).
[74] 21 CFR, S.522.841(d)(1)(i).
[75] 21 CFR, S.522.841(d)(2)(i) and (d)(3)(i).

use of estradiol benzoate on calves intended for reproduction or calves less than thirty days old is prohibited.[76]

Section 522.850 authorizes the combined use of the hormones 'estradiol valerate' and 'norgestomet' for synchronization of estrus or ovulation in cycling beef cattle and non-lactating dairy heifers.[77] Section 522.850 requires that the implant must be removed on day ten.[78] As the implants are removed they must be collected and burned.[79] However, this combination cannot be used in cows producing milk for human consumption.[80]

Estradiol is also identified as E2, or 17β-estradiol, or oestradiol. Many papers have been published which cite the carcinogenic properties of this hormone. For example, a typical example of the findings would be as follows:

> ... 17β-estradiol induces tumors in various organs of rats, mice, and hamsters. In humans, slightly elevated circulating estrogen levels caused either by increased endogenous hormone production or by therapeutic doses of estrogen medications increase breast or uterine cancer risk. ... The induction of tumors by E_2 and its esters was described in the late 1930s by Lipschutz and Vargas[81] in guinea pigs and by Gardner[82] in the early 1940s in mice. Since that time, many more reports of tumor induction by estrogens have been published, and many rodent tumor models have been introduced. In contrast, the potential carcinogenic activity of estrogen-containing medications in humans has not been recognized for many years. Estrogens have generally been considered beneficial, based on a variety of hormonal effects. However, in the past 15–20 years epidemiological studies have

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[76] 21 CF, S.522.841(d)(2)(iii) and (d)(3)(iii).
[77] 21 CFR, S.522.850(c)(2).
[78] 21 CFR, S.522.850(c)(3).
[79] *Ibid.*
[80] *Ibid.*
[81] A. Lipschotz, M.D. & L. Vargas, Jr., M.D. "Structure and Origin of Uterine and Extragenital Fibroids Induced Experimentally in the Guinea Pig by Prolonged Administration of Estrogens", (1941) *Cancer Research*, Vol.1, p.236–p.248.
[82] See generally, WHO International Agency for Research on Cancer, *Monographs on the Evaluation of Carcinogenic Risks to Humans*, (Lyon: IARC, 1987), Supplement 7, pp 280–285 and WHO International Agency for Research on Cancer, *Monographs on the Evaluation of Carcinogenic Risks to Humans: Hormonal Contraception and Postmenopausal Hormone Therapy*, (Lyon: IARC, 1999), Vol. 72.

> increasingly pointed in humans to an increased breast or uterine tumor risk associated with estrogens. ... Estrogen administration is accepted by most epidemiologists as a risk factor of human endometrial adenocarcinoma. Thus, estrogens unopposed by progestins increase the risk of uterine tumors. This risk increases with increasing doses of estrogen and with the length of treatment. ... These biological studies in animals and epidemiological studies in humans all clearly identify E_2 as a carcinogen.[83]

Other hormones, such as testosterone propionate,[84] progesterone,[85] and trenbolone acetate,[86] can be either used in isolation or by combining them with other hormones.[87] These approved hormones have several growth promotion and production functions, including increasing weight gain, improving feed efficiency, and synchronization of estrus and ovulation.[88]

(b) Testosterone

Section 522.842[89] Title 21 CFR authorizes the combined use of the hormones 'estradiol benzoate' and 'testosterone propionate' for increased rate of weight gain and improved feed efficiency.[90] The hormones may be administered to heifers weighing 400 pounds or more by subcutaneous ear implantation of one dose per animal.[91] The hormones are not to be used in dairy or beef replacement heifers or in calves that are going to be processed for veal.[92] The

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[83] See J. G. Liehr, "Is Estradiol a Genotoxic Mutagenic Carcinogen?", (2000) *Endocrine Reviews* Vol. 21 No. 1, p. 40-54.
[84] Testosterone treated beef has been banned in the E.U. See generally Council Directive 2003/74, O.J. L262.
[85] Progesterone is one of the six growth hormones that is prohibited in the E.U. See generally Directive 2003/74, O.J. L262.
[86] Trenbolone acetate is also one of the hormones prohibited by the E.U. See generally Directive 2003/74 O.J. L262.
[87] See 21 CFR, S.522.842 (2005); 21 CFR, S.522.1940 (2005); and 21 CFR, S.522.2476.
[88] *Ibid.*
[89] S.522.842 lists the labeler codes for these two hormones as 000856 and 021641. As listed in S.510.600, these labeler codes correspond to 'Fort Dodge Animal Health, Division of Wyeth, a wholly owned subsidiary of Pfizer, Inc., 235 East 42d St., New York, NY 10017' and 'Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond Street, Overland Park, KS 66214', respectively. Therefore, these two companies are the two companies with approved NADA's (&/or ANADA's) in the US for these two drugs/hormones. The drugs would then be marketed in the US under their proprietary names. For example, Fort Dodge Animal Health sells testosterone propionate under the brand name *Synovex®-H*. The Green Book would contain information on these two new animal drugs, such as details of these sponsors and the drugs trade name, the active ingredients, patent information and any applicable exclusivity period for marketability of the product.
[90] 21 CFR, S.522.842(2).
[91] 21 CFR, S.522.842(3).
[92] *Ibid.*

Section states that safety and effectiveness of the drug has not been established in veal calves.[93]

(c) Progesterone

Section 522.1940[94] authorizes the combined use of the hormones 'progesterone' and 'estradiol benzoate' for increased rate of weight gain.[95] The hormones may be administered to suckling beef calves (at least 45 days of age) up to 400 pounds (lb) of body weight via subcutaneous ear implantation of one dose per animal[96] and steer weighing 400 lb or more via subcutaneous ear implantation of one dose per animal.[97] The hormones may also be administered to steers weighing 400 lb or more via subcutaneous ear implantation of one dose per animal.[98]

Section 522.1940[99] also authorizes the combined use of the hormones 'progesterone' and 'estradiol benzoate' for 'steers fed in confinement for slaughter'. The hormones may be administered to the steers in order to achieve additional improvement in rate of weight gain.[100] The hormone must be administered via subcutaneous ear implantation.[101] Under the Limitations it is stated that 'safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal'.[102]

7.4.1.2 Three Synthetic Hormones

(a) Zeranol

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[93] *Ibid.*

[94] S.522.1940(a)(1) & (a)(2) lists the labeler codes for these two hormones as 000856 and 021641 – i.e. the same companies as for testosterone, namely 'Fort Dodge Animal Health, Division of Wyeth, a wholly owned subsidiary of Pfizer, Inc., 235 East 42d St., New York, NY 10017' and 'Ivy Laboratories, Div. of Ivy Animal Health, Inc., 8857 Bond Street, Overland Park, KS 66214', respectively. For example, Fort Dodge Animal Health sells progesterone and estradiol benzoate under the brand names *Synovex C and Synovex S.*

[95] 21 CFR, S.522.1940(B)(2).

[96] 21 CFR, S.522.1940(C)(1)(B)(iii).

[97] 21 CFR, S.522.1940(C)(2)(A) & (B).

[98] 21 CFR, S.522.1940(C)(2)(iii).

[99] S.522.1940(C)(3).

[100] 21 CFR, S.522.1940(C)(3)(ii).

[101] 21 CFR, S.522.1940(C)(3)(iii).

[102] *Ibid.*

Section 522.2680[103] Title 21 CFR authorizes the use of the hormone zeranol for beef cattle.[104] The 'indication for use' is for increased rate of weight gain and improved feed conversion in weaned beef calves, growing beef cattle, feedlot steers, and feedlot heifers and also for increased weight gain in suckling calves.[105] The dosage amount is 36 mg zeranol (one implant consisting of 3 pellets, each pellet containing 12 mg zeranol) per implant dose.[106] The drug is to be implanted subcutaneously in the ear only.[107] Its use in bulls intended for reproduction or in dairy animals is not authorised. It cannot be used before 1 month of age or after weaning in heifers intended for reproduction. It is advised that safety and effectiveness has not been established in veal calves and that a withdrawal period has not been established for this product in preruminating calves. It cannot be used in calves to be processed for veal.[108]

Aside from beef, Section 522.2680 also authorizes the use of the hormone zeranol for use on feedlot lambs.[109] The 'indication for use' is for increased rate of weight gain and improved feed conversion.[110] The dosage amount is 12 mg zeranol (one implant consisting of 1 pellet containing 12 mg zeranol) per implant dose.[111] The drug is to be implanted subcutaneously in the ear only.[112] The limitations of use are that it is not to be used in breeding animals. It is not to be implanted in animals within 40 days of slaughter. It is advised that safety and effectiveness have not been established in veal calves and that a withdrawal period has not been established in preruminating calves. It is not to be used in calves intended to be processed for veal.[113]

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[103] 21 CFR, S.522.2680(a)(1) & (a)(2) lists the labeler code for this hormones as 000061. As listed at Section 510.600(c), the corresponding sponsor for that labeler code is Intervet, Inc., 556 Morris Ave., Summit, NJ 07901. Intervet Inc. is part of Merck Animal Health. On November 4, 2009 Schering-Plough merged with Merck & Co. On June 29, 2011, the company announced that the animal health division would now be known as Merck Animal Health in the United States and Canada and it would be called MSD Animal Health elsewhere in the world. Zeranol is one of the most widely used anabolic agents used to promote the growth of cattle and other domestic animals, maximizing both rate of weight gain and feed efficiency. For many years, Zeranol has been commercially available worldwide from the aforementioned corporation, in a formulation known as *Ralgro®*.
[104] 21 CFR, S.522.2680(d)(2).
[105] 21 CFR, S.522.2680(d)(1)(A)&(B).
[106] 21 CFR, S.522.2680(d)(1)(i).
[107] 21 CFR, S.522.2680(d)(1)(iii).
[108] *Ibid.*
[109] 21 CFR, S.522.2680(d)(2).
[110] 21 CFR, S.522.2680(d)(2)(ii).
[111] 21 CFR, S.522.2680(d)(2)(i).
[112] 21 CFR, S.522.2680(d)(2)(iii).
[113] *Ibid.*

Section 522.2680 authorizes the use of the hormone zeranol for 'steers fed in confinement for slaughter'.[114] The 'indication for use' is for increased rate of weight gain and improved feed efficiency.[115] The drug is to be implanted subcutaneously in the ear only.[116] The dosage amount is 72 mg of zeranol (one implant consisting of 6 pellets, each pellet containing 12 mg zeranol) per implant dose. The limitations on use are that safety and effectiveness have not been established in veal calves. A withdrawal period has not been established in preruminating calves. It is not to be used in calves to be processed for veal.[117]

Section 522.2680 authorizes the use of the hormone zeranol for 'pasture cattle (slaughter, stocker, feeder steers, and heifers)'.[118] The 'indication for use' is for increased rate of weight gain.[119] The drug is to be implanted subcutaneously in the ear only.[120] The dosage amount is 138 mg of zeranol (one implant consisting of 7 pellets, each of 6 pellets containing 20 mg zeranol and a seventh pellet containing 18 mg zeranol) per implant dose.[121] The limitations of use are that safety and effectiveness have not been established in veal calves and a withdrawal period has not been established for zeranol product in preruminating calves. It is not to be used in calves to be processed for veal.[122]

(b) Trenbolone acetate

Section 522.2476 authorizes the use of the hormone trenbolone acetate for 'steers fed in confinement for slaughter' and 'heifers fed in confinement for slaughter'.[123] Section 522.2477 authorizes the use of the hormone trenbolone acetate combined with the natural hormone estradiol for 'steers fed in confinement for slaughter', 'heifers fed in confinement for slaughter' and 'pasture cattle'.[124] Section 522.2478 authorizes the use of the hormone

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[114] 21 CFR, S.522.2680(d)(3).
[115] 21 CFR, S.522.2680(d)(2)(ii).
[116] 21 CFR, S.522.2680(d)(2)(iii).
[117] *Ibid.*
[118] 21 CFR, S.522.2680(d)(4).
[119] 21 CFR, S.522.2680(d)(4)(ii).
[120] 21 CFR,S.522.2680(d)(4)(iii).
[121] 21 CFR, S.522.2680(d)(4)(i).
[122] 21 CFR, S.522.2680(d)(4)(iii).
[123] 21 CFR, S.522.2476(c)(1) & (c)(2).
[124] 21 CFR, S.522.2477(d)(1) ,(d)(2) &(d)(3).

trenbolone acetate combined with the hormone estradiol benzoate for 'steers fed in confinement for slaughter' and 'heifers fed in confinement for slaughter'.[125]

(c) Melengestrol

Melengestrol falls into the category defined in the legislation as 'Specific New Animal Drugs for Use in Animal Feeds'.[126] According to the drugs specification, the drug comes in both a 'dry form' and a 'liquid form'.

The 'indications for use' vary depending on the dosage amount per head. The drug is given to either 'heifers fed in confinement for slaughter' or 'heifers intended for breeding'. For heifers fed in confinement for slaughter the purpose of using the drug is for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).

The drug is added to the animal feed. A typical dosage would be to 'administer 0.5 to 2.0 pounds (lb)/head/day of medicated feed containing 0.125 to 1.0 mg melengestrol acetate/lb to provide 0.25 to 0.5 mg melengestrol acetate/head/day. Depending on which of the above indications of use is relevant, the melengestrol is sometimes administered in conjunction with lasalocid, tylosin, monensin or oxytetracycline.[127]

7.4.2 FDA – Conclusion Reached on Approval of a Growth Hormone

After the approval of a new animal drug, FDA issues a Freedom of Information Summary. On approval of the growth hormones 'progesterone' and 'estradiol benzoate' under the tradenames *Synovex C* and *Synovex S*, on October 28, 2004, FDA issued the following summary. It offers an insightful example of the practical approach taken to the sale and application of the drug. It is interesting to note the Agency's conclusions:

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[125] 21 CFR, S.522.2478(d)(1) & (d)(2).
[126] 21 CFR, S.558.342.
[127] 21 CFR, S.558.342(e).

> The information submitted in support of this NADA[128] satisfy the requirements of Section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations providing for the addition to the labelling of the statements 'A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal' to the warning section and 'Do not use in veal calves. Effectiveness and animal safety in veal calves have not been established' immediately following the indications....The Center for Veterinary Medicine has concluded that, for these products, adequate directions for use by the layperson have been provided and the product will have over-the-counter (OTC) status. Label directions are accompanied by pictorial diagrams and detailed instruction in plain language. The drugs are not controlled substances.[129] The product's status remains OTC. The labelling is adequate for the intended use and has sufficient warnings/statements to prevent illegal use in veal calves.[130]

This exemplifies the benign nature of the regulation surrounding the 'over the counter' sale classification and use of 'growth promotants' in the US. The very fact that the use of these drugs is permitted in the first place, negates the requirement for more onerous controls over their use. This can be contrasted with a situation where a drug has been banned. As we shall see with EU regulation of the banned growth hormones, a more strict framework is evident with penalties for any breaches.

More specifically, as is evident from the summary of the US requirements listed above, it appears that there is no record kept of the quantities sold to an individual, or the amounts administered and to which animals. The only monitoring possible afterwards is the random,

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[128] New Animal Drug Application.

[129] Under US federal law, the manufacture, importation, possession, use and distribution of certain substances is regulated – i.e. 'controlled substances'. The substances are regulated under the Controlled Substances Act (CSA), which was enacted into law as Title II of the Comprehensive Drug Abuse Prevention and Control Act 1970.

[130] See, United States Food and Drug Administration (FDA), *Freedom of Information Summary – Supplemental New Drug Application (NADA 009-576) SYNOVEX C and SYNOVEX S (Progesterone and Estradiol Benzoate)* - Approval Date: October 28, 2004, at: http://www.fda.gov/downloads/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/FOIADrugSummaries/ucm049523.pdf [Accessed: March 7, 2012]

on-the-spot inspection of carcasses at the time of slaughter.[131] However, this thesis submits that a form of end-point inspection such as this will not uncover the whole story surrounding the historical use of growth hormones on that animal.[132]

7.5 Regulation of Growth Hormones in the European Union

Prior to 1981, there was no official EU policy on the use of growth hormones in animals. However, national policies existed within individual EU Member States. EU antipathy towards growth hormones began in the 1970s with the diethylstilboestrol (DES)[133] scare involving cases of hormonal irregularities[134] in Italian adolescents.[135] Then, there was the discovery in 1980 of 30,000 jars of baby food in Italy containing dethylstilboestrol (DES).[136] The DES scare had created a consumer climate in the EU that was concerned over the potentially harmful health effects of using hormones in livestock production.[137] It was these events together with the discovery that DES was carcinogenic, that prompted European politicians to take action.[138]

7.5.1 EU Directives

From 1980 onwards the European Commission began to enforce various bans on the use of growth hormones in animal meat production which eventually culminated in 1988 with

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[131] In accordance with its remit under the Federal Meat Inspection Act, the Food Safety and Inspection Service (FSIS) of the US Department of Agriculture monitors beef for hormone residues. The FSIS does not have jurisdiction before an animal has been presented for slaughter, although some voluntary arrangements are in place. Prior to slaughter, FDA has jurisdiction. Again, FDA oversight is quite lax and dependent on the goodwill of the processor, with FDA simply pronouncing that it is 'required that the manufacturers demonstrate that the amount of hormone left in each edible tissue after treatment is below the appropriate safe level'. However, a more rigorous system is in place for beef that is to be exported to the EU. See the United States Food Safety and Inspection Service (FSIS), "Food Safety and Inspection Service's Program for Certifying Non-Hormone Treated Beef to the European Union" (June 12, 2007). Available at: fsis.usda.gov [Last Accessed: 7 August 2012].

[132] One example is that the growth promotants are often illegally injected directly into the animals muscle.

[133] DES was widely used as a growth hormone in the beef and poultry industry. It was later found to cause cancer and was phased out. From time to time, mainly in the US, allegations surface that some producers continue to use it. See, A.I. Marcus, note 186 Chapter 2 above.

[134] Exposure to the hormone was suspected as the cause for early puberty in girls. However, this has never been verified. See, R. Gandhi & S. Snedeker, note 187 Chapter 2 above.

[135] T. Josling, D. Roberts, & A. Hassan, note 188 Chapter 2 above, p.3.

[136] European Parliament, 1995, "Der illegale Einsatz von Hormonen zu Mastzwecken in Europa", note 187 Chapter 2 above.

[137] T. Josling, D. Roberts, & A. Hassan, note 188 Chapter 2 above, p.4.

[138] L. Caduff, note 189 Chapter 2 above, p.6.

Council Directive 88/146/EEC,[139] the first blanket ban on all of the six growth hormones concerned.[140] More importantly the measures banned the importation of meat and meat products treated with six specific growth hormones.[141] The relevant measures were EU Directives 81 /602/EEC,[142] 88/146/EEC,[143] 88/299/EEC,[144] and 96/22/EC.[145] Directive 96/22/EC repealed Directives 81/602/EEC,[146] 88/146/EEC[147] and 88/299/EEC.[148]

7.5.1.1 Directive 96/22/EC

Directive 96/22/EC which came into force on April 29, 1996, prohibits the use of hormonal, thyrostatic, and beta-agonist[149] substances in stock-farming.[150] The various clauses comprising the preamble to this Directive give a clear insight into the EU stance on the issue of growth hormone use in beef. For example, it is stated that because of the residues they leave in meat, certain substances having a thyrostatic, oestrogenic, androgenic or gestagenic action may be dangerous for consumers[151] and the improper use of beta-agonists can be a serious risk to human health.[152] The Directive reiterates that the prohibition on the use of hormonal substances for fattening purposes should continue to apply, but that certain substances for therapeutic or zootechnical purposes may be authorized.[153]

One of the most famous beta-agonists is clenbuterol. As a medicine, clenbuterol is sometimes used by people with chronic breathing disorders such as asthma. It acts as a bronchodilator

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[139] Council Directive 88/146/EEC, note 190 Chapter 2 above.
[140] Not all EU Member States agree with the ban on growth hormones in cattle. For example, the UK has consistently voted against the ban on the grounds that it could not be justified scientifically, but nevertheless has always implemented it. See, Explanatory Memorandum to the U.K. Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Amendment Regulations 2006, (2006, No. 755).
[141] The six hormones are oestradiol 17β, testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate. These six growth promotants are used widely in the US In the US, it is legally permissible to administer these six growth promotants to animals, under certain conditions, for growth promotion or fattening purposes.
[142] Council Directive 81/602/EEC, note 173 Chapter 3 above.
[143] Council Directive 88/146/EEC, note 190 Chapter 2 above.
[144] Council Directive 88/299/EEC, note 55 Chapter 7 above.
[145] Council Directive 96/22/EC, note 55 Chapter 7 above.
[146] Directive 81/602/EEC, note 173 Chapter 3 above.
[147] Directive 88/146/EEC, note 190 Chapter 2 above.
[148] Directive 88/299/EEC laid down the conditions for applying the derogations provided for in Article 7 of Directive 88/146/EEC from the prohibition on trade in certain categories of animals and their meat.
[149] Substances which increase the production of adrenaline and increase heart rate.
[150] Council Directive 96/22/EC, note 55 Chapter 7 above.
[151] *Ibid*, see recital 3 of the preamble.
[152] *Ibid*, see recital 6 of the preamble.
[153] *Ibid*, see recital 9 of the preamble.

and makes breathing easier. It has a knock-on effect which can result in an increase in aerobic capacity, stimulation of the central nervous system, an increase in blood pressure, and oxygen transportation. This is why it has been described as a non-steroidal anabolic and metabolism 'accelerator'. The net effect is that the drug increases the rate at which fat is metabolized or converted to lean meat or muscle.[154]

There have been accusations that clenbuterol has been used as a performance-enhancing drug, most famously in cycling. The Spanish cyclist Alberto Contador was banned from professional cycling for two years and stripped of the 2010 Tour de France title due to having tested positive for the drug at the 2010 Tour de France.[155] Contador alleged that the presence of clenbuterol in his system originated from eating contaminated meat. In the context of the EU-wide ban on growth hormones in animals, it is interesting to note that the Panel of the Court of Arbitration for Sport (CAS Panel) found that Spain was not noted for having a problem with clenbuterol contamination in meat and that Contador probably tested positive due to ingesting a contaminated food product.[156]

A principal objective of Directive 96/22/EC is the detection of the illegal use of substances in cattle as well as detecting the misuse of certain veterinary medicinal products. The various substances and groups of residues are listed in Annex I of the Directive. The list in Annex I in divided into two main categories - Group A and Group B. Group A is a list of substances having an anabolic effect and other unauthorised substances. Group B contains a list of veterinary drugs and contaminants. The Directive lays down measures requiring Member States to draft a national residue monitoring plan for the groups of substances detailed in Annex I. As a result, for example, in Ireland the Department of Agriculture, Food and the Marine (DAFM) administers a National Residues Monitoring Plan in order to safeguard consumers against any illegal residues from the substances. Member States are required to forward to the European Commission the results of their national residue monitoring by no later than the 31st March each year.

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[154] See generally, MoniQA (Monitoring and Quality Assurance in the Food Supply Chain), *Fact Sheet No 3 on Clenbuterol* (March, 2009).

[155] Clenbuterol is classified as an anabolic agent on the 2010 World Anti-Doping Agency (WADA) list of prohibited substances.

[156] See, Court of Arbitration for Sport – *Media Release Cycling-Doping: Alberto Contador found guilty of an anti-doping violation by the Court of Arbitration for Sport (CAS): Suspension of two years* (Lausanne: February 6, 2012).

It is important to note that these provisions also have an effect on third countries wishing to trade with the EU. There is a list of countries from which Member States can import animals or animal products. If a third country wants to be included on that list, it must submit a plan to the European Commission setting out the guarantees which it offers as regards the residue status of exported product with respect to all of the specified substance groups listed in Annex I.[157]

Article 1 of Directive 96/22/EC confirms that it applies to the definitions of meat and meat products given in Directives 64/433/EEC,[158] 71/118/EEC,[159] 77/99/EEC,[160] and 91/495/EEC.[161] For example, Directive 64/433/EEC defines 'meat' as 'all parts of domestic bovine animals (including the species Bubalus bubalis and Bison bison), swine, sheep, goats and solipeds which are suitable for human consumption'. Directive 64/433/EEC defines 'fresh meat' as 'meat, including meat vacuum-wrapped or wrapped in a controlled atmosphere, which has not undergone any treatment other than cold treatment to ensure preservation'. The 1964 definition is the main definition of meat and fresh-meat re-occurring in subsequent EU legislation.

By applying a broad terminology, Article 3 of Directive 96/22/EC institutes a blanket ban on all forms of growth hormones. It provides that Member States 'shall prohibit the administering to a farm ... animal,[162] by any means whatsoever, of substances having a thyrostatic, oestrogenic, androgenic or gestagenic action and of beta-agonists'. Article 11(2) of Directive 96/22/EC, prevents EU Member States from importing animals or the meat of animals to which these substances were administered.

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[157] See generally Food Safety Authority of Ireland, *Monitoring of Residues*, available at: http://www.fsai.ie/legislation/food_legislation/veterinary_medicines/monitoring_of_residues.html [Accessed: March 13, 2012]

[158] Council Directive 64/433/EEC on health problems affecting intra-Community trade in fresh meat [1964] O.J. 121/2012. This Directive also contains definitions for 'mechanically recovered meat', 'carcasse' and 'offal'.

[159] Council Directive 71/118/EEC of 15 February 1971 on health problems affecting trade in fresh poultry-meat, O.J. L055/23.

[160] Council Directive 77/99/EEC of 21 December 1976 on health problems affecting intra-Community trade in meat products, O.J. L26/85.

[161] Council Directive 91/495/EEC of 27 November 1990 concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat, O.J. L268/41.

[162] Article 1 of Directive 96/22/EC defines 'farm animals' as 'domestic animals of the bovine, porcine, ovine and caprine species, domestic solipeds, poultry and rabbits, as well as wild animals of those species and wild ruminants which have been raised on a holding'.

