Food Safety Regulation Across the Atlantic: Conflict or Cooperation?

by

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ABSTRACT

The European Union and the United States have the largest bilateral trade relationship worldwide: In 2016, the EU imported goods worth €246.8 billion from the US, while exporting the equivalent of €365 billion. Despite this high volume of trade and the resulting economic interdependence, their relationship has frequently been plagued trade disputes, notably in the area of food. This thesis examines and compares the regulatory approaches of EU and US in the area of food safety, with a focus on genetically modified crops, in order to determine whether regulatory convergence is realistic. Two conflicting hypotheses are examined: According to Realism, the outcomes of interaction between EU and US are determined by their relative power resources. In contract, the Government Network Paradigm predicts frequent interactions between regulators and convergence on best practices. The analysis suggests that there is little evidence for convergence in the area of genetically modified foods due to the politicisation of the conflict and insurmountable differences between EU and US regulatory cultures. At the same time, convergence in other areas can be observed, which is achieved through mutual recognition agreements rather than full regulatory harmonisation.

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List of Abbreviations

CETA	Comprehensive Economic and Trade Agreement
DG SANTE	Directorate General for Health and Food Safety
ECJ	European Court of Justice
EFSA	European Food Safety Authority
ENVI	Committee for Environment, Public Health and Food Safety of the European Parliament
EU	European Union
FDA	Food and Drug Administration
FAO	Food and Agriculture Organization of the United Nations
GMO	Genetically Modified Organism
HACCP	Hazard Analysis of Critical Control Points
NRAs	National Regulatory Authorities
NTB	Non-Tariff Barriers to Trade
PAFF	Standing Committee on Plants, Animals, Food and Feed
SPS	Sanitary and Phytosanitary Measures
TTP	Trans-Pacific Partnership
TTIP	Transatlantic Trade and Investment Partnership
TBT	Technical Barriers to Trade
US	United States of America
WHO	World Health Organization
WTO	World Trade Organization

1 Introduction

The European Union and the United States have the largest bilateral trade relationship worldwide: In 2016, the EU imported goods worth €246.8 billion from the US, while exporting the equivalent of €365 billion. Despite this high volume of trade and the resulting economic interdependence, their relationship has frequently been plagued trade disputes, notably in the area of food. Issues such as genetically modified organisms (GMOs), hormone beef or chlorine-treated poultry frequently make headlines, which gives reason to examine the nature of these conflicts.

The term genetic engineering refers to a number of techniques used to change certain characteristics of organisms. When applied to plants, modifications could for instance result in increased yield, improved insect resistance, or even enhance a crop's nutritional value. An example for the latter category is Golden Rice (*Oryza sativa*), a variety of rice conceived to alleviate vitamin A deficiency in developing countries. While proponents claim that genetic modification is the logical evolution of selective breeding of plants, a technique that has been used for thousands of years, NGOs like Greenpeace openly oppose the use of GMOs, voicing general concerns about their safety, and the efficacy of golden rice specifically. In response, a group of 107 Nobel laureates have addressed Greenpeace in an open letter, urging the group to recognise the findings of authoritative scientific bodies, and to abandon their campaign against GMOs in general and Golden Rice in particular.

Controversies about GMOs are also reflected in the ways which public authorities regulate these products. The United States employ the principle of substantial equivalence, arguing that a genetically modified plant should be considered as safe if it is sufficiently similar to a traditional crop. The European Union, on the other hand, evaluates GMOs on a case-by-case basis to determine their safety.

Similar conflicts exist in the area of animal products: In 1989, the European Union instituted a ban on US meat treated with growth hormones. Although the rules of the World Trade Organization permit import restrictions to uphold public health and safety standards, they party instituting the ban must be able to provide scientific evidence for justification. The WTO Dispute Settlement Body subsequently ruled that the EU had failed to conduct a scientific risk assessment, and authorised the US to impose retaliatory tariffs.

Not surprisingly, these regulatory issues are also being addressed in trade negotiations. After the suspension of the Doha Development Round trade negotiations in 2008, a number of countries have resorted to bilateral or multilateral trade agreements. Unlike traditional free trade agreements, which focus on the reduction or abolition of tariffs, treaties such as the recently concluded Comprehensive Economic and Trade Agreement (CETA) between the EU and Canada, or the proposed Transatlantic Trade and Investment Partnership (TTIP) between the EU and the United States, contain a number of innovations, including dispute settlement mechanisms, provisions on technical barriers to trade, and procedures for regulatory cooperation.

While these cases serve as examples to illustrate how perspectives on risk, precaution, and the role of regulators differ across the Atlantic differ, they also raise an important question: How is it possible for the EU to uphold its health and safety standards for products, while harmonising its regulations to facilitate trade with the US at the same time? These concerns have been articulated by a number of NGOs and activist groups, who fear that transatlantic regulatory cooperation will lower or circumvent EU product standards, allowing genetically modified or hormone-treated foods to circulate freely on the European market. Despite the fact that the talks for TTIP have come to a halt due to recent political developments, the United States remain Europe's largest trading partner, which necessitates some form of cooperation.

The aim of this thesis is twofold: On the one hand, it seeks to compare and contrast the regulatory approaches employed by the United States and the European Union in the area of food safety. On the other hand, it addresses the question whether the EU has the capacity to protect and uphold its product standards vis-à-vis the US by examining the mechanisms which determine the outcomes of regulatory cooperation and international standard setting.

The remainder of the first chapter is structured as follows: In order to gain a deeper understanding of different types of regulatory systems, a number of theoretical aspects of regulation in general and food safety specifically will be examined. The first section outlines the general objectives of regulation. Subsequently, a number of specific characteristics of food which necessitate regulation are discussed. In the second section, strategies governments can employ to regulate products are presented. It introduces the three related, but distinct processes of scientific risk assessment, political risk management and risk communication. Finally, the use of the precautionary principle and its impact on product safety are discussed.

The third section examines the role of institutions in the regulatory process. It analyses the reasons why governments choose to delegate regulatory tasks to specialised agencies, and the consequences of doing so. In addition, the concepts of agency independence and capture are introduced. The final section describes the prerequisites and obstacles to the free movement of goods. For this purpose, the role of non-tariff barriers to trade and (intergovernmental or supranational) harmonisation of product rules as potential remedies are discussed. Furthermore, the principle of mutual recognition and its impact on regulatory sovereignty will be examined. The chapter concludes with a brief summary of the most important points.

1.1. Why regulate?

Regulation can be justified on a number of technical grounds. In many cases, the need to regulate is the result of market failures, thus situations in which markets fail to deliver efficient outcomes. Consequently, in an idealised view, regulations are adopted in pursuit of the public interest (Baldwin, Cave, & Lodge, 2012, p. 15). For example, governments may regulate natural monopolies such as electricity or railway networks to prevent operators from reaping excessive profits, reduce negative externalities of economic activity such as environmental pollution by implementing a Pigovian tax, or prohibit anti-competitive strategies like predatory pricing.

For the case of food, a number of specific product characteristics necessitate regulation. Generally speaking, product attributes fall into three categories, depending on the point in time at which they become apparent to the consumer. *Search characteristics* are those attributes of a product with can be assessed prior to purchase, such as colour and price. *Experience characteristics*, on the other hand, can only be evaluated after purchase, for instance through consumption. Examples include taste, texture, and acute food risk factors such as food poisoning. Finally, *credence characteristics* are those attributes of a product which only become apparent some timer after consumption. For instance, long-term exposure to contaminants present in certain foods can increase the risk of cancer. Due to this time delay, credence characteristics are difficult to assess for consumers, since it is difficult to establish a clear link between cause and effect. Most attributes of food fall into the experience and credence categories (Henson & Traill, 1993; Katz, 2007).

Akerlof (1970) illustrates the implications of credence characteristics using the market for cars as an example. He explains that an individual who buys a new car is unable to determine

the quality of the car they buy. However, after owning the car for some time, the individual will be able to form a more accurate judgement about its quality, and can use this information to their advantage when reselling it. The buyer, on the other hand, is unable to determine the car's quality, and has to rely on the information the seller provides. Since the seller has no incentive to disclose potential risks or defects associated with the car, all cars in the market, regardless of their quality, have to sell at the same price. As a result, sellers of good cars a driven out of the market, since the price at which cars sell does not accurately reflect their value. If this process repeats several times, the market may ultimately even collapse.

Consequently, it is impossible for consumers to determine whether a product they buy actually contains the ingredients indicated on the label, whether the cold chain has been maintained for perishable foods, or if a product contains harmful substances. This issue becomes even more problematic in domains where scientific understanding is currently lacking or incomplete. This information asymmetry between producers and consumers is a crucial market deficiency that results in the need for regulatory intervention.

1.2. Regulatory Strategies

Governments can employ a number of strategies to regulate products. A distinction between four different categories of measure can be made (Henson & Traill, 1993): *Information Remedies* are measures which provide information to consumers. Processed foods generally feature a list of ingredients on the label, together with information about the product's nutritional value and allergy warnings. In other cases, regulatory authorities evaluate health claims producers make about their products, determining whether these claims stand up to scientific scrutiny. Other approaches use a traffic light system to inform consumers about the fat, sugar and salt content of a product, allowing them to make an informed purchase decision. Information remedies do not have to be connected to one specific product and can also be of a more general nature, which could include the promotion of a healthy and balanced diet to children via the public school system.

Process Standards establish benchmarks for the production process, for example Hazard Analysis of Critical Control Points (HACCP), a systematic approach to prevent biological and chemical contamination and other food-related risks. Food-related process standards are often monitored by inspections of factories and production facilities. By ensuring that

hygiene regulations are observed, it is possible to eliminate certain food risks before they arise.

Performance Standards define minimum safety and quality standards for products, while leaving it up to producers how to achieve them. Maximum residue limits for pesticides fall into this category. To meet these limits, producers may for instance choose to use fewer pesticides on their crops, or they may wash the harvested fruits and vegetables after harvest.

Finally, *pecuniary measures* affect production costs. They may either be *ex ante*, which is the case for taxes and subsidies, or *ex post*, which includes fines imposed on producers and awards to consumers who incurred damages. Taxes on products considered harmful to society, such as alcohol or sugar, are examples of these types of measures.

To reduce food-related risks, regulators often rely on scientific expertise, as part of a process which is known as risk analysis. The World Health Organization and the Food and Agriculture Organization of the United Nations (1995) define risk analysis as a process that consists of three components: *Risk assessment* refers to the scientific evaluation of foodborne hazards. In this stage, adverse health effects associated with biological, chemical or physical agents which may be present in food are identified and characterised. Subsequently, exposure assessments are conducted to determine the most likely degree of intake for various groups. Based on this analysis, risk assessors are then able to provide detailed risk characterisations which integrate the three previous steps to reach an estimate of the adverse health effects associated with a product.

Risk management refers to those activities which take place at the policy level. They include preliminary work such as the establishment of a risk profile based on available data, or the commissioning of a scientific risk assessment to gather additional evidence. Subsequently, risk managers compare and evaluate different policy options to address previously identified risks, which ultimately result in the implementation if regulatory measures. The final steps of risk management are monitoring of food safety and consumer health, and reviewing the effectiveness of implemented policies. If these activities lead to the identification of other risks which are not sufficiently addressed yet, the cycle repeats.

Risk assessment and management are supplemented by a third process, namely *risk communication.* Its purpose is to disseminate and exchange information about food risks among risk assessors, risk managers, and other stakeholders. Risk communication also refers to the strategies which are employed to communicate risks to the general public. For instance,

in the event of a food recall, often due to contamination of products with dangerous substances, it is necessary to inform consumers and retails in a timely fashion in order to prevent harm. Non-emergency measures include recommendations on the maximum intake of alcoholic beverages, which are targeted directly at consumers.

FIGURE 1.1: Type I and II Errors

	Risk suspected	**No risk suspected**
Product is safe	Type I error False Positive	Correct
Product is unsafe	Correct	Type II error False Negative

SOURCE: Own work

A special case arises when a certain risk is suspected, but has not (yet) been proven (Baldwin et al., 2012, pp. 94-95). Such a situation may occur when new types of products enter the market, and scientific evidence is conflicting or inconclusive. For regulators, this raises the question whether they should grant authorisation to a potentially unsafe product or ban a potentially safe product. If they choose to do the latter, they are employing the *precautionary principle,* a strategy used decrease the likelihood of committing Type II errors (false negatives) but making Type I errors (false positives) more likely. This phenomenon[1], which can also be expressed as "better safe than sorry", is illustrated in FIGURE 1.1, and has a number of implications for food regulation.

How much scientific certainty is needed to authorise a novel product? Likewise, do producers need to prove that their products are safe before marketing them, or do regulators have to prove that a product is not safe to ban it? These questions illustrate that regulation is not a neutral process, and is influenced by perceptions of acceptable risks, the need for precaution and the role of regulators in general. Regulators from different countries can be expected to address these questions in a variety of ways.

As Sandin (1999) points out, the precautionary principle lacks a clear definition and is thus difficult to operationalise and apply. Despite these difficulties, he suggests that the principle

[1] According to Error Management Theory, humans have evolved towards committing errors that are less costly from an evolutionary point of view, thus favouring one type of error over another. See Haselton and Buss (2000) for a more detailed explanation.

can in general terms be understood as an if-clause with four distinct dimensions: "*If* there is (1) a threat, which is (2) uncertain, *then* (3) some kind of action (4) is mandatory" (Sandin, 1999, p. 891, emphasis in original). Sadin explains that the strength of the precautionary principle depends on the precision and strength of each of the four dimensions, while the overall strength of the principle is determined by its weakest dimension:

1. *Threat:* the severity, reversibility and preventability of a situation
2. *Uncertainty:* the degree to which scientific evidence and certainty is lacking
3. *Action:* the type response to a threat that the principle envisions
4. *Command:* whether that response is allowable, justified, recommended, or mandatory.

While the command and action dimension are comparatively unambiguous, the threat and uncertainty dimensions are far less clear-cut. Consequently, depending on the way in which the precautionary principle is formulated, there is considerable scope for debate about its specific implications. This fact can be exploited by certain actors, such as entrepreneurs, lobbyists, experts or politicians, who may use a lack of scientific evidence as an argument to block decisions that are opposed to their own interests (Gollier & Treich, 2003). It is also important to keep in mind that Type I errors, by assuming risks which do not actually exist, can block safe products from entering the market, which can be detrimental to innovation.

1.3. Regulatory Institutions

As Thatcher and Stone Sweet (2002) point out, many regulatory tasks have been delegated to non-majoritarian institutions, thus governmental entities which possess and exercise specialised public authority without being directly elected or managed by elected officials. This is also true for the area of food regulation: In the EU, the responsible agency is the European Food Safety Authority, working together with the European Commission. In the US, these tasks are performed by the Food and Drug Administration, a federal agency of the Department of Health and Human Services.

Thatcher and Stone Sweet (2002) use the Principal-Agent framework to explain acts of delegation. They argue that the amount of discretion a principle enjoys is the sum of delegated powers minus the control mechanisms the principal possesses. Principals may either restrict the discretion of their agent *ex ante,* for example by conferring restrictive powers upon the agent, or *ex post,* by monitoring the agent's activities and intervening if the need arises. Both methods seek to minimise agency losses, which are discrepancies between

the principal's and the agent's preferences. Agency losses may either be the result of slippage, when the agent has developed own preferences which differ from those of the principal, or shirking, if they are caused by institutional incentives.

These issues are especially relevant for the European Union. While states can be expected to possess a certain amount of regulatory capacity and institutional capabilities a priori, the same cannot be taken for granted for the EU, which is neither a state nor a traditional international organisation. Consequently, one of the aims of this thesis is to determine whether the EU can be considered as a unitary regulatory actor with the capacity to enter into relations with its foreign counterparts, as opposed to a group of states coordinating their efforts in an intergovernmental manner.

Regarding the motivation of principals to delegate powers to agents rather than exercising these powers themselves, Thatcher and Stone Sweet identify a number of functional reasons. First, agencies can help to resolve collective action problems, and enhance the credibility of promises made, since revoking competences after they have been delegated entails significant costs for the principal. This is especially relevant when a composite principal, thus a principal comprised of multiple actors whose preferences are not stable over time, is involved. Secondly, specialised agencies can overcome information asymmetries in technical areas by developing expertise in a field. Such specialisation can increase the efficiency of the rule-making process. At the same time, the authors acknowledge that other factors may influence the decision of whether or not to delegate powers. Likewise, functional approaches cannot explain the considerable variation of delegated powers in different countries or the timing of delegation (see Thatcher (2002)).

