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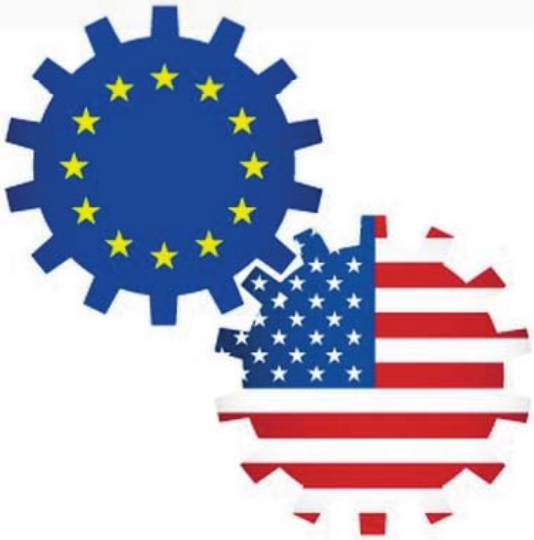
DISSERTATION

TTIP: EU GMO policy alignment?



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Executive Summary

TTIP was launched in 2013 and aims at tackling non-tariff trade barriers and foster regulatory cooperation between the US and the EU. The focus of this research is to measure the extent to which the TTIP agreement is going to result in an alignment of EU GMO policy with that of the US.

The literature review provides a critical background to the key issues. As to the definition, the term GMO will be used as referring to organisms that serve for the production of food and feed into which foreign genes have been inserted. Benefits of GMOs relate mainly to farmer efficiency and product qualities. Risk can be classified as environmental risks, those to humans and animals and ethical concerns. Turning to the GMO regulatory frameworks, developments were quite similar across the Atlantic until the 1990s. However, the legislation that is in place now is characterized by fundamentally different approaches. US legislation sets out that GMO assessment is based on a product-based approach that views GMOs as being substantially equivalent to their non-GM counterparts. In the EU a process-based approach is chosen that views GMOs as effectively different from their non-GM counterparts and the precautionary principle is applied, which allows banning a product when there is not sufficient evidence to guarantee its safety. A safeguard clause furthermore allows individual Member States to provisionally ban or restrict GMOs on their territory and labeling of GM products is made obligatory. The authors that were investigated in the literature review agree that there is a politicization of the EU regulatory process and that non-compliance with established timelines results in GMO applications getting stuck in the process. The last part of the literature review, ‘EU-US Trade Relations over GMOs’ points out that the trade of GMOs is currently disrupted and that this adversely affects various parties in the US as well as in the EU. It continues to explain reasons for these diverging policies and thus the trade disruption, including cultural factors with European preferences towards somewhat more ‘natural’ foods, a ‘romantic’ perception of agriculture and the emergence of risk-adverse policies in Europe. Proposed solutions to the transatlantic trade dispute mainly relate to mutual tolerance and proper application of the rules, rather than suggesting regulatory convergence. Overall, the literature review revealed a gap of research concerning TTIP’s potential effects on GMO policies. Hence, the research objective is to help fill this gap.

The method that was chosen to do so was obtaining data through the qualitative mixed method approach, gathering data by both carrying out six extensive elite-interviews with relevant stakeholder groups as well as desk research to substantiate these. The answer to the research question will be deliberated in light of stakeholder discussion of policy alignment as well as an evaluation of previous negotiation documents.

This research produced a number of key findings. Firstly, it became apparent that the different stakeholder groups have different levels of risk perceptions and positions on GMOs that are at conflict. Secondly, it was discovered that the stakeholders have different roles in TTIP negotiations that determine the extent to which they can influence their outcome. Relating to the opportunities stakeholders see in TTIP, they named mutual economic growth, a normalization of trade, and strengthening common values that result in a proper GMO assessment. Some look at TTIP more critically, perceiving a risk related to a weakening of standards. It is generally unlikely that the GMO issue will pose a threat to an overall agreement as it only constitutes a minor part. However, high expectations about a normalization of trade on the US side seem to put pressure on the EU to properly apply their system. Regarding EU risk assessment, stakeholders were to a great extent happy with the science-based assessment carried out by EFSA. Most stakeholders expressed their greatest critique on the risk management stage, pointing to current non-compliance with EU law and timelines. Abuses of the precautionary principle are moreover criticized. In contrast to the others, the activist group condemns the system itself, stressing that EFSA is asked to provide an assessment based on insufficient scientific data. As to the outcomes of TTIP, most stakeholders agreed that an actual change in policy and regulation is unlikely to occur. Stakeholder discussions hint to TTIP as being a likely catalyzer to strengthen the application of rules within the existing EU framework.