The use of certain hormones for therapeutic purposes only, is authorized by this Directive.[163] In accordance with Article 4, Member States may authorize the therapeutic administration to livestock of testosterone, progesterone, and their derivatives which readily yield the parent compound on hydrolysis after absorption.[164] Importantly, the products must be administered by a veterinarian.[165] The hormones can only be administered by injection. They can also be used for the treatment of ovarian dysfunction in the form of vaginal spirals.[166] In each Member State, farm animals which undergo this treatment must be clearly identified and the treatment must be registered by the veterinarian overseeing matters.[167] At a minimum, the veterinarian is required to record in a register the following details - the type of treatment, the type of products authorized, the date of the treatment, and the identity of the animal treated.[168]

Member States may authorize for therapeutic purposes, the administration of veterinary medicinal products containing beta-agonists to induce tocolysis in cows.[169] Similar registration measures recording the relevant information in a register, must also be followed for the administration of these beta-agonists. It is illegal for farmers to hold veterinary medicinal products containing beta-agonists.[170]

Article 5 authorizes veterinarians or their auxiliaries to administer hormonal preparations for the synchronization of oestrus and for the preparation of donors and recipients.[171] However, Article 6 prohibits the authorization of the following: (1) hormonal products acting as a deposit, (2) products which after the end of treatment have a withdrawal period of more than fifteen days, (3) products for which there are no reagents or equipment which detect the presence of residues in excess of the permitted levels, and (4) veterinary medicinal products containing beta-agonists which have a withdrawal period of more than twenty-eight days from the cessation of treatment.[172]

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[163] Article 4. Again, the prescriptive nature of these EU provisions is evident and this can be contrasted with the more lax regulations extant in the US where the use of growth promotants is permitted.
[164] Article 4(1).
[165] Article 4.
[166] See Article 4(1) of Council Directive 96/22, note 55 Chapter 7 above.
[167] *Ibid.*
[168] See Article 4(1) and Article 5 of Council Directive 96/22, note 55 Chapter 7 above.
[169] *Ibid*, Article 4(2)(ii).
[170] *Ibid*, Article 4(2)(ii).
[171] *Ibid*, Article 5.
[172] *Ibid*, Article 6.

Article 8 requires that Member States must restrict the possession of permissible substances to persons authorized by the Member State's national legislation.[173] Article 8 also provides that official checks must be carried out by the competent national authorities without prior notice, with a view to ascertaining:- (1) the presence in animals of prohibited substances which were administered for the purpose of increasing weight gain, (2) the illegal treatment of animals with any such products, and (3) any failure to observe the withdrawal periods and the restrictions on the use of certain substances.[174] Article 8 requires that tests be carried out for the presence of the substances and their residues in the drinking water provided to animals in places where the animals are kept and bred, and in their excrement, body fluids, animal tissues, and products.[175] Article 11 prohibits countries with legislation authorizing the placing on the market and administration of stilbenes,[176] stilbene derivatives, hormonal, thyrostatic, and beta-agonist substances to livestock, from being included on the lists of countries authorized to import farm animals, meat or meat products.[177]

7.5.1.2 Council Directive 2003/74

In 2003, Council Directive 96/22/EC was amended with Council Directive 2003/74/EC[178] in order to revise the prohibitions on the use of hormonal, thyrostatic, and beta-agonist substances in livestock farming. This amendment was made in light of the *Beef Hormones Dispute* which was then pending at the WTO and the recommendations made by the WTO Dispute Settlement Body on February 13, 1998. Indeed, the preamble to this Directive provides an invaluable insight into certain aspects of growth hormone regulation under EU food law.

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[173] *Ibid*, Article 8(1).
[174] *Ibid*, Article 8(2)(a) - (d).
[175] *Ibid*, Article 8(3).
[176] Stilbenes are synthetic steroids similar in basic structure to natural oestrogens. Therefore stilbenes are often described as synthetic oestrogens. In some EU Member States where growth hormones had already been banned, farmers were still injecting high doses of stilbenes in oily suspension directly into the shoulder muscle of veal calves. Furthermore, as a result of administration of the drug in this manner, it was believed that massive and persistent residues at the injection site presented a serious risk to human health, especially if contaminated veal was used in baby food. See, British Society of Animal Science, *Hormone Growth Promoters in Cattle*, Available at: http://www.bsas.org.uk/about_the_bsas/issue_papers/hormone_growth_promoters_in_cattle/ [Accessed: 16 March, 2012].
[177] See Article 11of Council Directive 96/22, note 55 Chapter 7 above.
[178] Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists. [2003] O.J. L267/17.

As outlined by recital 3 in the preamble to Council Directive 2003/74/EC, in response to the WTO Dispute Settlement Body (DSB) decision of 13 February 1998 in the *Beef Hormones Dispute*, the European Commission initiated a complementary risk assessment of the six hormones[179] prohibited by EU law, in accordance with the requirements of the SPS Agreement as interpreted by the WTO Dispute Settlement Body.

As part of this risk assessment brought about by the DSB's decision, the Commission initiated a number of scientific studies on the six hormones in order to obtain 'as much as possible of the missing scientific information'.[180] The preamble to the Directive goes on to outline how the Commission also addressed specific requests for 'any relevant and recent scientific' information to the US, Canada and other third countries, which authorise the use of these six hormones.[181]

The most important scientific study as far as the stance taken by the EU is concerned, was that carried out by the Scientific Committee on Veterinary Measures relating to Public Health (Scientific Committee),[182] on the potential adverse effects to human health from hormone residues in bovine meat and meat products. The Scientific Committee issued its first Opinion on 30 April 1999. As stated in the preamble to Council Directive 2003/74/EC, the major conclusions were:[183]

(i) with regard to the six hormones identified, firstly, with an excess intake of hormone residues and their metabolites and taking into account the intrinsic properties of hormones and the epidemiological findings, with different levels of conclusive evidence, a risk to the consumer had been identified;

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[179] Oestradiol 17β, testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate. These six growth promotants are used widely in the US In the US, it is legally permissible to administer these six growth promotants to animals, under certain conditions, for growth promotion or fattening purposes.

[180] See recital 4 of the preamble to Council Directive 2003/74/EC.

[181] *Ibid.*

[182] The SCVPH is mandated by the European Commission to deal with 'scientific and technical questions concerning consumer health and food safety, and relating to zoonotic, toxicological, veterinary and notably hygiene measures applicable to the production, processing, and supply of food of animal origin'. Article 6(1) of Commission Decision 97/579/EC of 23 July 1997 setting up Scientific Committees in the field of consumer health and food safety (O.J. L237/18), stipulates that 'Members of the Scientific Committees, in their capacity as such, shall act independently of all external influence'. However, it is difficult to envisage how the Committee could be entirely independent of the Commission.

[183] See recital 5 of the preamble to Council Directive 2003/74/EC.

(ii) secondly, 'endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic and carcinogenic effects could be envisaged'. Prepubertal children constituted the risk group of greatest concern; and

(iii) thirdly, in view of the intrinsic properties of the hormones and the epidemiological findings, when administered to bovine animals for growth promotion purposes, no threshold levels and no acceptable daily intake (ADI) can be established for the hormones.[184]

Therefore, the findings were consistent with the EU position that growth hormones pose a significant risk to human health and that it is not possible to estimate a dosage level at which they can be said to be safe – i.e. a threshold or ADI level.[185] However, it is clear from the Opinion that while the Scientific Committee had found a 'risk' to consumer health, it appears that there was no means of quantifying the magnitude of that risk.[186] For example, the Scientific Committee also stated in concluding its Opinion, that for the other five hormones (i.e. not including oestradiol 17β which came with a substantial body of recent evidence suggesting that it can be considered as a 'complete carcinogen'),[187] the data available does not allow a quantitative estimation of the risk. In addition, in respect of the various 'endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic and carcinogenic effects', the Opinion finds that 'the current state of knowledge does not allow a quantitative estimate of the risk'.[188] These findings by the Scientific Committee have been a

[184] In other words, no means of monitoring or limiting the dosage given to animals – therefore no means of limiting and quantifying the ultimate risk to human health.

[185] In the US there was significant criticism of the Opinion with one US commentator stating that 'In time of war, the first casualty is truth, ... [and] in the ongoing trade war between the European Union (EU) and the United States over the safety of dosing cattle with sex hormones, scientific truth may not be a casualty, but it is at least a rapidly moving target'. In addition a paediatric endocrinologist at the University of California, San Francisco described the Opinion as 'alarmist, uncritical, and selective' in its marshalling of the evidence. See, M. Balter, note 32 Chapter 5 above, p. 1453.

[186] In contrast, the stance taken by the US on growth hormone use in cattle, was also bolstered at this time, by the findings of a Joint FAO/WTO Expert Committee on Food Additives Meeting of 2nd – 11th February, 1999, which reviewed the evidence for some of the hormones used in cattle and concluded that the levels of residues normally found in beef for those hormones were safe i.e. there was no need to specify numerical MRLs for oestradiol 17β, progesterone and testosterone, when 'the products are used in accordance with good practice in the use of veterinary drugs'. See the Fifty-Second Report of the joint FAO/WTO Expert Committee on Food Additives, WTO Technical Report Series 893, (Geneva, 2000), p. 74. Available at: http://whqlibdoc.who.int/trs/WHO_TRS_893.pdf [Accessed: 20 March, 2012].

[187] However, again, the data available did not make it possible to give a quantitative estimate of the carcinogenic risk.

[188] "Opinion of the Scientific Committee on Veterinary Measures relating to Public Health Assessment of potential Risk to Human Health from Hormone Residues in Bovine Meat and Meat Products", note 52 Chapter 5 above, p.73.

significant factor in allowing the European Commission maintain its ban on the importation of beef from animals treated with the six banned growth hormones.

A number of additional studies from the United Kingdom's Veterinary Products Committee, the Committee on Veterinary Medicinal Products of the European Community (CVM), and the Joint FAO/WHO Expert Committee on Food Additives (JECFA or Expert Committee), were presented to the Scientific Committee.[189] For example, one study found that oestradiol 17β had a carcinogenic effect only after prolonged exposure and at levels which are considerably higher than those needed for a physiological (oestrogenic) response. However, the Scientific Committee concluded that the new information did not provide convincing data and that these new arguments were insufficient to require a revision of the conclusions drawn in its Opinion of 30 April 1999. Accordingly, in its opinion of 10 April 2002, the Scientific Committee re-confirmed the validity of its 1999 Opinion.

Therefore, the Commission concluded that in order to achieve the chosen level of protection in the EU from the risks posed to human health, by the routine use of these hormones for growth promotion and the consumption of residues found in meat derived from animals to which these hormones have been administered, it is necessary to maintain the permanent prohibition laid down in Directive 96/22/EC on oestradiol 17β and to continue provisionally to apply the prohibition to the other five hormones.[190]

The following substantive changes were introduced by Directive 2003/74/EC. Article 1 of Council Directive 2003/74/EC amended Article 2 of Directive 96/22/EC to prohibit the placing on the market of and any administration to animals regardless of species of thyrostatic substances, stilbenes, stilbene derivatives, their salts and esters. Article 1 also amended Article 2 of Directive 96/22/EC to prohibit the placing on the market for the administration to animals whose flesh and products are intended for human consumption of oestradiol 17ß, its ester-like derivatives, and beta-agonists.[191] Article 3 of Council Directive 2003/74/EC prohibits thyrostatic substances, stilbenes, stilbene derivatives, their salts and

[189] See recital 8 of the preamble to Council Directive 2003/74/EC.
[190] *Ibid*, see recital 10 of the preamble.
[191] Notwithstanding this amendment, the administration to animals whose flesh and products are intended for human consumption of estradiol 17ß, its ester-like derivatives, and beta-agonists is permissible for oestrus induction in cattle, horses, sheep or goats until 14 October 2006, in accordance with Directive 2001/82/EC and the treatment of foetus maceration or mummification in cattle, or the treatment of pyometra in cattle, in accordance with Directive 2001/82/EC. See Article 2 of Directive 2003/74.

esters, oestradiol 17ß and its ester-like derivatives, beta-agonists and provisionally prohibited any substances having oestrogenic (other than oestradiol 17ß and its ester-like derivatives), androgenic or gestagenic action.[192]

As we have seen, Council Directive 96/22/EC, specifically authorised certain veterinary medicinal products and one of those was oestradiol 17ß – a hormonal substance which helps the reproductive cycle of cows. Article 4 of Council Directive 2003/74 amended Council Directive 96/22 by requiring that the use of oestradiol 17ß, or its derivatives, to be completely phased out for oestrus induction in cattle, horses, sheep and goats by 14 October 2006.[193] Three specific lawful therapeutic uses of oestradiol 17ß would remain after 14 October 2006, namely, the treatment of pyometra, foetus maceration and mummification, in cattle only.[194] Article 5(a) allows Member States to authorize the administration to farm animals of veterinary medicinal products containing oestradiol 17ß or its ester-like derivatives for estrus induction in cattle until October 14, 2006.[195] The following stipulations remain in respect of the permitted veterinarian uses still existing for oestradiol 17ß:[196]

(i) the treatment must be carried out by the veterinarian himself or herself on farm animals that have been clearly identified;

(ii) the treatment must be registered by the veterinarian responsible;

(iii) the veterinarian must record the following details in a register – (i) the type of product administered, (ii) the nature of the treatment, (iv) the date of treatment, (v) the identity of the animals treated, (vi) the date of expiry of the withdrawal period; and

(iv) farmers are prohibited from holding on their farms veterinary medicinal products containing oestradiol 17ß or its ester-like derivatives.

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[192] Article 3 prohibits the administering of those substances to farm or aquaculture animals, by any means whatsoever, the holding, except under official control, of any animals which have been administered any of the said drugs, the placing on the market or the slaughter for human consumption of such animals, or the placing on the market of meat from such animals, unless it can be proven that any traces of certain of these drugs were administered under one of the allowed veterinarian exceptions.

[193] Article 4(2) of Council Directive 2003/74/EC.

[194] See Article 5(a) of Council Directive 96/22 as inserted by Article 4 of Council Directive 2003/74.

[195] Directive 2003/74, Article 1(4), at 19.

[196] See Article 5(a)(3) of Council Directive 96/22 as inserted by Article 4 of Council Directive 2003/74.

7.5.2 Effectiveness of the EU Prohibition

The legitimisation of growth hormone use creates its own set of problems insofar as that since the drugs are so readily available it would be impossible to ensure with absolute certainty that maximum dosage amounts are not exceeded or that methods of application are not abused. Similarly, at the other end of the regulatory spectrum, in the EU accusations have been made that, albeit small, a black market still exists in illegal growth hormones.

While there were incidences in the EU of the illegal use of growth hormones in the period immediately subsequent to the EU ban on their use, such occurrences appear to have fallen dramatically since the authorities across the EU started to vigorously enforce the legislation.[197] For example, there were quite a number of such prosecutions in Ireland at one time.[198] However, from time to time, there are still finds of 'angel dust'[199] on Irish farms. For example, Department of Agriculture special investigations unit officers and gardaí uncovered what they suspected was a quantity of liquid angel dust on a farm in Ballybay, Co. Monaghan, in July, 2011.[200] It was noted that tests for angel dust and other illegal growth substances are still routinely carried out in Ireland by Department of Agriculture officials at slaughtering yards.

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[197] For example, members of a special control team from the Irish Department of Agriculture, set up to combat the clenbuterol threat in Ireland, gave evidence in court that the abuse of growth hormones had dropped dramatically, especially since the publication of the prosecutions. See "Farmer Gets Jail Sentence as 99 Animal Drug Cases Await Hearing", The Irish Times of Friday, November 22, 1996 - the case of Michael Frisby of Clogga, Mooncoin, Co Kilkenny who was sentenced to 10 months and fined £1,000 for having clenbuterol or angel dust in animal feed on his farm on August 13th, 1992. It is interesting to note that a similar form of delayed reaction to a ban on growth hormones, was experienced in the US when the now notorious growth hormone diethylstilbestrol (DES) was banned from use in cattle in 1979. It seems that some feedlot operators and/or their suppliers had stockpiled the drug and its use continued even after the ban.

[198] In 1997, a farmer who admitted possession of illegal cattle growth promoters was given a suspended jail sentence and was fined £22,500 - See, The Irish Times of Friday, September 26, 1997. Another farmer was jailed for 15 months and fined £20,000 when convicted of 20 offences which included the possession of banned animal growth promoters - See "Farmer Jailed for Using Angel Dust", The Irish Times of Friday, September 26, 1997. The sentences were handed down at Athlone District Court, County Westmeath, Ireland, following a three-day hearing against Con Heagney, of Tully House, Eyrecourt, Co Galway. Another farmer received the maximum fines on the nine summonses to which he had pleaded guilty - see The Irish Times of Wednesday, October 16, 2002.

[199] The colloquial Irish sobriquet for the growth hormone, clenbuterol.

[200] See the article entitled 'Diesel Laundering Plant', in The Irish Times of Friday, July 22, 2011.

However, it seems eminently likely that EU law is more likely to achieve the desired goal of prohibition simply because farmers are not authorized to possess or administer the growth hormones where administration is allowed for therapeutic use.[201] Only official veterinarians and other authorized persons are allowed to possess and administer the drugs for those permitted therapeutic purposes.[202] Also, in keeping with the ban on growth hormones, the EU regulations are strengthened with detailed monitoring provisions such as spot-checks on animals especially at slaughter, their excrements, bodily fluids, drinking water, and confinement, in order to test for the existence of any residue of the prohibited drugs.[203]

However, it is likely that anyone unscrupulous enough to risk prosecution can succeed in purchasing animal growth hormones. For example, it is possible to purchase any one of the six banned growth hormones through the internet. On most of the websites, there does not appear to be anything to confirm that they will only ship to countries where the growth promoting hormones are legal. For example, if one takes the growth hormone Zeranol, what appears to be a very high-tech and reputable Chinese company called Shaanxi Sciphar Hi-Tech Industry Co., Ltd,[204] manufactures, and sells zeranol online, for $150 to $250 per kilogram. It is manufactured to 'medicine grade' and at 99 per cent purity.[205] Their website does state that 'zeranol is approved for use as a growth promoter in livestock, including beef cattle, in the United States. In Canada, it is approved for use in beef cattle only'.[206]

7.6 Risk Posed by the use of Growth Hormones in Beef Production

The majority of the main international scientific bodies such as the World Health Organization's Joint Expert Committee on Food Additives (JECFA or Expert Committee),[207]

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[201] See Directive 2003/74/EC, note 178 above.
[202] Article 4(2) of Council Directive 96/22/EC, note 55 Chapter 7 above.
[203] *Ibid*, Article 8.
[204] Registered address is C3102, Van Metropolis, No. 3, Tangyan Road, High And New Tech Zone, Xi'an, Shaanxi, China (Mainland) Zip: 710075. Their Legal Representative and CEO is listed as Mr. Xinkang Jin. They can ship, from Shanghai, up to 1000kg of the hormone per order per month.
[205] Its 'efficacy' is described as 'promote healthy and growth'.
[206] It must be stated that I did not make written or verbal contact with this company to verify whether or not they ship to the European Union.
[207] World Health Organization (WHO), *Evaluation of certain veterinary drug residues in food*, note 177 Chapter 2 above. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) is an international scientific expert committee administered jointly under the aegis of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). It has been meeting since 1956 and its work

the Food and Agricultural Organization of the United Nations (FAO), the Codex Committee on Residues of Veterinary Drugs in Food,[208] and the Codex Alimentarius Commission[209] itself – have all opined on the safety of hormones when used in accordance with good veterinary practice.[210] Similar conclusions were reached by the United Kingdom's 1999 and 2006 Veterinary Products Committee reports[211] and the 2003 Australian review.[212] In addition, neither of the two major EU initiatives – the Lamming Committee[213] scientific expert group and the 1995 Scientific Conference on Growth Promotion in Meat Production[214] – have found any evidence of health risks from the use of growth hormones.

However, in the previous Chapters of this thesis it was noted that science can never be 100 per cent certain. For example, scientific risk assessment involves the subjective choice of methodology, the acceptance or refusal of empirical data which is used to affect calculations and projections, and very often it is necessary to base conclusions on incomplete data. Likewise, the aforementioned scientific studies supporting the safety of growth hormones are based on current scientific knowledge as we now know it. Many of these scientific studies are carried out on data adduced in conditions where humans were administered a drug chemically-similar to a growth hormone, for some therapeutic purpose. Therefore, it seems reasonable to argue that they are not entirely comparing like with like. In other words, it is

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includes the evaluation of food additives, contaminants, naturally occurring toxicants and residues of veterinary drugs in food.

[208] The Codex Committee on Residues of Veterinary Drugs recommends Maximum Residue Limits (MRLs) for veterinary drugs. A Codex Maximum Limit for Residues of Veterinary Drugs (MRLVD) is the maximum concentration/residue for a veterinary drug that is recommended by the Codex Alimentarius Commission to be legally permitted or acceptable for use in food. An MRLVD (expressed by the Acceptable Daily Intake - ADI) is the amount of residue that does not have any toxicological hazard for human health.

[209] Codex Alimentarius Commission (CAC), *Report of the 8th Session of the Codex Committee on Residues of Veterinary Drugs in Foods*, note 179 Chapter 2 above. CAC develops food standards, guidelines and codes of practice under the Joint FAO/WHO Food Standards Programme.

[210] The concept of 'good veterinary practice' is merely a professional or ethical consideration for veterinarians. For example, in Europe, the Federation of Veterinarians of Europe ('FVE') operates a 'Code of Good Veterinary Practice'. This standard does not have any statutory basis and it is not a legal obligation, although it may have some persuasive value in court proceedings. It is a standard specifying the European veterinary ethics and principles of conduct as well as the requirements relating to the quality management system within a veterinary organisation.

[211] United Kingdom Veterinary Products Committee, "VPC Report - Risk Associated with the Use of Hormonal Substances in Food Producing Animals," note 180 Chapter 2 above. Also see USDA, *UK scientific report questions EU position on beef hormones*, note 180 Chapter 2 above.

[212] Australian Pesticides and Veterinary Medicines Authority, "A Review to Update Australia's Position on the Human Safety of Residues of Hormone Growth Hormones (HGPs) Used in Cattle," July 2003.

[213] The Lamming Committee was an EU expert working group (comprising members of the Scientific Committee for Food and the Scientific Committee for Animal Nutrition - the lead committee for issues concerning growth promoters), that in 1982 reached an interim conclusion that oestradiol and several other growth promoters with a hormonal action were safe for use as growth hormones in cattle.

[214] European Commission, Proceedings of the Scientific Conference on Growth Promotion in Meat Production, November 29, 1995, note 183 Chapter 2 above.

not ethically possible to carry out detailed testing on humans as part of these scientific tests and only by doing that would we know for sure. Moreover, it is likely that a very long time period of many years would have to pass before we would then know the full effects. Therefore, as a basis, these studies are forced to rely on disparate data from diverse studies. For example, the Expert Committee noted that 'the commonest uses of estrogens in humans are for oral contraception and post-menopausal replacement therapy'.[215] One immediately notes that this study of an oral administration of the drug to humans for an entirely different purpose, cannot entirely correlate with as a study carried out on a subcutaneous implant given to cattle, although it is accepted that it would be of persuasive value. In relation to the human study the Expert Committee went on to note that the xenobiotic estrogen ethinylestradiol is usually used for oral contraception. Another common use of oestrogen in humans is where fineparticle oestradiol-17β and conjugated equine estrogen preparations are commonly used for post-menopausal estrogen replacement therapy.[216] The Expert Committee did conclude that oestradiol-17β has 'genotoxic potential'.[217]

As already stated, since the 1950s in the US, FDA has approved a number of steroid hormone drugs for use in beef cattle and sheep.[218] The following introduction taken directly from FDA's website, provides a neat summary of the US approach to growth hormones in beef and in particular the issue of risk assessment:-

> [t]he FDA approves these drugs only after extensive studies have shown that the food from the treated animals is safe for people to eat, and that the drugs do not harm the treated animal or the environment ... Using scientific data, FDA establishes the acceptable safe limits for hormones in meat. A safe level for human consumption is a level of drug in the meat that would be expected to have no effect in humans based on extensive scientific study and review. All approved implant products have a zero day withdrawal. This means that the meat from the animal is safe for humans to eat at any time after the animal is treated. ... Some of the approved drugs are synthetic versions of the natural hormones, such

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[215] See the Fifty-Second Report of the joint FAO/WTO Expert Committee on Food Additives, note 186 above.
[216] *Ibid.*
[217] *Ibid.*
[218] These drugs increase the animal's growth rate, the efficiency by which they convert the feed they eat into meat, and the leanness of their meat.

> as trenbolone acetate and zeranol. Just like the natural hormone implants, before FDA approved these drugs, FDA required extensive toxicological testing in animals to determine safe levels in the animal products that we eat (edible tissue). Furthermore, FDA required that the manufacturers demonstrate that the amount of hormone left in each edible tissue after treatment is below the appropriate safe level. As described above, a safe level is a level which would be expected to have no effect in humans. All of the steroid hormone growth-promoting drugs are available for over-the-counter purchase in the US and are generally given by the livestock producer at specific stages of the animals growth.[219]

Some of the approved drugs are naturally produced[220] in people and animals, such as estradiol (oestrogen), progesterone, and testosterone. These three drugs were examined by the joint FAO/WTO Expert Committee on Food Additives (the 'Expert Committee') at its February 1999 meeting. The Expert Committee reviewed the evidence for estradiol-17ß, progesterone, and testosterone when used as growth hormones in cattle and concluded that the levels of residues normally found in beef for those hormones were safe i.e. there was no need to specify numerical MRLs for oestradiol 17β, progesterone and testosterone, when 'the products are used in accordance with good practice in the use of veterinary drugs'.[221]

Interestingly, however, the Expert Committee recommended that the total intake of estrogenic residues [presumably due to consuming, for example, beef from cattle raised on growth hormones] be kept below the above calculated excess intakes. Therefore, immediately one can see that these findings are only as good as the regulatory oversight of the use of growth hormones as administered by animal feeding lot operators. Only if the drugs are administered in the correct manner and in no greater a dosage that the maximum permitted, can they be considered as safe, based on the findings of this Expert Committee Report.

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[219] See FDA, "Steroid Hormone Implants Used for Growth in Food-Producing Animals", note 15 Chapter 7 above.

[220] Usually called 'Naturally-Occurring Hormones'. No regulatory monitoring of naturally occurring hormones is possible, since it is not possible to separate or tell the difference between the hormones used for treatment from those made by the animal's own body. However, it is possible to detect residues of synthetic hormones in the animal's meat.