While delegation often occurs to resolve commitment problems and ensure that issues are addressed in an efficient manner, it can also lead to some unintended side effects. One example is *regulatory capture*, a situation in which interests group gain power over regulators to the extent that the primary goal of regulation becomes to serve their special interests (Baldwin et al., 2012, pp. 43-45). This can occur because interest groups are able to voice their preferences more effectively than diffused and less organised groups, such as consumers at large. Makkai and Braithwaite (1992) demonstrate that the concept of regulatory capture encompasses three empirically distinct dimensions, which are identification with the industry, sympathy with problems that regulated firms are confronted with, and absence of toughness. Regarding the *revolving door* phenomenon, where staff moves from the industry into an

agency responsible for regulating the former, the authors note that the effects of attitudes towards the industry on regulatory behaviour are relatively weak. Nevertheless, it is possible that conflicts between public and private interests arise if a large proportion of regulators is recruited from the regulated industry.

One strategy to ensure that agencies act in the public interest is to embed them in democratic structures, so they can be held accountable for their actions. Curtin (2005) distinguishes between two types of accountability, namely public accountability, which refers to the duty of elected representatives to demonstrate that they have exercised their powers in accordance with the publics' preferences, and administrative accountability, which refers to a conformity of values between the (political) principal and the agency to which powers have been delegated.

1.4. Regulations as Barriers to International Trade

In international trade, food regulations are seen as *Non-Tariff Barriers to Trade* (NTB). This category encompasses all obstacles to trade which are not import or export duties, such as quotas, subsidies or product standards. FIGURE 1.2 offers an overview of the types of measures which fall into this category. For food safety, the group of *technical measures* is especially relevant.

The existence of NTBs has important regulatory implications for states who want to trade goods with each other. They are faced with a number of alternatives (Pelkmans, 2012): The first option is national treatment. In this scenario, the regulatory autonomy of both parties is being respected, and all products have to comply with the relevant national regulations in order to be sold in a given country. Since producers might find it too costly to adapt their products to two divergent sets of rules, trade would be severely limited. The second option is to abolish product standards altogether. At outlined in the first section of this chapter, this would be problematic, as standards serve important public interest objectives and their abolition would be detrimental for consumers.

FIGURE 1.2: Classification of Non-Tariff Measures

Imports	**Technical Measures**	**A.** Sanitary and Phytosanitary Measures **B.** Technical Barriers to Trade **C.** Pre-Shipment Inspection and Other Formalities
	Non-technical measures	**D.** Contingent Trade-Protective Measures **E.** Non-Automatic Licensing, Quotas, Prohibitions and Quantity-Control Measures other than for SPS or TBT Reasons **F.** Price-Control Measures, Including Additional Taxes and Charges **G.** Finance Measures **H.** Measures Affecting Competition **I.** Trade-Related Investment Measures **J.** Distribution Restrictions **K.** Restrictions on Post-Sales Services **L.** Subsidies (Excluding Export Subsidies Under P7) **M.** Government Procurement Restrictions **N.** Intellectual Property **O.** Rules of Origin
	Exports	**P.** Export-Related Measures

SOURCE: United Nations Conference on Trade and Development, 2012

The third option is the harmonisation of regulations. This may either be achieved in an intergovernmental way, for example via regulatory cooperation between the competent authorities, or via the establishment of a supranational institution which adopts rules for all involved parties (Tallberg, 2002). Furthermore, international product standards, which will be discussed in the following section, can help to facilitate trade.

Finally, free trade can be achieved via the principle of Mutual Recognition (Pelkmans, 2012): It requires both parties to recognise each other's standards and regulations as equivalent, meaning that producers who comply with one set of rules can also sell their products in the market of the other party. In practice, Mutual Recognition is only realistic if the standards of

two jurisdictions are already sufficiently aligned. In the European Union, Mutual Recognition was established by the European Court of Justice's ruling in the famous *Cassis de Dijon* case[2]. In practice, countries use a combination of these approaches to ensure that goods can move freely between different countries with different regulatory systems.

1.5. International Standard Setting

As Abbott and Snidal (2001) point out, differences between national regulations can also be overcome by developing international product standards. International standards are often the result of a variety of governance arrangements, characterised by complex patterns of interaction between public and private actors. This could mean that a standard is created by a national government, but implemented by private actors, or that standards emerge from the industry and governments are tasked with the enforcement. For the purpose of this work, however, a more important distinction can be made between the different types of problems international standard seeks to address (FIGURE 1.3).

FIGURE 1.3: A Typology of Standards Problems

	Network externalities (Coordination)	**Traditional externalities (Prisoner's Dilemma)**
Technological/ physical externalities	I Technological interconnectivity	III Physical externalities
Regulatory externalities	II Transactional connectivity	IV Policy externalities

SOURCE: Abbott and Snidal (2001)

The first distinction the authors make is between technological externalities on the one hand, and policy externalities on the other. Technological, or physical externalities include tangible effects such as pollution. Regulators externalities, on the other hand, lack physical impact, but do nevertheless affect both foreign and domestic producers. One example for regulatory externalities are product safety standards. The second distinction relates to the degree of

[2] The ECJ established that any product legally sold in one Member State can be sold in another, even if it does not fully comply with national regulations of that Member State. Any restriction on this principle must be justified (health, safety, etc.).

interdependence between individual participants. For the case of network externalities, participants prefer the adoption of a common standard. In contrast, for cases which resemble the famous Prisoner's Dilemma, participants prefer to set their own standards, possibly at the expense of others.

Abbott and Snidal (2001) point out that the adoption of standards is not a neutral process, and may often be influenced by the preferences of individual actors. For example, while states may in principle agree that the adoption of a common standard would be beneficial, each of them would prefer coordination on their own, national standard in order to avoid conversion costs. Likewise, difficulties can arise when preferences for standards are affected by differences in cultural norms or values, rather than economic concerns.

Issues relating to food and drugs generally fall into the category of *Policy Externalities* (Cell IV). On example is the strategic use of domestic regulations to disadvantage foreign competitors. In other cases, regulators may pursue legitimate public policy objectives and simply be unaware of the differential impact the adopted standards have on domestic and foreign producers.

1.6. Conclusion

The purpose of this chapter was to develop a general understanding of food regulation by examining objectives, strategies and institutions. Governments choose to regulate to serve the public interest and to address market deficiencies. For food safety, a number of factors, such as the inability of consumers to assess credence characteristics, require specific government responses. For this purpose, a number of policy options exist, including information remedies, process standards, performance standards and pecuniary measures. These activities are generally referred to as risk management, as opposed to scientific risk assessment, which is used to inform and guide the former. Both risk management and risk assessment are activities which are often delegated to specialised agencies in an attempt to enhance the efficiency of rule-making and let regulators develop expert knowledge.

Furthermore, a number of issues on which the view of EU and US regulators differ have been identified, such as GMOs and the use of hormones in beef. These issues, and how they affect transatlantic trade, will be discussed in greater depth in the empirical part.

The remainder of this thesis is structured as follow: The second chapter establishes a theoretical framework for the analysis, introducing two different perspectives on the process

of international standard setting, each of which is based on a different set of assumptions, and consequently makes different predictions about what determines the outcomes of cooperation: The Realist school of thought sees states as unitary actors which use power resources to influence the development of product standards according to their own preferences. In contrast, other authors focus on the role of Transgovernmental Networks, arguing that states should be seen as a set of disaggregated actors, who collaborate with their foreign counterparts on a regular basis. According to this view, network engagement should lead to convergence on best regulatory practices.

Chapter 3 deals with the methodological aspects of this research, establishing the scope of this thesis, methods of data collection and the principles on which the analysis in the empirical part will be based.

The empirical part of the thesis encompasses three chapters. Chapters 5 and 6 examine how food safety is regulated in the EU and the US, respectively. This includes an analysis of institutional characteristics and substantial issues, specifically, the regulation of genetically modified crops, which has proven to be a controversial issue. Chapter 7 draws a comparison between both approaches and analyses how EU and US regulators interact both bilaterally and within the context of international organisations. The thesis concludes with a summary of the main findings and their implications for future research.

2 Theoretical Framework

After exploring objectives and strategies of regulation, the purpose of this chapter is to present a theoretical framework that can be used to make predictions about how two different types of regulatory systems will interact, and which factors determine the outcomes of such interaction. Two contrasting perspectives are presented, each of which are based on different assumptions, and predict different outcomes.

As discussed previously, the EU and the US differ in a number of aspects. The most obvious difference is that the EU is not a state, but a Union of 28 sovereign Member States who chose to delegate certain competences to supranational institutions, while developing their own internal decision-making procedures at the same time. Consequently, comparing the EU and the US is a challenge, and may require some additional analytical detours at times. The second difference between both jurisdictions is the way in which they approach regulatory issues in general, and food safety specifically. This is expressed in both institutional design choices and substantial issues such as levels of protection and the types of measures employed to achieve them.

2.1. Realism: Standard Setting as Power Politics

According to Realists such as Drezner (2008), international standards primarily reflect the preferences of powerful actors. Drezner's argument is based on a number of assumptions: First, a state's preference for an international, harmonised standard will be the domestic status quo, thus the pre-existing national regulatory framework. The underlying reasoning for this is that the adoption of a different standard would lead to significant adjustment costs. Secondly, a state's ability to influence the development of an international standard in its favour depends on the power resources it possesses. Specifically, powerful actors such as the United States or the European Union[3] are characterised by large internal markets and reduced vulnerability to external shocks. Due to their relatively large market size, these 'great powers' have less to gain from securing market access to smaller economies than vice versa. Consequently, third states have an incentive to converge towards the standards of one of the great powers, as the benefits of market access make up for adjustment costs. If they do not

[3] Drezner argues that the EU can be considered as a single actor, since Member States have delegated significant regulatory and bargaining powers to the European Commission.

adapt, the great powers may also employ coercion, for example by instituting economic sanctions, which factor into the aforementioned cost-benefit analysis. Finally, Drezner points out that globalisation has increased the benefits of harmonised standards, while adjustment costs have remained the same.

FIGURE 2.1 illustrates, based on the degree of conflict among various international actors, the possible outcomes of regulatory coordination. For cases where distributional concerns are low, there is a realistic possibility for a global, harmonised standard. If only the great powers agree on a given issue, the most likely result is a club standard, which excludes other international actors. Rival standards emerge if the great powers have diverging preferences. Each of them may try to convince third states to adopt their respective standard to form a coalition. Finally, for issues where no consensus exists between great powers and other international actors, coordination is unlikely. If it does occur, the outcome will presumably be a sham standard, which lacks monitoring and enforcement mechanisms.

FIGURE 2.1: A Typology of Regulatory Coordination Outcomes

		Divergence of interests between great powers and other international actors	
		High conflict	*Low conflict*
Divergence of interests among great powers	*High conflict*	Sham standards	Rival standards
	Low conflict	Club standards	Harmonized standards

SOURCE: Drezner (2008)

It is worth noting that market size and the ability to withstand external shocks are not the only power resources states possess. In the context of transatlantic regulatory cooperation of securities markets, Posner (2009) identified institutional characteristics of regulatory regimes

as another crucial factor. He points out that while initially, cooperation in this area was heavily skewed towards U.S. preferences, this balance changed after institutional reforms occurred in the EU. More specifically, Posner identifies regulatory centralisation as the main factor that increased the EU's bargaining leverage and caused the U.S. to become more accommodating and willing to make concessions. This change of U.S. behaviour was motivated by fears that the EU could implement regulations detrimental to U.S. firms operating in the European market if no compromise were reached. In contrast to Drezner, who argues that the EU constitutes a great power, Posner's observations suggest that this status cannot be taken for granted. Instead, the EU can only be considered as a great power in a given sector if the Member States have delegated a sufficient amount of their competences.

As Drezner notes, if the preferences of the EU and the US on a given issue differ, neither of them has the capacity to coerce the other party to adjust. Consequently, harmonisation is not an option. Instead, Realists would expect that both the EU and the US maintain their rival standards, and attempt to impose these standards on weaker states, leading to the emergence of competing regulatory blocks. They may also use international organisations, whose membership and governance structure benefits their own position, to advance their agenda. If either party succeeds at reaching a global tipping point by forming a sufficiently large coalition, this may induce rival states to switch.

On the other hands, if EU and US preferences are sufficiently lined up, the emergence of a harmonised standard is possible. This may either be a club standard, adopted on a bilateral basis, or, if other international actors share their preferences, a truly global harmonised standard.

To sum up, Realists see international standard-setting as a zero-sum game, in which any benefit a great power acquires necessarily occurs at the expense of the other party. To predict the expected outcomes of transatlantic regulatory cooperation, it would be necessary to examine the power resources the EU and the US have at their disposal.

2.2. Networks: Standard Setting as Transgovernmental Cooperation

In contrast to the Realist school of thought, Slaughter (2009) offers a different perspective, focussing on the role of networks. Rather than seeing states as unitary actors with one set of preferences, she argues that states are in fact disaggregated: A number of sub-state actors frequently interact with their foreign counterparts. Slaughter observes networking among

regulators, legislators, and even judges, although extent and forms of cooperation vary. The analytical focus of this thesis lies on networks between government bureaucracies, thus the various EU and US agencies and government departments involved in the process of food safety regulation. Specific attention will be paid to the degree to which cooperation is formalised (executive agreements, memoranda of understanding, or spontaneous and informal interaction), and how the domestic legal system affects the capacity of regulators to interact with their foreign counterparts.

Frequent interaction of these various sub-state actors with their foreign counterparts can lead to the emergence of networks, with professional expertise acting as common ground between the different network participants. Slaughter identifies three types of networks: Information networks, which are used to exchange data between national regulators, enforcement networks, used to enforce existing laws and regulations collectively, and harmonisation networks, created for the purpose of harmonising national product standards. A necessary precondition for the establishment of any type of network is a certain degree of commonality in terms of objectives and institutions among the cooperating parties. For instance, it seems unlikely that two states with vastly different regulatory approaches would establish a harmonisation network, since any adjustment would be politically sensitive and therefore encroach upon the prerogatives of legislators. Instead, harmonisation is more likely if it entails small, technical adjustments between two (or more) sufficiently similar regulatory regimes. On the other hand, engagement in networks itself can also change the nature of interaction over time: The establishment of an information network can lead to convergence, since network participants will increasingly have access to the same data on which they base their decisions, while also facing similar regulatory challenges. Consequently, they may seek to coordinate or harmonise their efforts. Even if diverging cultural or political norms lead regulators to choose different courses of action, they find it useful to share their motivation for doing so with other network participants to increase mutual understanding. Slaughter refers to this phenomenon as ‘informed dissent’.

Kahler (2015) identifies two approaches to network analysis that can be applied to international politics. The first approach considers networks as structures that can influence the behaviour of participants via network effects. In contrast, the second approach views networks as a specific institutional form that stands in contrasts to markets and hierarchies, and whose effectiveness and aims are determined by agent characteristics.

An example of the effects of network structures is offered by Majone (1997), who explains how networks can contribute to professionalisation, using an information game for illustration (Figure 2.2).

FIGURE 2.2: The Information Game

Player A	**Player B**	
	High Quality	Low Quality
Ask information	10,10	-5,15
Don't ask	0,0	0,0
	Pay-offs to: (A, B)	

SOURCE: Majone (1997)

In this game, Player A can choose whether or not to request information from Player B. Player B, in turn, can either provide high quality information, maximising the utility of both players, or low-quality information, maximising his own utility by lowering research costs, but at the expense of Player B. For single interactions, Player B's dominant strategy is to provide low quality information. However, if repeated interactions occur, and Player A would cease to interact with Player B if presented with low quality information, Player B has an incentive to provide high quality information, since he would otherwise lose utility by forgoing future interactions.

An example of an actor-centred approach is offered by Singer (2004), who observes regulators entering into network relations with their foreign counterparts to avoid political intervention. He identifies competitiveness and public confidence in the adequacy of regulatory stringency as the two main factors regulators have to take into consideration. In order to avoid attempts of politicians to directly influence regulatory policy, which would reduce the regulator's autonomy, they need to balance both factors by adjusting regulatory stringency: If regulations are too lax, competitiveness will be high, at the detriment of public confidence in regulation. Likewise, too stringent regulations may boost confidence, but will necessarily decrease competitiveness. As long as a win-set, thus a degree of regulatory stringency that satisfies requirements of both confidence and competitiveness, exists, regulators can avert political intervention by making small adjustments to their policies. However, if exogenous shocks to both competitiveness, often in the form foreign competitors which face less stringent regulation, and public confidence, for example due to a scandal that casts doubt on the adequacy of regulations, occurs, regulators are unable to satisfy the

demands of their political principals. Consequently, when facing exogenous shocks, regulators have an incentive to engage in regulatory harmonisation with their foreign counterparts: If each of them adopt a more stringent set of rules, confidence will increase without harming competitiveness. Singer's Confidence-Competitiveness framework can also be applied to other areas, such as food safety. If regulators are faced with low consumer confidence in the adequacy of food safety regulations, for example due to a recent food scandal, while increasing regulatory stringency would hurt the competitiveness of the domestic food industry, they may address this problem by harmonising regulations with their foreign counterparts.