This dissertation came to the conclusion that the TTIP agreement is very unlikely to result in a GMO policy alignment in the EU with that of the US, due to a deeply entrenched policy framework and a fundamentally different risk culture. However, both the willingness to negotiate the issue within TTIP and pressures to end the trade disruption are likely to reinforce a more accurate and timely application of the EU system and furthermore establish an increased flow and exchange of information. If a substantial policy alignment were ever to be achieved, a bottom-up approach would have to be applied.

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List of Abbreviations

DG	Directorate General
DG SANCO	DG Health and Consumers
EC	European Commission
EFSA	European Food and Safety Association
EGC	General Court of the EU
EP	European Parliament
EPA	Environmental Protection Agency
EU	European Union
EuropaBio	European Association for Bioindustries
FDA	Food and Drug Agency
GE	Genetically Engineered
GEO	Genetically Engineered Organism
GM	Genetically Modified
GMO	Genetically Modified Organism
SPS	Sanitary and Phytosanitary
TTIP	Transatlantic Trade and Investment Partnership
US	United States
USDA	US Department of Agriculture
USTR	Office of the United States Trade Representative

Introduction

"America and Europe have done extraordinary things together before. And I believe we can forge an economic alliance as strong as our diplomatic and security alliances."

US President Barack Obama about the Transatlantic Trade and Investment Partnership (TTIP) (as quoted in US Department of State, 2013)

Negotiations on the TTIP have been launched in July 2013. If successful, the trade partnership would constitute "the biggest bilateral trade deal ever negotiated" (EC, 2013a) and establish a huge free trade zone. Given the fact that the tariffs that will be removed are already quite low with averages lying under three percent (EC, 2013a), the tackling of non-tariff barriers and thus closer regulatory cooperation between US and EU to eliminate duplication of effort wherever possible poses a key issue. As the US Department of State (2013) declared during the first negotiation round in Washington D.C. from July 7-12, 2013, "TTIP will seek to break new ground by addressing bilateral *non-tariff barriers*". "Improved cooperation when it comes to setting international standards" (EC, 2014c) is among the other objectives. This trade agreement affects trade in all areas, agriculture and genetically modified organisms (GMOs) being just one of them. So far, five negotiation rounds have taken place, the latest one to date in Washington D.C. from May 19-23, 2014 (EC, 2014b).

Non-tariff barriers originate from diverging regulatory systems. Next to GMOs, the EU and the US have different regulatory approaches when it comes to granting market access to a number of products and technologies, including beef from cattle treated with growth hormones, food additives, nanotechnology, chlorine-washed chicken and animal testing, to name only a few (Lynch & Vogel, 2001; Pollack, 2013b). GMOs are relatively new; the molecular DNA structure was only discovered in 1953 by Crick and Watson (BBC, 2014) (see figure 1). The technology of genetic engineering has

Figure 1: DNA double helix.

been commercialized since 1976 (Calton, 2013) and the effects that modifying genes have on foods and their consumers is continuously being explored. Generally speaking, the US claims to have a "science-based" approach while it accuses the EU to have in place a more "politicized system" (Pollack, 2013b). Europe justifies its approach by the so-called precautionary principle that allows restricting market access of a certain product that might be hazardous if there is insufficient scientific data available. In the context of the TTIP negotiations, the discussions on GMO-related topics are a key issue where finding a compromise is proving difficult.

The debate on GMOs is complex, and there are many competing interests at stake. As Zerbe (2007) points out, "Consumers, farmers, seed producers, pharmaceutical companies, governments, and activists all have an interest in the outcome of debates over the emerging regulatory system". Stakeholders such as Greenpeace question the safety of GMOs for the environment at large, while multinationals such as Monsanto, a seed producing company, are keen to sell GMOs in Europe and industry associations like the European Association for Bioindustries (EuropaBio) are supporting them in doing so. Next to activist groups there are also governments of Member States in the EU like Austria who stress the lack of sufficient scientific risk evidence on the subject (GMO Compass, 2013). Responding to all these concerns, the European Commission (EC), who is responsible for managing risk in the EU and has to take into account the science-based risk assessments the European Food Safety Authority (EFSA) carries out, adopts a precautionary policy towards GMOs. As complex as the debate itself is its nature with various inter-related issues such as food safety, environmental protection, public health, and competitive advantage in agricultural technologies.