[221] See the Fifty-Second Report of the joint FAO/WTO Expert Committee on Food Additives, note 186 above, p. 74. As previously stated, 'good veterinary practice' places only a professional or ethical obligation on the veterinarian. Therefore, it is not a guarantee of proper administration of the drugs, if for no other reason than it may not even be veterinarians who administer the growth promotants.

However, contradictory viewpoints also exist. For example, another eminent scientist stated that if you assume no threshold, you should continually be taking steps to get down to lower levels, because 'no level is safe'. In effect, 'the jury is still out on these hormones' – i.e. the three 'naturally occurring'[222] hormones - oestrogen,[223] testosterone & progesterone.[224]

In what would appear, by comparison to be a sweeping generalisation, FDA says that people are not at risk from eating food from animals treated with these drugs[225] because the amount of additional hormone following drug treatment is very small compared with the amount of natural hormones that are normally found in the meat of untreated animals and that are naturally produced in the human body. FDA goes on to state that some of their approved drugs are synthetic versions of the natural hormones, such as trenbolone acetate and zeranol. Just as with the natural hormone implants, before FDA approved these drugs, FDA required extensive toxicological testing in animals to determine safe levels in the animal products destined for human consumption. Furthermore, FDA required that the manufacturers demonstrate that the amount of hormone left in each edible tissue after treatment is below the appropriate safe level.[226] As described above, a safe level is a level which would be expected to have no effect in humans.[227]

No regulatory monitoring of naturally occurring hormones is possible, since it is not possible to separate or tell the difference between the hormones used for treatment from those made by the animal's own body.[228] In other words, even if someone administers excess doses of these three hormones to animals, then it would not be possible to detect that abuse of the prescribed procedure. Because of this, neither FDA nor the Food Safety Inspection Service (FSIS)[229] carries out any pre-market testing or after-market monitoring of naturally occurring hormones. However, it is possible to detect residues of synthetic hormones in the animal's

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[222] That is, hormones that already naturally exist in the animal. The other three hormones were the 'synthetic' ones, namely zeranol, trenbolone acetate (TBA), and melengestrol acetate (MGA).

[223] i.e. oestradiol-17β.

[224] Professor Jim Bridges, a toxicologist at the University of Surrey and a member of an EU working group on the use of growth hormones as quoted in M. Balter, note 32 Chapter 5 above, p. 1453.

[225] i.e. any of the six growth hormones banned in the EU.

[226] See generally FDA, "Steroid Hormone Implants Used for Growth in Food-Producing Animals", note 15 Chapter 7 above.

[227] The FDA does not approve steroid hormones for growth purposes in dairy cattle, veal calves, pigs, or poultry. All of the steroid hormone growth-promoting drugs are available for over-the-counter purchase (i.e. the least regulated form of drug) in the US and are generally given by the livestock producer at specific stages of the animals' growth.

[228] S.S. Epstein, "The Chemical Jungle: Today's Beef Industry", (1990) *International Journal of Health Studies*, Vol.20, No.2, p.277.

[229] The Food Safety and Inspection Service of the United States Department of Agriculture.

meat – i.e. trenbolone acetate, zeranol and melengestrol acetate. FDA has set the tolerance levels for these hormones.[230] A tolerance is the maximum amount of a particular residue that may be permitted in or on food. The Food Safety Inspection Service[231] of the US Department of Agriculture (USDA) monitors meat from cattle for these residues.[232] FSIS is mandated to carry out inspections under the Federal Meat Inspection Act 1906. In order to ensure that meat products satisfy the food safety requirements and are correctly labelled and packaged, FSIS inspects all raw meat sold in interstate and foreign commerce. In addition, the Wholesome Meat Act 1967 requires that individual state inspection programs must be 'at least equal to' the Federal inspection programs.[233]

7.7 Conclusion

The USDA, FDA, and their predecessors have been implementing laws to regulate the US meat industry since 1906, whereas, because the EEC was established in 1957, EU wide regulation of the beef industry began much more recently. Nonetheless, both the EU and the US face the Herculean task of regulating cattle and beef production in each of their many constituent Member States and States. This calls for complex and multifaceted regulatory schemes.[234] In relation to their animal drug regulatory schemes and more particularly their regulation of growth hormones in animals, both the EU and the US have clearly articulated rules that are easy to comprehend.

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[230] 21 USC, S.556 lists the tolerance for residues of drugs in animals. 21 USC 552 lists the amount, the conditions of use, and the limitations of use for hormones and other drugs in animals,

[231] In accordance with the United States Federal Meat, Poultry and Egg Products Inspection Acts, the FSIS inspects and monitors all meat, poultry and egg products sold in interstate and foreign commerce in order to ensure compliance with mandatory US food safety standards and inspection legislation. Slaughterhouses can opt for either Federal or State inspection. As stated by the FSIS, all slaughterhouses approved for the export of meat to the EU are required to participate in the EU Additional Residue Testing Program. The program, initiated in 1989, covers all red meat slaughterhouses approved for export of meat and/or offal to the EU. The FSIS Office of International Affair (OIA) and the Import Export Program Staff (IEPS), coordinate the EU additional residue testing program.

[232] The FSIS publishes 'Residue Repeat Violator Lists' which list the producers who have more than one residue violation in the previous twelve months.

[233] See, Food Safety and Inspection Service, *Inspection & Grading of Meat and Poultry:* note 194 Chapter 3 above.

[234] C.S. Houston, note 166 Chapter 2 above, p. 269.

As confirmed in this Chapter, the economic benefits of using growth hormones are substantial.[235] Commercial or industrial interests, provided they can obtain the relevant scientific approval in good faith, stand to reap significant financial rewards from their use. The US drug regulatory system is a wholly science driven mechanism for approving 'new animal drugs' with no provision for the consideration of public opinion. This can be contrasted with the more consumer orientated and tradition favouring nature of EU food law, with the interests of the consumer being mentioned time and time again in the EU legislation regulating animal growth hormones.

The issue of the uncertainty of science is also apparent. Under the US regulatory system, if the recommended MRL[236] for any of the hormones is not found after slaughter in any part of the animal to be used for human consumption, then the issue of whether or not the hormone is carcinogenic does not arise.[237] However, this seems anomalous since it is in any event scientifically impossible to test for residues from the three natural hormones.[238] The EU operates on the premise that growth hormones in the beef supply are detrimental to human health and consequently a tolerable daily intake at any level cannot exist for any of them.[239]

Moreover, some highly respected scientific bodies such as the Expert Committee[240] have concluded that the hormones are not deleterious to human health, but only if used in accordance with 'good veterinary practice.' In other words, the drugs can only be considered safe provided they are administered in the correct manner and in no greater a dosage that the maximum permitted. However, the US regulatory system does not appear to make any provision for record keeping of the quantities sold to an individual, or the amounts administered and to which animals.

The US regulations do prohibit the administration of growth hormones in unsafe ways – i.e. the regulations specify the 'conditions of use' for the specific hormones, such as the

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[235] Apparently, growth hormones used in cattle typically increase lean tissue by between 8 – 20 per cent over the cattle-raising cycle. See generally C.S. Houston, note 166 Chapter 2 above, p. 269.
[236] Maximum Residue Limit.
[237] While the carcinogenic potential of the other five hormones appears to be contested, the natural growth hormone Estradiol or 17β-estradiol is widely regarded as a carcinogen.
[238] Oestradiol 17β, testosterone, and progesterone.
[239] See, 'Opinion of the Scientific Committee on Veterinary Measures relating to Public Health Assessment of potential Risk to Human Health from Hormone Residues in Bovine Meat and Meat Products', note 52 Chapter 5 above, p.73.
[240] Joint FAO/WHO Expert Committee on Food Additives.

hormones may not be administered to certain categories of animals, and the regulations specify the combination of hormones – i.e. the dosage amount or quantity and the method of application.

While the majority of the world's most eminent scientific bodies are in agreement on the relative safety of at least five of the six hormones, as outlined in this Chapter, some eminent scientists are not convinced that the hormone residues are not deleterious to human health. Because animal growth hormones are legitimised in the US, there is no requirement for their regulatory framework to be as onerous as that in the EU. EU regulation is more effective because it is more likely to achieve the desired goal of prohibition simply because due to the blanket ban it is not legal to possess or administer the growth hormones.

This Chapter has provided a thorough understanding of not only the regulations governing animal growth hormones but more especially their safety or otherwise. Therefore, it is submitted that this Chapter has provided an ideal foundation for the next Chapter of this thesis which deals with how the WTO Dispute Settlement Body dealt with the *Beef Hormones Dispute*. The combination of the knowledge gleaned from the investigations in this Chapter and the outcome of the *Beef Hormones Dispute* in the next Chapter, will assist in the formulation of many of the conclusions reached in the concluding Chapter of this thesis.

CHAPTER 8

CULTURAL REGULATORY DIVERGENCES AND THE BEEF HORMONES DISPUTE

8.1 Introduction

The *Beef Hormones Dispute* is a veritable case in point which exemplifies the difficulty involved in affording deference to cultural considerations while at the same time allaying alleged protectionist motives in the formulation of sanitary measures. The Dispute began when the EU banned the use of animal growth hormones and the importation of meat from animals treated with growth hormones.[1] As evidenced by the analysis in this Chapter, the ban was precipitated by a number of factors, not least of all by high levels of public concern about health risks associated with imported produce.

As we shall see, there were two main stages to the ban. In 1981, the first stage was initiated by Directive 81/602/EC[2] which effectively banned all growth hormones and the importation of meat containing their residues, but the ban did not affect five specific growth hormones - oestradiol-17β, progesterone, testosterone, trenbolone acetate (TBA) and zeranol.[3] Six specific growth hormones were in dispute with the US, namely, oestradiol 17β, testosterone, progesterone, trenbolone acetate (TBA), zeranol, and melengestrol acetate (MGA). While all animal growth hormones were banned in the EU, it is these six in particular that were in dispute with the US, as it is these six specific hormones which have been legitimised for use

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[1] The two stages to the *Beef Hormones Dispute* when it came before the WTO Dispute Settlement Body were: *EC Measures Concerning Meat and Meat Products ('EC-Hormones')* WT/DS26, and *United States – Continued Suspension of Obligations in the EC – Hormones Dispute ('US-Continued Suspension')* WT/DS320. The EU provisions instituting the ban were: Council Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action, [1981] O.J. L222/32; Council Directive 88/146/EEC prohibiting the use in livestock farming of certain substances having a hormonal action, [1988] O.J. L70/16; Council Directive 88/299/EEC on trade in animals treated with certain substances having a hormonal action and their meat, as referred to in Article 7 of Directive 88/146/EEC, [1988] O.J. L128/36; Council Directive 96/22/EC concerning the prohibition on the use in stock-farming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC, [1996] O.J. L 125/03.

[2] Council Directive 81/602/EEC, note 173 Chapter 3 above.

[3] See, World Trade Organisation, "EC Measures Concerning Meat and Meat Products (Hormones)", Panel Report WT/DS/48/R/CAN, 18 August, 1997, para 2.2, p.2.

under US law. As the second stage to the Dispute, in 1988 Directive 88/146/EEC[4] banned all form of growth hormones and that ban applied to growth hormone residues in imported meat or live cattle. Since animal growth hormones are used extensively in North America, the blanket ban meant that the US and Canada had lost the valuable EU export market.

This ban on animal growth hormones instigated by the EU resulted in a long-standing acrimonious transatlantic trade dispute with the US[5] over growth hormone treated beef. The US was angered that its beef could not be exported to the EU because of the EU ban against growth hormones in cattle. Due to the unavailability of the EU market, the US lost hundreds of millions of dollars. Prior to its import ban the EU was not a major importer of US beef but it was one of the largest importers of beef offal from the US. It was estimated that in the early 1980s, the EU imported approximately 74,000 metric tons of edible offal per annum worth $144 million.[6] Throughout the 1990s, US beef exports increased steadily. However, the valuable EU export market had been lost to the US because of the ban.[7] At one time, the cost of the ban to the US beef sector was estimated to be in the region of $250 million annually.[8] However, it is interesting to note that it has been estimated that the total elimination of the use of growth hormones in US beef production would cost US producers much more than any benefits gained through sales to the EU and that the cost associated with a ban on growth hormone use in the US would probably be in the region of $314 million annually.[9] It has been reported that approximately 95 per cent of US cattle are at some time during their life cycle, implanted with growth hormones.[10]

In justifying the ban to the US, the EU argument was based on the apparent importance of the place of democracy in addition to science in formulating food regulation, with the EU

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[4] Council Directive 88/146/EEC, note 190 Chapter 2 above.

[5] And Canada.

[6] US Department of Agriculture, Foreign Agricultural Service. FAX to J.L. Lusk Containing US Agricultural Export Data: January 1977- December 1997 of June 8, 1998, as cited in, J. L. Lusk, J. Roosen & J. A. Fox, note 29 Chapter 6 above, p.17.

December 1997. June 8, 1998.US Department of Agriculture, FAS, 1998

[7] Save and except for more recent measures that permit the export to the EU of growth-promotant-free US (and Canadian) beef. J. L. Lusk, J. Roosen, J. A. Fox, note 29 Chapter 6 above, p.17.

[8] D.R. Kelch, 'The US-EC Hormone Dispute', (1989) *Agricultural Outlook. Economic Research Service, US Department of Agriculture*, Issue 50, pp. 35-38, as cited in, J. L. Lusk, J. Roosen & J. A. Fox, note 29 Chapter 6 above, p.17.

3 J. L. Lusk, J. Roosen & J. A. Fox, note 29 Chapter 6 above, p.17.

[9] E.W. Peterson, M.P. Paggi and G. Henry, "Quality Restrictions as Barriers to Trade: The Case of European Community Regulations on the Use of Hormones." (1988) 13 *Western Journal of Agricultural Economics*, P. 82.

[10] E.J. Kuchler, J. McClelland and S.E. Offutt, note 168 Chapter 2 above, p.25.

Commissioner for Agriculture, Franz Andriessen, stating that in respect of growth hormones, 'scientific advice is important, but it is not decisive. In public opinion, this is a very delicate issue that has to be dealt with in political terms'.[11]

8.1.1 Hormone Ban Contravenes the terms of the SPS Agreement

As outlined in Chapter 2 of this thesis, the WTO deals with regulation of trade between participating countries. It provides a framework for negotiating and formalizing trade agreements, and a dispute resolution process aimed at enforcing participants adherence to the WTO agreements. The difficulty for the EU in instigating the ban, was that WTO Members such as the EU[12] (and the US) must show compliance with the SPS Agreement.[13] WTO rules permit such bans, but only where the WTO Member presents scientific evidence proving that the ban is a valid health and safety measure under the terms of the SPS Agreement. The US opposed the EU ban and in 1995 lodged a Request for Consultations[14] with the WTO Secretariat under the WTO Dispute Settlement Understanding.[15] While a number of trade problems have been resolved at the bilateral level, without recourse to a WTO Dispute Settlement Panel, the same cannot be said of the *Beef Hormones Dispute*.

Under the terms of the WTO Dispute Settlement Understanding, when a dispute arises, the offended Member government (the 'complainant') may take a case against the other Member government (the 'defendant') setting out its objections to the trade measures of the defendant government.[16] Of course, the preferred solution is for the countries concerned to discuss the

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[11] As quoted by A. Gowers & I. Dawnay, "*Another Shot of Politics for the Beef Farmer; EEC Hormones Ban*", (1986) The Financial Times, January 24, p.15. Andriessen's statement, made at a press conference in November 1985, can be contrasted with statements such as that found on the US Department of Agriculture Food Safety Inspection Service (FSIS) website, which states that "ensuring the quality of the nation's meat, poultry, and egg products is a process that is increasingly dependent upon science".

[12] i.e. individual EU Member States and the EU customs area.

[13] As discovered in Chapter 6 of this thesis, the SPS Agreement is science based and any food regulatory measures enacted by a member aimed at protecting human health must be based on sound science and risk analysis. The SPS Agreement was drafted without explicit reference to cultural considerations. The *Beef Hormones Dispute* was the first ruling to interpret the SPS Agreement. The *Beef Hormones Dispute* provides a window through which we can view the WTO framework in action.

[14] The first step in filing a Dispute with the WTO is to lodge a Request for Consultations.

[15] The Dispute Settlement Understanding is attached at Annex 2 to the WTO Agreement. It sets out the rules and procedure governing dispute resolution at the WTO. The Dispute Settlement Body (which is effectively the WTO General Council in another guise and consists of all WTO members) then appoints a Panel of experts in that field, to arbitrate on the matter.

[16] In addition, a third group of countries can declare that they have an interest in the case, by notifying the WTO and confirming that they have a 'substantial interest' in the case.

issue and hopefully reach a settlement or agreement between themselves. Therefore, as the first stage of the WTO dispute settlement process, in order to try and negotiate a mutually satisfactory solution to the dispute, both parties are required to consult for 60 days. Indeed, a large proportion of the disputes are successfully resolved during these consultations.[17]

As outlined in Chapter 2 of this thesis, the complainant can seek a Panel proceeding in the event that the matter is not resolved during the consultation process.[18] Testimonies are taken by the Panel and they then prepare and issue an 'Interim Report'. After considering and if appropriate incorporating any comments received from the complainant and the defendant, then the Panel will issue its Final Report. In most cases the WTO will then adopt this Final Report. However, the Report will not be adopted if both parties agree not to adopt the Report, or if either party decides to appeal the Report.

If either or both parties to the dispute appeal a Panel's ruling, then that appeal is to the Appellate Body. The Appellate Body is a standing body of jurists, designed to ensure greater consistency across its rulings. An appeal must be based on a point of law such as legal interpretation.[19] The appeal can uphold, modify or reverse the Panel's legal findings and conclusions.[20] If a decision is reached against the defendant to an action, then that defendant should bring its policy into line with the ruling or recommendation(s) made by the Panel. After such a verdict, the case typically ends.

The Dispute Settlement Understanding[21] emphasises that 'prompt compliance with recommendations or rulings of the Dispute Settlement Body is essential in order to ensure effective resolution of disputes to the benefit of all Members'. If a situation arises where immediate compliance with the recommendation proves impractical, the Member is given a

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[17] 46 per cent of all disputes brought to the WTO end at this stage, and three-quarters of those yield at least partial concessions from the defendant. See, M. Busch & E. Reinhardt, note 123 Chapter 2 above, p.457.

[18] The Dispute Settlement Body has the sole authority to establish "panels" of experts to consider the case. The Dispute Settlement Body monitors the implementation of the rulings and recommendations made by the panel. The Body has the power to authorize retaliation when a country does not comply with a ruling. The panel's report can only be rejected by consensus in the Dispute Settlement Body and therefore its conclusions are difficult to overturn. The panel's findings must be made in accordance with the WTO agreements.

[19] Each appeal is heard by three members of the permanent seven-member Appellate Body. The Appellate Body broadly represents the range of WTO membership. Members of the Appellate Body hold office for a four-year term. They are individuals with recognized standing in the field of law and international trade and cannot be affiliated with any particular government.

[20] Normally appeals should not last more than 60 days, with an absolute maximum of 90 days. The Dispute Settlement Body has to accept or reject the appeals report within 30 days — and rejection is only possible by consensus.

[21] Article 21 of the Dispute Settlement Understanding.

'reasonable period of time' in order to comply. However, if it fails to act within this period, it is required to enter into negotiations with the plaintiff country in an effort to determine mutually acceptable compensation.[22] Then, if after 20 days a package of compensation is not agreed, the complainant can request the Panel to set the level at which it can 'retaliate' against the defendant. Typically, this retaliation would involve trade sanctions such as imposing tariffs on the defendant's exports.[23]

If and when sanctions are agreed, they are to be imposed in the same trade sector as that in which the dispute arose. However, if that is not possible, the sanctions may be imposed in a different sector of the same Agreement. Likewise, if this is not possible or practicable, and depending on the seriousness of the circumstances, the action can be taken under another WTO Agreement. The objective of this approach is to try and minimize the possibility of actions spilling over into unrelated sectors. In general terms, the Dispute Settlement Body monitors how adopted rulings are implemented and each case remains on its agenda until the issue is fully resolved. Insofar as the WTO deals with contentious disputes, it is true to state that food occupies a central role within it. For example, of the 380 or so disputes initiated between the WTO inception in 1995 and 2008, over a third involved food. In this regard, except for 'metals', no other product category came close.[24]

8.1.1.1 Why did the EU Ban Animal Growth Hormones?

As outlined in Chapter 7 of this thesis, the United States Department of Agriculture (USDA), US Food and Drug Administration (FDA), and their predecessors have been implementing laws to regulate the US meat industry since 1906, whereas, because the EEC was initiated in 1957, EU wide regulation of the beef industry began much more recently. In the EU, the supranational events of European integration and cross-border trade liberalisation have caused EU consumers to become unusually sensitive to food safety policies. In addition, a series of food-safety scares and several trade disputes have heightened consumer sensitivity even further. The most notable of these were mad cow disease, dioxin contamination, growth

[22] This may take the form of tariff reductions in areas of particular interest to the complainant.
[23] The Dispute Settlement Body must grant this authorization and it must do so within 30 days of the expiry of the "reasonable period of time" unless there is a consensus against the request.
[24] M. Bronckers & R. Soopramanien, note 131 Chapter 2 above, p.361.

hormones, and GMOs.[25] This convergence of events – heightened sensitivity to food safety in the EU versus globalisation and technological advances in the food supply - have served to create new transatlantic trade tensions and have accentuated the consumer's sense of loss of control over food as a trusted commodity imbued with cultural atavism.

Prior to 1981, there was no official EU policy governing the administration of growth hormones to animals. However, national policies existed within individual EU Member States. In Italy the use of growth hormones had been banned since 1961, in Denmark since 1963 and the use of synthetic growth hormones[26] were banned in Germany in 1977. Belgium and Greece had never permitted the use of growth hormones for fattening purposes. Other countries such as the United Kingdom, Luxembourg and France had permitted the use of most growth hormones in beef cattle while a partial ban existed in Ireland. By 1980, the use of natural growth hormones[27] were still legal in Germany and the use of both natural and synthetic growth hormones were prohibited in the Netherlands.[28]

A number of factors had brought about a new antipathy towards growth hormone use in the EU. It is widely believed that it was a suspected oestrogen contamination of an uncontrolled supply of poultry and beef in Italy in 1977 that ignited consideration at official EU level of a ban on growth hormones. This 1977 case involved hormonal irregularities in school-going children. The root cause of the hormonal imbalance was never fully verified.[29] Then, in 1980, there was the discovery of 30,000 jars of baby food in Italy containing the carcinogenic

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[25] P.W.B. Phillips & R. Wolfe, *Governing Food: Science, Safety and Trade* (Kingston, Ontario: McGill-Queen's University Press, 2002), p.17.

[26] Growth-promotants or hormones that have been synthesized in a laboratory. The three 'synthetic hormones' at issue in the *Beef Hormone Dispute* were zeranol, trenbolone acetate (TBA), and melengestrol acetate (MGA).

[27] 'Bioidentical' hormones that act in the body the same way as the hormones produced by the animal. The three 'natural hormones' at issue in the *Beef Hormone Dispute* were oestradiol-17β, testosterone, and progesterone. It is the aforementioned six growth-promotants which are used widely in the US The reason their use is widespread in the US is because in the US it is legally permissible to administer combinations of these six specific growth-promotants to animals, under certain conditions, for growth promotion or fattening purposes. This is the reason why it was these six growth promotants (as against any of the many other growth-promotants in existence) that were central to the *Beef Hormone Dispute*.

[28] See, Current National Legislation Relating to the use of Certain Hormones in Animal Production - An annotated chronological index of legislative and regulatory provisions of various countries (FAO Legislation Branch, Legal Office, May 1982), FAO Corporate Document Repository. Available at: http://www.fao.org/DOCREP/004/X6533E/X6533E03.htm#refeecstr [Accessed, 19 March, 2012]. In Ireland, historically, the Animal Remedies (Control of Oestrogenic Substances) Regulations, 1962 (S.I. No. 96 of 1962), made under Section 7 of the Animal Remedies Act, 1956, prohibited 'the manufacture, preparation, packing or sale of 12 substances specified in the Schedule and of any oestrogenic substance or preparation, natural or synthetic, which, on being administered to animals or incorporated in feeds, produces oestrogenic effects'.

[29] G.M. Fara, G. Del Corvo, S. Bernuzzi, A. Bigatello, C. Di Pietro, S., Scaglioni & G., Chiumello, note 170 Chapter 3 above, p. 295.

growth hormone dethylstilboestrol (DES).[30] The use of DES had been banned in Italy since the late 1960s.[31] The source of the contamination was believed to be French veal.[32] Italy banned imports of veal from other EU Member States. Non-governmental organisations (NGOs) especially in the form of European consumer groups latched on to the issue and garnered sufficient public support to boycott veal consumption and to call for a ban on all growth hormones in livestock. The call for a boycott on veal had a significant adverse effect on the market.[33] Subsequently, when the issue of possible negative health effects of using growth hormones in livestock production arose, it came as no surprise that consumers within the EU were alarmed. The DES scare had created a consumer climate within the EU that was concerned over the potentially harmful health effects of using growth hormones in livestock production.[34]

After growth hormone scandals similar to the DES scandal erupted in France and Germany, the French Consumers Union organized a veal boycott and with the help of BEUC this spread to a European wide boycott. Baby food manufacturers such as Alete[35] and Hipp[36] pulled their products containing veal off the market.[37] Within a short time, veal prices dropped 13.7 per cent in France, and fell in Belgium, West Germany, Ireland and the Netherlands.[38] More significantly, after the boycott, overall sales of meat dropped by as much as 50 per cent in France and West Germany.[39]

In addition, a number of major food safety health scares had put EU consumers on edge. The most significant during this period was 'Mad Cow Disease' which arose in the mid 1980s. The first official cases of bovine spongiform encephalopathy (BSE)[40] in animals were indentified in 1986, and with confirmation of the existence of these cases came the question

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[30] From time to time, mainly in the US, allegations surface that some producers continue to use it. See, A.I. Marcus, note 186 Chapter 2 above.

[31] The now notorious cancer causing growth hormone diethylstilbestrol (DES)[31] was banned from use in cattle in 1979.[31] In 1981, the EU banned the use of DES.

[32] European Parliament, 1995, "Der illegale Einsatz von Hormonen zu Mastzwecken in Europa", note 187 Chapter 2 above.