Compared to the Realist view, the network approach is generally more optimistic, as it considers the possibility of mutually beneficial cooperation. Rather than viewing standards as constant and given, Slaughter argues that networking of EU and US officials can lead to convergence on best practices. This view also resonates with Singer's and Majone's perspectives, who argue that networking can boost both confidence and competitiveness, or contribute to professionalisation. Slaughter also notes that harmonisation may not occur in all cases. However, cooperation does allow the involved parties to appreciate each other's positions and 'agree to disagree', if their economic, political or cultural circumstances are irreconcilable. Even in these cases, technical or scientific cooperation can help to ensure that both parties have had access to all the available data, allowing them to make an informed decision.

2.3. Conclusion

This chapter pointed to a number of difficulties in international trade which arise from differences between regulatory regimes. Two contrasting approaches were presented, Realism and the Transgovernmental Network Paradigm. The main differences of these two approaches are summarised in FIGURE 2.3.

FIGURE 2.3: Key aspects of Realism and Networks

	Realism	**Networks**
States are…	Unitary actors	Disaggregated
Reference point of actors is…	The National Interest	A mix of professional, personal and national interests
Cooperation is…	A zero-sum game	Mutually beneficial

Outcomes reflect…	Preferences of Great Powers	Best practices
Methods of Interaction are…	Voluntary adjustment or coercion	Information sharing, cooperation

For the purpose of this thesis, each of the two perspectives will be reformulated in terms of a testable hypothesis:

H_1: If networks exist, they will reflect the distribution of power resources between network participants. Outcomes of interaction will therefore reflect the preferences of the stronger participants.

H_2: Networks are ubiquitous and contribute to the dissemination of best practices. Over time, network engagement will lead to convergence by means of policy learning.

Both perspectives differ in terms of assumptions and expected outcomes. In the empirical part, they will be applied to interactions between the EU and the US in order to determine which possibilities for regulatory cooperation exist, and what the expected outcomes are. Specific attention will be paid to the capacity of the EU to protect and promote its own interests externally. Some of the controversial issues in the EU-US identified until this point include the treatment of beef with growth hormones, genetically modified crops, and chlorine-treatment of poultry. At the same time, it is worth noting that trade disputes only account for a small percentage of EU-US trade: According to estimates of the European Commission[4], these disputes only affect about 2% of the total volume of trade. Consequently, despite the fact that some conflicts do exist, the similarities of EU and US regulation outweigh the differences, which suggests that a large potential for the harmonisation of product standards in the area of food safety exists.

[4] http://ec.europa.eu/trade/policy/countries-and-regions/countries/united-states/

3 Methodology

This chapter discusses a number of methodological considerations. In particular, it seeks to clarify the scope of the analysis, methods of data collection, and possible difficulties which arise from this particular research design. Furthermore, the way in which the analysis will be conducted, and the steps of which it consists, is described.

3.1. Scope

The focus of this thesis lies on the different regimes the EU and the US employ to regulate food safety. Regulatory regimes are composed of the various institutions and agencies involved in the process of product regulation, and the relevant legislation and procedures.

For the EU, the analysis focusses on regulations adopted on the supranational level, thus by EU institutions. Actions taken by Member States unilaterally will not be considered, unless they have an impact on decision-making processes in the EU. Similarly, the analysis of the US will be limited to federal regulations. These limitations are appropriate, since the purpose of this thesis is to demonstrate how both regulatory systems interact, rather than to offer a comprehensive analysis of food safety regulation in all 28 EU Member States or all 50 US states.

Within the context of this thesis, the term ‘food’ refers to processed or unprocessed food products intended for human use. Consequently, animal feed or live animals are excluded from the analysis. Likewise, mechanisms such as rapid alert systems and market recalls will not be discussed in any great detail, since they are only applicable in extraordinary circumstances. Instead, the primary purpose of this thesis is to explain and compare the conditions food business operators must comply with to gain market access for their products.

The time frame of the analysis is limited to laws and regulations which are currently in effect. This does not preclude the possibility of giving an outlook of likely future developments, or discussing reform proposals which would affect regulations currently in place. Reference to prior events will only be made if this is necessary to gain a deeper understanding of the current structure of a regulatory environment.

3.2. Data Collection

To analyse and compare the institutional aspects of food and drug regulation in the EU and the US, data will be collected from various sources. The first category is legislative documents. For the EU, the list of documents comprises Treaties, Regulations, Directives, Decisions, and International Agreements. For the US, this includes Acts adopted by Congress, Regulations adopted by Federal Agencies, and International Agreements.

The second category consists of other official publications, such as Green Papers, White Papers, official reports, summaries of committee meetings, guidance documents published by government bodies or agencies, and data obtained from official websites.

The third and last category includes secondary sources, such as academic literature. While primary sources listed in the previous two categories are generally preferred, it may not always be feasible to use these sources exclusively, for instance due to a lack of available data. In these cases, academic publications can fill this gap and add to the analysis.

3.3. Analysis

The analysis consists of two steps. The first part is a cross-sectional stakeholder analysis, focussing on the institutional aspects of regulation in the EU and the US. For this purpose, the role of legislative, executive and specialised agencies exercising delegated powers will be analysed. This includes an outline of the procedures according to which legislation is being adopted. Regarding the delegation of powers to specialised agencies, the question which instruments the political principal can employ to control agency behaviour, either *ex ante* or *ex post*, and reduce agency losses will be examined. In addition to institutional aspects of regulation, the strategies employed by regulatory authorities and values on which regulation is based will be analysed. This could allow the identification of a "regulatory culture" for both the EU and the US, which might for instance express itself as a preference for using pecuniary measures and information remedies rather than more rigid instruments such as performance and process standards. If a precautionary principle is employed, its exact wording will be analysed regarding the four dimensions of threat, uncertainty, action, and command (Sandin, 1999). These findings about regulation in the EU and the US will then be compared and contrasted.

The second part of the analysis focusses on interaction between EU and US regulators. For this purpose, existing patterns of regulatory cooperation between the relevant authorities of both parties are examined, paying specific attention to the legal framework under which cooperation occurs, and the limitations of the current approach. At the same time, building on Posner's work, insights about the institutional setup from the first part of the analysis will be employed to predict whether we would expect cooperation to be based on mutual accommodation, or if it would rather be skewed towards the preferences of one of the two parties. Likewise, Singer's prediction, according to which regulators cooperate strategically to avoid political intervention will be examined in the context of food and drug regulation to determine whether it also applies in this context. In order to determine whether outcomes of interaction between the EU and the US can be explained by Realism or the Network approach, it is helpful to recall the two conflicting hypotheses presented in the previous section:

H_1: If networks exist, they will reflect the distribution of power resources between network participants. Outcomes of interaction will therefore reflect the preferences of the stronger participants.

H_2: Networks are ubiquitous and contribute to the dissemination of best practices. Over time, network engagement will lead to convergence by means of policy learning.

The purpose of this part of the analysis is to find evidence of convergence between EU and US regulations, in order to determine which hypothesis is more applicable. Furthermore, the role of networks will be examined. The Realist perspective, as reflected in H_1, would suggest that states primarily seek to spread their own standards, whereas H_2 would indicate that convergence on best practices is possible via networks. By examining indicators such a formal cooperation agreement between regulators, or an international agreement that harmonises standards between the EU and the US, it will be possible to determine whether convergence has taken place.

This chapter concludes the first part of the thesis. The following three chapters form the empirical part, discussing food safety regulation in the EU, in the US, and how both systems interact with each other. Chapter 7 summarises the main findings of the empirical part and links back to the previously established hypotheses in order to answer the central research question.

4 Food Safety Regulation in the European Union

The EU has adopted a number of regulations in the area of food safety. To ensure a high level of consumer protection, an integrated approach is employed, which covers all aspects of the food chain, including production, processing, packaging, and labelling. This is also known as the *farm-to-fork*[5] approach.

The current legal and institutional characteristics of EU food law have been influenced by a reform process that started in the mid-1990s (van der Meulen, 2013). Previously, legislative efforts had been focussed on the completion of the internal market for food products, first by adopting product-specific legislation, and after the ECJ's *Cassis de Dijon* ruling and the incorporation of the principle of mutual recognition into EU law by establishing general rules for broad categories of foodstuffs. This approach was seriously challenged by a number of food crises, most notable the bovine spongiform encephalopathy (BSE) crisis. To investigate the actions of Member States and the EU in the BSE crisis, the European Parliament established a temporary enquiry committee. In 1997, the committee published the Medina Ortega report, named after the committee's rapporteur, which criticised both the British government's and the Commission's response the crisis. The report noted that industry interests had been put ahead of concerns about public health and consumer safety, and that independent and unbiased scientific risk assessments were lacking. To address the points raised by the report and initiate a public debate on food law reform, the Commission published a Green Paper[6] on food law that examined and review current practices. Subsequently, in 2000, a White Paper[7] on Food Safety was published, which, among other things, envisioned the establishment of an independent food safety agency that would conduct scientific risk assessments to assist the Commission.

This chapter is structured as follows: After the introduction, the main stakeholders in the area of food safety and their respective roles will be introduced. At the same time, the EU's Ordinary Legislative Procedure, and the ways in which the Commission exercises delegated competences within the framework of the *Comitology* system, will be discussed. The second section examines the role of the European Food Safety Authority in greater detail, while also

[5] http://ec.europa.eu/dgs/health_food-safety/information_sources/docs/from_farm_to_fork_2004_en.pdf

[6] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:1997:0176:FIN:EN:PDF

[7] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:51999DC0719&from=EN

covering issues such as institutional design choices, the role of scientific expertise in the regulatory process, and legal restraints for establishing regulatory agencies.

In the second half of this chapter, a number of current regulatory issues, specifically, the regulation of genetically modified crops, will be discussed. Chapter 5 examines how these issues are addressed in the United States, to allow for a comparison in Chapter 6.

4.1. Stakeholders and Procedures

Legislation in the area of food safety is adopted using the Ordinary Legislative Procedure, laid down in Article 294 of the Treaty on the Functioning of the European Union (TFEU): Based on a proposal from the Commission, the Council of the European Union, and the European Parliament, acting as co-legislators, adopt Directives and Regulations. The Council configuration responsible for this policy area is the Agriculture and Fisheries Council (AGRIFISH Council), composed of the agricultural and fisheries ministers from the 28 Member States. For the European Parliament, food safety issues are dealt with by the Committee on the Environment, Public Health and Food Safety (ENVI Committee). Within the European Commission, the administrative branch in charge of these issues is the Directorate General for Health and Food Safety (DG SANTE), headed by Vytenis Andriukaitis, the Commissioner of Lithuania, who assumed office in November 2014 under President Jean-Claude Juncker. The final stakeholder in the area of food safety regulation is the European Food Safety Authority (EFSA), which provides independent scientific advice to the European Commission and the Member States. The role of regulatory agencies in the EU, and of EFSA specifically, will be outlined in greater detail in the following sections.

Comitology

In addition to legislative acts adopted by Council and Parliament, the Commission can also modify existing legislation or adopt new acts within a framework of rules and procedures known as *Comitology*. The possibility for Council and Parliament to delegate these competences to the Commission is established by Articles 290 and 291 TFEU. The first category, outlined in Article 290 TFEU, concerns the so-called *delegated competences*, which allow the Commission to amend non-essential elements of existing legislative acts in cases where the basic act provides for this possibility. The two co-legislators are required to specify objectives, content, scope and duration of the delegation, and the Commission can subsequently exercise its powers in accordance with these parameters. Delegation allows

Council and Parliament to focus on core legislative tasks, whereas the Commission can make adjustments to certain technical aspects of legislation which does not require political input (Hardacre & Kaeding, 2011). Despite not being directly involved, Council and Parliament still exercise control over the Commission, as either of them can object to the adoption of a delegated act, or revoke delegation altogether. This type of delegation does not involve a committee; instead, the Commission submits its proposals directly to the two co-legislators, who can then object to a proposal, or inform the Commission that they have no objections. If both legislators indicate agreement with the proposal or fail to object within a specified time period, it comes into effect.

The second category of delegated competences, outlined in Article 291 TFEU, are *implementing powers*, which allow the Commission to adopt basic legislative acts. The procedures for doing so are further specified in Regulation 182/2001, known as the *Comitology Regulation*, which replaces Council Decision 1999/468/EC. The regulation defines two procedures, each of which involve consultations between the Commission and a committee composed of experts from the 28 Member States. For the area of food safety, the responsible Committee is the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee). The Committee adopts decisions by qualified majority, defined by Article 16(4) TFEU as 55% of the Member States representing 65% of the EU's population. Voting weights in the Committee are identical to those used by the Council.

The less frequently used *Advisory Procedure* requires the Commission to obtain an opinion from a committee, which it must take into account when adopting a decision. However, the Commission is not legally obliged to follow this opinion. This procedure is used for uncontroversial and straight-forward issues such as small grants and funding approvals.

The *Examination Procedure* is used for more sensitive matters, such as market authorisations. Under this procedure, the Commission is required to obtain an opinion from a Committee to adopt a decision, delivered by Qualified Majority. If the Committee is divided on the issue, the matter is referred to the Appeal Committee, a procedural tool that allows for a discussion at a higher level. In most cases, this means that Member States are represented by members of their Permanent Representation to the EU, thus ambassadors or other diplomatic personnel. If the Appeal Committee is unable to deliver a clear opinion as well, the Commission enjoys a certain degree of flexibility: It may either choose whether or not to adopt the act, or modify the original proposal for resubmission to the committee. In addition, both Council and

Parliament enjoy the right to scrutinise draft measures by adopting non-binding resolutions if they deem that the Commission has exceeded the implementing powers provided for in the basic act.

Import Conditions

Generally speaking, all products sold in the EU have to comply with the applicable food safety regulations, including imported products. However, it is possible for the EU to recognise regulations of third countries as equivalent, as stipulated in Article 11 of Regulation 178/2002, also known as *General Food Law* (emphasis added):

> **Food and feed imported into the Community**
>
> Food and feed imported into the Community for placing on the market within the Community *shall comply with the relevant requirements of food law or conditions recognised by the Community to be at least equivalent thereto* or, where a specific agreement exists between the Community and the exporting country, with requirements contained therein.

This provision allows the EU to recognise food safety regulations as equivalent in order to facilitate trade, without being forced to fully harmonise product rules. In addition to this general provision, a number of specific procedures exist, such as those established by Regulation 854/2004 on official controls for products of animal origin: As stated in Article 12(1), animal products may be imported into the EU from establishments that appear on a Community list, or

> when, on a case-by-case basis, it is decided, in accordance with the Committee procedure, that the guarantees that a specified third country provides […] are such that the procedure provided for in this Article is unnecessary to ensure compliance with [EU requirements].

While the recognition of equivalence provided for by Regulation 178/2002 generally requires the conclusion of an international agreement, involving Council, Parliament, and Commission, the procedure established by Regulation 854/2004 only requires a positive opinion of the PAFF committee, and is consequently less demanding.

Specific import conditions, outlined in Regulation 854/2004, apply to products of animal origin. Generally speaking, products which fall into this category can only be imported into the EU if the establishment responsible for dispatch, obtainment or preparation appears on a

list of authorised third country establishments. A precondition for adding establishments to this list is that the competent food safety authority of the country of origin has undergone an audit procedure. The audit is carried out by the Health and Food Audits and Analysis Office[8], a Directorate of DG SANTE, located in Grange, Ireland.

The Precautionary Principle

One specific feature of food safety regulation in the EU is the use of the precautionary principle. It is codified in Article 7(1) of Regulation 178/2002:

> **Precautionary principle**
>
> In specific circumstances 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 chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.

Following Sandin (1999), who distinguishes between the four dimensions of threat, uncertainty, action, and command, the version of the precautionary principle can be broken down as follows: A *Threat* constitutes "the possibility of harmful effects on health". Rather than just relying on a suspected harmful effect, it must be identified in some way. The *Uncertainty* dimension is not very specific, with the exception of the final part of the principle, which states that a more comprehensive risk assessment should be conducted to obtain more information. This clearly indicates the epistemological perspective that all uncertainties can ultimately be resolved, given enough time and resources. The possibility of 'unknowable' uncertainties is therefore precluded. The *Action* dimension allows for the adoption of "provisional risk management measures", while the *Command* dimension indicates that such measures "may be adopted", and are thus not mandatory. In addition, Article 7(2) establishes that measures must satisfy the principle of proportionality and may not be more trade-restrictive than necessary to achieve the objectives of protecting human health.