This dissertation is an attempt to determine the extent to which negotiations on the TTIP will alter GMO policies in the EU, the research question being,

To what extent will the Transatlantic Trade and Investment Partnership result in an alignment of European Union Genetically Modified Organisms policy with that of the United States?

Research Objectives

In order to answer the research question, four research objectives were formulated to enable a systematic evaluation:

1. *Investigation* of the EU and US GMO policies and standards and their evolution since the emergence of genetic engineering
2. *Examination* of the impact of these policies on GMO trade between the two parties, discussing reasons for and solutions to the trade disruption
3. *Exploration* of high-level trade representatives', civil servants' and other relevant stakeholders' opinions on the impact of TTIP on EU GMO policy
4. *Evaluation* of the extent to which TTIP is going to impact EU GMO policies

Structure

The report has been structured as follows in order to methodically meet each research objective. It begins with a Literature Review that has two purposes. It firstly aims at providing the reader with a basic understanding of GMOs generally and secondly reviews literature that is relevant for the purpose of this study. Thereby it addresses the first two research objectives. The Research Methods chapter that follows explains the methods chosen within this dissertation. As you will find, a qualitative mixed methods approach was applied through conducting six elite-interviews supplemented and substantiated by desk research. Next, a Findings section will present the data collected. This section addresses objective 3. An analysis chapter follows to meet the forth objective by discussing the findings in the light of the examined literature and research question. Finally, a Conclusion section summarizes the findings and provides an answer to the research question. Additionally, recommendations are made.

Literature on GMO Policies and their Impact on Transatlantic Trade

This Literature Review will discuss the key topics related to the subject of this dissertation. The study within this review focuses on objectives 1 and 2 as described in under the research objectives section. A sensible point of departure is to examine what is meant by the term GMO, and what benefits and risks are associated; this will be done in the first section. Next, the evolution of biotechnology regulation until present legislation in both regions will be laid out, so that the reader becomes aware of policy divergence and understands how GMOs are regulated in North America and the EU. Having explored to what extent differences exist, the underlying reasons for these will be discovered in the following section – 'Trade Relations between the EU and the US over GMOs' – also discussing implications of the trade disruption. Additionally, academic views on proposed solutions to the GMO trade conflict will be analyzed and contrasted.

After this major chapter, a clear focus will hopefully have emerged, justifying the need for research on the impact of TTIP on EU GMO policy alignment.

GMOs: Definitions and Benefit/Risk Analysis

Definitions

The Dictionary of Biology (Martin & Hine, 2008) defines GMOs, sometimes also referred to as transgenics or genetically engineered organisms (GEOs), as organisms "created by genetic engineering […] whose genomes incorporate and express genes from another species". These organisms "can exhibit quite novel characteristics". The Encyclopedia Britannica (Diaz & Fridovich-Keil, 2013) gives a similar definition, emphasizing the novel characteristics, which "would not be obtained easily through conventional selective breeding". While Feldmann et al. (2000) and Verma et al.'s (2011) definitions are generally similar, they restrict the term 'organisms' to plants, animals, and bacteria, and exclude human beings. Thus, general consensus on the 'GM' part of the term exists; however, some authors leave the 'O', the definition for organisms, more open than others.

In order to clarify the term genetically modified foods (GM foods) Verma et al. includes this term by definition, stating that "the term GM foods or GMOs […] is most commonly used to refer to crop plants created for human or animal consumption using the latest molecular biology techniques" (2011). The EC, in contrast, puts more emphasis on the difference between GM foods and GMOs: "Organisms, such as plants and animals, whose genetic material (DNA) has been altered in such way are called genetically modified organisms (GMOs). The food and feed which contain or consist of

such GMOs, or are produced from GMOs, are called genetically modified (GM) food or feed" (DG Health and Consumers, 2014). Within this dissertation the importing of GM foods will be differentiated from the cultivation of (imported) GMOs in the EU in conformity to the distinction provided by the EC.

The United States Food and Drug Administration (FDA) (2014) does not define GMOs explicitly, but rather the method used to obtain them. Thus, the term 'genetic engineering' (GE) – which is different from traditional breeding techniques in so far that *modern* biotechnology is applied – is referred to as "methods that scientists use to introduce new traits or characteristics to an organism […] to produce characteristics that enhance the growth or nutritional value of food crops". The emphasis is therefore put on the engineering process, while the outcome (the GMO) does not seem to require an explicit definition.