[33] T. Josling, D. Roberts, & A. Hassan, note 188 Chapter 2 above, p.4. Available at: http://fsi.stanford.edu/people/timothyejosling/ [Accessed: May 9, 2011]

[34] *Ibid.*

[35] Baby food produced by Nestle.

[36] Bavarian manufacturer of organic baby food.

[37] *Der Spiegel* (1985) Issue No. 46, p.153 in L. Caduff, note 189 Chapter 2 above, p.7.

[38] R. Cohen, *Boycott Shows EEC's Consumer Power* (Toronto: The Globe and Mail, October 16, 1980) as cited in L. Caduff, note 189 Chapter 2 above, p.7.

[39] *Der Spiegel* (1982) Issue No.3, p.76.

[40] For more details on BSE, see Chapter 5 of this thesis dealing with Risk.

of whether or not the disease was transmissible to humans. By the end of 1988, BSE was officially designated a zoonosis – a disease which could potentially be transmitted to humans.[41] It was the accumulation of these events that prompted EU politicians to take action.[42]

Consumer groups and the pharmaceutical industry were the main NGOs operative in the lead up to the EU's first growth hormones directive in 1981. The European Consumers Organization (BEUC),[43] acting as the umbrella association of national consumer groups, called for a total ban on growth hormones.[44] Surprisingly, the Committee of Professional Agriculture Associations (COPA) representing European farmers and the Liaison Centre of the Meat Processing Industries (CLITRAVI) representing the meat processors, did not enter the debate on the use of growth hormones during this period.[45]

The European pharmaceutical companies supplying growth hormones in the EU were determined to prevent additional regulatory restrictions. Rather than succumb to an immediate ban, these companies lobbied the European Commission to begin a scientific investigation into the public health effects of growth hormones.[46] Most of the growth hormones used in the EU at that time were actually produced by firms in Europe. The five largest of these companies were Elanco, Pitman Moore, Roussel Uclaf (Distrivet), Syntex, and Upjohn.[47] It has been suggested, that given the growth hormone manufacturers were only loosely organized at that time,[48] their partial success in lobbying the Commission was

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[41] The first official certification of a human death from variant Creutzfeldt-Jakob disease ('vCJD') was in 1995.
[42] L. Caduff, note 189 Chapter 2 above, p.6.
[43] BEUC (Bureau Européen des Unions de Consommateurs) is the European Consumers' Organisation. It has a membership of 42 national consumer organisations from 31 European countries (EU, EEA and applicant countries). BEUC acts as the umbrella group in Brussels for these organisations and BEUC's sees its main task as representing its members and defending the interests of Europe's consumers.
[44] *Die Zeit* (1980) Issue No.44, in L. Caduff, note 189 Chapter 2 above, p.7.
[45] European Parliament, 1995, "Europäisches Verbot der Verwendung von Hormonen in der Rindfleischproduktion" in *Reihe Umwelt, Volksgesundheit und Verbraucherschutz*, W 10, Strasbourg: European Parliament, in L. Caduff, note 189 Chapter 2 above, p.7.
[46] D. Vogel, "The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics", (2000) *Council on Foreign Relations*, as cited in L. Caduff, note 189 Chapter 2 above, p.7.
[47] See L. Caduff, note 189 Chapter 2 above, p.7.
[48] It wasn't until 1987 that FEDESA (Fédération Européenne de la Santé Animale) or European Federation of Animal Health was founded - an organisation whose collective membership then represented 90 per cent of the animal health product market. FEDESA represented 23 European and eight American pharmaceutical companies. FEDESA was founded upon an initiative of eight US manufacturers with seven of them being companies that produced growth hormones. See generally, W.P. Meng, "The Hormone Conflict between the EEC and the United States within the Context of GATT", (1989) *Michigan Journal of International Law*, Issue 11, p. 819.

somewhat surprising.[49] Their lobbying was successful as Directive 81/602/EEC[50] banned only one of the six contentious growth hormones outright,[51] while initiating research into the other five growth hormones, as suggested by the manufacturers.[52]

It has been estimated that in the period immediately preceding the 1981 partial ban on growth hormones, growth hormone treated meat accounted for about 80 per cent of the total meat sales in Europe.[53] Therefore, a significant portion of the meat produced in the EU at that time was growth hormone treated, the majority of EU Member States favoured at least some utilisation of growth hormones in meat production. It comes as no surprise that the 1981 partial ban was strongly influenced by the interests of the pharmaceutical industry which produced the growth hormones and the agricultural groups which used them. In addition, it has been suggested that Commission Directorate VI (agriculture) was primarily sympathetic to industrial agricultural interests.[54] It was also believed that the pharmaceutical industry had a strong relationship with the European Commission and that this was why it was successful in its demands for further scientific inquiries before a total ban was entertained.[55]

This partial ban was initiated when on September 20, 1980, the EC Council of Agriculture Ministers adopted a declaration favouring a ban on the use of the growth hormones oestrogen and endorsing the principle across the EU of further harmonization of legislation on veterinary medicines, and additional controls on the production and slaughtering of animals. Subsequently, the European Council adopted its first Directive on growth hormones.

The first EU Directive banning animal growth hormones - Directive 81/602/EEC[56] - prohibited the administering to farm animals of substances having a thyrostatic action or substances having an oestrogenic, androgenic or gestagenic action; the placing on the market or slaughtering of farm animals to which these substances have been administered; the

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[49] L. Caduff, note 189 Chapter 2 above, p.7.
[50] Council Directive 81/602/EEC, note 173 Chapter 3 above.
[51] The one growth promotant (out of the six specific controversial growth promotants) specifically banned although not specifically mentioned by Directive 81/602/EC was melengestrol.
[52] There are six specific growth-promotants which are used widely in the US The reason their use is widespread in the US is because in the US it is legally permissible to administer combinations of these six specific growth-promotants to animals. This is the reason why it was these six growth-promotants (as against any of the many other growth-promotants in existence) that were central to the *Beef Hormone Dispute*.
[53] A. Brand & A. Ellerton, *Report on Hormone Treated Meat* (Brussels: Club de Bruxelles, 1989), at 3.9.
[54] E. Millstone, "Analysing Biotechnology's Traumas", (2000) *New Genetics and Society*, Vol.19, p.117.
[55] L. Caduff, note 189 Chapter 2 above, p.9.
[56] Council Directive 81/602/EEC, note 170 Chapter 3 above.

placing on the market of meat from such animals; the processing of meat from such animals and the placing on the market of meat products prepared from or with such meat. One of the exceptions was that substances with an oestrogenic, androgenic or gestagenic action could be used for therapeutic purposes when administered by a veterinarian. In addition, Article 5 of Directive 81/602/EEC[57] provided:

> [t]he Council acting ... on a proposal from the Commission shall take a decision as soon as possible on the administering to farm animals of oestradiol 17ß, Progesterone, Testosterone, Trenbolone and Zeranol for fattening purposes. Pending adoption of this decision, the national regulations in force and the arrangements made by Member States concerning these substances shall continue to apply...Member States may not authorize the use of new substances during this transitional period.

Therefore, Directive 81/602/EC effectively banned all growth hormones but it made an exception for the use of oestradiol-17β, progesterone, testosterone, trenbolone acetate (TBA) and zeranol - when they were used for growth promotion purposes and their use was governed according to the individual regulatory schemes maintained by EU Member States.[58] Therefore, the one growth hormone (out of the six specific controversial growth hormones) specifically banned although not specifically mentioned, was melengestrol (MGA).

The European Commission then arranged for a body of scientists to examine the effects of the five growth hormones still in use for animal growth promoting purposes.[59] This group was known as the Lamming Committee[60] after its head Professor G.E. Lamming[61] and it

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[57] *Ibid.*

[58] See World Trade Organisation, "EC Measures Concerning Meat and Meat Products (Hormones)", Panel Report WT/DS/48/R/CAN, 18 August, 1997, para 2.2, p.2.

[59] Article 5 of Directive 81/602/EC confirmed that 'the Council, acting unanimously on a proposal from the Commission shall take a decision as soon as possible on the administering to farm animals of oestradiol 17/ß, Progesterone, Testosterone, Trenbolone and Zeranol for fattening purposes'.

[60] The Lamming Committee was an EU expert working group (comprising members of the Scientific Committee for Food and the Scientific Committee for Animal Nutrition - the lead committee for issues concerning growth promoters).

[61] Eric Lamming was Professor of Animal Physiology at Nottingham University from 1964 to 1992. His ground-breaking research into the reproduction and fertility (using hormonal substances to improve fertility) of farm animals brought him into contact with the veterinary profession. Prior to the establishment of the Lamming Committee, in the U.K., Professor Lamming had been a longstanding member of the Government's Veterinary Products Committee and of a number of the Agricultural and Food Research Council livestock research groups and of the EC Standing Veterinary Committee.

issued its interim findings in 1982. The Committee concluded that the three natural[62] growth hormones (estradiol, progesterone and testosterone) 'would not present any harmful effects to the health of the consumer when used under the appropriate conditions as growth promoters in farm animals'. Their findings on these three 'natural' growth hormones is usually taken to mean that beef from animals that have been administered any of these three growth hormones for growth promotion purposes, is safe for human consumption. As a result of the findings of the Lamming Committee, the Commission proposed to approve the three natural growth hormones for general use. Meat produced with the three natural growth hormones oestradiol 17ß, progesterone and testosterone was to receive a special label informing the consumer of the presence of these animal growth hormones residues. However, this proposal was never adopted.[63]

On November 9, 1982 the EC Scientific Veterinary Committee (Scientific Committee) gave its reaction to the Lamming Report and this was followed by the commentary from the EC Scientific Committee for Animal Nutrition on November 17, 1982 and by the EC Scientific Committee for Food on February 4, 1983. The Committees supported the conclusions and recommendations of the Lamming Report, but recommended the need to lay down provisions for the establishment of programmes to control and monitor the use of growth hormones as anabolic agents and in particular a framework including instructions for use, surveillance programmes and analysis methods. Subsequently, in January 1984, the European Commission asked a group of experts within the EC Scientific Committee on Anabolic Agents to review the scientific knowledge on trenbolone and zeranol (i.e. the two remaining 'synthetic' growth hormones).

Discussions in the European Parliament during this period disclosed that three EU Member States (Belgium, Ireland and the United Kingdom) were in favour of the use of some growth hormones in livestock at a minimum, with Ireland and the United Kingdom arguing for the retention of the synthetic growth hormones trenbolone and zeranol.[64] Third countries such as the US, Canada, Australia, New Zealand, Argentina, and South Africa raised their concerns

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[62] 'Natural' refers to hormones that are naturally produced in animals and would in any event exist (in small quantities) in animals.
[63] L. Caduff, note 189 Chapter 2 above, p.9.
[64] A. Passantino, note 178 Chapter 3 above, p.38.

regarding a ban on growth hormones use due to the potential impact on their beef exports to the EU.[65]

Then, on June 12, 1984, the EU Commission published a proposal[66] for a Council Directive amending Directive 81/602/EEC. The proposal envisaged the controlled use of the three natural growth hormones and a re-examination of the proposed ban on the two synthetic growth hormones. However, the European Parliament, the EC Economic and Social Committee and the EC Council of Ministers rejected this proposal from the Commission.[67]

Consequently, the EU Commission amended that proposal and in 1985 the EC Council adopted Directive 85/649/EEC.[68] The Directive banned the use of all growth hormones and created a more detailed set of provisions for the authorized therapeutic uses.[69] However, the Directive was then challenged in the European Court of Justice and annulled on procedural grounds.[70]

In 1987, in consultation with the Committee on Technical Barriers to Trade of the General Agreement on Tariffs and Trade (GATT), the EU and the US failed to resolve the empasse over animal growth hormones. The tension escalated later that year when US President Ronald Reagan imposed the first round of retaliatory tariffs of 100 per cent ad-valorem duty, worth about $100 million, on EU imports into the US[71]

The proposals from 1985 were eventually re-introduced by the EU Commission and readopted by the EU Council as Council Directive 88/146/EEC.[72] Directive 88/146/EEC

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[65] WTO, 1997. EC measures concerning meat and meat products (hormones), complaint by the United States. Report of the WTO Panel, WT/DS26/R/USA, August 18, 1997, 2: 26-28, as cited in A. Passantino, note 178 Chapter 3 above, p.38.

[66] Communication from the Commission to the Council concerning the use of certain substances having a hormonal action in animal production: 'Proposal for a Council Directive amending Directive 81/602/EEC concerning the prohibition of certain substances having a hormonal action and of any substances having a thyrostatic action', COM (84)295 Final, Brussels 12 June, 1984.

[67] A. Passantino, note 178 Chapter 3 above, p.40.

[68] Council Directive 85/649/EEC, note 176 Chapter 3 above.

[69] Around this time, in regard to the decision to implement an EU-wide ban on hormones, Professor Lamming commented - 'I never thought scientific evidence would be disregarded in favour of misinformed consumer pressure.' See R. Wright, note 52 Chapter 3 above, p.9.

[70] A. Passantino, note 178 Chapter 3 above, p.38.

[71] See US Presidential Proclamation No. 5759 of 24 December 1987, 102 Stat. 4942. The Proclamation announced that the '[c]ouncil Directive prohibiting the use in livestock farming of certain substances having a hormonal action ... adopted in December 1985 by the European Community ... constitutes a burden or restriction on United States commerce'.

[72] Council Directive 88/146/EEC, note 190 Chapter 2 above.

extended the prohibition imposed by Directive 81/602/EEC to the administration to farm animals of trenbolone acetate and zeranol for any purpose, and oestradiol-17β, testosterone and progesterone for fattening purposes. There was now a complete ban on the use of all growth hormones for animal fattening purposes.[73] This ban remains in place to this day.

In addition to the ban on all animal growth hormones, the entire group of six specific growth hormones in dispute with the US, was now also banned.[74] To reiterate, the six specific animal growth hormones banned were:

(i) the three natural growth hormones (that occur naturally in the animal), namely, oestradiol-17β (responsible for female characteristics), testosterone (responsible for male characteristics), and progesterone (responsible for maintaining pregnancy); and
(ii) the three synthetic growth hormones, namely zeranol, trenbolone acetate (TBA),[75] and melengestrol acetate (MGA).[76]

With regard to whether or not a complete or partial ban on the growth hormones was necessary, the Lamming Committee had noted that ten out of the twelve veterinary authorities of the (then) EU Member States had submitted that it would be easier to police a total ban on the administered growth hormones than a partial ban because a veterinarian could usually tell by visual signs when an animal had been administered with growth hormones but not whether this had been a treatment with legal versus illegal substances or the quantities involved.[77]

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[73] There was a minor exception to the ban for therapeutic and zootechnical purposes. Britain decided to introduce the hormone ban in 1989, a year later than the rest of the EEC. See R. Wright, note 52 Chapter 3 above, p.9.

[74] As we have seen, Directive 81/602 had the effect of banning the synthetic growth promotant, melengestrol. Directive 88/146 now prohibited the administration to farm animals of the synthetic hormones, trenbolone acetate and zeranol, for any purposes, as well as the administration of the natural hormones, oestradiol - 17β, progesterone and testosterone, for growth promotion or fattening purposes. See also, WTO Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, AB-1997-4, WT/DS/26/AB/R, para 4, p.2. These six growth promotants are used widely in the US In the US, it is legally permissible to adminsiter these six growth promotants to animals, under certain conditions, for growth promotion or fattening purposes.

[75] Zeranol and trenbolone acetate hormones are implanted behind one of the animal's ears as a time-release implant, releasing hormones during key growth stages. The hormones provide a substantial cost saving to the cattle-producer as they may eliminate as much as twenty days feeding equivalent each time they are used.

[76] Approved for use as a feed additive in the United States. Usually mixed-in with cattle feed and is used to improve weight gain and feed efficiency.

[77] See "EC Measures Concerning Meat and Meat Products (Hormones)", Panel Report WT/DS26/R/USA, August 18, 1997, para 4.39, p.735.

Directive 88/146/EEC maintained the permission to administer the three natural growth hormones to animals for therapeutic and zootechnical purposes under certain conditions.[78] When used for therapeutic treatment the growth hormones could only be administered by a veterinarian, in the form of an injection only, to farm animals which had been clearly identified.[79]

A ban was placed on the importation from third countries of animals and meat that had been administered substances with thyrostatic, oestrogenic, androgenic or gestagenic action. However, again, where animals had been treated for therapeutic or zootechnical purposes, trade in those animals and meat from those animals could be imported from third countries. Article 4 of the Directive 88/146/EEC made it a requirement that companies producing and marketing the growth hormones within the EU had to keep a detailed register recording (in chronological order) the quantities produced and sold or used in the production of pharmaceutical or veterinary products.

Subsequently, Directive 88/299/EEC[80] was introduced which laid down the conditions for applying the derogations from the prohibition in trade in certain categories of animals and their meat provided for by Article 7 of Directive 88/146/EEC. Basically, it authorised and laid down the condition for trade within the EU of animals (and their meat) that had been treated therapeutically with the growth hormones. Directive 88/299/EEC also authorised imports from third countries of treated animals (or their meat) under guarantees equivalent to those that applied to the EU animals and meat.

In 1987, immediately before the introduction of these Directives, Professor Lamming and his group had conducted additional studies into the two remaining synthetic growth hormones – zeranol and trenbolene acetate.[81] They concluded that these two growth hormones were likely to be safe when used in accordance with 'good husbandry practice'. Before the WTO, the EU would later argue that Professor Lamming had not defined the concept of 'good husbandry

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[78] In particular, therapeutic treatment would involve giving an animal one of the substances to treat a fertility problem diagnosed on examination by a veterinarian.

[79] The treatment had to be registered by the veterinarian and the animals could not be slaughtered before expiry of a fixed period.

[80] Council Directive 88/299/EEC, note 55 Chapter 7 above.

[81] Despite these findings, much to the chagrin of Professor Lamming, the EU still went ahead and implemented a ban on all growth-promotants.

practice' and that Professor Lamming's conclusion was based on the unsupported assumption that the carcinogenicity of the growth hormones was related to their hormonal effects.[82]

Another important development in this regard occurred in 1988, when the European Parliament established a 'Committee of Enquiry into the Problem of Quality in the Meat Sector'. The Committee's Report (the 'Pimenta Report') was adopted by the European Parliament on 29 March, 1989. The Pimenta Report concluded that there was no discernible health risk in the use of the three natural growth hormones when administered to castrated steers in the form if slow-release-implants in a part of the animal not consumed (e.g. the ear), and where a specific withdrawal period was observed before slaughter. As to the two other synthetic growth hormones, the Pimenta Report concluded that zeranol was as safe as the three natural growth hormones. However, with trenbolene acetate, a small residual doubt existed as to its long term carcinogenicity.[83] However, the Committee endorsed the EU ban on growth hormones, opining that:

> [s]cientific evidence does not address the question of potential interaction of these substances with other substances or the multiplier effect of these substances in a worst case scenario (e.g. the administering of growth hormones to an animal with an already high level of endogenous growth hormones and the ingestion of the meat (or milk) of that animal by a female taking the oestrogen based contraceptive pill).[84]

Of particular relevance to this thesis, is the fact that the Pimenta Report opined that successful regulations could not be based solely on scientific information, partly due to the 'current state of knowledge' argument and partly because the regulator was required to deal with social and political conflicts that extended beyond scientific considerations.[85]

Then, in 1995, the EC Scientific Conference on Growth Promotion in Meat Production concluded that there was no evidence substantiating possible health risks to consumers due to the use of the three natural growth hormones for growth promotion, since the daily

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[82] See 'EC Measures' Panel Report, note 77 above, p.733.
[83] *Ibid*, p.734.
[84] European Parliament, Session Documents, Report drawn up on behalf of the Committee of Inquiry into the Problem of Quality in the Meat Sector, Rapporteur: Mr. Carlos Pimenta, Document A2-11/891/PARTS A-B, March 1989 ('Pimenta Report'), p.6.
[85] See 'EC Measures' Panel Report, note 77 above, para 4.37, p.734.

production of the growth hormones in humans is significantly higher than the amounts which could be consumed. They found that this was still the case with the most sensitive categories of humans - i.e. prepubescent children and menopausal women.[86]

Notwithstanding this body of opinion which advocated the likely safety of the hormones when administered in accordance with 'good animal husbandry' and 'good veterinary practice', eventually, the current Directive, Directive 96/22/EC,[87] was introduced. Directive 96/22/EC repealed Directives 81/602/EEC, 88/146/EEC and 88/299/EEC. It maintained the blanket prohibition on the use of all hormones as growth promoters and extended the prohibition on the use of beta-agonists, restricted the use of growth hormones for therapeutic or zoo-technical purposes and reinforced in particular the role of the veterinarian. The use of certain growth hormones for therapeutic purposes only, is authorized by this Directive.[88] Article 8 requires that Member States must restrict the possession of permissible substances to persons authorized by the Member State's national legislation.[89] Article 8 of Directive 96/22/EC also provides that official checks must be carried out by the competent national authorities without prior notice, with a view to ascertaining: (1) the presence in animals of prohibited substances which were administered for the purpose of increasing weight gain; (2) the illegal treatment of animals with any such products; and (3) any failure to observe the withdrawal periods and the restrictions on the use of certain substances.[90]

In 2003, Council Directive 96/22/EC was amended by Council Directive 2003/74/EC[91] in order to revise the prohibitions on the use of hormonal, thyrostatic, and beta-agonist substances in livestock farming.[92] Directive 2003/74/EC can be viewed as merely a refinement of Directive 96/22/EC as the changes introduced are not particularly substantive.[93]

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[86] A. Passantino, note 178 Chapter 3 above, p.38.
[87] Council Directive 96/22/EC, note 55 Chapter 7 above.
[88] Article 4. Again, the prescriptive nature of these EU provisions is evident and this can be contrasted with the more lax regulations extant in the US where the use of growth promotants is permitted.
[89] See Directive 96/22, Article 8(1).
[90] *Ibid*, Article 8(2)(a)-(d).
[91] Directive 2003/74/EC, note 178 Chapter 7 above.
[92] This amendment was made in light of the Beef Hormones Dispute which was then pending at the WTO and the recommendations made by the WTO Dispute Settlement Body on February 13, 1998.
[93] The most important provision is Article 1 of Council Directive 2003/74/EC which prohibits (a) the placing on the market of and any administration to animals regardless of species of thyrostatic substances, stilbenes, stilbene derivatives, their salts and esters (b) the placing on the market for the administration to animals whose flesh and products are intended for human consumption of oestradiol 17ß.

8.2 *Beef Hormones Dispute* goes to the WTO

After the US had brought its complaint to the WTO Dispute Settlement Body, the EU lodged a Request for Consultations with the WTO on 17 April 1996. In its Request, the EU claimed that the retaliatory measures taken under the US Presidential Proclamation No. 5759 of 24 December 1987[94] which resulted in tariff increases on products from the EU were inconsistent with GATT Articles I, II and XXIII, and DSU[95] Articles 3, 22 and 23. Then, on 19 June 1996, the EU requested the establishment of a Panel.[96] In its request, the EU put forward the additional claim that the US failed to 'ensure the conformity of its laws, regulations and administrative procedures with its obligations' under the WTO, with respect to the application of Section 301 of the 1974 Trade Act.[97] The US withdrew the Proclamation measure on 15 July 1996, and as a result the EU decided not to pursue its Panel request, reserving its rights to reconvene, if necessary, a further meeting of the DSB at an early date.

8.2.1 *EC-Hormones*: Establishment of the WTO Panel

Separately in 1996, DSB Panels were established in response to respective complaints made by the US[98] and Canada on the ground that the EU violated the SPS Agreement.[99] This first official stage of the *Beef Hormones Dispute* at the WTO is often referred to colloquially as '*EC-Hormones*'.[100] The EU Directives mentioned above, banning the importation of meat

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[94] 102 Stat. 4942. The Proclamation imposed increased rates of duty on certain EU produce, in response to the EU's implementation of the Council Directive Prohibiting the Use in Livestock Farming of Certain Substances Having a Hormonal Action.

[95] WTO Dispute Settlement Understanding. It is the WTO mechanism for resolving trade disputes which enables enforcement of the WTO rules.

[96] WTO/DS39. The WTO Dispute Settlement Body makes arrangements for the formation of a Panel of experts (in the field) to hear the Dispute.

[97] WTO Agreement Article XVI: 4.

[98] WT/DS26. On 25 April 1996, the US requested the establishment of a panel. A panel was established at the DSB meeting on 20 May 1996. On 2 July 1996, the Panel was composed. The report of the Panel was circulated to Members on 18 August 1997.

[99] WT/DS48. On 16 September 1996, Canada requested the establishment of a Panel. The DSB established a Panel at its meeting on 16 October 1996. On 4 November 1996, the Panel was composed. The report of the Panel was circulated to Members on 18 August 1997.

[100] The second official stage of the *Beef Hormones Dispute*, dealt with later in this Chapter, is called '*US Continued Suspension*'.

and meat products treated with the six growth hormones,[101] were the focus of the complaints. The DSB Panels issued their final reports simultaneously in August 1997.[102]

In its submission to the Panel, the EU essentially put forward four arguments in support of its ban on the use of growth hormones.[103]

(i) firstly, it argued contrary to the US assumption, that the scientific data supporting the safety of growth hormones was not sufficient to warrant lifting the ban;
(ii) secondly, the EU asserted that despite scientific studies suggesting that some growth hormones posed no health threat to humans, the internal lack of adequate control over the growth hormones within the US market meant that their safety could not be guaranteed in any event;
(iii) thirdly, the EU said that it had assessed the risks associated with growth hormones and concluded that the growth hormones were unsafe; and
(iv) fourthly, the EU claimed that historically it had in any event employed a higher level of protection for its citizens than the current ban and therefore its ban was in keeping with those higher standards and on that basis did not violate the SPS Agreement.[104]

It was consumer concerns regarding the safety of growth hormones that encouraged the public campaign leading to the growth hormones ban.[105] But the question remains as to how significant a role issues such as public risk perception, tradition or consumer concern should play in a country's decision to impose a ban that restricts international trade. Of course, for the US, the answer to this question is obvious – such a ban cannot be upheld unless it is based

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[101] There are six specific growth-promotants which are used widely in the US The reason their use is widespread in the US is because in the US it is legally permissible to administer combinations of these six specific growth-promotants to animals. This is the reason why it was these six growth-promotants (as against any of the many other growth-promotants in existence) that were central to the *Beef Hormone Dispute*.