This version of the precautionary principle allows for a wide variety of responses to actual or assumed risks. However, it does not give risk managers a carte blanche, allowing them to

[8] Previously known as the Food and Veterinary Office (FVO). The new name reflects the expansion of the Directorate's tasks.

adopt any time of measure they deem justified to avoid uncertain risks. Three notable limitations apply: First, a harmful effect that might occur must explicitly be identified. Consequently, it is not permittable to restrict the sale of certain products simply because a degree of uncertainty exists. The second limitation relates to the temporary nature of measures adopted with reference to the precautionary principle. While no specific time limit exists, it is made clear that measures are primarily implemented in anticipation of further scientific information. Measures may therefore not be adopted if they are de facto permanent, for instance if no further risk assessment is conducted. Finally, the principle of proportionality requires that measures adopted do not exceed what is necessary to protect human health. This could indicate that a complete ban of a product for which some a small risk is suspected might not be legal.

The precautionary principle is frequently cited as a justification for certain risk management measures. However, at a closer look, not all of these measures may actually be justified. It is therefore important to distinguish between actions which can be justified by the precautionary principle, and other actions, which are most likely adopted for other reasons, which are not necessarily risk-related.

4.2. The European Food Safety Authority

In addition to the institutions established by the Treaties, the EU's administrative system comprises a number of decentralised agencies, which are located in various European cities and established by secondary legislation to accomplish specific tasks. One of these agencies is the European Food Safety Authority, located in Parma, Italy. It was established by Regulation 178/2002, which also defines the general principles of EU food law. EFSA's purpose is to provide scientific and technical assistance to the European Commission, the European Parliament, and the Member States. Like all agencies, EFSA is governed by a management board composed of Member States' representatives. It also possesses a certain degree of organisational autonomy, and is equipped with legal personality.

The Role of Agencies in the EU's Administrative System

As Shapiro (1997) points out, creating an independent agency separate from the Commission may seem surprising, as the divide between technocracy and (intergovernmental) politics is already reflected in the Commission-Council separation. Nevertheless, he identifies three motives for doing so: First, since centralising competences in Brussels in generally unpopular

among the public, the creation of decentralised agencies, which are scattered all across Europe, will most likely be met with more acceptance. Secondly, following Haas' theory of Neofunctionalism, the creation of technical and politically innocuous agencies can lead to indirect integration if further political integration is not viable. Finally, by focussing on purely technical and scientific issues, such as the assessment of food-related risks in the case of EFSA, agencies may contribute to the creation of Europe-wide epistemic communities, whose technical truths transcend intergovernmental politics.

In contrast, Kelemen and Tarrant (2011) argue that the design of EU regulatory institutions is primarily driven by political considerations of the various EU actors (FIGURE 4.1): While Commission and Parliament generally favour deeper integration, thus the centralisation of regulatory competences at the European level, Member States are confronted with a tension between two conflicting aims:

FIGURE 4.1: Design Options for EU Regulatory Institutions

Institutional Design	Centralisation	Description
National Regulatory Authorities	None	Member States retain full regulatory autonomy
Network of NRAs	Low	National regulatory authorities cooperate via loose regulatory networks
European Agency	Medium	Delegation to a European agency, controlled by Member States via management board. Commission still exercises formal legal discretion.
Euroregulator	High	Delegation to the European Commission or a specialised body with extensive competences (i.e. the European Central Bank)

SOURCE: Own work, based on Kelemen and Tarrant (2011)

On the one hand, they want to reap the benefits of collective action by creating centralised and independent regulatory bodies. On the other hand, they have a strong desire to manipulate the distributional consequences of regulatory decisions in their favour. Consequently, creating an agency over which the Member States exercise a certain degree of control by being represented on the management board constitutes a compromise between these two objectives.

At the same time, the possibility to delegate competences to agencies is limited by a number of legal constraints, established by the European Court of Justice in the 1958 Meroni case[9]. Among other things, the Court ruled that discretionary powers could not be delegated to agencies via secondary legislation, since this would disrupt the balance of powers between the institutions. Establishing an agency with discretionary powers would thus require a Treaty change. Subsequently, the Commission outlined a number of conditions for the creation of EU agencies in a 2001 White Paper[10]. Among other things, the paper explains that agencies

- can be granted the power to take individual decisions in specific areas, but cannot adopt general regulatory measures
- cannot be granted decision-making powers in areas in which they would have to arbitrate between conflicting public interests
- must be subject to an effective system of supervision and control.

When applying the Principal-Agent framework to EFSA, it is not entirely clear who the principal is. Although agencies closely cooperate with the Commission, Dehousse (2008) points out that newly created agencies are generally tasked with powers previously exercised by national authorities, which would suggest a vertical transfer of powers rather than a horizontal one. Consequently, he argues that a multi-principal model, in which Parliament, Council and Commission each possess a number of control mechanisms to influence agency behaviour, is most appropriate for analysing EU agencies.

EFSA's Internal Organisation

As specified in Regulation 178/2002, EFSA consists of a Management Board, the Executive Director, an Advisory Forum, and a Scientific Committee and several Scientific Panels, whose roles are outlined in the following paragraphs.

The Management Board, composed of 15 members, is EFSA's governing body. 14 of these members are appointed by the Council in consultation with the European Parliament from a list drawn up by the Commission. The final member of the board is a Commission representative. The board adopts EFSA's internal rules and the agency's annual work programme, in accordance with the EU's current policy priorities in the area of food safety.

[9] Case 9/56, Meroni & Co., Industrie Metallurgiche, SpA v. High Authority of the European Coal and Steel Community, 1958

[10] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52001DC0428&from=EN

In contrast to other agencies, members of the board are not representatives from Member States, but independent experts for food safety or consumer protection. Nevertheless, Member States exercise some degree of control over EFSA via the Advisory Forum.

The Executive Director, appointed by the Management Board for a (renewable) period of five years based on a list of candidates proposed by the Commission, is EFSA's legal representative and responsible for the agency's day-to-day administration. The director also implements the work programme and other decisions adopted by the board, and submits draft reports on administrative and financial matters to the latter for approval.

The Advisory Forum is composed of representatives from national food safety authorities, with one representative being designated by each Member State. The forum provides advice on scientific and organisational matters, and serves as a platform for exchanging scientific data. At the same time, EFSA and the Member States can use the forum to coordinate their approaches of communicating risks to the general public, to address contentious issues, and to ensure that duplication of scientific assessments is avoided.

The Scientific Committee, comprising the Chairs of the Scientific Panels and six independent scientific experts who are not part of any of the Scientific Panels, is responsible for the coordination of scientific activities and the harmonisation of working procedures. It also provides opinions on issues which fall within the competences of more than one Scientific Panel.

The Scientific Panels consist of independent scientific experts, with each panel focussing on a different aspect of food safety. Currently, there are ten panels, dealing with issues such as genetically modified organisms, food additives, or food chain contaminants. Before EFSA was established, these tasks were performed by a number of Scientific Committees hosted by the European Commission, such as the Scientific Committee on Food.

EFSA cooperates with a number of stakeholders. It has a close relationship with the European Commission, specifically the Directorate General for Health and Food Safety (DG SANTE), which is also represented on the Management Board, and regularly attends EFSA's scientific and stakeholder meetings as an observer. The Commission is also makes the most use of requests for scientific advice from EFSA, which directly impacts legislative drafts and amendments. There is a clear division between risk assessment, which is conducted by EFSA, and risk management activities, for which the Commission is responsible. Consequently, the Commission will grant market authorisations for products, or draft legislative proposals,

based on EFSA's advice. If the Commission chooses to deviate from EFSA's conclusions, it is required to explain the reasons for doing so. Likewise, it is the Commission that may invoke the precautionary principle if it deems the available amount of scientific data in a certain case insufficient.

The European Parliament also cooperates with EFSA via its ENVI Committee. EFSA's Executive Director is required to brief the committee on the agency's current work and future priorities on an annual basis, in addition to answering questions from MEPs.

EFSA also maintains a number of scientific networks, which consists of over 300 competent organisations, such as universities, institutes, governmental and other scientific bodies. These competent organisations are designated by the Member States, while the eligibility requirements for participation are specified in Commission Regulation 2230/2004.

4.3. Regulation of Genetically Modified Crops

In the European Union, genetically modified crops are regulated by a number of core pieces of legislation. The *Genetically Modified Food and Feed Regulation* (Regulation 1829/2003) covers the authorisation of genetically modified crops in food for human consumption and animal feed. Its objectives are to protect people's lives and health, animal health and welfare, and environmental and consumer interests. The Regulation also establishes a register for genetically modified food and feed, which is available to the public.

The *Deliberate Release Directive* (Directive 2001/18/EC) regulates the cultivation of GM crops. Producers who intend to grow these products within the EU are required to obtain authorisation before doing so, either via the procedure outlined in this directive, or via the integrated procedure specified in Regulation 1829/2003, covering both cultivation and consumption. Recently, the Deliberate Release Directive has been amended by Directive 2015/412, adding a safeguard clause, which allows Member States to restrict or prohibit the cultivation of authorised GM crops in their territory (FIGURE 4.2).

FIGURE 4.2: Member States invoking the Safeguard Clause for GMO Cultivation

SOURCE: *gmo-free-regions.org* (based on European Commission data)

Prohibitions are adopted on a case-by-case basis, must satisfy the principles of proportionality and non-discrimination, and they must be justified on grounds such as

- environmental policy objectives
- town and country planning
- land use
- socioeconomic impacts
- avoidance of GMO presence in other products
- agricultural policy objectives
- public policy.

Currently, 19 countries or regions in the EU are making use of the safeguard clause, meaning that cultivation of GM crops is prohibited in the majority of Member States.

Finally, Regulation 1830/2003 establishes a number of traceability and labelling requirements for products containing GMOs and food and animal feed derived from them. Its purpose is to allow consumers to identify products containing GMOs, and to withdraw these products from the market if environmental or health risks become apparent. The Regulation stipulates that any product with a GMO content of more than 0.9% needs to be labelled accordingly. Products containing less than 0.9% are exempt from this rule, as long as these traces of GMOs are technically unavoidable.

To receive market authorisation in the EU, producers can submit a single application under the Genetically Modified Food and Feed Regulation, which covers the use of a GMO in food for human consumption and animal feed, in addition to its cultivation. This is known as the "one door, one key" principle. Despite the possibility of receiving authorisation for marketing and cultivation simultaneously, stakeholder interviews conducted by van der Meulen and Yusuf (2013) suggest that this option is in fact not as attractive for applicants as it may seem: As an integrated procedure, where authorisations for both uses are granted at the same time, the slower procedure will generally delay the faster one. While risk assessments for consumption are usually completed after three to four years, risk assessment for cultivation can take more than ten years, causing a significant delay for overall authorisation. Likewise, if, based on the dossier submitted by the applicant, authorisation for one use could be granted, while authorisation for the other could not, then the application will be rejected in its entirety, rather than granting partial authorisation. As a result, the applicant may prefer to submit two separate dossiers. The authors conclude that, due to the relatively strict regulatory framework for the cultivation of GMOs in the EU, and the safeguard clause for cultivation invoked by several Member States, applicants often see Europe as a consumption market rather than a production market, meaning that they will only apply for a consumption authorisation and import GM crops from abroad instead of cultivating them locally.

GMO Authorisation Procedure

To receive market authorisation, producers are required to submit an application to a competent national authority, which acknowledges receipt and forwards the application to both EFSA and the Commission[11]. EFSA then has 6 months to assess the application. Subsequently, the Commission prepares a draft measure based on EFSA's scientific opinion,

[11] http://www.efsa.europa.eu/en/efsajournal/pub/3491

either accepting or rejecting the application. Based on the Examination Procedure, outlined in the Comitology Regulation, the draft is then submitted to the Section on Genetically Modified Food & Feed and Environmental Risk of the PAFF Committee. If the Committee is unable to deliver an opinion, the matter is forwarded to the Appeal Committee, which serves as a procedural tool, allowing Member States to discuss the matter at a higher level of representation.

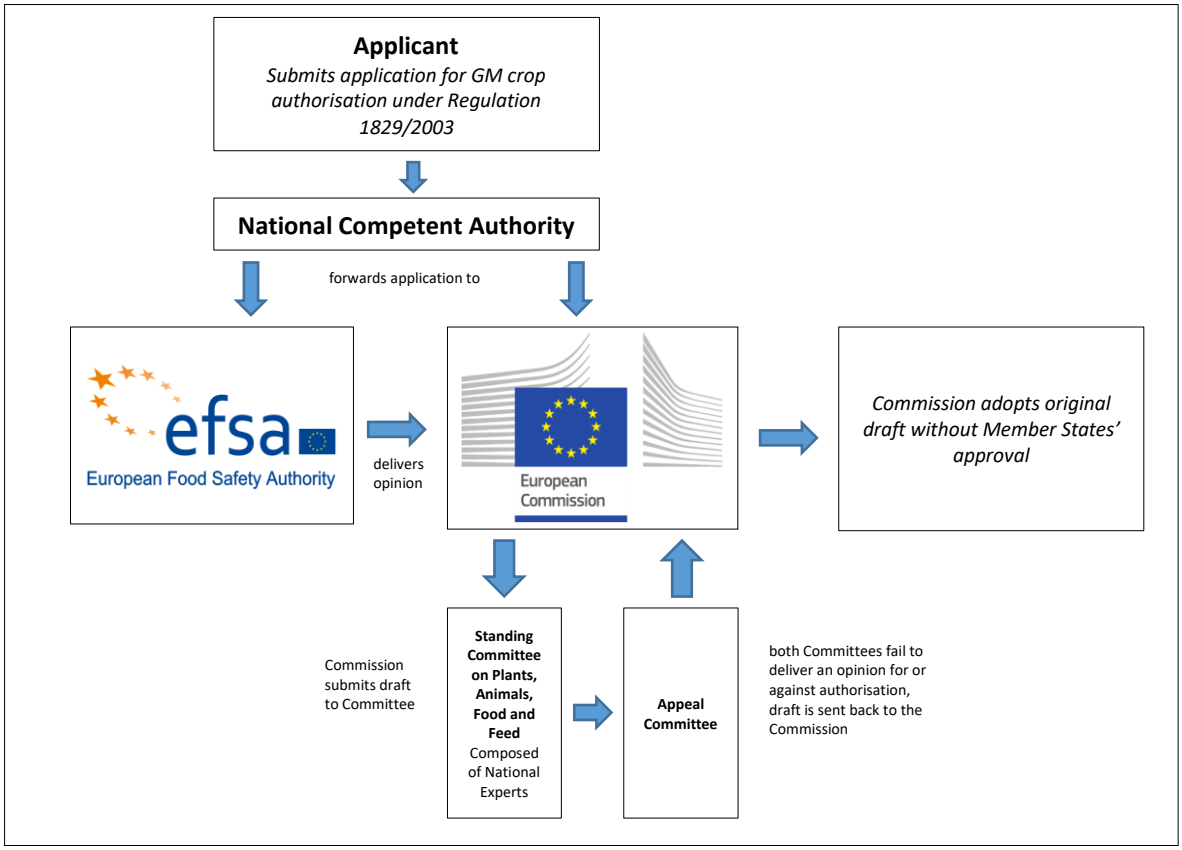
As Christiansen and Polak (2009) explain, the authorisation of GMOs does generally not follow the envisioned procedure (FIGURE 4.3): Since the PAFF Committee is consistently unable to approve or reject the Commission's proposal, the application is sent to the Appeal Committee as a matter of practice. However, since the Appeal Committee is equally divided, it does not deliver a decisive vote either, meaning that the Commission can adopt the original proposal without requiring the Member States' approval. The authors point out that this irregular procedure has become the norm, making the authorisation of GMOs a time-consuming process that lacks political control. They point out that this practice goes against the original idea of Comitology as an efficient process that allows Member States to have a say in important decisions, and also raises questions of political accountability.

The situation is aggravated by the fact that EFSA operates under temporal and budgetary constraints: Since the agency is required to deliver an opinion within 6 months, it is forced to rely on data submitted by the applicant. Consequently, EFSA is de facto conducting a meta-review of the application, rather than independently assessing the safety of GMOs. Compared to the FDA's budget[12] of $4.36 billion, EFSA's annual budget of €73 million[13] is much smaller.