[102] Report WT/DS26/R/USA of the World Trade Organisation Dispute Settlement Panel, *EC Measures Concerning Meat and Meat Products (Hormones) Complaint by the United States,* (18 August, 1997) and Report WT/DS48/R/CAN of the World Trade Organisation Dispute Settlement Panel, *EC Measures Concerning Meat and Meat Products (Hormones) Complaint by Canada,* (18 August, 1997). The reports of the hormone panels are publicly available as documents.

[103] *See generally*, M. D. Carter, note 149 Chapter 2 above, p.625.

[104] As outlined in Chapter 6 of this thesis, under Article 3(3) of the SPS Agreement, WTO Members can decide to adopt divergent regulatory measures 'which result in a higher level of sanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations' but only 'if there is a scientific justification'.

[105] M. D. Carter, note 149 Chapter 2 above, p.652.

on scientific evidence – a clear risk to human health supported by sound science.[106] By contrast, as confirmed by the analysis carried out in this thesis, the EU places a stronger emphasis on the preferences and needs of its consumers and it caters for such concerns by allowing them to play a key role in formulating health regulations. As far as the EU is concerned, allowing its citizens a voice in matters of scientific question is an important aspect of its political system.[107]

In its 1997 Report, the WTO Panel concluded that the burden of proving compliance with the SPS Agreement rested largely on the importing party – i.e. the EU.[108] The Panel found that the EU had not shown sufficiently, based on a 'scientific' risk assessment, that the Codex standards[109] were insufficient to ensure the EU's desired level of health protection. The Panel further opined that the EU's permitted use of the growth hormones for therapeutic purposes was at odds with its prohibition on imports of growth hormone treated beef.

8.2.1.1 *EC-Hormones*: Appeal of the Panel decision to the Appellate Body

In September 1997, the EU appealed the Panel's Report to the WTO Appellate Body. In January 1998, in response to that appeal, the Appellate Body issued its final Report.[110] In its Report, the Appellate Body overturned some of the Panel's findings. The Appellate Body confirmed that the Applicant (the complainant government – i.e. the US) must establish a prima-facie instance of violation of WTO provisions and that the burden of proof then shifts to the Respondent (the defending government – i.e. the EU). As noted by the Appellate Body,[111] under Article 3.3 of the SPS Agreement a WTO Member is allowed to instigate a

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[106] First Submission of the United States (Public Version), WTO Dispute Settlement Panel, European Communities - Measures Concerning Meat and Meat Products, (Aug. 28, 1996).
[107] M. D. Carter, note 149 Chapter 2 above, p.652.
[108] However, the Appellate Body reversed the Panel's general interpretative ruling that the SPS Agreement allocates the evidentiary burden of proof to the Member imposing an SPS measure, and also reversed the Panel's conclusion that when a Member's measure is not based on an international standard in accordance with Article 3.1, the burden is on that Member to show that its SPS measure is consistent with Article 3.3 of the SPS Agreement. Paragraph 253(a) of Appellate Body Reports WT/DS26AB/R and WT/DS48/AB/R
[109] i.e. the international standards referred to in Article 3.3 of the SPS Agreement.
[110] There are two Reports which are identical – one for the US and one for Canada. However, this thesis refers to 'Report', singular, as this thesis only deals with the United States. The two Reports were: Appellate Report WT/DS26AB/R of 16 January, 1998, adopted 13 February, 1998 (WT/DS26/13) and Appellate Report WT/DS48/AB/R of 16 January, 1998, adopted 13 February, 1998 (WT/DS48/11). The two Reports of the Appellate Body were adopted by the DSB in February 1998.
[111] Paragraph 172 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.

level of protection which differs from that implicit in the international standard.[112] In addition, the Member's level of protection may be higher than that implied in the international standard.

The Appellate Body noted that the right of a Member to determine its own appropriate level of sanitary protection is an important right and is affirmed in the sixth preambular paragraph of the SPS Agreement. However, the Appellate Body noted that as made clear in Article 3.3 of the SPS Agreement, the exception was not an absolute or unqualified right, but must be based on a 'scientific justification'.[113] In response, the EU claimed that it had maintained SPS measures higher than the relevant Codex standard[114] and that there was a scientific justification for the measures. The EU also argued that accordingly the requirement of a risk assessment under Article 5.1 of the SPS Agreement, did not apply.

As noted in Chapter 6 of this thesis, Article 5.1 of the SPS Agreement provides that 'Members shall ensure that their sanitary ... measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations'.

The Appellate Body disagreed with the EU assertions and found in favour of the Panel's finding that although the EU had established for itself a level of protection higher, or more exacting, than the level of protection implied in the relevant Codex standards, the EU was still required to comply with the risk assessment requirements established in Article 5.1 of the SPS Agreement.[115] Therefore the EU import ban was not based on the requisite (scientific) risk assessment. The Appellate Body found that:

> The absence of such a risk assessment, when considered in conjunction with the conclusion actually reached by most, if not all, of the scientific studies relating to the other aspects of risk noted earlier, leads us to the conclusion that no risk assessment that reasonably supports or warrants the import prohibition embodied in the EC Directives was furnished to the Panel.[116]

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[112] In this case the Codex standard.
[113] Paragraph 172 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.
[114] i.e. higher than the 'international standard' as referred to in Article 3.3 of the SPS Agreement.
[115] Paragraph 176 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.
[116] *Ibid*, paragraph 208.

In paragraph number 177 of its Report, the Appellate Body made some interesting observations. It noted that its consideration of the objective and purpose of Article 3[117] and of the SPS Agreement as a whole, reinforced its belief that compliance with Article 5.1 was intended as a counterbalance to the right of Members to set their own appropriate level of protection.

The Appellate Body noted that Article 3 was intended to promote the harmonization of the SPS measures implemented by the WTO Members on as wide a basis as possible, while at the same time recognizing and safeguarding Members' entitlement to protect the life and health of their citizens. They further noted that the ultimate goal of the harmonisation of SPS measures is to prevent the abuse of such measures as a means of arbitrary or unjustifiable discrimination between Members or as a means of implementing disguised restrictions on international trade. This finding is in keeping with the confirmation in earlier Chapters of this thesis that the main goal of the SPS Agreement is the furtherance of trade liberalisation.

The Appellate Body stated that this consideration is further personified in the requirement for a risk assessment under Article 5.1 as well as the 'sufficient scientific evidence' requirement under Article 2.2.[118] These two requirements are essential for the maintenance of this delicate balance between the shared, but sometimes competing interests of promoting international trade while simultaneously protecting the life and health of citizens.

More generally, as evidenced from the quote above, the risk assessment must sufficiently warrant and reasonably support the measures taken.[119] However, the Appellate Body noted

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[117] Article 3.1 of the SPS Agreement provides that '[t]o harmonize sanitary ... measures on as wide a basis as possible, Members shall base their sanitary ... measures on international standards, guidelines or recommendations, where they exist ...' Article 3.3 provides that 'Members may ... maintain sanitary ... measures which result in a higher level of sanitary ... protection than would be achieved by measures based on the relevant international standards ... if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate ...'

[118] Article 2.2 of the SPS Agreement requires that 'Members shall ensure that any sanitary ... measure is applied only to the extent necessary to protect human ... health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5'.

[119] In anti-dumping cases, the Panels and the Appellate Body have developed an 'unbiased and objective evaluation' criterion whereby they ask, would it have been possible for an unbiased and objective investigating authority to properly have reached the conclusions actually reached by the national authorities. See *Mexico-Anti-Dumping Investigation of High Fructose Corn Syrup (HFCS) from the US* (Recourse to Article 21.5 of the DSU by the US) WT/DS132/AB/R AB Report adopted 21 November 2001, *Argentina-Definitive Anti-Dumping Duties on Poultry from Brazil*, WT/DS241/R, and *Guatemala-Definitive Anti-Dumping Measures on Grey Portland Cement from Mexico* WT/DS156/R. In *EC-Hormones*, because it was in their interest, the EU sought

that the risk assessment does not have to be quantitative,[120] and that it can set out both mainstream as well as divergent views, provided that the risks are ascertainable.[121] The Appellate Body agreed with the Panel that theoretical uncertainties were not the type of risk intended to be assessed.[122] Again, this finding on 'theoretical uncertainties' evidences that emphasis placed on 'science' as the arbiter in this instance.

The Appellate Body disagreed with the Panel's findings that the EU was not consistent because while it accepted no risk from the growth hormones, at the same time it was not limiting exposure to the growth hormones when they occurred naturally in other foods and because they allowed their use for therapeutic purposes.[123]

The Appellate Body concluded that there was a 'fundamental distinction between added growth hormones (natural or synthetic) and naturally occurring hormones in meat and other foods'.[124] However, the Appellate Body agreed with the Panels that the treatment by the EU of the growth hormones at issue was 'arbitrary and unjustified'.[125] Importantly, the Appellate Body did not uphold the Panel's findings that this different treatment 'resulted in discrimination or a disguised restriction' to trade.[126]

8.2.1.2 *EC-Hormones*: 'Scientific' Basis of the Risk Assessment

In relation to the factors to be taken into account in assessing risk, Article 5.2 of the SPS Agreement provides that:

> In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence

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to have a substantially similar standard of review applied. See *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26//AB/R, (n.9) paras 112-113, citing paras 128-29 of the submission.

[120] Paragraph 186 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.

[121] *Ibid*, paragraph 194.

[122] *Ibid*, paragraph 186.

[123] *Ibid*, paragraph 221.

[124] *Ibid*.

[125] Paragraph 225 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.

[126] *Ibid*, paragraph 240.

> of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

The Appellate Body noted that 'available scientific evidence' was only the beginning and that the Panel had found that for purposes of the disputed EU measures, the risk assessment required by Article 5.1 was 'a scientific process aimed at establishing the scientific basis for the sanitary measure a Member intends to take'.[127]

The Appellate Body noted that to the extent that the Panel purported to exclude from an Article 5.1 risk assessment, all matters not capable of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences, then the Panel was in error. The Appellate Body opined that some of the kinds of factors listed in Article 5.2 such as 'relevant processes and production methods' and 'relevant inspection, sampling and testing methods' are not necessarily capable of being investigated according to the laboratory methods used by biochemistry or pharmacology. More generally, there is nothing to indicate that it was intended that the list of factors to be taken into account in an Article 5.2 risk assessment was intended to be a closed list. Then the Appellate Body makes one of its most profound findings in its Report when it states that:

> .... it is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Article 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.[128]

This interpretation from the Appellate Body indicates that to some degree, the risk element need not be based solely on science and instead when formulating regulatory measures it may be possible to take into account the 'potential' for harm. Therefore, in addition to not having a complete reliance on science as the means of assessment, some commentators have noted that it

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[127] Paragraph 8.107 of Panel Report WT/DS26/R/USA and paragraph 8.110 of Panel Report WT/DS48/R/CAN.
[128] Paragraph 187 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.

may even be possible to take into account other more arbitrary considerations such as public risk perception or cultural biases.[129]

8.2.1.3 *EC-Hormones*: Sanitary Measure to be 'based on' a Risk Assessment

The Appellate Body noted that under Article 5.1 it is not mandatory when adopting a sanitary measure, for a Member to have carried out its own risk assessment. The provision only requires that the sanitary measures be 'based on an assessment, as appropriate for the circumstances'. Therefore, the sanitary measure, such as the EU ban on the growth hormones, may well be based on an objective justification in a risk assessment carried out by another WTO Member or by an international organisation.[130]

However, the Appellate Body said that Article 5.1 should be contextually read in conjunction with Article 2.2 of the SPS Agreement. Then it becomes clear that the results of the risk assessment used must at least 'reasonably support' the disputed regulatory measure. In other words, the requirement that the regulatory measure be 'based on' a risk assessment means that there should be some relationship between the sanitary measure and the risk assessment.[131]

The Appellate Body went on to note that a risk assessment does not have to come to a monolithic conclusion that concurs with the scientific conclusion or with a view implicit in the sanitary measure. Instead, it would be sufficient for the risk assessment to set out both the prevailing view representing mainstream scientific opinion, as well as the opinions of scientists taking a divergent view. Indeed, in some cases, the very existence of divergent scientific views indicates a state of scientific uncertainty. However, the Appellate Body noted that in most cases responsible governments based their legislative and administrative measures on 'mainstream' scientific opinion.[132] The Appellate Body stated that the 'risk' evaluated in a risk assessment

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[129] See for example, J. Scott, note 186 Chapter 5 above, p.101. However, this seems somewhat ironic or contradictory in light of the Appellate Bodies findings on the requirement for a 'sufficient scientific evidence' requirement under Article 5.1 and 2.2 of the SPS Agreement. However, those findings are best understood in isolation as findings regarding those particular aspects of the SPS Agreement.

[130] Paragraph 190 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.

[131] *Ibid*, paragraph 193.

[132] *Ibid*, paragraph 194.

must be ascertainable – 'theoretical uncertainty' is not the kind of risk which is to be assessed.[133]

8.2.1.4 *EC-Hormones*: Appellate Body findings on the EU Scientific Reports

The Appellate Body then went on to consider the nature of the various scientific reports referred to by the EU in its submissions. The Panel had noted that several of these scientific reports had met the requirements for a risk assessment. However, all of the reports came to the conclusion that the use of the growth hormones at issue for growth promotion purposes in animals, posed no definite quantifiable danger to human health. More specifically, the findings in the scientific reports did not rationally support the EU ban.

The Appellate Body found that the articles and opinions of individual scientists submitted by the EU constituted general studies which do indeed show the existence of a general risk of cancer. However they did not focus on and do not address the particular kind of risk which must be addressed in accordance with paragraph 4 of Annex A of the SPS Agreement. Paragraph 4 of Annex A of the SPS Agreement defines 'risk assessment' as:

> the evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of [a] Member according to the sanitary ... measures which might be applied, and ... the evaluation of the potential for adverse effects on human ... health arising from the presence of additives, contaminants, toxins ... in food, beverages or feedstuffs.

Based on the paragraph 4 definition, the Appellate Body found that the EU scientific reports did not support 'the carcinogenic or genotoxic potential of the residues of those growth hormones found in meat derived from cattle to which the growth hormones at issue had been administered for growth promotion purposes'. Therefore, while the EU's scientific opinions were relevant, they did not appear to be sufficiently specific to this case that was now before the WTO Dispute Settlement Body.[134]

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[133] *Ibid*, paragraph 186.

[134] See Paragraph 200 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.

Therefore, the Appellate Body found that the EU had in fact restricted itself to only pointing out the significance of not administering the growth hormones 'in accordance with good veterinary practice' and that the EU did not go further and provide an assessment of the potential adverse effects related to non compliance with such practice.[135]

Therefore, the Appellate Body found that the absence of this particular risk assessment, in conjunction with the conclusion reached in most, if not all, of the scientific studies submitted by the EU, would lead to the conclusion that no risk assessment which would reasonably support or warrant the EU import ban was furnished to the Panel.

The Appellate Body affirmed the ultimate conclusion reached by the Panel that the EU import ban was not based on a risk assessment within the meaning of Articles 5.1 and 5.2 of the SPS Agreement and was, therefore, inconsistent with the requirements of Article 5.1 of the SPS Agreement.[136]

8.2.1.5 *EC-Hormones*: Reaction to the Appellate Body Report

The Report of the Appellate Body was adopted by the DSB[137] on February 13, 1998.[138] After arbitration, the EU was given until May 13, 1999 to comply with the decision.[139] When the EU indicated that it would not be in a position to comply by that date, the US requested the DSB to authorize suspension of concessions for EU exports, as a retaliatory measure against the EU, in order to compensate the US for its loss of trade in beef.[140] The original WTO Panel was then reconvened in order to determine the appropriate amount of retaliation.

The decision of the reconvened Panel issued on July 12, 1999. The US[141] obtained authorization from the DSB to suspend concessions in favour of the EU on 26 July 1999,

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[135] *Ibid*, paragraph 207.
[136] *Ibid*, paragraph 208.
[137] WTO Dispute Settlement Body.
[138] WT/DS26/13 & WT/DS48/11.
[139] Award of the Arbitrator, *EC – Hormones*, paragraph 48.
[140] In accordance with Article 22.2 of the Dispute Settlement Understanding if no agreement is reached on compensation then the DSB can authorise retaliation (usually trade tariffs) pending full implementation of the agreement.
[141] Along with Canada.

following arbitration at the EU's request.[142] Since then, the US has been imposing 100 per cent tariffs on various products imported into the US from EU Member States. With DSB authorization, on 29 July 1999, the US imposed retaliatory tariffs of 100 per cent import duties worth $116.8 million annually on a range of EU imports.[143]

Some have described this as the EU's acceptance of retaliation as the preferred outcome when it did not win the case. Accepting retaliation has been specifically built into the WTO (and before it the GATT) as the ultimate escape clause (albeit at a price) for politicians when faced with a judgement that carries too high a domestic political cost for it to be implemented.[144]

After losing *EC-Hormones*, the EU commissioned seventeen scientific studies in the area of possible adverse health risks from growth hormone treated beef.[145] Reviewing these studies, the EU's Scientific Committee on Veterinary Measures relating to Public Health (Scientific Committee), issued a series of opinions (Opinion 1999, Opinion 2000, and Opinion 2002) which concluded that oestradiol-17β was a carcinogen but the committee noted that threshold levels could not be defined for any of the six growth hormones in question.[146] They also found that current knowledge would not allow a quantitative estimate of the risk associated with the five other growth hormones. Based on the Scientific Committee's opinions, the EU amended Directive 96/22/EC with Directive 2003/74/EC.[147]

Directive 2003/74/EC specifies that, even though the scientific information available showed the existence of risks associated with the growth hormones, 'the current state of knowledge

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[142] Decision by the Arbitrators, *EC – Hormones (Article 22.6 – United States)*, para. 84; Decision by the Arbitrators, *EC – Hormones (Article 22.6 – Canada)*, paragraph 73.

[143] For example, Bordeaux wine.

[144] W.A. Kerr & J.E. Hobbs, note 164 Chapter 2 above, p. 284. The high political cost results from cultural biases and public risk perception which demand that the ban remain in-situ. Should the politicians go against the public demand and lift the ban, then there would be a high political price to pay.

[145] There is an obligation to conduct such studies, insofar as when the legislation is silent on the matter and when the Commission lacks the requisite scientific evidence, it must consult with the appropriate scientific committees so as to try and ensure that the measures taken to protect human health are appropriate. See Case C-212/1991, *Angelopharm GmbH v Freie Hansestadt Hamburg* [1994] ECR I-171.

[146] The six growth promotants are – (a) the three 'natural hormones' (that occur naturally in the animal), namely, oestradiol-17β, testosterone, and progesterone, and (b) the three 'synthetic hormones', namely zeranol, trenbolone acetate (TBA), and melengestrol acetate (MGA). These six growth promotants are used widely in the US In the US, it is legally permissible to administer combinations of these six growth promotants to animals, under certain conditions, for growth promotion or fattening purposes.

[147] Directive 2003/74/EC, note 178 Chapter 7 above.

does not make it possible to give a quantitative estimate of the risk to consumers'.[148] The Directive provides that the prohibition of the growth hormones applies 'while the Community seeks more complete scientific information from any source, which could shed light and clarify the gaps in the present state of knowledge on these substances'.[149]

Therefore, based on the findings of the scientific committees and given the available scientific data, even after *EC-Hormones*, the EU reaffirmed its position that there are possible risks to human health associated with eating growth hormones treated beef. In respect of the precautionary principle, dealt with in detail in Chapter 6 of this thesis, the general approach taken by the EU along with the commissioning of the scientific studies, can be seen as the EU's application of the precautionary principle in its approach to food safety policy.

On 27 October 2003, the EU notified the WTO Dispute Settlement Body of the adoption, publication, and entry into force of Directive 2003/74/EC. The EU also notified the Dispute Settlement Body of the Scientific Committee's 1999, 2000, and 2002 Opinions, on the basis that under the terms of the SPS Agreement they were now armed with a sufficient justification for the permanent and provisional prohibitions on the importation of meat from cattle treated with the six growth hormones. Based on this, the EU claimed that it had now fully implemented the DSB's recommendations and rulings in *EC – Hormones*. As a result, the EU considered that the suspension of import tariff concessions by the US was no longer justified. However, the US refused to lift the suspension of concessions,[150] because in their view Directive 2003/74/EC had not brought the EU into compliance with the DSB's recommendations and rulings.[151]

There appeared to be a certain amount of liaison between the US and Canada on the matter. Subsequently, Health Canada's Veterinary Drugs Directorate (VDD) undertook a review[152] of the seventeen studies commissioned by the EU in order to assess scientific information on the safety of growth hormone treated beef. At this time, FDA issued various announcements

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[148] Recital 7 of Directive 2003/74/EC.
[149] *Ibid*, recital 10.
[150] i.e. imposed pursuant to the authorization that they had obtained from the DSB.
[151] See WTO Memorandums WT/DSB/M/157 and WT/DSB/M/159.
[152] See Health Canada, 'Hormonal Growth Promoters', Available at: http://www.hc-sc.gc.ca/dhp-mps/vet/issues-enjeux/hormon/index-eng.php [Accessed: 27 May, 2011]

reaffirming its stance.[153] The VDDs' scientific review of the EU studies concluded that the residues found in meat from animals treated with growth hormones (when administered according to good veterinary practices) did not pose any undue risk to human health and that this finding was in accordance with FDA's position on the matter.

8.2.1.6 *EC-Hormones*: EU Application of the Precautionary Principle

In its defence, the EU had invoked the precautionary principle in support of its claim that its regulatory measures were based on a risk assessment. The issue was whether or not the principle could be considered as part of customary international law and that it might be possible that it could be used to interpret Articles 5.1 and 5.2 of the SPS Agreement on the assessment of risks.

In *EC-hormones*, the Panel did not make any definitive finding with regard to the status of the precautionary principle in international law. The Panel found that the principle would not override the explicit wording of Articles 5.1 and 5.2 in particular, since the precautionary principle has been incorporated and given a specific meaning in Article 5.7 of the SPS Agreement. However, this thesis notes that the terminology of Article 5.7, only allows a particularly narrow interpretation of the precautionary principle.

Article 5.7 of the SPS Agreement provides that:

> [i]n cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary ... measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary ... measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary ... measure ...within a reasonable period of time.

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[153] See M. Smith "Beef Hormone Trade Dispute", (2005) *FDA Veterinarian Newsletter* - November/December, Volume XX, No VI.

On that basis, the Panel adhered to its finding that the EU import ban of meat and meat products from animals treated with any of the growth hormones at issue for growth promotion purposes was not based on a scientific risk assessment in the manner required under the terms of the SPS Agreement.[154] When appealed to the Appellate Body, the EU asked that the findings of the Panel in regard to the precautionary principle be reversed.

In its Report in 1998, the Appellate Body noted that the basic submission of the EU was that the precautionary principle is, or has become, 'a general customary rule of international law' or at least 'a general principle of law'.[155] In the view of the EU, applying the precautionary principle to Articles 5.1 and 5.2 of the SPS Agreement meant that it was not necessary for all scientists around the world to agree on the possibility and magnitude of the risk, nor was it necessary for all or most of the WTO Members to perceive and evaluate the risk in the same way.[156]

The Appellate Body acknowledged that the US did not consider the precautionary principle as representing customary international law and noted that the US suggested it was more an 'approach' than a principle.[157] The Appellate Body took the view that the precautionary principle, at least outside the field of international environmental law, still awaited authoritative formulation.

Nevertheless, the Appellate Body placed importance on certain aspects of the relationship between the precautionary principle and the SPS Agreement. In particular, the Appellate Body noted that the principle has not been written into the SPS Agreement so that it could be used as a ground for justifying sanitary measures that would otherwise be inconsistent with the obligations of Members. In addition, when a panel was faced with deciding whether or not 'sufficient scientific evidence' existed to support a Member's use of a particular sanitary measure, the Panel should bear in mind that governments were required to act from 'perspectives of prudence and precaution where risks of irreversible damage to human health

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[154] See generally paragraph 120 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.
[155] Paragraph 91 of the EU submission to the Appellate Body.
[156] Paragraph 121 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.
[157] Paragraph 92 of the United States appellee's submission to the Appellate Body. In its submission, Canada, took the view that the precautionary principle was not yet incorporated into the corpus of public international law, but conceded that it was an emerging principle of law which may in the future crystallize into one of the 'general principles of law recognized by civilized nations' within the meaning of Article 38(1)(c) of the Statute of the International Court of Justice. See, Paragraph 34 of Canada's appellee submission to the Appellate Body.

are concerned'.[158] However, the precautionary principle by itself, especially if it does not have a clear textual directive to that effect in the SPS Agreement, does not relieve a Panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the SPS Agreement. It was on that basis the Appellate Body agreed with the findings of the Panel that the precautionary principle does not override the provisions of Articles 5.1 and 5.2 of the SPS Agreement.

The SPS Agreement is effectively a contract signed by the participating Members. Accordingly, the Panel as arbiter is largely confined to restrictively adhering to the terms of the Agreement. As discovered by the investigations carried out in Chapter 7 of this thesis, the terminology of the Agreement is wholly science centred. This thesis confirms that, in addition to the fact that there is no explicit inclusion of cultural considerations in the SPS Agreement, the fact that the Panels hands are tied by the terms of the Agreement itself ensures an over reliance on science as a basis for risk analysis.

8.2.2 *US-Continued Suspension*: Panel Report

The second stage of the *Beef Hormones Dispute*, when the Dispute again went before a WTO Panel and Appellate Body hearing, is referred to in this thesis as *US–Continued Suspension*. In November 2004, the EU filed a complaint against the US and Canada due to their continued suspension of tariff concessions[159] even after the EU notified the WTO Dispute Settlement Body (DSB) of Directive 2003/74/EC.[160] The EU asserted that the US should have removed its retaliatory measures since the EU had removed the measures found to be WTO-inconsistent in the *EC-Hormones* case. At its meeting on 17 February 2005, the DSB established a Panel. Due to the complexities of the issues involved in the Dispute by this time, it was March 31, 2008, before the WTO Panel issued its Report,[161] which can best be described as a mixed ruling.

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[158] Paragraph 124 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.

[159] The EU asserted that the continued use by the US of retaliatory measures in the case were violations of Articles I and II of GATT 1994, and Articles 21.5, 22.8, 23.1 and 23.2 (a) and (c) of the DSU.

[160] Request for Consultations by the European Communities, US- Continued Suspension, WT/DS320/1 (November 8, 2004) and Request for Consultations by the European Communities, Canada - Continued Suspension, WT/DS321/1 (November 8, 2004)

[161] Report WT/DS320/R of the World Trade Organisation Dispute Settlement Panel, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute* (31 March, 2008) and Report WT/DS321/R of the

In the submissions made by the parties, the EU had acknowledged that its ban on one of the growth hormones, oestradiol-17β, was not based on international standards (i.e. the Codex standard) which requires no average daily intake or maximum residue levels for oestradiol-17β. However, the EU argued that it was permitted to prohibit the placing on the market (including a ban on imports) of meat and meat products treated with oestradiol-17β for growth promotion purposes because its decision was based on a comprehensive risk assessment, which is not in violation of Article 5.1 of the SPS Agreement.[162] The EU also submitted that in any event it regarded the Codex recommendations as old and that they did not allow the EU to achieve the level of protection it considers appropriate in its territory.

In respect to the other five growth hormones, the EU submitted that it was possible in the presence of an international standard, guideline or recommendation that is based on a risk assessment, to adopt a provisional sanitary measure on the grounds that the relevant scientific evidence is insufficient. A Member may disagree with the risk assessment for scientific reasons and, in particular, on the issue of whether the scientific evidence relied upon is sufficient.[163]

Article 3.3 of the SPS Agreement provides that:

> [M]embers may introduce or maintain sanitary ... measures which result in a higher level of sanitary ... protection than would be achieved by measures based on the relevant international standards ... if there is a scientific justification, or as a consequence of the level of sanitary ... protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5. Notwithstanding the above, all measures which result in a level of sanitary .. protection different from that which would be achieved by measures based on international standards ... shall not be inconsistent with any other provision of this Agreement.

World Trade Organisation Dispute Settlement Panel, *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute* (31 March, 2008).

[162] See paragraph 7.841 of Panel Report WT/DS320/R of the World Trade Organisation Dispute Settlement Panel, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute* (31 March, 2008).

[163] *Ibid.*

In a footnote to the SPS Agreement, it is explained that for 'the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an ... evaluation of available scientific information ... a Member determines that the relevant international standards ... are not sufficient to achieve its appropriate level of sanitary ... protection'.

The US lodged counter-arguments against the EU submissions, asserting that; the EU's import ban was not 'based on' international standards within the meaning of Article 3.3 of the SPS Agreement as the relevant standards adopted by Codex permit trade in meat and meat products from cattle treated with growth hormones by setting Minimum Residue Limits (MRLs); that although Members may introduce or maintain sanitary measures which result in a higher level of sanitary protection than would be achieved by measures based on the relevant international standards, the EU was not permitted to do so because it does not satisfy the requirement in Article 3.3 that such stricter measures be in accordance with paragraphs 1 through 8 of Article 5; that the EU measure were not based on a (scientific)[164] risk assessment within the meaning of Article 5.1 and therefore the EU was acting contrary to Article 3.3.[165]

The mixed nature of the ruling in *US-Continued Suspension* is evident from the conclusions reached by the Panel. In considering the risk assessment carried out by the EU on one of the growth hormone (oestradiol-17β), the Panel consulted with scientific experts and found that the EU had failed to evaluate health risks which originated specifically from residues in meat resulting from growth hormone treatment. As to the provisional EU ban on the five other growth hormone, because the EU had not furnished any 'critical mass' of new evidence that would justify the provisional ban, the Panel found that the EU had not met the condition of insufficient scientific evidence (i.e. the SPS Agreement's application of the precautionary principle) as required under Article 5.7 of the SPS Agreement.

The Panel concluded that the EU did not comply with Article 5.1 and with Article 5.7 of the SPS Agreement and that it had not been established that the EU had removed the measure found to be inconsistent with the SPS Agreement. Therefore, to the extent that the measure found to be inconsistent with the SPS Agreement in the *EC–Hormones* dispute had not been

[164] The Panel has found that Article 5.1. and Article 5.2 must be read together, which means that it is a 'scientific' risk assessment – as Article 5.2 stipulates that Members shall take the 'available scientific evidence' into account.

[165] Paragraphs 7.838-40 of Panel Report WT/DS320/R (31 March, 2008).

removed by the EU, the US had not breached Article 22.8[166] of the Dispute Settlement Understanding (DSU).[167] Furthermore, to the extent that Article 22.8 has not been breached, the EU had not established a violation of Articles 23.1 and 3.7 of the DSU as a result of a breach of Article 22.8.

With regard to the US, the Panel found that the suspension of concessions or other obligations as a retaliatory measure because the EU implemented Directive 2003/74/EC, was in effect the redress of a violation of the obligations under the SPS Agreement, without the US having recourse to, and abiding by, the rules and procedures of the DSU. As a result the US had breached Article 23.1 of the DSU.[168] The Panel then proceeded to recommend that the Dispute Settlement Body request the US to bring its measure into conformity with its obligations under the DSU.[169]

In the context of this thesis, it is also worthwhile to consider some of the submission made by other WTO Member States, where the use of growth hormones is permitted.

8.2.2.1 *US-Continued Suspension*: Australia's submission

In its submission to the Appellate Body in *US-Continued Suspension*, Australia maintained that the standard of review to be applied by a WTO Panel 'may vary between different obligations under the SPS Agreement' and must reflect the 'balance between regulatory autonomy and international supervision' that is reflected in that Agreement.[170] According to the Australian submission, Panels must accord 'considerable deference (but not total deference)' to a Member's risk assessment provided that Member has performed a 'comprehensive and transparent' risk assessment.[171] Australia submitted that in relation to the

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[166] Article 22.8 of the Dispute Settlement Understanding provides inter alia – 'The suspension of concessions or other obligations shall be temporary and shall only be applied until such time as the measure found to be inconsistent with a covered agreement has been removed'.

[167] The Dispute Settlement Understanding is attached at Annex 2 to the WTO Agreement. It sets out the rules and procedure governing dispute resolution at the WTO. The Dispute Settlement Body (which is effectively the WTO General Council in another guise and consists of all WTO members) then appoints a Panel of experts in that field, to arbitrate on the matter.

[168] The US had effectively made a determination within the meaning of Article 23.2(a) of the DSU without going through the formal WTO dispute settlement framework.

[169] Paragraph 8.3 of Panel Report WT/DS320/R (31 March, 2008).

[170] Paragraph 228 of Appellate Body Report WT/DS320/R, *US – Continued Suspension.*

[171] *Ibid.*

existence of international standards, those standards may be relevant in interpreting the SPS Agreement, but they are not 'dispositive' of the meaning of the provisions and therefore they should not be 'elevated' to binding treaty obligations.[172]

8.2.2.2 *US-Continued Suspension*: New Zealand's submission

New Zealand 'strongly' disagreed with the EU arguments in relation to Articles 5.1 and 5.7 of the SPS Agreement. They submitted that the EU arguments if they were allowed to stand, would 'seriously undermine the principles and obligations' of the SPS Agreement.[173] New Zealand submitted that the SPS Agreement imposed a 'very important' requirement that SPS measures be developed and implemented by a Member in a manner that is 'transparent, consistent, scientifically-based, and the least trade-restrictive'.[174]

New Zealand believed that Article 2.2 of the SPS Agreement imposed a general obligation on WTO Members that SPS measures be based on scientific principles and that those measures not be maintained without sufficient scientific evidence.[175] There must be a 'rational relationship between the measure and the risk assessment' whereby the result of the risk assessment sufficiently warrants the SPS measures to be taken. New Zealand was of the view that the Panel had correctly concluded that Directive 2003/74/EC was not based on a 'scientific' risk assessment within the meaning of Article 5.1.[176]

8.2.3 *US-Continued Suspension*: Appellate Body Report

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[172] *Ibid*, paragraph 231.
[173] *Ibid*, paragraph 252.
[174] Article 5.6 of the SPS Agreement imposes a 'least trade restrictive' obligation on a Member when instigating a sanitary measure. However, it is unlikely that in order to enhance the availability of problematic alternative measures, Members are obliged to mitigate those problems – i.e. it is unlikely that the Article 5.6 obligation goes that far. See *US Gasoline: US Standards for Conventional and Reformulated Gasoline*, WT/DS2/AB/R, p.28.
[175] Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R, para 180. Indeed, Article 5.1. can be viewed as a 'specific application of the second and third obligations provided for in Article 2.2'. Panel Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/R, para 74.
[176] Paragraph 254 of Appellate Body Report WT/DS320/R, *US – Continued Suspension*.

The Panel's decision in *US-Continued Suspension* was eventually appealed by the EU, and also by the US. On October 16, 2008, the Appellate Body circulated its Report[177] to the WTO Members. The Appellate Body Report rejected the Panel's findings on most grounds. The Appellate Body's rejection of the Panel's findings can be seen as an effort to broaden the policy space as to risk factors and scientific evidence.[178] The Appellate Body placed more emphasis on a broadened notion of scientific justification than that based on the form of risk assessment as defined in *EC-Hormones*. Ostensibly, this approach would take certain non-scientific policy considerations such as the acceptable level of protection, into account.

The Appellate Body admonished the Panel's alleged deference towards mainstream science as symbolized by its use of international standards, such as Codex. The Appellate Body ruled that the Panel violated EU due process rights in the manner by which it consulted with scientific experts.[179] The Appellate Body felt that these scientific experts may have been prejudiced against the EU simply because certain aspects of the EU's regulatory position on the six growth hormones diverged from the Codex standards and these scientific experts had at one time in their career been involved in formulating those very same Codex standards.[180] The Appellate Body felt that the Panel's reliance on certain scientists was egregious and that it could invalidate the Panel's findings under Articles 5.1 and 5.7 of the SPS Agreement.[181] Some commentators have criticised the Appellate Body's position, classifying their stance as accusing the scientists of guilt by association.[182]

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[177] Report WT/DS320/AB/R of the World Trade Organisation Dispute Settlement Appellate Body, *United States – Continued Suspension of Obligations in the EC – Hormones Dispute* (16 October, 2008), AB-2008-5 and Report WT/DS321/AB/R of the World Trade Organisation Dispute Settlement Appellate Body, *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute* (16 October, 2008), AB-2008-6. The DSB adopted the Appellate Body report and Panel report, as modified by the Appellate Body report, at its meeting on 14 November 2008. The findings of the Appellate Body report on the US appeal and the Canadian appeal were almost identical, so for the sake of convenience and because this thesis only deals with the US position, the comments in this section of the thesis concentrate on the US report findings.

[178] S. Cho, "United States: Continued Suspension of Obligations in the EC-Hormones Dispute", (2009) *The American Journal of International Law*, Vol. 103, No. 2, p. 302.

[179] The Panel usually consults directly with experts as distinct from procuring a group report as it allows the Panel more flexibility in formulating its eventual position. See *Japan-Measures Affecting the Importation of Apples*, WT/DS245/R.

[180] Paragraph 477 of Appellate Body Report WT/DS320/R, *US – Continued Suspension*.

[181] Paragraph 484 of Appellate Body Report WT/DS320/R, *US – Continued Suspension*. However, the Appellate Body is always quick to defend any over criticism of a Panel or allegations that a Panel did not conduct as objective assessment of the facts. See *EC-Measures Affecting the Importation of Certain Poultry Products* WT/DS69/AB/R, para 133.

[182] See S. Cho, note 178 above, p. 302.

The Appellate Body also found in favour of the EU in relation to risk assessment. They noted the opinions from some scientists outlining possible risks from abuse or misuse of the growth hormones when not administered according to 'good veterinary practices'.[183] The Appellate Body noted that the experts emphasised the risks posed by oestradiol-17β were predicated on good veterinary practices being followed. Accordingly, the abuse or misuse in the administration of oestradiol- 17β has a bearing on the particular risks being assessed by the EU. In that manner, the Appellate Body combined an objective risk assessment under Article 5.1 of the SPS Agreement, with a subjective policy determination regarding the level of protection under paragraph 5 of Annex A of the SPS Agreement.[184] This evidences quite a clear-cut broadening of the role of science in the operation of the SPS Agreement provisions. However, in itself, it does not go so far as to confirm the inclusion of 'other factors' such as culture in all its forms, especially public risk perception.

However, crucially, the Appellate Body again recognized that the level of protection must not affect the nature of the risk assessment, which must be based on scientific methods.[185] Therefore, the above evaluation of the potential risk from the abuse or misuse of the growth hormones is not a 'risk assessment' consideration, but a WTO Members autonomous determination of the appropriate or acceptable level of protection.

The Appellate Body's broadening of objective science is further evidenced in its deliberations regarding Article 5.7 of the SPS Agreement.[186] While the Panel had concluded that the relevant international standards would not exist without availability of sufficient evidence, the Appellate Body undermined that reasoning by referring to the EU zero tolerance of health risks from the consumption of growth hormone treated beef (i.e. a higher level of protection than that reflected in the international standards) as being something that should feed into the EU's risk assessment.[187] The Appellate Body went further by stating that this determination should be the EU's call, noting that the insufficiencies in the scientific evidence identified by the EU had to be evaluated on its own terms.[188]

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[183] Paragraph 547 of Appellate Body Report WT/DS320/R, *US – Continued Suspension.*
[184] See S. Cho, note 178 above, p. 302.
[185] Paragraph 534 of Appellate Body Report WT/DS320/R, *US – Continued Suspension.*
[186] Article 5 of the SPS Agreement deals with the 'Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection'. Article 5.7 provides that "in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations...."
[187] Paragraph 685 of Appellate Body Report WT/DS320/R, *US – Continued Suspension.*
[188] *Ibid*, paragraph 711.

Similarly, the Appellate Body lowered the trigger threshold of Article 5.7 from the 'paradigm shift' expressed by the Panel, to a mere level of suspicion while noting that the paradigm shift was 'too high a threshold'.[189] Indeed, it may even be possible for a Member to predicate its provisional sanitary safeguard on a scientific study which casts doubt on the prevailing version of science.

The Appellate Body found that the Panel drew too rigid a distinction between the EU's chosen level of protection and the 'insufficiency' of the relevant scientific evidence under Article 5.7 of the SPS Agreement.[190] They found that the Panel had 'incorrectly interpreted and applied' Article 5.7 in its determination of whether or not the relevant scientific evidence in relation to the five growth hormone was 'insufficient' within the meaning of that provision.

They also reversed the Panel's finding that, where international standards exist, a 'critical mass of new evidence and/or information that calls into question the fundamental precepts of previous knowledge and evidence' is required to render the relevant scientific evidence 'insufficient' within the meaning of Article 5.7.[191]

In the light of what the Appellate Body regarded as those 'errors' made by the Panel, the Appellate Body reversed the Panel's finding that 'it has not been demonstrated that relevant scientific evidence was insufficient, within the meaning of Article 5.7 of the SPS Agreement, in relation to any of the five growth hormones with respect to which the EU applied a provisional ban'.[192]

As a consequence of the foregoing finding, the Panel had also concluded that 'the European Communities' compliance measure does not meet the requirements of Article 5.7 of the SPS Agreement as far as the provisional ban on progesterone, testosterone, zeranol, trenbolone acetate and melengestrol acetate is concerned'. The Appellate Body found that because the Panel had premised this on its earlier finding concerning the 'insufficiency' of the relevant

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[189] *Ibid*, paragraph 706.
[190] *Ibid*, paragraph 733.
[191] *Ibid.*
[192] *Ibid*, paragraph 734.

scientific information (which the Appellate Body had reversed), then the Panel's conclusion there, could not stand either.

Under Article 5.7 of the SPS Agreement, the preliminary evaluation centres on the 'assessability' of risks, that is, 'whether the relevant evidence ... is sufficient to permit the evaluation' of the risks in question.[193] According to the Appellate Body's new construction in *US-Continued Suspension*, this preliminary test of assessability is a subjective matter, reserved to the regulating Member.[194] Therefore, the Member may in practice escape the risk assessment obligation under Article 5.1 by electing not to make any choice when confronted with two or more conflicting scientific opinions and instead opting for a provisional measure under Article 5.7. Opting for a provisional measure under Article 5.7 can be done if the Member defines the situation as a 'qualitative' deficiency of available scientific evidence in which two competing scientific views exist in an unreliable and inconclusive manner.[195]

Therefore, based on this new construction from *US-Continued Suspension*, subjective or political determinations may overshadow objective scientific investigations harnessed by international standards and risk assessment.[196] Back in 1998, the Appellate Body in *EC-Hormones* had noted that when conducting risk assessment, a WTO Member could even rely on a minority opinion, and when confronted with two different scientific opinions, the Member could simply pick one.

In respect of the growth hormone oestradiol-17β, the Appellate Body found that in respect of the EU ban on this growth hormone, it was 'unable to complete the analysis and therefore makes no findings as to the consistency or inconsistency of the import ban relating to oestradiol-17β with Article 5.1 of the SPS Agreement'. As regards the consistency with Article 5.7 of the SPS Agreement of the EU's provisional import ban (pursuant to Directive 2003/74/EC) on meat from cattle treated for growth-promotion purposes with the other five growth hormones,[197] the Appellate Body reversed the Panel's finding that the provisional import ban did not meet the requirements of Article 5.7 of the SPS Agreement. However, the Appellate Body was unable to complete the analysis and therefore made no findings as to the

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[193] See S. Cho, note 178 above, p. 302.
[194] Paragraph 711 of Appellate Body Report WT/DS320/R, *US – Continued Suspension*.
[195] *Ibid*, paragraph 712.
[196] See S. Cho, note 178 above, p. 302.
[197] testosterone, progesterone, trenbolone acetate, zeranol, and MGA.

consistency or inconsistency[198] of the provisional EU import ban. Inexplicably, the Appellate Body stated that 'given the numerous flaws that we identified in the Panel's analysis, and the highly contested nature of the facts, we do not consider it possible to complete the analysis'.[199]

Because the Appellate Body was unable to complete the analysis as to whether or not Directive 2003/74/EC had brought the EU into substantive compliance within the meaning of Article 22.8 of the WTO Dispute Settlement Understanding, they found that the recommendations and rulings adopted by the Dispute Settlement Body in *EC–Hormones* would remain operative – an eventuality which can only be described as unsatisfactory, especially from the EU perspective.[200] It seems at least possible that what happened was, the legal experts making up the Appellate Body could not reach a full decision because the food science experts making up the Panel did not handle their deliberations in a sufficiently arbitrational fashion.

In the end, the Appellate Body decided that it was in order to recommend that the Dispute Settlement Body request both parties to launch Article 21.5 Dispute Settlement Understanding[201] proceedings in order to resolve their disagreement as to whether the EU had removed the measure found to be inconsistent in *EC–Hormones* and whether the application of the suspension of concessions by the US remained legally valid.[202]

8.3 Stalemate and Eventual Compromise in the *Beef Hormones Dispute*

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[198] i.e. consistency or inconsistency with (Article 5.7 of) the SPS Agreement.

[199] Paragraph 735 of Appellate Body Report WT/DS320/R, *US – Continued Suspension.* There are limitations on reviewability of the Panel's factual determinations by the Appellate Body, where it will only overturn them if there has been an egregious error calling into question the good faith of the Panel. *EC Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, (n.9) para 133. See also, *Korea-Taxes on Alcoholic Beverages* WT/DS75/AB/R and *US-Definitive Safeguard Measures on Imports of Wheat Gluten from the EC*, WT/DS166/AB/R.

[200] Paragraph 737 of Appellate Body Report WT/DS320/R, *US – Continued Suspension.*

[201] Article 21 deals with 'Surveillance of Implementation of Recommendations and Rulings' and Article 21.5 provides that 'Where there is disagreement as to the existence or consistency with a covered agreement of measures taken to comply with the recommendations and rulings such dispute shall be decided through recourse to these dispute settlement procedures'.

[202] Paragraph 737 of Appellate Body Report WT/DS320/R, *US – Continued Suspension.*

In May 2009, the EU and the US signed a Memorandum of Understanding[203] that promised to finally end the long standing *Beef Hormones Dispute*. This Agreement envisages a phase of expansion by the EU of market access for High Quality Beef[204] (from animals not treated with growth hormones) and a corresponding reduction by the US in the level of increased duties applied to certain EU products authorized by the WTO in 1999.[205] Therefore, the EU maintains its ban on the import of beef from animals treated with growth hormones and in return it has to provide a new tariff-free import quota for 'high-quality-beef' from the US. As part of the agreement reached, the US would 'maintain the currently reduced level of existing sanctions against EU products (68 per cent or $79 million lower), and would eliminate all sanctions beginning in the fourth year of the agreement'.[206] Then, before the end of the four-year period, the two sides are to 'seek to agree on the conditions for the settlement applicable beyond that period'.[207]

Under the terms of the 2009 Agreement, the US Food Safety and Inspection Service (FSIS) is responsible for certifying that beef exported from the US to the EU originates from animals that have never been treated with growth hormones.[208] All cattle must be slaughtered in a federally inspected slaughterhouse which has been approved for export to the EU. Each slaughterhouse must have a control program manual and procedures in place that will ensure the production and shipment of only non-growth hormone treated beef. In addition, all slaughterhouses approved for export of beef to the EU are required to participate in the EU Additional Residue Testing programme which is administered by the FSIS. The programme

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[203] WT/DS26/28 of 30 September 2009. The Agreement relates to the WTO dispute officially entitled '*European Communities – Measures Concerning Meat and Meat Products (Hormones)* (DS26)'.

[204] High Quality Beef is defined as – 'Beef cuts obtained from carcasses of heifers and steers less than 30 months of age…The carcass from which beef cuts are derived shall be evaluated by an evaluator employed by the national government who bases the evaluation, and a resulting classification of the carcass, on a method approved by the national government….The cuts shall be labelled in accordance with Article 13 of Regulation (EC) No. 1760/2000. [of the European Parliament and of the Council establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97, [2000] O.J. L204/01] The indication "High Quality Beef" may be added to the information on the label.'

[205] The Memorandum allows the EU to avoid a number of new tariffs that would have effected a range of EU products including Italian mineral water, Roquefort cheese and a number of other food products. Special cheeses like *Stilton* and *Roquefort*, which are protected by EU country of origin rules, were popular with Americans, but it became basically impossible to export these specialist products due to the high tariffs.

[206] See, Europa Press Release, *EU and US reach provisional agreement in Beef Dispute* (Brussels, May 6, 2009), Ref', IP09/707.

[207] Ibid.

[208] See generally, the information provided by the FSIS on its website. Available at: http://www.fsis.usda.gov/pdf/nhtcprog06122007.pdf [Accessed: 11 May 2011].

requires that in accordance with the requirements of EU Directive 96/23/EC,[209] a number of beef samples are collected and then analyzed for the presence of growth hormone residues.[210] Another major development occurred in May 2011, when the US[211] agreed to suspend all of its retaliatory sanctions on EU produce. On March 14, 2012, the European Parliament approved the latest stage in the deal, which will see the EU raise its high quality beef import quota to 48,200 tonnes. EU Agriculture Commissioner Dacian Ciolos, said he hoped the deal would lead to a definitive resolution to the *Beef Hormones Dispute*.[212]

In the end, the retaliation imposed by the US (and Canada) after the *EC-Hormones* and *US – Continued Suspension* cases at the WTO, has not succeeded in securing the withdrawal of the EU ban on growth hormones which was found to be inconsistent with the EU's WTO obligations under the SPS Agreement. In particular, dispute settlement under the SPS Agreement, did not get the EU to drop the sanitary measure, nor did it succeed in having the US accept the legitimacy of the EU position.

8.4 Culture in Food Safety Regulation: Lessons from the *Beef Hormones Dispute*

8.4.1 Members Ability to set Desired Level of Sanitary Protection

Under Article 3.3 of the SPS Agreement a Member is allowed to instigate a level of protection which differs from that implicit in the international standard.[213] In other words, in implementing the ban on hormone produced beef, the EU might be able to ignore the Codex standards and implement the ban even though many of the scientific studies did not find the

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[209] Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC, [1996] O.J. L125/10.

[210] The results provide verification of the effectiveness of the NHTC program. On an annual basis, the FSIS summarizes and reports the results to the EU. An EU spot-check carried out in 1998 of 258 US meat samples from the hormone-free cattle program, indicated that 12 per cent of the samples still contained detectable levels of hormones, even though those samples had been certified as coming from cattle raised without growth hormones. That hormone-free certification would mean that the meat was eligible for export to the EU. See generally, M. Balter, note 32 Chapter 5 above, p.1453.

[211] And Canada.

[212] See, Europa (Europarl) Press Release, *Win-win ending to the "hormone beef trade war"*, Brussels, March 15, 2012.

[213] In this case the Codex standard. Paragraph 172 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.

hormones to be detrimental to human health. However, in *EC-Hormones*, the Panel held that the EU was not permitted to do that because the right of a Member to determine its own appropriate level of sanitary protection must be based on a 'scientific justification'.[214] The EU was still required to carry out the risk assessment required by Article 5.1.[215] The Panel's interpretation of Article 5.1 in *EC–Hormones* represents a severe limitation on the extent to which a Member can set its own desired level of sanitary protection.[216]

This can also be interpreted as a curtailment of Article 1 of the General Food Law which assures a 'high level of protection of human health' within the EU.[217] Article 1 evidences the importance which EU food law attaches to human health and resonant within this is a broad notion of human health similar to that expressed at the global level by the World Health Organisation.[218] Therefore, irrespective of free trade considerations, there is also an element of irony when another global organisation, the WTO, penalises the EU for its decision to ban animal growth hormones in accordance with its adherence to these same principles of human health.

It is the economic imperative at the core of the SPS Agreement that is evident in *EC-Hormones* with the Appellate Body's con-joining of Article 5.1 and Article 2.2. The Appellate Body referred to the requirement for a risk assessment under Article 5.1[219] as well as the 'sufficient scientific evidence' requirement under Article 2.2.[220] They found that these two requirements

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[214] Paragraph 172 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R. The Panel in *US-Continued Suspension* found that Article 5.1 and Article 5.2 of the SPS Agreement must be read together, which means that it is a 'scientific' risk assessment – as Article 5.2 stipulates that Members shall take the 'available scientific evidence' into account. See, Paragraphs 7.838-40 of Panel Report WT/DS320/R (31 March, 2008).