[12] https://www.fda.gov/downloads/Training/ClinicalInvestigatorTrainingCourse/UCM283299.pdf

[13] https://www.efsa.europa.eu/en/efsahow/funding

FIGURE 4.3: Authorisation Process of GMOs in the EU



SOURCE: Own work

Similarly, Timmerman and Andoura (2008) conclude that EFSA possesses *quasi decision-making power*, since the Commission heavily relies on the agency's expertise. In practice, the Commission's decisions will almost inevitably follow EFSA's conclusions and rarely deviate from them. Nevertheless, the formal role of EFSA is restricted to risk assessment, while the Commission is responsible for risk management.

As FIGURE 4.4 shows, the Commission tends to adopt the proposed measure if Member States fail to deliver an opinion. This is particularly true for market authorisations, which must be granted or rejected within a reasonable amount of time, and for which the Commission is inclined to follow EFSA's scientific opinion.

FIGURE 4.4: Overview of Commission Decisions

	No opinions in examination procedure	Commission adopted measure	Commission did not adopt measure
2011	67	63	4
2012	73	70	3
2013	49	47	2

2014	45	42	3
Total	234	222	12

SOURCE: Commission Report on the Implementation of Regulation 182/2011[14]

Finally, FIGURE 4.5 illustrates the various steps the application for a GM crop has to go through based on a concrete example. As shown, the entire application procedure, from the initial application to the granting of market authorisation, takes more than three years. As Chapter 5 will show, the procedure takes much longer than the one applicants in the US generally go through.

FIGURE 4.5: Authorisation timeline of A2704-12, a genetically modified soybean

07/2005	Bayer CropScience AG submits application to the competent authority of the Netherlands, which is forwarded to EFSA
07/2007	EFSA delivers favourable opinion, declaring adverse effects on human or animal health or the environment unlikely
02/2008	Commission presents Draft Decision, but the Committee is divided on the issue (156 votes in favour, 102 votes against, 84 abstentions, 3 votes not represented). The matter is referred to the Council[15].
07/2008	Council confirms the lack of a qualified majority among the Member States required to adopt the decision, the proposal is sent back to the Commission
09/2008	Commission adopts original proposal Authorisation is granted for 10 years, expires in 09/2018

SOURCE: Own work (based on Commission Decision 2008/730/EC)

Regarding the regulatory framework for GMOs in the EU, Van Asselt and Vos (2008) describe a phenomenon known as the uncertainty paradox, a particular pattern of risk regulation that arises in cases where scientific uncertainty is acknowledged, but the role of science is framed as providing certainty. The uncertainty paradox is fuelled by four distinct mechanisms: The first mechanism, uncertainty intolerance, refers to the tendency of various actors to dismiss the possibility of uncertain risks, rather than investigating them systematically. Risk producers, thus biotechnology companies such as Bayer and Monsanto

[14] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016DC0092&from=EN

[15] Under the old Comitology framework, issues were referred to the Council if the Committee failed to deliver an opinion. Following the reform of Comitology, this role is now performed by the Appeal Committee, which generally consists of Member States' permanent representatives to the EU.

who seek market authorisation for their products, typically exhibit this behaviour. Assessments conducted by these companies are focussed on demonstrating no adverse side effects, rather than examining the possibility of uncertain risks. Likewise, they frame the issue in a favourable way by using terms such as 'safety assessment' rather than 'risk assessment', and by avoiding terms such as uncertainty and risk in general. Uncertainty avoidance even goes so far as to dismiss certain evidence as irrelevant: When a rat study conducted by Monsanto showed some abnormal findings in the test group which were not present in the control group, the company claimed that these findings has 'no biological significance' and were 'not test-related', without presenting any evidence or justification (Van Asselt & Vos, 2008).

At the same time, the authors suggest that biotechnology companies are not the only actors exhibiting uncertainty intolerance: The same is true for EFSA's GMO panel, which tends to reject the possibility of scientific uncertainties. On the one hand, this may be the results of risk assessors' inability to recognise the limits of their own knowledge. Another possible reason for this behaviour is that EFSA does in fact conduct meta-reviews of the submitted application, rather than to investigate possible risks independently. Consequently, it is conceivable that EFSA 'inherits' some degree of uncertainty intolerance from the applicant. The authors note that, according to their analysis, EFSA does not deliberately advance or defend the position of the applicant. Rather, the similarities between the assessments of the applicant and EFSA are the result of a shared uncertainty intolerance, as opposed to regulatory capture, of which NGOs such as Friends of the Earth have accused the agency in the past[16].

The second mechanism behind the uncertainty paradox is boundary work. The term refers to the practice of strategically and purposefully drawing boundaries between different realms, for example between science and non-science, or between science and politics. By engaging in boundary work, EFSA has been able to dismiss certain concerns voiced by Member States about the safety of GMOs as non-scientific and as issues of risk management, and therefore falling outside of the agencies mandate. By employing this strategy, EFSA has been able to minimise the scope of its risk assessments, thus avoiding question about uncertainty.

[16] Over the course of this research, no evidence for EFSA's regulatory capture could be identified. Consequently, this analysis is based on the idea that EFSA is fulfilling its role as intended, while possible deviations can be explained by other factors, such as budgetary or temporal restraints. However, it is worth noting that the phenomenon of regulatory capture is difficult to observe, and can therefore not be excluded with absolute certainty.

Thirdly, another contributing mechanism is the tendency to equate uncertainty with risk. While uncertainty-averse actors tend to subscribe to the formula

zero uncertainty = zero risk = 100% safe,

risk protestors such as NGOs and other civil society stakeholders base their reasoning on the idea that

uncertainty = risk = 100% hazard.

Both perspectives fail to recognise the possibility of safe uncertainties. For instance, by pointing to small irregularities not included in an assessment of a GM crop conducted by EFSA, Greenpeace has been able to discredit the agency and raise doubts about the safety of the analysed product. This has led to a politicisation of uncertainties, thus turning risk assessment from a scientific into a political issue.

The final mechanism involved in the uncertainty paradox are technocratic provisions. As outlined earlier in this chapter, the authorisation of GM crops does generally not follow the envisioned procedure, since Member States are divided on the issue. Consequently, the Commission is ultimately empowered to adopt a decision without obtaining a positive committee opinion. The tendency of the Commission to grant market authorisation in these cases, following EFSA's opinion, does make EFSA the de facto risk manager, as opposed to Commission and Member States. This technocratic way of decision-making fails to take societal concerns into account, which indicates a severe political deficit in the process. In conjunction with the fact that the applicant essentially provides risk assessments, and therefore acts as a risk assessor, this highlights the deficiencies of the currently employed procedures.

With its stringent procedures for GMO authorisation, the EU places a strong emphasis on food safety. According to Singer's confidence-competitiveness framework, this would result in a decline of competitiveness for the European biotechnology industry. Evidence shows that the EU's troubled relationship with GMOs has indeed had an impact in the past: Following a de facto moratorium on GMO authorisations before the adoption of the current authorisation framework, a European Commission investigation[17] notes a sharp decline in GMO research. According to the report, field trials for genetically modified crops have dropped by 87%

[17] http://www.europarl.europa.eu/stoa/webdav/shared/3_activities/biotechnology/general/fi_genetechnology_en.pdf

between 1998 and 2003. Furthermore, due to the EU's political antagonism towards GMOs, researches working in the field of biotechnology have experienced difficulties to secure grants.

Reform Proposals

The Commission, having recognised the shortcomings of current Comitology procedures regarding GMO authorisations, and the reluctance of Member States to grant authorisations in general, has made two proposals for amending the current legal framework. The two proposals and their impact on current practices will be discussed in the following.

The first proposal[18], adopted in 2015 and amending Regulation 1829/2003 on Genetically Modified Food and Feed, would allow Member States to impose national bans on the use of GMOs in food and feed, similar to the safeguard clause of the Deliberate Release Directive, which allows Member States to opt out of cultivation for authorised GM crops within their territories. The proposed amendment would require Member States to base their decisions on "compelling grounds", and to notify the Commission of their intentions in advance. Justifications related to health or environmental risks are not permitted, since both are already covered by the risk assessment carried out by EFSA. Furthermore, in cases where new risks associated with already authorised products become apparent, Article 34 of Regulation 1829/2003 and Article 53 and 54 General Food Law already allow both the Commission and Member States to adopt emergency measures to suspend import and market placement of these products. However, unlike the safeguard clause envisioned by the proposed amendment, these measures are temporary in nature.

The addition of a safeguard clause would put an end to the practice of Member States adopting unilateral bans, which have successfully been challenged before national courts or the ECJ in the past. By separating concerns about scientific questions such as product safety and environmental impact from other, political considerations, it may be possible to overcome the current gridlock the GMO authorisation process is facing. At the same time, this approach raises new questions: If scientific risk assessment and political risk management are already institutionally separated, with EFSA evaluating product safety, while Member States and to some extent also the Commission are in charge of risk management, which is a political activity, why would it be necessary to introduce the

[18] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52015PC0177&from=EN

possibility of national restrictions in addition? As noted in the explanatory memorandum of the draft regulation published by the Commission, Member States' concerns voiced in the PAFF Committee are "usually not based on science but on other considerations". Consequently, it seems unlikely that a Member State would vote in favour of granting market authorisation for a GM crop, only to impose a national ban on the use of that same crop in food and animal feed later. At the same time, the proposed amendment would lead to an increased fragmentation of the European Single Market: If the national bans on cultivation (FIGURE 4.1) are at any rate indicative of the bans which would be imposed under this new amendment, the purpose of a centralised authorisation procedure for GMOs would essentially be defeated. Likewise, national bans would be susceptible to challenges in front of the WTO, since they are by definition not based on scientific evidence.

The second proposal[19] tabled by the European Commission is more procedural in nature: It would introduce a number of changes to the Comitology Regulation (Regulation 182/2011). The proposed reform primarily affects the workings of the Appeal Committee, which, as the Report of the Commission on the Implementation of Regulation 182/2011[20] notes, "has mainly been convened in relation to one policy area, namely health and consumer protection, and more specifically in relation to genetically modified food and feed and plant protection products". As a result, the vast majority of decisions taken under the Comitology framework would be unaffected by these changes, while other controversial issues, on which a Committee is unable to deliver an opinion, might equally benefit from the reform.

Under the new rules, Member States which are not represented in the Appeal Committee or abstain from voting would be considered as 'non-participating Member States', meaning that they are not factored into the calculation of the qualified majority required to adopt an opinion. To ensure that decisions are still representative, the Commission envisions a quorum of a simple majority of Member States. The explanatory memorandum for the amendment notes that abstentions have increased the likelihood of no opinion outcomes in the past, forcing the Commission to decide whether or not to authorise a product. By only counting positive and negative votes, it would be easier to attain a majority for or against authorisation in the Appeal Committee.

[19] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017PC0085&from=EN

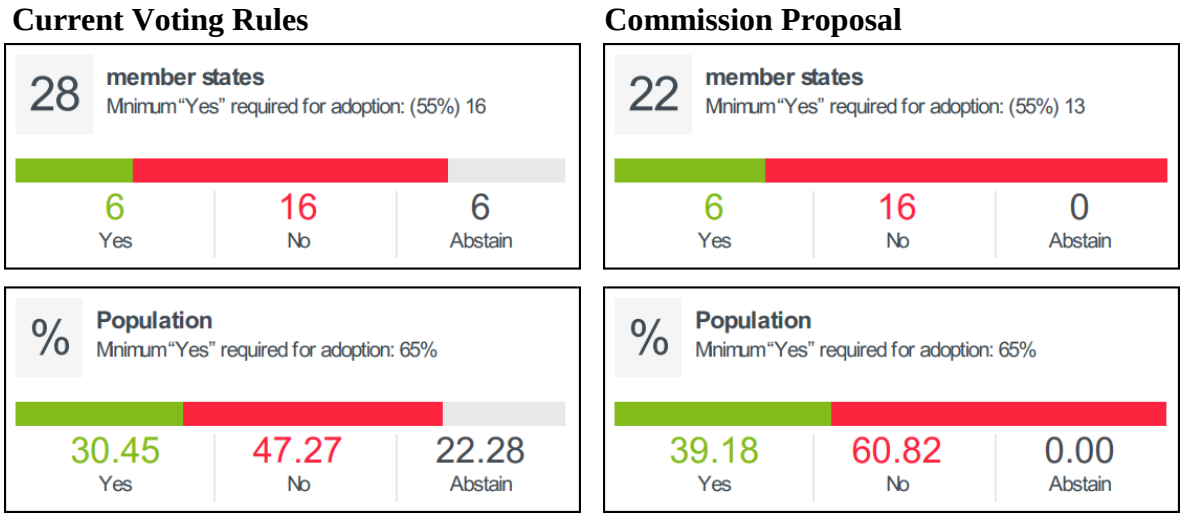
[20] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016DC0092&from=EN

While the Comitology Regulation notes that the Appeal Committee should meet at the "appropriate level of representation", it does not specify further details. In practice, Member States have been represented by their permanent representatives. The proposed amendment would allow the Chair to submit matters to the Appeal Committee for a second time, if a first meeting does not deliver any results, which would then convene at the ministerial level. This would allow Member States to elevate the discussion to a higher political level. As a measure of last resort, the Commission would also be able to refer matters to the Council, in cases where the Appeal Committee is divided. Rather than taking a vote, the Council would then adopt a non-binding resolution, which the Commission can use as political guidance.

The final change proposed by the Commission relates to transparency: While currently, voting in the Appeal Committee is covered by confidentiality rules, meaning that both the contents of the discussion and Member States' voting behaviour are not published, under the new rules, individual Member State votes would be made transparent, thereby clarifying the position of each Member State towards authorisation.

FIGURE 4.6: Outcome of PAFF Committee vote under current and proposed rules

Authorisation of GM maize 1507 and GM maize Bt 11



SOURCE: Own work, based on Data from IFOAM EU[21] and the Council QMV Calculator[22]

As FIGURE 4.6 shows, the proposed change of voting rules would not have made a difference for GM maize 1507 and GM maize Bt 11, two crops for which the Commission presented proposals for authorisation to the PAFF Committee in 2017: Although a qualified majority of

[21] http://www.ifoam-eu.org/en/news/2017/03/27/press-statement-member-states-still-reject-gmo-cultivation

[22] http://www.consilium.europa.eu/en/council-eu/voting-system/voting-calculator/#

Member States against authorisation is reached in both cases, the threshold of 65% of the EU's population is not reached. Consequently, the change of voting rules would not immediately result in a clear majority for or against authorisation. However, it is possible that the six Member States which abstained from voting (Germany, Belgium, Czech Republic, Slovakia, Croatia, and Malta) would either vote against or for authorisation if abstentions would no longer be taken into account. Furthermore, the increased voting transparency could make Member States more susceptible to pressure from their constituents, which is especially true for Member States in which the public is strongly opposed to GMOs. Finally, since the UK is a strong supporter of GMO authorisations and has consistently voted in favour, the declared plans of the British government to withdraw from the European Union could tip the scale towards a negative committee opinion in the future.

4.1. Conclusion

As illustrated, the EU does not employ a fully coherent approach for regulating genetically modified crops. Although a legal framework for authorising crops exists, featuring the scientific expertise from EFSA and political control by the Member States, the latter are generally unable to reach a common position on applications, meaning that the Commission has the final say. This raises questions about political accountability, since it means that products are being authorised by the Commission, an institution that is not directly accountable to the general public, and without explicit consent from the Member States. In addition, the submission of each application to the Appeal Committee, which has de facto become standard procedure for GMO authorisations, causes delays. Consequently, this goes against the idea of the Comitology system as an efficient procedure that allows Member States to exercise control over powers delegated to the Commission.