[215] *Ibid*, paragraph 176. Article 5.1of the SPS Agreement stipulates that '[m]embers shall ensure that their sanitary ... measures are based on an assessment ... of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations'.

[216] Therefore the EU import ban was not based on the requisite (scientific) risk assessment.

[217] Article 1 of European Parliament and Council Regulation (EC) No 178/2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, [2002] O.J. L31/1.

[218] See generally A. Garde, *EU Law and Obesity Prevention* (Alphen aan den Rijn, The Netherlands: Kluwer Law International, 2010), p.23.

[219] Article 5.1 of the SPS Agreement provides that 'Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations'.

[220] Article 2.2. of the SPS Agreement requires that '[m]embers shall ensure that any sanitary ... measure is applied only to the extent necessary to protect human ... health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5'. Paragraph 7 of Article 5 provides that '[i]n cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary ... measures on the basis of available pertinent information ... In such circumstances, Members shall seek to obtain the additional information ... within a reasonable period of time'.

are essential for the maintenance of this delicate balance between the shared, but sometimes competing interests of promoting international trade while simultaneously protecting the life and health of citizens.[221]

As outlined by the analysis in Chapter 5 of this thesis, culture in the form of public risk perception must be included in the formulation of sanitary measures if the resultant measures are to be acceptable to the citizenry of the implementing nation. Obviously, there is a conflict between the furtherance of the 'economic' imperative and a Member's desire to formulate appropriate sanitary measures based on these domestic consumer and political considerations. It seems that the most the SPS Agreement can hope to do is to strike a delicate balance between the preservation of domestic sanitary regulatory autonomy and the promotion of international economic integration. However, as evidenced by this Chapter's discovery that the Panel and Appellate Body persisted with the emphasis on science as the core arbiter under SPS, it is not possible to strike such a balance.

8.4.2 Contractual nature of the SPS Agreement

The Panel and Appellate Body also have their hands tied due to the contractual nature of the SPS 'Agreement'. They must also act within the parameters of the terms agreed as espoused by the terminology contained in the SPS Agreement. The WTO Dispute Settlement Understanding[222] requires the arbiters of a dispute (i.e. the Panel or the Appellate Body) to interpret words in the WTO rules in accordance with the Vienna Convention on the Law of Treaties.[223] Therefore, if the Panel/Appellate Body were to take a literal meaning of this, words in the SPS Agreement must be attributed 'their ordinary meaning, in their context and

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[221] Paragraph 186 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.

[222] Article 3.2 of the Dispute Settlement Understanding requires that the Members 'recognize that it serves to preserve the rights and obligations of Members ... and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements'.

[223] Vienna Convention on the Law of Treaties, 1969, 1155 U.N.T.S. 331, 8 I.L.M. 679. A WTO Panel has opined that the general rule of interpretation [as set out in Article 31(1) of the Vienna Convention on the Law of Treaties] has attained the status of a rule of customary or general international law. As such, it forms part of the 'customary rules of interpretation of public international law' which the Appellate Body has been directed, by Article 3(2) of the *DSU*, to apply in seeking to clarify the provisions of the *General Agreement* and the other 'covered agreements'. That direction reflects a measure of recognition that the *General Agreement* is not to be read in clinical isolation from public international law. See, *United States – Standards for Reformulated and Conventional Gasoline* (WT/DS2/AB/R), p. 17 and *Japan – Taxes on Alcoholic Beverages*, Report of the Appellate Body adopted on 1 November 1996, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R

in light of the Treaties objects and purposes'.[224] In order to attribute terms their ordinary meaning, we see Panels using other multilateral agreements for insight.[225] According to the Vienna Convention, WTO arbiters would also be required to take account of other 'relevant rules of international law applicable in the relations between the parties'.[226] Rules of international law include treaties, customary international law[227] and general principles of law.[228] Sometimes, a Panel/Appellate Body looks outside of the WTO Agreement for inspiration. For example, in *EC-Pipe Fittings* the Panel looked to an external recommendation for insight.[229] However, they cannot bend the terms of the Agreement to include something such as culture and public risk perception, when there is no explicit provision in the Agreement that permits this.

8.4.3 Sound science

WTO Members will identify a threat of harm posed by a certain product or practice and will attempt to mitigate its deleterious effects through regulation. In deciding upon the appropriate sanitary measure, scientific information is utilised either as a form of prevention (probability of the hazard can be measured using empirical methods) or precaution (based on and acknowledging the concept of 'scientific uncertainty'). The concept of using 'sound science' as the sole arbiter in risk analysis is more closely aligned to prevention. Prevention is the preferred option in governing the legitimacy of national sanitary measures as it allows for an internationally common and uniform medium of risk analysis.

In *EC-Hormones*, the Appellate Body agreed with the Panel that theoretical uncertainties were not the type of risk intended to be assessed[230] and that the treatment by the EU of the growth hormones at issue was 'arbitrary and unjustified'.[231] The Appellate Body found that

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[224] Article 31 of the Vienna Convention on the Law of Treaties, note 223 above.
[225] See *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, para 168.
[226] Vienna Convention on the Law of Treaties, note 223 above, Article 31(3)(c)
[227] Customary international laws are 'unwritten' rules that evolve over time through practice and conviction and which bind all states. D. Palmeter and P.C. Mavroidis, "The WTO Legal System: Sources of Law", (1998) *American Journal of International Law*, Vol.92, p.398.
[228] *Ibid*, p.398.
[229] See *EC-Anti-Dumping Duties on Malleable Cast Iron Tube or Pipe Fittings from Brazil*, WT/DS219/R, para 7.316. See also *EC-Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, WT/DS290/R, para 7.451.
[230] Paragraph 186 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.
[231] *Ibid*, paragraph 225.

the EU had in fact restricted itself to only pointing out the significance of not administering the growth hormones 'in accordance with good practice' and that the EU did not go further and provide an assessment of the potential adverse effects related to non compliance with such practice.[232] More generally, the Appellate Body found that the absence of this particular risk assessment, in conjunction with the conclusion reached in most, if not all, of the scientific studies submitted by the EU, would lead to the conclusion that no risk assessment which would reasonably support or warrant the EU import ban was furnished to the Panel.[233] In other words, the EU had applied the precautionary principle and acted to implement the ban on that basis.

When the Appellate Body opined that 'theoretical uncertainty is not the kind of risk which, under Article 5.1, is to be assessed',[234] then this means that Members must produce evidence for the risk that is more than purely theoretical.[235] The requirement under the SPS Agreement for sufficient scientific evidence cannot be based in theoretical science – i.e. 'scientific uncertainty' or precaution. A scientific theory is also a scientific work, albeit one which employs present day observations in the making of predictions for the future. As already outlined in this Chapter, one of the arguments which the EU put forward in support of its ban on growth hormones was that we cannot be certain that everything is already known about the adverse effects of growth hormones on human health.

These findings by the Appellate Body in *EC-Hormones* follow on from the previous decision on this point in *Japan-Apples* where the Panel had concluded that only evidence gathered through scientific methods could be presented.[236] Issues such as a 'non-demonstrated hypothesis' and circumstantial evidence are not acceptable.[237] It is in this way that the SPS Agreement arbitrates using 'sound science', upon the legitimacy of any particular risk perception. Public risk perception, per se, whether based on fear, or distrust of the regulatory authorities to get it right, is not a factor that the SPS Agreement acknowledges.

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[232] *Ibid*, paragraph 207.
[233] *Ibid.*
[234] *EC Measures Concerning Meat and Meat Products (EC-Hormones)*, WT/DS26/AB/R, para 186. Ironically, in the same breath the Appellate Body refers to the 'uncertainty that theoretically always remains since science can never provide absolute certainty that a given substance will not ever have adverse health effects' - WT/DS26/AB/R, para 186.
[235] J. Scott, note 186 Chapter 5 above, p.107.
[236] *Japan-Measures Affecting the Importation of Apples (Japan-Apples)*, WT/DS245/R, paras 8.92-8.93. Panel Report issued on 15 July, 2003. The Panel concluded 'that, in the context of Article 2.2, the evidence to be considered should be evidence gathered through scientific methods'.
[237] *Ibid*, paras 8.92-8.94.

In *US-Continued Suspension*, the Panel found that because the EU had not furnished any 'critical mass' of new evidence that would justify the provisional ban,[238] the Panel found that the EU had not met the condition of insufficient scientific evidence as required under Article 5.7 of the SPS Agreement.[239] In other words, the EU had effectively still not proven their argument that based on the available scientific information, it was reasonable to conclude that growth hormones were deleterious to the health of its citizens.

However, on a more optimistic note regarding the inclusion of culture, the Appellate Body placed more emphasis on a broadened notion of scientific justification based on a risk assessment than that defined in *EC-Hormones*. This approach would take certain non-scientific policy considerations such as the level of protection acceptable to a nation's citizenry, into account. However, notwithstanding this, the Appellate Body recognized that the level of protection must not affect the nature of the risk assessment, which must be based on scientific methods.[240] The Panel in *US-Continued Suspension* found that Article 5.1 and Article 5.2 of the SPS Agreement must be read together, which means that a 'scientific' risk assessment is required – as Article 5.2 stipulates that Members shall take the 'available scientific evidence' into account.[241] Again, these findings by the Panel and the Appellate Body, display an inability to move away from the reliance on science as the arbiter of sanitary measure compliance, and since this thesis has exemplified that cultural regulatory divergences exist, then the SPS Agreement as it currently stands will not succeed in resolving trade disputes such as the *Beef Hormones Dispute*.

8.4.4 Acceptability of the Precautionary Principle

This Chapter has already outlined that the precautionary principle has been given a specific meaning within Article 5.7 of the SPS Agreement. However, the Panel/Appellate Body findings on scientific evidence mean that only a very limited interpretation of the application of the precautionary principle will be permissible. With specific reference to the precautionary principle, in its defence in *EC-Hormones*, the EU had invoked the precautionary principle in support of its claim that its regulatory measures were based on a

[238] i.e. the provisional ban on the five hormones save and except for oestradiol-17β.
[239] Paragraph 228 of Appellate Body Report WT/DS320/R, *US – Continued Suspension*.
[240] *Ibid*, paragraph 534.
[241] See Paragraphs 7.838-40 of Panel Report WT/DS320/R (31 March, 2008).

risk assessment.[242] The Panel found that Article 5.7[243] was an interpretation of the precautionary principle and that was the extent of the precautionary principle's relevance. In other words, since the precautionary principle has been incorporated and given a specific meaning in Article 5.7, the principle would not override the explicit wording of Articles 5.1 and 5.2.[244] Therefore, any argument based on the use of the precautionary principle, would not override the Panel's finding that the EU import ban was not based on a scientific risk assessment in the manner required under the terms of the SPS Agreement.[245]

On appeal, the Appellate Body found that the reason the principle has not been written into the SPS Agreement is to ensure that it could not be used as a ground for justifying SPS measures that would otherwise be inconsistent with the economic obligations of Members.[246] Again, this reasoning evidences the contractual nature of the SPS Agreement, as representing a signed-contract made between the WTO Members. In addition, the Appellate Body found that the precautionary principle by itself, especially if it does not have a clear textual basis to that effect in the SPS Agreement, does not relieve a WTO Panel/Appellate Body from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the SPS Agreement.[247]

Subsequently, a degree of optimism arises due to the findings in *Japan-Varietals* – a decision which came too late for *EC-Hormones*. In *Japan-Varietals* the Panel break down Article 5.7 into its constituent parts and opine that Members may instigate provisional measures 'when relevant scientific information is insufficient', when the available 'pertinent' information

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[242] The Appellate Body acknowledged that the US did not consider the precautionary principle as representing customary international law and noted that the US suggested it was more an 'approach' than a principle. See paragraph 92 of the United States appellee's submission to the Appellate Body. In its submission, Canada, took the view that the precautionary principle was not yet incorporated into the corpus of public international law, but conceded it may in future crystallize into one of the 'general principles of law recognized by civilized nations' within the meaning of Article 38(1)(c) of the Statute of the International Court of Justice. See, Paragraph 34 of Canada's appellee submission to the Appellate Body.

[243] Article 5.7 provides that '[i]n cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary ... measures on the basis of available pertinent information, including that from the relevant international organizations ...'

[244] Again, the Panels hands are tied by the terminology of the SPS Agreement. In *EC-Hormones*, the Appellate Body agreed with the Panel's findings and concluded that the precautionary principle would not override the explicit wording of Articles 5.1 and 5.2, and that the precautionary principle has been incorporated in, *inter alia*, Article 5.7 of the SPS Agreement. Paragraph 253(c) of Appellate Body Reports WT/DS26AB/R and WT/DS48/AB/R

[245] See generally paragraph 120 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.

[246] Paragraph 124 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.

[247] Again, the precautionary principle does not override the provisions of Articles 5.1 and 5.2 of the SPS Agreement.

suggests a risk, when the Member imposing the measure does so to obtain the additional information necessary for a more objective risk assessment, and so long as the measure is reviewed within a reasonable period of time.[248] This represents the potential for applying the precautionary principle albeit in a limited capacity, and can be seen as introducing greater freedom on the risk management side.

8.4.5 Possibility of Including 'Other Factors' – Broad Interpretation of Article 5.2

The Appellate Body in *EC-Hormones* found that there is nothing to indicate that it was intended that the list of factors to be taken into account in an Article 5.2 risk assessment was intended to be a closed list and that it is not only risk ascertainable in a science laboratory operating under strictly controlled conditions,[249] but also risk in human societies as they actually exist.[250] This is a wide interpretation of what passes for a risk assessment under the terms of the SPS Agreement.

More specifically, the Appellate Body held that the Panel could not purport to exclude from the scope of a risk assessment under Article 5.1, matters which could not be quantitatively analysed 'by the empirical or experimental laboratory methods'.[251] However, the Appellate Body then refers to these additional considerations as factors 'not necessarily or wholly susceptible of investigation according to laboratory methods of, for example, biochemistry or pharmacology'.[252] Therefore, while the Appellate Body finds that the list of factors under Article 5.2 is not a closed list and that the additional factors to be included are those which cannot be quantitatively analysed, this thesis disagrees with the observations made by many commentators on this point. This thesis concludes that it still appears evident from the aforementioned terminology applied by the Appellate Body in its Report,[253] that factors such as public risk perception or cultural considerations are not allowable for inclusion in a risk

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[248] *Japan–Measures Affecting Agricultural Products (Japan-Varietals)*, WT/DS76/R, para 89, p.24.

[249] In *EC-Hormones*, the Appellate Body held that neither Articles 5.1 and 5.2 nor Annex A.4 of the SPS Agreement require a risk assessment to establish a minimum quantifiable magnitude of risk. In addition, Article 5.1 and 5.2 do not exclude *a priori*, from the scope of a risk assessment, factors which are not susceptible of quantitative analysis by the empirical or experimental laboratory methods commonly associated with the physical sciences. Paragraph 253(j) of Appellate Body Reports WT/DS26AB/R and WT/DS48/AB/R

[250] Paragraph 187 of Appellate Body Reports WT/DS26AB/R and WT/DS48/AB/R.

[251] *Ibid.*

[252] *Ibid.*

[253] Especially the eventual reference again to 'laboratory methods'.

assessment as defined under the SPS Agreement. There is nothing which indicates with any degree of certainty that the Appellate Body intended to widen the definition to that extent.

In order for it to be possible to take into account other more arbitrary considerations such as public risk perception or cultural biases, then a very broad interpretation indeed of the Appellate Body's findings would be required.[254] The Appellate Body goes on to note that in most cases responsible governments base their legislative and administrative measures on 'mainstream' scientific opinion.[255]

However, some commentators believe that it is feasible to adopt the wider of the two interpretations. They believe that the terminology adopted by the Appellate Body in its findings means that non-scientific factors can be considered as part of the risk analysis. In other words, the Appellate Body has combined an objective risk assessment under Article 5.1 of the SPS Agreement, with a subjective policy determination[256] regarding the level of protection under paragraph 5 of Annex A of the SPS Agreement.[257] This is a WTO Member's autonomous determination of the appropriate or acceptable level of protection.[258] However, yet again, this thesis notes that the Appellate Body effectively placed a limitation on this line of reasoning by recognizing that the level of protection must not affect the nature of the risk assessment, which must be based on scientific methods.[259]

An additional tier of confusion is added by the Appellate Body's deliberations regarding Article 5.7 of the SPS Agreement in *US-Continued Suspension*.[260] Opting for a provisional measure under Article 5.7 (such as the EU provisional ban on five of the six growth hormones) can be done if the Member defines the situation as a 'qualitative' deficiency of available scientific evidence in which two competing scientific views exist in an unreliable

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[254] This view is also supported by the Appellate Body's findings on the requirement for a 'sufficient scientific evidence' requirement under Article 5.1 and 2.2 of the SPS Agreement.

[255] Paragraph 194 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.

[256] i.e. a risk management consideration.

[257] See, S. Cho, "United States: Continued Suspension of Obligations in the EC-Hormones Dispute", (2009) *The American Journal of International Law*, Vol. 103, No. 2, p. 302. Paragraph 5 of Annex A provides a definition for the 'appropriate level of sanitary or phytosanitary protection' and defines it as '[t]he level of protection deemed appropriate by the Member establishing a sanitary ... measure to protect human ... health within its territory'. Paragraph 5 also notes that Members refer to this as the 'acceptable level of risk'.

[258] i.e. it is a risk-management consideration.

[259] Paragraph 534 of Appellate Body Report WT/DS320/R, *US – Continued Suspension*.

[260] Article 5 of the SPS Agreement deals with the 'Assessment of Risk and Determination of the Appropriate Level of Sanitary or Phytosanitary Protection'. Article 5.7 provides that "in cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations...."

and inconclusive manner.[261] Therefore, based on this new construction from *US-Continued Suspension*, subjective or political determinations[262] may overshadow objective scientific investigations harnessed by international standards and risk assessment.[263] Again – a broadening of the scientific basis for risk assessment. However, because of the Appellate Body's eventual decision not to make an affirmative ruling on the matter one way or the other,[264] these ambiguities left by the Appellate Body have created a grey area between risk assessment (objective science) and risk management (subjective policy determination, possibly including an element of 'scientific uncertainty').

If one is to accept the broader of the two interpretations here (i.e. that arbitrary issues such as risk perception and cultural considerations can be taken into account), then the question arises as to whether or not the WTO Dispute Settlement Body through the medium of the SPS Agreement, should be adjudicating on what are in effect political rather than scientific regulatory positions. Indeed, if the critique of scientific certainty has been watered down, then all the more reason why cultural and risk perception considerations should be included as a valid argument for justifying sanitary measures. However, unfortunately, as this thesis asserts, that would also produce the ramification of diluting the possibility of a harmonisation of international sanitary measures, because it is an implicit acceptance of cultural regulatory divergences between Members and a move away from science as the sole basis for risk analysis under the SPS Agreement. In other words, an anomaly exists, because science alone is also inadequate to resolve issues as shown by the analysis in this thesis of the *Beef Hormones Dispute*.

Fundamentally, much depends on how the role of science in the SPS Agreement is defined. The perceptions of risk depend on scientific arguments.[265] Some have argued that the role of

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[261] Paragraph 712 of Appellate Body Report WT/DS320/R, *US – Continued Suspension.*

[262] According to the Appellate Body's new construction in *US-Continued Suspension*, this preliminary test of assessability of the potential risk is a subjective matter, reserved to the regulating Member State. Paragraph 711 of Appellate Body Report WT/DS320/R, *US – Continued Suspension.* Therefore, the regulating state may in practice escape the risk assessment obligation under Article 5.1 by electing not to make any choice when confronted with two or more conflicting scientific opinions and instead opting for a provisional measure under Article 5.7.

[263] See S. Cho, note 178 above, p. 302.

[264] In the end, because the Appellate Body was unable to complete the analysis as to whether or not Directive 2003/74/EC had brought the EU into substantive compliance within the meaning of Article 22.8 of the Dispute Settlement Understanding, they found that the recommendations and rulings adopted by the Dispute Settlement Body in *EC – Hormones* would remain operative. Paragraph 737 of Appellate Body Report WT/DS320/R, *US – Continued Suspension.*

[265] U. Beck, note 79 Chapter 4 above, p.30.

science is to provide snap shot of current reality and that a sanitary measure can then be based on that result – i.e. prevention combined with 'scientific certainty'.[266] This view of science is closely related with the cause-effect evidentiary concept based on empirical evidence. However, another school of thought sees science as subjective in nature due to social, cultural, and political influences – i.e. precaution is necessary and 'scientific uncertainty' is a legitimate and natural reaction to the ('perceived') threat to human health.[267] Therefore, science has to be viewed within the overall political framework because of its relationship with national identities creating divergent interpretations between states.[268] In other words, how risk is perceived is also relevant. The consumer either see science as providing absolute certainty or else as providing only as close to certainty as one can get. In conclusion, unless in future a Panel adopts a more expansive approach to science under the SPS Agreement, in the meantime it is only likely to accept a limited precautionary approach. The two concepts are in direct conflict with one another and it is this which impinges upon a WTO Member's ability to set its own 'desired' level of protection. Unfortunately, as previously outlined in this thesis, the SPS Agreement was negotiated as part of the overall WTO construct and accordingly the imperative is trade liberalisation through harmonisation of regulatory standards. As a result, the WTO Panel and Appellate Body are limited in their scope for an ever broader interpretation of the requirement for a 'scientific' risk analysis and therefore it seems unlikely that they will persist along the lines of a broader interpretation.

EU citizens do genuinely fear growth hormone residues in beef and as evidenced in this thesis, this fear can be traced to various historical experiences, especially food health scares, and the resultant cultural values imbued. Therefore, it is disingenuous of US officials to dismiss the ban as merely a form of EU protectionism over its food sector. An imposition of new food technologies on the EU for economic reasons without proper deference to other factors such as consumer concern is only likely to lead to further consumer discontent. Indeed, these misunderstandings combined with the failings in the capacity of the SPS Agreement to deal with all of the issues involved, jeopardize the very concept of global free trade.

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[266] J. Bohanes, "Risk Regulation in WTO Law: A Procedure Based Approach to Risk Regulation", (2002) *Columbia Journal of Transnational Law*, Vol.40, p.345.

[267] K. Popper, *The Logic of Scientific Discovery* (New York: Routledge, 2000), p.30.

[268] S. Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton, New Jersey: Princeton University Press, 2005), p.7. Jasanoff makes the point that policies concerning the life sciences have become embroiled in projects involving nation building.

8.4.6 Acknowledging Cultural Divergences as part of Dispute Resolution

It is submitted that due to the prevalence of cultural biases, invariably, divergences in law are likely to exist between nations. Moreover, it is challenging to successfully impose a foreign law which effects something culturally symbolic at the national level. Food is one such area. Consequently, in an effort to avert disputes such as the *Beef Hormones Dispute*, the promulgators of international trade laws such as the SPS Agreement should apply an understanding of the cultural background existing in the nations effected. Therefore, it is useful to indentify various avenues by which this goal might be fulfilled.

One such method of accommodating these cultural divergences is by making allowance for the precautionary principle. It is here submitted that the overly restrictive interpretation of the precautionary principle as expounded in *EC-Hormones*, should be broadened. Similarly, as evidenced by the analysis in Chapter 3 of this thesis, there is a clear division between risk assessment and risk management under EU food law and this allows for the inclusion of 'other factors' at the risk management stage. Accordingly, in the context of the global regulatory regime, the WTO Panel should not insist on an overly restrictive interpretation of the SPS Agreement and instead permit some recognition of factors such as public risk perception. In other words, this solution involves combining both scientific risk assessment and non-scientific aspects of decision-making about risk – a middle ground between the EU and US regulatory models.

The SPS Agreement itself represents a political compromise between the WTO Members. The *Beef Hormones Dispute* represents a trade problem that could not be resolved at the bilateral level and this can be viewed as an indication that renegotiation and amendment of the SPS Agreement may be necessary. The resulting substantive amendments would negate the requirement for a change in interpretation of the SPS Agreement provided the cultural element is included in a more prescriptive manner.

Another solution is to try and resolve disagreement caused by cultural regulatory divergences before they arrive at the WTO Dispute Settlement Body. One means of achieving this is to try and head-off likely areas of conflict by applying an expanded system of negotiation and

mediation. In recent years, a number of developments have taken place in this context. In particular, WTO Members have been encouraged to consider mediation through the 'good offices' of the Chairperson of the Committee on Sanitary and Phytosanitary Measures (SPS Committee) as a means of resolving some of their differences before the matter develops into a formal dispute.

The first substantial discussion of a more developed approach in this regard took place at the SPS Committee meeting in June 2008. Since then the parties have agreed on a draft procedure document governing the use of the 'good offices' facility and it is envisaged that the Members may soon agree to adopt this.

Article 12.2 of the SPS Agreement had always provided that the SPS Committee should encourage and facilitate ad-hoc negotiations among Members on specific sanitary issues. A greater application of this provision in conjunction with the aforementioned 'good offices' proposal would provide significant assistance in allaying future trade disputes.

8.4.7 TTIP and the Potential for Regulatory Convergence

As previously outlined, the negotiations which led to the creation of the SPS Agreement were primarily aimed at reducing barriers to free trade between WTO Member nations. Interestingly, the pursuit of ever greater trade relations continues to this day with ongoing negotiations between the EU and the US under the auspices of the Transatlantic Trade and Investment Partnership (TTIP) which has as its goal increased trade and investment between the EU and the US by realizing the untapped potential of a truly transatlantic marketplace. Should agreement be reached, with the goal of harmonisation of regulatory divergences, there are likely to be new measures which will build upon agreements such as the SPS Agreement and thereby negate the negative consequences of future trade disputes.

The TTIP negotiations are likely to have significant implications for the use of science in policymaking and its application as the arbiter of international trade disputes. Interestingly, under the banner of 'sustainable development' (i.e. meeting the needs of the current generation without jeopardizing the needs of future generations), apparently an EU position paper applicable to the negotiations stipulated that any agreement reached here should

"reflect the importance of using international guidelines and principles on the use of scientific and technical information".[269]

The aspect of the negotiations aimed at achieving a more integrated transatlantic market through regulatory compatibility and convergence of the general method in which regulators approach standard setting has been colloquially termed the 'horizontal chapter' (i.e. a cross-sectoral regulatory coherence chapter).[270] The concept underpinning the horizontal chapter is that substantive convergence of the general method in which regulators approach standard setting can facilitate a more integrated transatlantic market. Indeed, it does seem plausible that methodological convergence in regulatory formulation would improve the quality and practicality of legislation. Therefore, in time it could remove existing regulatory divergences such as that which arose in the *Beef Hormones Dispute*. Specifically, the horizontal chapter is aimed at promoting regulatory convergence through procedural innovations involving public consultation, regulatory impact assessments, conflict early warning mechanisms and ex-post analysis of existing regulations.[271] For example, the analysis of the existing regulations would build upon the procedures existing under the SPS Agreement rather than duplicating those procedures.