At the same time, the procedure for GMO authorisation employed by the EU is fairly sophisticated, especially compared to the mechanisms employed by the United States, as Chapter 5 will illustrate: It is a centralised procedure, allowing to producers to receive authorisation for all 28 Member States (and theoretically for both cultivation and use in food) simultaneously. Likewise, scientific risk assessments, conducted by EFSA, are mandatory, and decisions for authorisation include a layer of political control, rather than relying on technocratic provisions entirely. This allows for consideration of both scientific risks, and other factors, which are more difficult to quantify, such as the impact of authorisation on society or the environment. Based on this characterisation alone, it would be reasonable to

assume that the EU's authorisation procedure for GMOs, by taking a large number of factors into account, could serve as a blueprint for other countries trying to regulate the use of GMOs in their territory. However, this perspective would ignore a number of shortcomings that arise in practice: One point of criticism is the rather limited scope of EFSA's risk assessment, which largely rely on data submitted by the applicant and do not involve long-term impact studies or independently conducted tests. This may be owed to the fact that EFSA lacks the resources to conduct such extensive assessments, but also because the agency operates under temporal constraints. A second shortcoming lies in the fact that the Commission has become the de-facto decision maker for market authorisations due to the inability of the responsible committee to deliver a decisive opinion. Instead, both the PAFF Committee and the Appeal Committee have consistently been divided on the issue, with some Member States being in favour, some against authorisation, while others have chosen to abstain from voting. As the summaries of committee meetings published by the European Commission suggest, there are various reasons for negative votes or abstentions, which include negative public opinion; references to the precautionary principle; the lack of a national position on the issue, which could for instance be the result of a coalition government in which the composing parties disagree on the issue of GMOs; the notion that the risk assessment conducted by EFSA was insufficient due to the lack of long-term studies; the existence of uncertainties; or environmental concerns. While some of these issues could be addressed, for example by conducting more rigorous risk assessments which take Member States' concerns into account, others, such as negative public opinion, are much more difficult to remedy.

5 Food Safety Regulation in the United States

In the United States, a number of agencies are involved in the regulatory process, specifically, the US Department of Agriculture (USDA), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). The USDA is responsible for ensuring that products are safe to grow, the EPA monitors the impact on the environment, and finally, the FDA determines whether a product is safe to eat. For the purpose of this research, which is focussed on food safety, primarily, the role of the FDA will be examined, whereas the role of the USDA and the EPA will not be discussed in greater detail.

5.1. Stakeholders and Procedures

In the United States, the process of delegating regulatory competences to a federal agency begins with the adoption of primary legislation by Congress, based on a bill proposed by one of its members. If both houses approve a bill, it is submitted to the president, who can either approve or veto it. If the president signs the bill, it comes into effect and is from that point called an *act* or a *statute*.

Generally, acts adopted by Congress do not specify detailed outcomes, but define general objectives which are to be achieved by means of regulations[23]. In the area of food safety, the basic act might specify that food can only be legally sold if it is safe for human consumption, while leaving it up to the FDA to define testing procedures and threshold values for toxic substances such as pesticide residues. An act can either delegate regulatory competences to an existing federal agency or create a new agency.

The way in which agencies adopt regulations is a three-step process[24]: First, an agency proposes a new regulation, which is also known as a *Notice of Proposed Rulemaking*. The proposal is published in the Federal Register, allowing citizens and stakeholders to submit their view on the proposal within a defined time period. The agency may then revise the proposal based on the comments it received and issue a final rule.

In general, legislators are not involved in the process of federal rulemaking. One exception to this is the *Congressional Review Act*[25], adopted in 1996 under the Clinton administration,

[23] https://www.reginfo.gov/public/jsp/Utilities/faq.jsp

[24] https://www.epa.gov/laws-regulations/basics-regulatory-process

[25] https://www.senate.gov/CRSpubs/316e2dc1-fc69-43cc-979a-dfc24d784c08.pdf

which allows Congress to overrule a new federal regulation by adopting a joint resolution. This 'veto power' can be used within a period of 60 legislative days, meaning days that Congress is in session. Once a rule has been overturned, the agency that proposed the rule is prohibited from adopting a substantially similar rule.

5.2. The United States Food and Drug Administration

The Food and Drug Administration is a federal agency, subordinated to the United States Department of Health and Human Services. The FDA's primary responsibility is to enforce the Federal Food, Drug, and Cosmetic Act, regulating, among other things, food safety, pharmaceutical products, cosmetics, animal food and feed. For the area of food safety, the FDA's mandate is to ensure the security of the food supply and to provide accurate, science-based information to the general public. Head of the agency is the Commissioner of Food and Drugs, appointed by the President after consulting with the Senate. The current Commissioner in office is Scott Gottlieb, who was appointed in May 2017. He reports to the Secretary of Health and Human Services.

In addition to the Commissioner's Office, the FDA consists of four directorates, which oversee the core functions of the agency:

- Office of Foods and Veterinary Medicine
- Office of Medical Products and Tobacco
- Office of Global Regulatory Operations and Policy
- Office of Operations

The Office of Foods and Veterinary Medicine handles matters of food and feed safety and nutrition. Considering the focus of this thesis on food safety, this directorate is of primary concern.

The Office of Medical Products and Tobacco is responsible for the regulation of drugs, medical devices and tobacco products.

The Office of Global Regulatory Operations and Policy is in charge of enforcement, ensuring that producers comply with the requirements of federal legislation. The Office is organised into five regions, each of which are subdivided into a number of districts. It oversees not only domestic, but also international operations, such as safety inspections carried out abroad.

The Office of Operations is responsible for providing agency-wide services, which includes a number of administrative tasks such as financial management, technical support, and facility maintenance.

5.3. Regulation of Genetically Modified Foods

The FDA classifies GM foods as "generally recognised as safe", which means that they do not require special labelling or market authorisation. FDA approval is only necessary if a product contains high levels of toxic substances, allergens or if the levels of nutrients are lower than those of non-modified foods of the same category. Therefore, agency recommends that companies go through a voluntary consultation process to determine that their product does not require approval. Generally, producers can gain an exemption from premarket approval if they are able to demonstrate "substantially equivalence" to other products in terms of composition, nutrition, and safety. The principle of substantial equivalence was employed for the first time in 1994, when the FDA concluded that the genetically modified tomato *Flavr Savr* was equivalent to its non-modified parent plant after conducting a number of field trials and analyses of its molecular and chemical composition between 1992 and 1994 (Schauzu, 2000).

Compared to the EU authorisation procedure for GMOs, outlined in the previous chapter, these voluntary consultations are far less demanding. Essentially, it is up to the applicant to prove that the product under consideration is safe by conducting a safety assessment and submitting the conclusions drawn from this assessment to the FDA. The letter will then confirm that the product does not require premarket approval (FIGURE 5.1). It is worth noting that the applicant, as mentioned in the final paragraph of the FDA's response letter, has a continued responsibility to ensure compliance with the applicable rules and regulations.

Since GMOs are generally considered as safe by the FDA, the agency does not impose any labelling requirements on producers. While some producers have made attempts to introduce a voluntary labelling scheme for non-GM foods, these attempts are plagued by a number of difficulties (Harlander, 2002): Due to the complexity of the food supply chain, with products changing hands 14 to 17 times from raw grain to processed food, tracing is difficult. Although the FDA publishes guidance documents for intending to introduce a voluntary labelling scheme, which require labels to be truthful, non-misleading and any claims to be substantiated by data, there are no established procedures for maintaining GM-free products.

Likewise, there are disagreements about testing methods, with some methods detecting proteins produced by modified crops, while other methods directly test for the presence of modified DNA. The fact that the FDA does not define thresholds GMO-free labelled products

FIGURE 5.1: FDA Response Letter regarding GM Soybean A2704-12

Dear Dr. Van Wert:

This is in regard to AgrEvo's consultation with the Food and Drug Administration (FDA) (Center for Veterinary Medicine and Center for Food Safety and Applied Nutrition) on its glufosinate-tolerant soybean lines A2704-12 and A5547-127. According to AgrEvo, the new soybean varieties have been rendered tolerant to glufosinate ammonium herbicides through expression of a modified phosphinothricin acetyltransferase (pat) gene from Streptomyces viridochromogenes.

As part of bringing the consultation regarding these varieties to closure, you submitted a summary safety and nutritional assessment of the genetically modified soybean varieties on March 31, 1998. This communication informed FDA of the steps taken by AgrEvo to ensure that these products comply with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessment AgrEvo has conducted, it is our understanding that AgrEvo has concluded that the new soybean varieties are not materially different in composition, safety, or any other relevant parameters from soybean lines currently on the market and that they do not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0055 that will be maintained in the Office of Premarket Approval.

Based on the information AgrEvo has presented, we have no further questions concerning these new soybean varieties at this time. However, as you are aware. it is AgrEvo's continued responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,

Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety

SOURCE: FDA

must comply with creates additional uncertainties among producers. Harlander (2002) points out that a number of labelled product showed significant degrees of contamination. Due to the difficulties associated with labelling, but also due to a lack of consumer demand, GMO-free products are a niche market in the US. Labelling would require consumers to pay price premiums, allowing producers to recover the additional costs they incurred for doing so. However, since companies and consumers generally have confidence in the safety of GM crops and the regulatory framework in place. A number of interest groups who actively

campaign against the use of GMOs, such as Friends of the Earth, do in fact not represent the majority of US consumers.

5.4. Systems Recognition

The Systems Recognition procedure, established by the Food Safety Modernization Act (FSMA), allows the FDA to recognise the food safety regulations of third countries as equivalent, if they provide a similar, though not necessarily identical, system of protections, while the country's food safety authority provide similar oversight and monitoring activities for food produced under its jurisdiction.

Due to the uncertain future of TTIP, the EU applied for Systems Recognition in February 2016. As the leaked TTIP chapter on Sanitary and Phytosanitary measures[26] suggests, Systems Recognition would otherwise have been a part of the agreement.

The first step of the Systems Recognition procedure is the International Comparability Assessment Tool, which assesses compatibility between the US food safety system and that of the country under scrutiny. This assessment does not only cover the legal framework and procedures employed by food safety authorities of the third country, but also other aspects, such as training programmes for food safety personnel; efforts to reduce the risk of food borne illness or allergies; whether or not food safety authorities conduct periodic self-assessments to identify their own strengths and weaknesses; reactions to food crises; measures to ensure compliance and the evaluation of their effectiveness; stakeholder and consumer engagement; resources available to the responsible authorities, including staff, equipment and funding; efforts of international cooperation and harmonisation; and access to laboratories to evaluate safety of food products.

In addition, the FDA considers other factors, which include the volume of trade between the US and the assessed country, the number of refusals of admission and reason(s) for refusal, and country reports, in order to determine whether the conclusion of a systems recognition agreement would create tangible benefits for both parties.

The number of assessment criteria illustrates that the Systems Recognition procedure takes a holistic perspective on food safety, rather than limiting the scope to the assessment of formal

[26] https://www.iatp.org/files/2014.07_TTIP_SPS_Chapter_0.pdf

procedures. Consequently, countries which do live up to their own standards have limited chances to complete the assessment successfully.

Until now, only three countries have successfully concluded a Systems Recognition agreement with the US: The first of these two is New Zealand, recognised as equivalent in 2012, while the second is Canada, which was recognised in 2016. In addition, an agreement between the US and Australia was signed in 2017. Regarding the progress of the EU application, an FDA official noted in July 2017 that efforts were still in early stages, while the envisioned scope of the agreement would be comparable to the one concluded with Canada[27]. This would mean that dietary supplements, certain milk and dairy products, and those products regulated by the US Department of Agriculture would be excluded.

5.5. Conclusion

As this chapter has shown, the authorisation procedure for GMOs in the US is far less demanding than the one employed by the EU. Rather than relying on a mandatory market authorisation scheme that determines whether or not a particular GM crop is safe on a case-by-case basis, the FDA only recommends voluntary consultations for producers, while the company which has introduced the crop to the market has the ongoing responsibility of ensuring that it complies with the applicable health and safety regulations. The US system is based on the principle of substantial equivalence, which posits that GMOs can be considered as safe if they do not differ significantly from unmodified crops of the same type.
At the same time, the analysis reveals that the FDA has far more extensive competences than its European counterpart, the Commission. For once, the FDA is empowered to adopt regulations without requiring approval from a committee. The only possibility for the agency's political principal to exercise control over the process of rulemaking is to adopt a joint resolution under the Congressional Review Act. Compared to the way in which the European Commission exercises delegated competences under Article 290 TFEU, the requirements for blocking a proposal are far higher in the US. In the EU, either legislator can object to a proposal from the Commission, in which case it cannot become effective. In the US, a veto requires majorities in both House and Senate. Furthermore, Congressional Review is relatively rare in the US, with only 15 successful uses since the adoption of the act, 14 of which were used recently to revoke regulations adopted under the Obama administration.

[27] http://www.usfoodimports.com/wp-content/uploads/2017/07/EU-Food-Systems-Recognition.pdf

Consequently, it is reasonable to assume that federal agencies in the US generally do not have to anticipate legislative intervention, meaning that they are much less restrained than the Commission, which is frequently required to obtain a positive committee opinion.

6 Interaction

After exploring the regulatory systems employed by the EU and the US in the previous two chapters, the purpose of this chapter is to examine how both of them interact. This will be done in two ways: The first part of the chapter analyses multilateral cooperation, for instance within the context of international organisations such as the World Trade Organisation, the Codex Alimentarius, and the Cartagena Protocol on Biosafety. The second part of the chapter focusses on bilateral interaction, which includes both formal international agreements between the EU and the US (or between sub-state actors such as regulators), and less formalised attempts of cooperation. The purpose of this last chapter of the empirical part is to determine whether the trade relationship between the EU and the US can primarily be characterised by conflict or cooperation.

6.1. The World Trade Organization

The World Trade Organization (WTO) is an international organisation established for the purpose of regulating international trade. Based in Geneva, Switzerland, the WTO became operational in 1995. The organisation incorporates the previously applicable General Agreement on Tariffs and Trade (GATT) from 1948, subject to certain modifications.

Rather than specifying specific outcomes, the WTO provides a framework for trade negotiations. The current multilateral round of trade negotiations is the Doha Development Round, which has been suspended due to ongoing disagreements over agricultural subsidies, tariff and non-tariff barriers, services and trade remedies. As a response to the failure of multilateralism, a number of WTO members have engaged in plurilateral (TPP) or bilateral (TTIP, CETA) negotiations.

The WTO framework is based on a number of principles. The principle of *non-discrimination* stipulates that WTO members must apply the *most favoured nation* rule, thus to treat all other members equally favourably rather than granting preferential treatment to some. Exceptions allow countries to grant preferential treatment to developing countries, regional free trade areas and customs unions. Secondly, the principle requires members to apply *national treatment* to legally imported goods, treating them similarly to those produced domestically.

To avoid free-riding behaviour, the principle of *reciprocity* requires members to reciprocate benefits they gain from unilateral liberalisation.

Finally, the WTO makes use of a *dispute settlement mechanism.* It is used when one WTO member is under the impression that another member is engaging in unfair practices, for instance by using regulations to discriminate against foreign producers and to protect a domestic industry from foreign competition. The case is submitted to a WTO panel, which, after considering all available evidence, rules whether or not a certain practice is in conformity with WTO rules. If a violation is identified, the panel can even authorise the party that incurred damages to establish retaliatory tariffs against the former country as a measure of last resort.

For the area of food safety, a number of specific agreements apply in addition to GATT. The *Sanitary and Phytosanitary Agreement* (SPS) defines conditions under which governments can restrict imports for health reasons, whereas the *Technical Barriers to Trade Agreement* (TBT) deals with technical issues such as labelling requirements and conformity assessment procedures. For issues relating such as patents on GM crops, the *Agreement on Trade-Related Aspects of Intellectual Property* (TRIPS) applies, however, these fall outside the scope of this thesis.

The SPS Agreement, which was negotiated during the WTO's Uruguay round and entered into force in 1995, covers measures that aim to protect human, animal or plant life or health from certain risks. For food safety, these are risks arising from additives, contaminants, toxins, and plant- or animal-carried diseases. Some of the principles which the agreement embodies are that measures must be based on scientific evidence, be no more trade restrictive than necessary, and that they may not arbitrarily or unjustifiably discriminate between cases in which conditions are similar (Article 2.2). Furthermore, they may not constitute a disguised restriction on international trade (Article 2.3).

International standard-setting bodies play a special role in the agreement. While previously, international standards, guidelines and recommendations could be adopted by governments on an entirely voluntary basis, these standards now enjoy an elevated status. Three organisations, also known as the 'three sisters', fall within the scope of the agreement:

- Codex Alimentarius
- World Organization for Animal Health (OIE)
- International Plant Protection Convention (IPPC).

Regarding food safety, Codex Alimentarius is the relevant organisation. Its role will be discussed further in the following section. While standards adopted by these organisations still remain voluntary, compliance with them now leads to a presumption of conformity with the obligations of the SPS agreement. Although governments may still choose to establish higher levels of protection than those envisioned by international standards, or may choose not to use them altogether, they are now required to provide scientific justification for doing so.

In cases where scientific evidence is lacking, governments may adopt provisional measures. This is not an endorsement of the precautionary principle, as the application of such measures must be temporary, and should serve as an opportunity to gather more information in order to conduct a more accurate assessment.

Furthermore, the agreement stipulates that if regulatory regimes of two WTO countries offer the same level of protection, they should accept each other's standards as equivalent on a bilateral or regional basis (Article 4).