However, at the time of writing, it remains to be seen where these negotiations will lead. At the outset, the EU position appeared to be entrenched. It is interesting to note key objectives of the EU position as set out in a policy speech made by EU Commissioner for Trade, Mr. Karel De Gucht.[272] Among these objectives, he stated that it was the EU position that there would be no lowering of present levels of protection for consumers or health and as an example he mentioned EU approaches to the regulation of animal growth hormones and GMOs. He stated that the levels of protection in this regard as reflected in the EU laws and regulations are not to be changed because of TTIP. However, importantly, he noted the necessity to avoid to the extent possible, unnecessary regulatory divergences when

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[269] See, Institute for Agriculture and Trade Policy, *Summary of EU TTIP Position Papers*, September 19, 2013.

[270] See, A. Alemanno, "TTIP: Where Do We Stand" (February 9, 2014). Available at http://albertoalemanno.eu/articles/438188 [Accessed: 28 February, 2014]

[271] *Ibid*, p.1.

[272] A speech made by EU Commissioner for Trade, Mr. Karel De Gucht at the Aspen Institute conference in Prague, Czech Republic, on 10 October, 2013. The conference dealt with the impact of the Transatlantic Trade and Investment Partnership (TTIP) on the economies of the Euro-Atlantic area.

developing new legislation or revising existing legislation and when developing international standards.

8.5 Conclusion

As envisaged in Chapter 1 of this thesis, following this Chapter's analysis of the *Beef Hormones Dispute*, we now have an understanding of why the *Beef Hormones Dispute* between the EU and the US was not merely a dispute concerning a potential risk posed by food to human health, but the broader issue of a sometimes acrimonious interplay between culture and science in food safety regulation.

As outlined in Chapter 7 of this thesis, the US position is that there exists as close to a scientific consensus as one is likely to get, evidencing that the consumption of growth hormone residue in beef is not deleterious to human health. The EU regulatory authorities were not convinced of the safety of consuming growth hormone residue in beef. The analysis here, of how the *Beef Hormones Dispute* was dealt with at the WTO, has proven that any interpretation of the SPS Agreement must remain faithful to its extensive emphasis on science as the arbiter of the legitimacy of domestic sanitary measures. Indeed, a WTO Member's ability to set the desired level of sanitary protection is curtailed by the terms of the Agreement. Even if a Panel/Appellate Body wished to entertain other legitimate factors such as culture in the broader sense or public risk perception, it is unlikely that they could deviate to that extent from the binding terms of the SPS Agreement.

As confirmed by the analysis in Chapters 3 and 4 in particular, science alone is unlikely to be an adequate arbiter of sanitary measure legitimacy in most situations, especially where cultural regulatory divergences exist between nations. It will not be possible in such situations, for the domestic political establishment to foist wholly science based determinations upon its reluctant citizenry.

In response to pubic risk perception and the unknown element of the risk associated with the hormones, the EU authorities applied the precautionary principle and instigated provisional sanitary measures until more was known, about the dangers or otherwise, posed to human health by animal growth hormone residues in beef. As noted in Chapter 6 of this thesis, the

Article 5.7[273] precautionary provision of the SPS Agreement may present the best means for adopting this wait and see approach. However, the analysis in this Chapter has evidenced that Article 5.7 is unlikely to ameliorate this issue should a similar set of facts arise again.

It is intended that to conclude this thesis, the next Chapter will utilise the lessons learned from each of the previous Chapters, and combine those lessons with the WTO Dispute Settlement Body's[274] interpretation and application of the SPS Agreement as evidenced in this Chapter. This assimilation will enable a conclusion to be reached regarding the central question posited in Chapter 1 of this thesis, namely, whether the absence of recognition of the role played by cultural influences in creating regulatory divergences between states (cultural regulatory divergences) gives rise to inherent difficulties in the application of aspects of international trade law.

[273] Article 5.7 of the SPS Agreement provides that 'In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary ... measures on the basis of available pertinent information ...'.
[274] i.e. the Panel and/or Appellate Body.

CHAPTER 9

CONCLUSION

1.1 Conclusion

As confirmed by the analysis contained in Chapter 2 and especially in Chapter 3 of this thesis, there is a clear division between risk assessment and risk management extant under EU food safety law which allows for the expression of national cultural traditions involving food at the pan-EU risk management level. Individual EU Member States still hold substantial risk management powers thereby allowing a social factor to be introduced into the formulation of food safety law. Culture has a role to play in all its forms, including public risk perception. The General Food Law makes reference to the role of the consumer time and time again. The investigations carried out in Chapter 3 evidenced that the General Food Law provides that scientific risk assessment does not provide all of the information necessary for the formulation of the most appropriate sanitary measure and that other factors should also be taken into account. This is in keeping with the philosophy that health goals should be determined by society and only then should science play a role. In contrast, the US food safety system operates on virtually the opposite premise.

The comparative element of this thesis highlighted stark differences between the EU and US food regulatory systems. In particular, the analysis in Chapter 3 and in Chapter 4 disclosed a US food culture which is dominated by big business, possessing the ability to exert enormous pressure on the food regulatory authorities and on politicians. Localised food production methods have for the most part been obliterated in the US whereas in Chapter 3 this thesis verified that deep-rooted culinary traditions symbolizing strong national identity values still exist in the EU. This cultural clash is also an ideological one – the investigations carried out in this thesis have confirmed that the more industrialised US food sector believes in science-based risk regulation whereas the EU with its reverence for traditional farming and in deference to the consumer, advocates a more nuanced approach with reliance in some instances on the precautionary principle. The outline contained in this thesis, of the substantive food law of the EU and the US, has shown that these cultural divergences have been carried through into the food law of each jurisdiction. Overall, the analysis contained in

this thesis supports the assertion that culture influences the regulatory measures enacted and that cultural regulatory divergences exist between nations.

This analysis of the *Beef Hormones Dispute* in Chapter 8 of this thesis has shown that, from the outset, the EU and the US regulatory approaches were diametrically opposed, simply because the US permits the administration to animals of growth hormones in the production of beef intended for human consumption, whereas the EU has banned such practices. The use of animal growth hormones was already long established in the US – it is a cultural norm there. US consumers perceive the potential risk through their own cultural model and perceived little or no risk in consuming beef produced with growth hormones. In stark contrast, at a time of food health scares in Europe and in response to pubic risk perception and the unknown element of the risk associated with the hormones, the EU authorities applied the precautionary principle and banned the use of animal growth hormones for fattening purposes.[1]

This thesis has argued in Chapter 3 that it is not possible to eliminate cultural biases in the short term, whether those biases take the form of public risk perception, traditional food methods, or simply, individual taste. Instead, these shared values should play a vital role alongside scientific knowledge in informing regulatory approaches to risk. Yet, this has not limited the appeal of science as a resource for risk decision making where international institutions employing global regulatory constructs seek the acceptance of their determinations as neutral and universally valid.[2] The examination provided in Chapter 2 and Chapter 4 has shown how, unlike in the EU, internationally science plays the lead role both in the SPS Agreement and in Codex. We have seen that it also plays the lead role in the US food safety regulatory system. There is no explicit reference to cultural considerations in any of these forums.[3] Under the terms of the SPS Agreement, the EU was required to show that its decision to ban growth hormones was based on 'scientific principles' using 'sufficient scientific evidence'.[4] Notwithstanding the multilateral nature of international trade law, this seems somewhat antithetical to the goal of legal enforceability. The analysis in this thesis has

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[1] Other controversial food production technologies such as GM foods have caused and will continue to cause even greater controversy than the *Beef Hormones Dispute*.
[2] V. Walker, note 34 Chapter 1 above, p. 197-8.
[3] With the exception, possibly, of the explicit acknowledgment of other legitimate factors by Codex in its Statement of Principles.
[4] Article 2.2 and Article 5.2 of the SPS Agreement.

confirmed that laws which do not take account of cultural considerations are likely to be met with resistance.

After all, law is a reflection of the culture it governs. As a result law is as capable of revealing the distinctive quality of a particular cultural personality as are other cultural constructs such as art, religion, or language. Laws should represent a formalized analogy to a culture, doing things in the manner authorized by a culture.[5] It is thereby entrusted with the preservation of the identity of a culture.[6] Therefore, rather than an over reliance on science, the SPS Agreement should be more flexible so as to accommodate all the disparate food cultures of the nations affected by it.

The physical formulation of the SPS Agreement and in particular the way it has been interpreted by the Panel/Appellate Body shows that it is almost completely science based. For example, as outlined in Chapter 8, despite the right of a WTO Member to determine its own appropriate level of sanitary protection,[7] it must still be based on a 'scientific justification'.[8] The SPS Agreement does not specify the extent to which consumer preferences (including pubic risk perception) may be taken into account in the domestic food regulatory measures of WTO Members.[9] Consumers have little or no opportunity to directly influence the formulation of the WTO Agreements or procedures.

However, science can never be 100 per cent certain that new foods or changes in the food production process are not deleterious to human health. Science is only a process comprised of transparent and reproducible steps involving the collection and analytical verification of data based within the limitations of current scientific knowledge. Science should only be used to provide information that can then be part of the decision-making process, a process which must also consider the economic, social and political imperatives. Essentially, science can

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[5] R. A. Falk, note 153 Chapter 3 above, p.14.
[6] *Ibid.*
[7] Under Article 3.3 of the SPS Agreement a Member is allowed to instigate a level of protection which differs from that implicit in the international standard. A Member must always comply with the 'scientific' risk assessment required by Article 5.1. of the SPS Agreement.
[8] Paragraph 172 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R. The Panel in US-Continued Suspension found that Article 5.1 and Article 5.2 of the SPS Agreement must be read together, which means that it is a 'scientific' risk assessment – as Article 5.2 stipulates that Members shall take the 'available scientific evidence' into account. See, Paragraphs 7.838-40 of Panel Report WT/DS320/R (31 March, 2008).
[9] However, scientific focus of the Agreement suggests that a priority will be placed on rational, scientifically driven regulation. See, C. Button, note 105 Chapter 4 above, p.103.

inform the regulatory process but it cannot by itself determine the end result.[10] The fundamental proposition of this school of thought is that health goals are determined by a society and it is only afterwards that science plays a role in the emotive area of food safety regulation.[11]

Much of it depends on how the goal of scientific risk analysis is defined. It depends on whether one takes the viewpoint that science can provide 100 per cent certainty, or alternatively, if one takes the stance that science can never be 100 per cent certain. In *EC-Hormones*, the Appellate Body concluded that 'theoretical uncertainty is not the kind of risk which, under Article 5.1 [of the SPS Agreement] is to be assessed'.[12] In other words, Members must produce evidence for the risk that is more than purely theoretical.[13] Western legal tradition itself is deeply rooted in empirical methodology and therefore it leads us to distrust and disdain those who bother us with abstract speculation about general matters.[14] However, to apply only empirical science will inevitably lead on occasion to political conundrums for governments as sometimes they will be under pressure to take public concern over a risk into account. It was outlined in Chapter 8 that this was precisely the argument made by the EU when it came before the WTO Dispute Settlement Body. To say that science can always be certain misinterprets a fundamental tenet of scientific theory as widely accepted by scientists. Therefore, this thesis has shown that the WTO Dispute Settlement Body applies an overly limited definition of science, if the goal is to mitigate against the number of trade disputes arising. Economic and political rationales are in themselves scientific information relevant to the decision making process. Therefore, this is one way in which the WTO Dispute Settlement Body can broaden its interpretation of science. In so doing, the WTO Dispute Settlement Body can widen its acceptance of cultural considerations in the application of the SPS Agreement.

Ultimately, successful dispute resolution in international trade law and in particular under the SPS Agreement, may only be possible at the cost of permitting a new approach. It is an

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[10] D.A. Wirth, note 52 Chapter 3 above, p. 817.
[11] M. D. Carter, note 149 Chapter 2 above, p.652.
[12] *EC Measures Concerning Meat and Meat Products (EC-Hormones)*, WT/DS26/AB/R, para 186. In the same breath the Appellate Body refers to the 'uncertainty that theoretically always remains since science can never provide absolute certainty that a given substance will not ever have adverse health effects' - WT/DS26/AB/R, para 186.
[13] J. Scott, note 186 Chapter 5 above, p.107.
[14] R. A. Falk, note 153 Chapter 3 above, p.12.

approach which allows for a greater degree of cultural influence. In the context of this thesis, the investigation contained in it has served to confirm that both culture and science contribute to risk analysis. In fact, not only do they both contribute to risk analysis, they underpin it. Therefore, the question becomes one of how best to accommodate or combine both issues.

Unfortunately, the acceptance of cultural considerations as a valid argument for justifying sanitary measures, creates a difficulty for a trade liberalisation advancing organisation such as the WTO. Any implicit acceptance of cultural regulatory divergences between Members means a move away from science as the sole basis for risk analysis under the SPS Agreement. However, we saw in Chapter 4 and in Chapter 8 of this thesis, that science is necessary for the acceptance of a global regulatory construct as neutral and universally valid. Any watering down of the collective commitment to science based risk regulation will go some way towards defeating the purpose of pursuing the harmonisation of international sanitary standards as a means of promoting trade liberalisation.

In addition, there is an overlap between implementing the sanitary measures that citizens demand and protectionist desires. It may prove futile to try and draw an imaginary line in the sand demarcating where one goal ends and the other begins.[15] The real solution will involve openly accepting that where mixed motives are suspected, the existence of a genuine motive for the (trade restrictive) sanitary measure will have to be entertained. Therefore, it seems indisputable that culture and public risk perception must be better accommodated than at present. This does not mean abandoning science as the arbiter of risk analysis under the SPS Agreement. Instead the question becomes how best to combine both scientific risk assessment and non-scientific aspects of decision-making about risk – a middle ground between the EU and US regulatory models.

As highlighted in Chapter 6, science only ever confirms that there is no evidence of risk whereas risk-averse EU consumers want evidence proving that there is no risk.[16] Due to their experiences with food health scares and loss of confidence brought about with the internationalisation of their food supply, European consumers are adamant that a danger may

[15] A complex web of political considerations lie within this overlap and as evidenced by the findings in *EC-Hormones*, science alone is inadequate to disentangle it.
[16] See generally, P. Belton & T. Belton (eds), note 9 Chapter 2 above, p.138.

exist even when scientists remain unconcerned. Therefore, if a middle ground does exist, surely it is precaution – allowing more frequent recourse to the precautionary principle.

One of the arguments which the EU has put forward in support of its ban on growth hormones is that we cannot be certain that everything is already known about the adverse effects of growth hormone residues on human health. As a result, the EU felt justified in applying the precautionary principle in the circumstances. However, as outlined in Chapter 9, the precautionary principle has been given a specific meaning within Article 5.7 of the SPS Agreement. In *EC-Hormones*, the WTO Panel found that since the precautionary principle has been incorporated and given a specific meaning in Article 5.7, the principle would not override the explicit wording of Articles 5.1 and 5.2.[17] In other words, any application of the precautionary principle by a Member cannot override the requirement for a scientific risk assessment.[18] This overly restrictive interpretation of the precautionary principle should be broadened to ensure that the incidence of trade disputes are minimised.

In relation to the inclusion of 'other legitimate factors', this thesis disagrees with the observations made by many commentators that the Appellate Body has effectively broadened the list of factors allowable, as set out in Article 5.2 of the SPS Agreement, to such an extent that 'other legitimate factors' are now permissible as part of a risk assessment. While the Appellate Body finds that the list of factors under Article 5.2 of the SPS Agreement is not a closed list, and that the additional factors to be included are those which cannot be quantitatively analysed, it still appears evident from the terminology applied by the Appellate Body in its Report,[19] that factors such as public risk perception or cultural considerations are not allowable for inclusion in a risk assessment as defined under the SPS Agreement.[20] The scientific emphasis inherent in the SPS Agreement favours economic considerations and business rather than the consumer.

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[17] Again, the Panels hands are tied by the terminology of the SPS Agreement. In *EC-Hormones*, the Appellate Body agreed with the Panel's findings and concluded that the precautionary principle would not override the explicit wording of Articles 5.1 and 5.2, and that the precautionary principle has been incorporated in, *inter alia*, Article 5.7 of the SPS Agreement. Paragraph 253(c) of Appellate Body Reports WT/DS26AB/R and WT/DS48/AB/R

[18] On appeal, the Appellate Body found that the reason the principle has not been written into the SPS Agreement is to ensure that it could not be used as a ground for justifying SPS measures that would otherwise be inconsistent with the obligations of Members. Paragraph 124 of Appellate Reports WT/DS26AB/R and WT/DS48/AB/R.

[19] Especially the eventual reference again to 'laboratory methods'.

[20] As confirmed by the analysis in Chapter 8 of this thesis, since the *Beef Hormones Dispute*, the dominant role of science under the SPS Agreement has also been affirmed by the rulings in the *Australia Salmon* and *Japan Varietals* cases. See *Australia – Measures Affecting Importation of Salmon* (WT/DS18) and *Japan – Measures Affecting Agricultural Products* ('Varietals') (WT/DS76).

More generally, due to the information gleaned from the analysis contained in the preceding Chapters of this thesis, the genesis of the SPS Agreement should be examined or refined in the context of its reliance on Codex standards. Since the foundation of the WTO, Codex standards have supposedly been formulated using a so-called scientific consensus as their basis. As evidenced in Chapter 6 and Chapter 7 of this thesis, the truth is that at Codex meetings, when a nation recognizes it does not have the votes nor the political clout to block a Codex standard, then that nation usually simply acquiesces in the issuance of that particular standard.[21] The point is, Codex standards sometimes reflect political compromises and not the best science.

Another solution is to try and resolve disagreement caused by cultural regulatory divergences before they arrive at the WTO Dispute Settlement Body. One means of achieving this is to try and head-off likely areas of conflict. This has been achieved successfully in a number of instances globally. For example, In 1996, Australia and New Zealand agreed to establish a joint system for developing and regulating food standards – Food Standards Australia New Zealand (FSANZ). This system is now regarded as one of the prime examples of a successful bilateral agreement on issues pertaining to food regulation.[22] The Asia Pacific Economic Cooperation Process (APEC) is an even more ambitious effort to establish a regional partnership in international food regulation. The countries involved debated establishing an APEC food system, to include both food safety and trade liberalisation objectives. The food safety part of the program has yielded a food safety framework in the form of the APEC Food Mutual Recognition Agreement. The Agreement is designed to facilitate trade in foodstuffs in the Asia Pacific Region. The analysis in this thesis has shown that even within the EU and the US, there have been instances where, successfully, allowance has been made for cultural divergences in food tradition.[23]

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[21] And this works both ways. For example, in 1999 when the US did not object to the adoption of Codex pesticide residue standards even though they provided less protection than US law. B. Silverglade, note 184 Chapter 3 above, p.84.

[22] T.E. Josling, D.H. Roberts & D. Orden, *Food Regulation and Trade: Towards a Safe and Open Global System* (Washington: Institute for International Economics, 2004), p. 39.

[23] For example, the permitted sale within State boundaries of raw milk cheese products in the US, or the role for protected geographical indications and designations of origin under EU food law as outlined in the conclusion to Chapter 3 of this thesis.

Deciding on which legal technique should be used to achieve a particular result is in itself a cultural determination.[24] However, typically the resultant legal framework is forced to react to its historical environment and oftentimes the impact is different from that which had been expected.[25] This phenomenon is particularly evident in the sphere of international trade liberalisation. The study in this thesis has indicated that while a number of trade problems have been resolved at the bilateral level, without recourse to a WTO Panel, the same cannot be said of the *Beef Hormones Dispute*. The *Beef Hormones Dispute* represented a breakdown in the political compromise underpinning the WTO Agreements and it is a strong indication that renegotiation and amendment of the Agreements may be necessary. As confirmed by the analysis in this thesis, science alone is an inadequate arbiter of the legitimacy of sanitary measures. It is submitted that the SPS Agreement should be reopened for negotiation in order to accommodate cultural considerations and public risk perception within it.

Therefore, to conclude, the assertion that our culture influences the nature of the sanitary measures enacted has been supported by the analysis contained in this thesis which has showed that cultural biases towards the food supply exist.[26] The analysis in Chapter 5 confirmed that culture in the form of public risk perception varies across jurisdictions. Public risk perception dictates how the consumer views a certain food product and therefore influences the nature of public representations made to politicians and food regulatory authorities. More generally, it was confirmed in Chapter 3 that culture influences the formulation and application of law.

As outlined in Chapter 3, it is not possible to fully understand the mechanism by which legal change happens without studying the cultural context in which legal reforms occur.[27] It is more difficult to impose a divergent foreign law that is more closely identified with local cultural and national symbols.[28] Food is personal. In most EU Member States, food culture is a particularly well entrenched aspect of national identity. Therefore, this thesis submits that any international law which has the effect of constraining the free hand of EU domestic food culture is likely to encounter opposition. International legal agreements such as the SPS

[24] R. A. Falk, note 153 Chapter 3 above, p.17.
[25] *Ibid.*
[26] This has been supported in particular by the analysis contained in Chapter 3.
[27] D. Nelken & J. Feest (eds), note 11 Chapter 3 above, p.9.
[28] *Ibid*, p.25.

Agreement represent an exercise in the 'transfer of law'.[29] This is because the SPS Agreement exemplifies a situation where, in the event of a trade dispute, an international ordinance can be applied on the domestic legal culture preventing it from enacting sanitary measures which would act as barriers to free trade. Deliberate attempts to change legal culture highlight differences between the legal culture where the adaptation is to take place and that from which the model is taken.[30] In order to fully understand the role of any particular law, attention must also be paid to the context in which the law operates.[31] Therefore, it is contended that the promulgators of international trade laws such as the SPS Agreement should apply an understanding of the cultural background existing in the nations affected. Reference should be had to the socio-cultural variables in the application of a given rule.[32]

The term 'cultural-match' has been defined as the successful transfer or implementation of a legal norm that is alien to the target society, when the prescriptions embodied in that international norm are convergent with domestic norms.[33] The concept of cultural-match has been used to explain the mechanisms underpinning the reception of international regulations by nation states. A regulation will be adopted into a legal system provided it conforms to the cultural environment characterizing that legal system.[34] There was an insufficient cultural-match between EU food culture and the consumption of beef treated with growth hormones.[35] The analysis in Chapter 8 covering the *Beef Hormones Dispute* has exemplified how cultural influences played a significant role in the EU decision to ban animal growth hormones. As a result, legislation was enacted which banned the use of animal growth hormones and the importation of beef containing hormone residues. However, the enactment of this legislation led to an international trade dispute.

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[29] The 'transfer of law' has been described as 'the operation by which, through constraint, or its absence, law is transmitted from one society to another'. See N. Rouland, note 15 Chapter 3 above, p.292

[30] D. Nelken & J. Feest (eds), note 11 Chapter 3 above, p.25.

[31] D. Gerber, note 20 Chapter 3 above, p. 190.

[32] J.Q. Whitman, note 14 Chapter 3 above, p.1151. James Whittman compared the different privacy rules adopted in Europe and in the US, highlighting the different cultural context in which these rules have been created and the influence it had on moulding them.

[33] See J.T. Checkel, note 22 Chapter 3 above, p.87.

[34] E.A. Feldman, note 31 Chapter 1 above, p.743.

[35] The physical exportation of hormone treated beef into the EU would have by default been the equivalent of the EU authorities enacting legislation permitting the use of animal growth hormones and the sale of beef containing growth hormone residues.

These cultural regulatory divergences or differing food standards can have the affect of acting as non-tariff barriers to international free trade. As a result, despite the fact that legitimate considerations motivated by cultural influences resulted in the enactment of these measures, accusations of protectionism arise and trade disputes often follow. Therefore, as discussed in Chapter 8, when the existence and significance of cultural regulatory divergences are not properly accommodated in international legal constructs, they create difficulties for the harmonious operation of international trade arrangements and in particular, the SPS Agreement.

Chapter 8 highlighted the importance of incorporating into the WTO dispute resolution framework a mechanism which acknowledges cultural regulatory divergences. The Chapter identified a number of avenues for achieving this, including permitting greater use of the precautionary principle and 'other factors', either through a broadened interpretation of the SPS Agreement, or through substantive amendments following renegotiation between the Members. In addition, the difficulty may be remedied through an expanded system of mediation, for example, incorporating the proposed 'good offices' facility of the Chairperson of the Committee on Sanitary and Phytosanitary Measures (SPS Committee) as a means of resolving differences between WTO Member policies before the matter develops into a formal dispute. Similarly, as outlined in Chapter 8, the ongoing international negotiations facilitated under the Transatlantic Trade and Investment Partnership (TTIP), may in time create a mutually agreed mechanism to increase convergence in regulatory formulation which will result in greater harmonisation of regulatory standards.

This thesis has shown that due to the existence of cultural biases, divergences in law are likely to exist between nations. In addition, the analysis in this thesis has shown that these divergences can create difficulties in the application of aspects of international trade law. It has also been shown that when multilateral international regulatory constructs attempt to resolve those difficulties by applying a neutral and universally valid solution, that solution is likely to be met with resistance because the domestic regulations possess a cultural essence.[36]

This thesis set out to examine the question of whether the absence of recognition of the legitimate role played by cultural biases in creating cultural regulatory divergences, gives rise

[36] In this instance, the neutral and universally valid solution of science based risk assessment.

to inherent difficulties in the application of aspects of international trade law.[37] It is here contended that, in light of the evidence presented and the analysis undertaken, this can be answered in short by stating that, yes, cultural considerations matter. Culture influences the formulation and application of food law and any international trade law which ignores the cultural prerogative will encounter difficulties in its application.

[37] The absence of recognition of the role played by culture in creating regulatory divergences both between nation states and under global regulatory constructs such as the SPS Agreement.

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