To sum up, the WTO's agreements on Technical Barriers to Trade (TBT) and Sanitary and Phytosanitary Measures (SPS) explicitly recognise the right of governments to implement measures to achieve legitimate policy objectives, while prohibiting discriminatory and protectionist measures. Specifically, national measures must satisfy the following criteria (Abbott & Snidal, 2001, p. 361):

- be no more trade-restrictive than necessary
- reflect scientific principles and evidence
- be based on risk assessment
- not draw arbitrary or unjustifiable distinctions
- be based on international standards if they exist.

While these criteria serve as guidelines for trade-friendly and unobtrusive regulations, they are also open for interpretation, and can be used to justify a wide range of measures. Even if we consider scientific risk assessment as an objective and value-free process, the findings it generates can be interpreted in a number of ways, and their interpretation will almost inevitably be influenced by cultural norms and values. Consequently, despite the fact that both the EU and the US are members of the WTO and subscribe to these principles, conflicts about their correct application arise regularly. For the EU, Skogstad (2011) identifies a

tension between internal and external accountability claims: On the one hand, the EU and its Member States are primarily accountable to its citizens via democratic procedures. On the other hand, this can be difficult to reconcile with obligations towards other WTO members. This is partly the result of the WTO's bias towards free trade, which views any regulation that cannot be justified as an unnecessary barrier to trade. As discussed in Chapter 4, the EU's scepticism towards GMOs is however not purely scientific, which explains why regulations have been challenged in the past: In 2003, the US, together with Argentina and Canada submitted a formal complaint to the WTO's dispute settlement mechanism, as a reaction to the EU's moratorium on genetically modified crops. While the moratorium was implemented in anticipation of legal reform in the EU, it effectively banned agricultural products from the US (Strauss, 2008). The established dispute settlement panel ultimately ruled in 2006 that the EU had violated its international obligations under WTO rules by failing to authorise GMOs. The ruling was based on the inability of the EU to provide scientific justifications for the ban, which illustrates how both the US and the WTO lean towards a scientific-rational view on regulation, whether the EU takes a more precautionary stance, which is necessarily at odds with the former.

6.2. The Codex Alimentarius

The Codex Alimentarius, Latin for "Food Code", was established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organisation (WHO). It serves two objectives: To protect public health, and to promote fair and non-discriminatory practices in food trade by developing common standards. The Codex is recognised by the WTO as a reference point for food safety standards. It produces standards, recommendations, and guidelines, which are adopted by the Codex Alimentarius Commission, a body with 188 members, which include both the EU and the US. In addition, 219 organisations participate as observers, including other intergovernmental organisations, NGOs and UN bodies. Members do not have to adopt Codex standards, but are encouraged to do so. In addition, the WTO SPS agreement allows members to adopt more stringent standards if they consider it necessary and can provide scientific justification for doing so.

However, the potential of Codex standards to contribute to regulatory convergence is limited. Although the EU's *General Food Law* explicitly makes reference to the use of international standards in food law, the exact wording of Article 5(3) stipulates that they should only be "taken into consideration", and that this does not include cases where the adoption "would

result in a different level of protection from the one determined as appropriate" for the EU. The same is true for the US: As Sikes (1998) notes, Codex standards often offer less protection than those adopted by the FDA. Furthermore, the standards-setting process lacks public participation and will often result in the adoption of a less-rigorous standards that acts as the lowest common denomination for a large number of countries.

Regarding GMOs, a clear differences between EU and US preferences can be observed in Codex Committee negotiations (Poli, 2004): The European Members of the Commission supported a comprehensive labelling scheme, covering all foods derived from biotechnology, regardless of whether or not they exhibited substantial equivalence to conventional foods. They argued that adequate labelling would be crucial to gain consumers' trust, and that consumers had a right to know how these products were produced. In contrast, the US favoured voluntary labelling requirements for foods which differ substantially from their conventional counterparts, while food that is not substantially different would not require additional labelling. Their argument was based on the ideas that mandatory labelling would give consumers the impression that these foods might be unsafe, and that labelling requirements could act as non-tariff barriers.

These negotiations ultimately resulted in the adoption of a number of guidelines and principles for risk analysis of foods derived from modern biotechnology. They suggest pre-market assessments of GM foods on a case-by-case basis, while explicitly referencing scientific uncertainties, and the need for examining them systematically. Rather than constituting a standard in its own right, these Codex elements can be used by governments as a basis for establishing their own regulatory mechanisms. Furthermore, the possibility of labelling and post-market monitoring as possible strategies of risk management are identified. It is striking how much resemblance these Codex recommendations on case-by-case assessments and scientific uncertainties bear to the regulatory system for GM foods established by the EU, which suggests that the EU has actively been involved in shaping the final outcome of the negotiations. This shows how the EU tries to promote its values and standards externally, just as the US were able to prevent stricter recommendations on labelling obligations. However, as the FAO stresses, these guidelines do not constitute internationally-agreed recommendations on GM food labelling, meaning that governments are free to apply their own regulations.

On the other hand, the WTO frequently makes use to Codex standards, which has led some scholars to argue that they can be considered as *de facto* legally binding (Matthee, 2008): Specifically, the interpretation of the SPS Agreement by WTO dispute panels, which requires members to base their own standards on those developed by the Codex Commission, and the assumption standards adopted in this manner are necessary trade restrictions (presumption of conformity). This should not be surprising, as the purpose of the SPS Agreement is trade liberalisation, as opposed to the dual objectives of food safety and trade facilitation embodied by Codex. Consequently, it is not surprising that the EU-US conflict over GM foods prevented the adoption of a binding, harmonised standard, since it could subsequently be used, depending on which of them dominates the standard-setting procedure, to defend or challenge regulatory decisions of the other party in front of a WTO panel.

6.3. The Cartagena Protocol on Biosafety

Negotiations for the Cartagena Protocol were launched after a number of developing countries voiced concerns that they would become testing grounds for novel and potentially risky substances. Specifically, tests of a genetically modified rabies vaccine by an American research institute in Argentina, without the knowledge or consent of the Argentinian government, served as a catalytic event (Gupta, 2000).

During the negotiations, a number of groups with common positions emerged. The Miami Group, comprising GM crop exporting countries and developed countries with biotechnology industries, such as Argentina, Australia, Canada, Chile, the United States, and Uruguay, favoured free and unrestricted trade of GM products. They argued that a savings clause should be part of the agreement, which would stipulate that WTO rules would have precedence over the protocol. Likewise, any restrictions on GM crop trade should be based on scientific risk assessments. The group was also opposed to the use of the precautionary principle and labelling obligations.

The EU, acting as a common bloc, favoured a protocol with strong obligations for all signatories. Against the backdrop of recent food scandals in the EU, the protocol was seen as an opportunity for adopting higher food safety standards, which would entail compulsory labelling requirements, the use of the precautionary principle, and the omission of a savings clause regarding the protocol's relationship with WTO rules.

The Like-minded Group consisted of developing countries, excluding Argentina, Chile, and Uruguay. Their position came close to that of the EU due to growing domestic concerns in some countries about the use of GMOs, and lobbying activity of NGOs in this area.

Two additional groups, the Compromise Group and the Central and Eastern European Group, emerged during the final days of the negotiations. However, since their respective positions are attempts to find a compromise between the Miami group on the one hand, and the EU and the Like-minded group on the other hand, their contribution to the outcome of the negotiations is of lesser importance (Gupta, 2000).

As Fisher (2009) suggests, the adoption of the Cartagena Protocol is a clear example of an attempt by the EU to reinforce existing internal obligations, such as the use of the precautionary principle, externally.

6.4. Memorandum of Cooperation between EFSA and the FDA

EFSA and the FDA concluded a Memorandum on Scientific Cooperation in 2007. The agreement allows the two agencies to exchange non-public information with each other, including risk assessment methodologies and other scientific data. While the agreement ensures that confidential information, such as product data submitted by applicants, is protected adequately under the applicable legal framework in the EU and the US, it does not create any legal obligations for either agency to share data. Due to the confidential nature of the subject matter, it is difficult to determine how cooperation works in practice, and whether it has led to convergence of assessment methods.

6.5. EU-US Agreement on Sanitary Measures regarding Animal Products

The EU has concluded a number of sanitary and phytosanitary agreements with third countries, including the US. The so-called *Agreement on sanitary measures to protect public and animal health in animals and animal products* (also known as Veterinary Equivalence Agreement), adopted in 1998 and subsequently amended in 2003, 2005, and 2006, essentially constitutes a mutual recognition agreement, recognising various sanitary measures adopted by the EU and the US as equivalent. It applies to both live animals and animal products, while excluding measures related to food additives, processing aids, flavours, colour additives, contaminants, and labelling requirements. TTIP proposals published by the EU

suggest that the agreement would be fully integrated into the treaty's chapter on sanitary and phytosanitary measures, given that negotiations are resumed.

As explained in Annex II of the agreement, which lists the responsible regulatory authorities of each party, regulatory responsibilities are shared between the EU and Member States: While the latter are responsible for enforcement of regulations, inspections, and the issuing of health certificates, the EU is in charge of overall coordination, which includes audits of (national) food safety systems and legislative action to ensure uniform application of regulations across the single market.

In the US, the division of competences is horizontal rather than vertical, involving several agencies and departments: The US Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS) has exclusive responsibility over poultry (defined as any domesticated bird), cattle (such as sheep, swine, goats, and horses), egg products, and processed foods containing more than 3% raw meat or 2% cooked meat. The remaining products animal products, including wild game, meat from other species, unprocessed or hard-boiled eggs, and dairy products, are regulated by the FDA.

The agreement establishes a consultative process, allowing EU and US to identify measures which have similar objectives and offer comparable levels of protection. Once equivalence is established, it is sufficient for producers to comply with domestic regulations when exporting to the respective other party. It is worth noting that the agreement does not establish a strict obligation for recognising equivalence: Instead, determining whether or not a measure of the exporting party satisfies the requirements of the importing party is the sole responsibility of the latter.

To avoid the creation of additional barriers to trade, the agreement establishes information obligations: If either the US or the EU intend to adopt new or modify existing sanitary measures, they are required to inform the other party about their intention of doing so. This also entails the dissemination of scientific evidence on which the proposed measure would be based. Following the notification submitted by the party intending to adopt or modify a measure, the respective other party is given the opportunity to comment on the proposal.

To guide the activities carried out under the agreement, a Joint Management Committee, consisting of EU and US representatives, is established. The task of the committee, which meets at least once a year, is to review the annexes to the agreement, which list the sanitary measures recognised as equivalent (and possible limitations). The recommendations drawn

up by the committee are then used as a basis for modifications. The EU is represented in the committee by the Commission, while US representatives are most likely recruited from USDA and FDA staff.

6.6. Bilateral Cooperation in GMO Regulation

Attempts to harmonise regulatory standards for genetically modified crops date back to the 1990s (Murphy, Levidow, & Carr, 2006). The Transatlantic Business Dialogue (TABD), a network created by EU and US business leaders, began to campaign for liberalisation and regulatory harmonisation in various sectors, including agri-food biotechnology. The TABD championed the idea that the long-term goal for GM crops should be a fully harmonised procedure, following the 'approved once, approved everywhere' principle. These ideas were subsequently picked up by the Transatlantic Economic Partnership (TEP), an EU-US government dialogue established to examine the potential for regulatory harmonisation. The TEP's working group on Biotechnology envisioned a pilot project, which would entail the simultaneous assessment of a GMO by EU and US authorities. The expected outcomes were that either both jurisdictions would draw the same conclusion, or that the project could highlight differences between the two employed approaches, which could then be examined further. The working group brought together representatives of the EU's DG Industry and the US FDA, who engaged in bilateral meetings and compared molecular data requirements for scientific assessments (Pollack & Shaffer, 2009). Despite these regular interactions between both sides, no visible regulatory convergence was achieved.

A second attempt to harmonise regulations was made with the establishment of an EU-US Biotechnology Consultative Forum, composed of twenty independent scientific experts, and civil society stakeholders such as NGO representatives. The forum was tasked to make policy recommendations, and publishes its final report in 2000. While the report endorsed both the EU's and the US' view, it appeared to be skewed towards the former perspective, endorsing pre-market examination of GMOs, the use of the precautionary principle, and mandatory labelling requirements. These elements were either part of the EU's existing legal framework for GMO regulation, or were subsequently adopted. Consequently, the report was initially welcomed by both sides, but subsequently disregarded, rather than forming the basis for regulatory harmonisation.

Regarding attempts to reconcile EU regulatory objectives with the requirements of free trade, Skogstad (2011) identifies a tension between internal and external accountability for GMO regulation: While the EU's authorisation procedures are based on a precautionary culture of risk regulation, which emphasise the role of society in co-producing knowledge, and is sceptical about the capacity of science to know and assess uncertain risks, the United States regulatory culture of the United States is one of scientific rationality. This means that extensive competences are delegated to an independent agency, which uses scientific methods to evaluate risks. Political contestation is largely absent in this model.

At the same time, there is very little pressure for regulators to engage in harmonisation. When applying Singer's confidence-competitiveness framework, it becomes clear that US regulators have a considerably larger win-set, due to the lack of public concern about genetic modification. This means that they do not have to implement stricter regulations to improve confidence, but can keep the level of regulatory stringency at a minimum, thereby maximising competitiveness. In the EU, on the other hand, adjustments are equally unlikely: Regardless of the procedures in place, Member States have repeatedly expressed concerns about GMO approvals, partly due to unfavourable public opinion on the issue. At the same time, GMOs are nevertheless approved by the Commission in virtually all cases due to the inability of Member States to agree on a common position. Adjustments to simplify the authorisation procedure to increase competitiveness on domestic biotechnology companies therefore seem highly unlikely. On the contrary, it would be more likely that Member States would push for stricter procedures, or ban authorisation altogether.

6.7. Conclusion

As shown in this chapter, the EU and the US interact internationally in a number of ways, either on a bilateral or multilateral basis. In the previous two chapters, it has been established that the regulatory approaches employed on both sides of the Atlantic differ significantly in some cases. It is therefore not surprising that this would lead to conflicts when both parties interact. Interactions within the WTO, the Codex Alimentarius Commission, and the negotiations for the Cartagena Protocol on Biosafety show how this conflict materialises in a multilateral context: Both the EU and the US attempt to proliferate their own regulatory approaches externally. The US has made use of the dispute settlement mechanism of the WTO to successfully challenge EU rules, anticipating that the WTO shares its scientific-rational approach to regulation. The EU, on the other hand, has used the Cartagena Protocol

negotiations to codify the precautionary principle in an international agreement by building consensus within a coalition of sympathetic third countries. Both cases are clear examples of attempts to carry out disputes in a friendly forum, as Realists would expect.

On the other hand, it is important to understand that conflicts only account for a small proportion of EU-US trade. Multiple examples of cooperation exist, such as the cooperation agreement between EFSA and the FDA, or the Veterinary Agreement, which establishes mutual recognition for a number of regulations. Likewise, the EU's application for systems recognition suggests that a large potential for harmonisation exists, with the exception of a small number of controversial issues, such as GMO regulation. Contrary to the predictions of the Transgovernmental Network Paradigm, these conflicts are unlikely to be resolved through networking between risk assessors and managers. This is partly the result of the politicisation of these conflicts. While attempts to harmonise rules were made in the past, this has now become increasingly unlikely, and it seems more plausible that the EU and the US will continue to maintain their own, rival standards.

7 Conclusions and Discussion

In this final chapter, the main findings of this research project will be summarised and discussed. It is structured as follows: After recalling the most important results of the empirical part, the implications of these findings for the EU will be discussed. Furthermore, possible limitations to these findings, which might either arise due to the choice of research design or other factors, such as data availability, will be examined. Based on this critical examination, a number of suggestions for further research will be proposed.

7.1. Main Findings

The EU and the US differ significantly in the way in which they regulate food safety. This becomes especially evident when looking at how both jurisdictions deal with GMOs: In the EU, applicants are required to obtain market authorisation before they can sell products containing genetically modified ingredients. For this purpose, a centralised authorisation procedure exists, involving EFSA as a risk assessor and the Commission, assisted by representatives of the 28 Member States, as risk managers. Consequently, the approach employed by the EU relies on both scientific expertise and political control. For authorised GMOs, strict labelling requirements apply, except for cases in which contamination is technically unavoidable and does not exceed the level of 0.9%.

In practice, however, this authorisation scheme does not always work as intended. In virtually all cases, Member States are unable to agree on a common position for or against authorisation, forcing the Commission to make the final decision. This raises questions of accountability, since Member States do not, as originally intended, control the authorisation process by providing political input. Furthermore, it causes delays, which prevents companies to obtain market authorisation within the time period envisioned by the applicable legislation.

The Commission has recognised these deficiencies, and proposed a number of modifications to the current procedure. A proposal to change the voting rules of the responsible committee could potentially have an effect, although it would not immediately lead to a clear majority for or against authorisation immediately. Instead, by not taking abstentions into account, Member States which have remained neutral on the issue until now might see an incentive to adopt a clearer position, either in favour or against authorisation. The second proposal, which would allow Member States to invoke a safeguard clause, allowing them to block the use of

genetically modified ingredients within their territory, is more problematic. It would lead to an increased fragmentation, essentially defeating the point of a centralised authorisation procedure.

Compared to the procedure employed by the EU, marketing of GMOs in the US is less difficult. Producers are encouraged to engage in voluntary consultations with the FDA before introducing a genetically modified crop to the market. Rather than requiring risk assessments on a case-by-case basis, like the EU does, the FDA employs the principle of substantial equivalence, according to which GMOs can be considered as safe if they do not differ significantly from their conventional, unmodified counterparts. In addition, producers are required to ensure that their products are safe.

EU and US both embody two different approaches to risk regulation: While the EU represents a precautionary culture, emphasising the possibility of uncertain risks and the need to ensure a high level of food safety, the US approach is based on a culture of scientific rationality, which is more optimistic about the amount of certainty science can deliver, while downplaying the role of unknowable risks. The EU's perspective has been shaped by a number of food scandals in the past, but also by negative public attitudes towards GMOs. In the US, where the use of GMOs is already far more common, this public backlash has not occurred, which has allowed regulators to maintain a lower level of regulatory stringency. As a result, both EU and US risk managers have reached a regulatory equilibrium, which favours consumer confidence in the EU, and competitiveness in the US. Consequently, incentives to harmonise GMO regulations have been low for regulators on both sides of the Atlantic.

EU and US also differ in terms of how they delegate competences to agencies: In the EU, the Commission is required to obtain a positive Committee opinion whenever it wants to exercise delegated competences. Furthermore, both Council and Parliament can unilaterally decide to revoke delegation altogether. In the US, Congressional Review of regulations adopted by federal agencies is relatively rare, meaning that the FDA does generally not have to anticipate political intervention, and is therefore much less constrained than the Commission.

As illustrated in the empirical part, EFSA cannot be considered as a regulatory agency like the FDA. Instead, the European counterpart to the FDA is the Commission, due to the division of risk assessment and risk management employed in the EU, whereas EFSA's role is to provide scientific expertise and to evaluate applications. Although the Commission cannot issue regulations like the FDA, it can initiate new legislative proposals, taking

international developments into account, or modify existing legislation via the Comitology procedure. While the Commission may not have exclusive regulatory competences in the area of food safety, it is the only body of the EU that regulates food, whereas the FDA shares competences horizontally with other agencies such as the

- US Department of Agriculture (USDA)
- Animal and Plant Health Inspection Service (APHIS)
- Department of the Interior (DOI)
- Fish and Wildlife Service (FWS)
- Food Safety Inspection Service (FSIS)
- Department of Commerce (DOC)
- National Marine Fisheries Service (NMFS)
- Agricultural Marketing Service (AMS)

This puts the Commission in an advantageous position, enabling it to negotiate comprehensive equivalence agreements with third countries on behalf of the entire EU. For the US, this is much more difficult, since the FDA lacks this extensive scope. As a result, food safety systems recognition negotiations between the FDA and the Commission can only cover those products for which the FDA possesses the required competences, while most animal products, which fall under the jurisdiction of the USDA, are excluded.

As predicted by Drezner (2008), both EU and US have attempted to make use of friendly fora to proliferate their respective standards. For the EU, the negotiations of the Cartagena protocol were used as a vehicle to codify the use of the precautionary principle with regards to GMO regulation in an international agreement. The US have made use of the WTO framework, which exhibits a bias towards free trade by design, to question EU regulations that they perceive as unnecessary barriers to trade.

At the same time, following Slaughter's (2009) logic, several instances of networking between EU and US could be observed. This includes a Memorandum of Cooperation between EFSA and the FDA on the exchange of confidential information, and cooperation between the EU and the US within the framework of the Veterinary agreement. It is difficult to determine whether cooperation has in fact led to convergence of regulations or assessment methods. Instead, it seems more likely that mutual recognition of equivalent standards is the rule, while non-compatible standards are excluded. While the US Food Safety Modernisation

Act has led to a shift from performance to process standards, it is difficult to solely attribute this change to interaction with the EU, which employs a similar approach.

Answering the question whether or not cooperation between EU and US authorities has led to convergence of regulations over time is more difficult. While the US Food Safety Modernization Act has led to a shift from performance to process standards, resembling the EU's *farm to fork* approach, which also focusses on the production process, this shift cannot easily be interpreted as convergence.

At the same, attempts of private actors to establish transatlantic networks could be observed, for instance the Transatlantic Business Dialogue. Although networking of private actors was not the main focus of this thesis, such attempts could indicate that while private actors are advocating regulatory harmonisation or mutual recognition as a strategy to reduce costs, these demands are not always met by political actors, or are difficult to implement due to the idiosyncrasies of the political process.

7.2. Implications for the EU

Although the EU employs a market authorisation scheme that relies on both scientific expertise and political input, it is difficult to consider this a sound system, as Member States are unable to adopt a common position, making the Commission responsible for adopting the final decision. If the EU intends to become a global standard-setter for GMO authorisation practices, it needs to demonstrate that the current procedures work, or make appropriate adjustments. One option would be to broaden the scope of EFSA's risk assessments, allowing for the inclusion of other assessment criteria, such as environmental or societal impact. Likewise, EFSA's reliance on data submitted by the applicant, and the agency's uncertainty avoidance has narrowed the scope of assessments, a problem that is aggravated by budgetary and temporal constraints. Similar criticism can be directed at the risk managers: Member States need to agree on a level of scientific certainty which they deem acceptable, or block GMO authorisations on other grounds.

If the US-EU systems recognition process succeeds, mutual recognition will be established for most categories of foods. Animal products are already covered by the veterinary agreement adopted in 1998, whereas non-animal products would be covered by the systems recognition agreement. It is worth noting that regulatory cooperation in the area of food safety has generally not lead to the adoption of common standards. Instead, both the EU and

the US have recognised that different food safety measures can be considered as equivalent if the levels of protection they offer are comparable. Consequently, mutual recognition, rather than harmonisation is the most common strategy to facilitate trade.

In a number of areas, such as GMOs, but also the use of chlorine for disinfection, and growth hormones for beef, convergence between the EU and the US is highly unlikely, and they will most likely be excluded from any EU-US trade agreement. Consequently, US companies are still required to obtain market approval for GMOs in order to gain access to the European market, or to comply with EU sanitary regulations in areas where no equivalence agreement could be reached. One reason for the persistence of these conflicts is the politicisation of these issues: Previously, attempts to launch a pilot project on GMO safety assessments were made, which could have enhanced mutual understanding of the respective perspectives EU and US risk assessors. The EU could have benefitted from recognising what an acceptable level of scientific certainty constitutes, rather than perpetually invoking the precautionary principle by raising new safety concerns, whereas for the US, this could have resulted in an appreciation of the EU's perspective on food-related risks, influenced by a number of food scandals, and the resulting need for a comprehensive regulatory framework.

There is some evidence that the US approach to food safety has been criticised by EU officials as insufficient. Specifically, the of use of chlorine to disinfect meat, which is common in the US, is not permitted in the EU, due to concerns that a "single preventive measure" might compromise food safety[28]. While the EU does not necessarily consider the use of chlorine as a risk to humans, the main purpose of its regulatory framework is to avoid contamination rather than to removing it. However, it was impossible to find statements from US officials that would indicate that the EU approach served as a reference point for the reform.

7.3. Limitations

Due to the author's personal background, this research was written from a European perspective. Consequently, it is possible that the analysis of the EU's regulatory framework and institutions was in some aspects more rigorous than that of the US due to the existence of prior knowledge. This does however not necessarily constitute a shortcoming, since the primary objective of this project was to examine the implications of a possible trade

[28] http://europa.eu/rapid/press-release_MEMO-97-37_en.htm

agreement for the EU, and to identify deficiencies of the regulatory framework currently in place.

A second limitation relates to data availability. In several cases, it has proven difficult to obtain data on the extent of cooperation between EU and US. Specifically, it was not possible to determine the scope of a cooperation agreement concluded between EFSA and the FDA, and whether it has led to convergence of risk assessment methods. Similarly, the voting behaviour of Member States in the PAFF Committee could only partly be examined by making use of secondary literature, while raw data could not be obtained to confidentiality rules.

7.4. Recommendations for Further Research

This research project was originally conceived within the context of the TTIP negotiations, and concerns that the agreement might lower European standards, specifically in the area of food safety. As a result, conflicts over different approaches towards food safety regulation have received a considerable amount of attention. However, food safety is only one of many areas for transatlantic regulatory cooperation. Further research could explore the current state of affairs for other product categories. For instance, EU and US have recently concluded a comprehensive agreement on medicine inspections[29], which allows regulators of both jurisdictions to exchange confidential information. While this project specifically focussed on one controversial issue, namely GMO regulation, it is likely that convergence between regulations can be observed in other areas. Examining these issues could help to gain a more comprehensive understanding of the EU-US trade relationship.

29 http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/08/news_detail_002800.jsp&mid=WC0b01ac058004d5c1

Bibliography

Abbott, K. W., & Snidal, D. (2001). International 'standards' and international governance. *Journal of European Public Policy, 8*(3), 345-370.

Akerlof, G. (1970). The Market for "Lemons": Quality Uncertainty and the Market Mechanism. *Quarterly Journal of Economics, 84*(3), 488-500.

Baldwin, R., Cave, M., & Lodge, M. (2012). *Understanding regulation: theory, strategy, and practice*: Oxford University Press.

Christiansen, T., & Polak, J. (2009). Comitology between political decision-making and technocratic governance: regulating GMOs in the European Union. *EIPAScope, 2009*(1), 7.

Curtin, D. (2005). Delegation to EU non-majoritarian agencies and emerging practices of public accountability.

Dehousse, R. (2008). Delegation of powers in the European Union: The need for a multi-principals model. *West European Politics, 31*(4), 789-805.

Drezner, D. W. (2008). *All politics is global: Explaining international regulatory regimes*: Princeton University Press.

Fisher, E. (2009). Opening Pandora's box: contextualising the precautionary principle in the European Union. *Uncertain risks regulated. Routledge-Cavendish, Abingdon, UK*, 21-45.

Gollier, C., & Treich, N. (2003). Decision-making under scientific uncertainty: the economics of the precautionary principle. *Journal of Risk and Uncertainty, 27*(1), 77-103.

Gupta, A. (2000). Governing trade in genetically modified organisms: The Cartagena Protocol on Biosafety. *Environment: Science and Policy for Sustainable Development, 42*(4), 22-33.

Hardacre, A., & Kaeding, M. (2011). Delegated & Implementing Acts The New Comitology. *EIPA Essential Guide, 4*.

Harlander, S. K. (2002). Safety assessments and public concern for genetically modified food products: the American view. *Toxicologic pathology, 30*(1), 132-134.

Haselton, M. G., & Buss, D. M. (2000). Error management theory: a new perspective on biases in cross-sex mind reading. *Journal of personality and social psychology, 78*(1), 81.

Henson, S., & Traill, B. (1993). The demand for food safety: Market imperfections and the role of government. *Food Policy, 18*(2), 152-162.

Kahler, M. (2015). *Networked politics: agency, power, and governance*: Cornell University Press.

Katz, A. (2007). Pharmaceutical lemons: innovation and regulation in the drug industry. *Michigan Telecommunications and Technology Law Review, 14*(1), 1-41.

Kelemen, R. D., & Tarrant, A. D. (2011). The political foundations of the Eurocracy. *West European Politics, 34*(5), 922-947.

Majone, G. (1997). The new European agencies: regulation by information. *Journal of European Public Policy, 4*(2), 262-275.

Makkai, T., & Braithwaite, J. (1992). In and out of the revolving door: Making sense of regulatory capture. *Journal of Public Policy, 12*(01), 61-78.

Matthee, M. D. (2008). The Codex Alimentarius Commission and its food safety measures in the light of their new status. *Uncertain risks regulated*, 323.

Murphy, J., Levidow, L., & Carr, S. (2006). Regulatory standards for environmental risks: understanding the US-European Union conflict over genetically modified crops. *Social Studies of Science, 36*(1), 133-160.

Pelkmans, J. (2012). Mutual recognition: economic and regulatory logic in goods and services. *Research Handbook on the economics of EU law, Cheltenham: E. Elgar*, 113-145.

Poli, S. (2004). The European Community and the adoption of international food standards within the Codex Alimentarius Commission. *European Law Journal, 10*(5), 613-630.

Pollack, M. A., & Shaffer, G. C. (2009). *When cooperation fails: The international law and politics of genetically modified foods*: Oxford University Press on Demand.

Posner, E. (2009). Making rules for global finance: transatlantic regulatory cooperation at the turn of the millennium. *International Organization, 63*(04), 665-699.

Sandin, P. (1999). Dimensions of the precautionary principle. *Human and Ecological Risk Assessment: An International Journal, 5*(5), 889-907.

Schauzu, M. (2000). The concept of substantial equivalence in safety assessment of foods derived from genetically modified organisms. *AgBiotechNet, 2*(044), 1-4.

Shapiro, M. (1997). The problems of independent agencies in the United States and the European Union. *Journal of European Public Policy, 4*(2), 276-277.

Sikes, L. (1998). FDA's consideration of Codex Alimentarius Standards in light of international trade agreements. *Food & Drug LJ, 53*, 327.

Singer, D. A. (2004). Capital rules: The domestic politics of international regulatory harmonization. *International Organization, 58*(03), 531-565.

Skogstad, G. (2011). Contested accountability claims and GMO regulation in the European Union. *JCMS: Journal of Common Market Studies, 49*(4), 895-915.

Slaughter, A.-M. (2009). *A new world order*: Princeton University Press.

Strauss, D. M. (2008). Feast or famine: the impact of the WTO decision favoring the US biotechnology industry in the EU ban of genetically modified foods. *American Business Law Journal, 45*(4), 775-826.

Tallberg, J. (2002). Delegation to supranational institutions: why, how, and with what consequences? *West European Politics, 25*(1), 23-46.

Thatcher, M. (2002). Delegation to independent regulatory agencies: Pressures, functions and contextual mediation. *West European Politics, 25*(1), 125-147.

Thatcher, M., & Stone Sweet, A. (2002). Theory and practice of delegation to non-majoritarian institutions. *West European Politics, 25*(1), 1-22.

Timmerman, P., & Andoura, S. (2008). Governance of the EU: The reform debate on European agencies reignited.

Van Asselt, M. B., & Vos, E. (2008). Wrestling with uncertain risks: EU regulation of GMOs and the uncertainty paradox. *Journal of risk research*, *11*(1-2), 281-300.

van der Meulen, B. M. (2013). The structure of European food law. *Laws*, *2*(2), 69-98.

van der Meulen, B. M., & Yusuf, N. (2013). One-Door-One-Key Principle: Observations regarding Integration of GM Authorization Procedures in the EU. *Penn St. L. Rev.*, *118*, 877.

World Health Organization. (1995). *Application of Risk Analysis to Food Standards Issues*. Report of the Joint FAO/WHO Expert Consultation. Retrieved from http://apps.who.int/iris/bitstream/10665/58913/1/WHO_FNU_FOS_95.3.pdf.

Legislation

Regulation 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 [*General Food Law*], 2002 O.J. L 31/1

Regulation 1829/2003 on Genetically Modified Food and Feed, 2003 O.J. L 268/1

Regulation 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms [*Traceability and Labelling Regulation*], 2003 O.J. L 268/24

Regulation 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers [*Comitology Regulation*], 2001 O.J. L 55/13

Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms [*Deliberate Release Directive*], 2001 O.J. L 106/1

Commission Regulation 2230/2004 laying down detailed rules for the implementation of Regulation 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority's mission, 2004 O.J. L 379/64

Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission [*Comitology Decision*], 1999 O.J. L 184/23

Agreement between the European Community and the United States of America on sanitary measures to protect public and animal health in trade in live animals and animal products [*Veterinary Equivalence Agreement*], 1998 O.J. L 118/3

Proposal for a Regulation amending Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, COM(2017) 85 final

Proposal for a Regulation amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory, COM(2015) 177 final