Overall there is a general consensus amongst academics when it comes to defining GMOs and differences lie primarily in wording and depth of detail. Within this report the term GMO(s) will be used in connection with organisms that serve for the production of food and feed into which foreign genes have been inserted using genetic engineering techniques, thus adhering to Feldmann et al. (2000) and Verma et al.'s (2011) definitions that constrain the term to plants, excluding animals, bacteria and humans. This will be done since trade of such agricultural products is one of the primary focuses of TTIP negotiations in the sense that it has been facing most challenges in the past as will be seen. Having clarified what GMOs are, we will now examine scientific opinions on their benefits and risks.

Benefits and Risks

It seems, opinions that different stakeholders have about GMOs depend on the weight that each party gives to the opportunities and risks associated with GMOs. These stakeholders then (try to) influence the TTIP negotiations based on their views. Somerville (2000) brings the nature of the discussion on GMOs to the point when he declares that the "opponents of the technology have framed the issue as black and white – GMOs are dangerous and must be stopped. Proponents are faced with the difficult task of trying to educate the public about the many shades of gray". In this section these different 'shades of gray' will be looked at, providing an overview of scientific literature on GMO benefits and risks.

Benefits

Feldman et al. (2000) state two main purposes related to genetically modified crops, not to be achieved simultaneously, namely "(1) lower farm-level production costs," and "(2) enhance product quality". All benefits can generally be classified into those two groupings.[1] They are summarized in figure 2 and will be elaborated on in the following section.

Farmer benefits: Lower farm-level production costs	Consumer benefits: Enhanced product quality
Reduced pesticide use through • Herbicide tolerance • Cold tolerance • Drought tolerance • Salinity tolerance	• Improved nutritional qualities • Increased shelf life • Better taste

Figure 2: GMO benefits

Rollin et al. (2011) refer to GMOs in the category of lower farm-level production costs as first-generation transgenic crops. Numerous authors name as benefits the reduction of pesticide use by pest resistant genes (Batista & Oliveira, 2009; Feldmann et al., 2000; Guruswamy, 2002; Hails, 2000; Somerville, 2000; Verma et al., 2011; Wolfenbarger, 2000) or "insecticidal properties [and] viral resistance" (Batista & Oliveira, 2009; Wolfenbarger, 2000). Batista (2009) and Wolfenbarger (2000) add herbicide tolerance. Furthermore, Verma et al. (2011) add to this by naming cold tolerance, drought tolerance, salinity tolerance and pest resistance. All these benefit lower farm-level production costs by raising productivity and thereby also helping to stop the expansion of agriculture by minimizing agricultural land use (Feldmann et al., 2000; Somerville, 2000; Wolfenbarger, 2000).

Benefits of what Batista et al. (2009) and Rollin et al. (2011) refer to as second-generation transgenics relate directly to enhanced product quality and thus concern the consumer rather than the farmer. Among these are enhanced nutritional qualities such as added Vitamin A in so-called 'golden rice' (Batista & Oliveira, 2009; Feldmann et al., 2000; Guruswamy, 2002). Guruswamy (2002) contributes to the list of benefits of second-generation GMOs by naming increased shelf life and better taste.

Having discussed what benefits authors see in GMOs, in the next section potential risks shall be discussed.

[1] Other benefits relate to medical applications (Guruswamy, 2002; Verma et al., 2011).

Risks

Batista (2009) points out, "in spite of all the scientific studies reporting obvious advantages of using transgenic crops, their beneficial effects are not widely acknowledged". She states that genetic engineering is a quite new technique and, as evident from the past, new techniques as e.g. electricity at the time of its discovery have often been attacked by public concern. Nevertheless, with GMOs this concern is supported by various studies. Authors have generally grouped risks into environmental risks, those that impact human (animal) health and ethical concerns (see figure 2).

Environmental	Impacts on human (animal) health (*theoretical*)	Ethical concerns
• Increased pesticide use • Nontarget effects • Cross-pollination • Degradation of natural ecosystem	• Transfer of antibiotic resistant genes • Allergenicity	• Interfering with the natural order

Figure 3: GMO risks

Academics generally agree that a couple of the environmental risks relate directly to the initial benefits. In contrast to using less pesticides, authors name increased input use due to the emergence of 'super pests' and 'super weeds' (Baetens, 2007; Benbrook, 2012; Feldmann et al., 2000; Gucciardi, 2013; Hails, 2000; Keese, 2008; Lynch & Vogel, 2001; Wolfenbarger, 2000). Moreover non-target effects on beneficial organisms such as insects or birds feeding upon the plants that carry insecticidal properties are listed here (Feldmann et al., 2000; Lynch & Vogel, 2001; Wolfenbarger, 2000). Thus, next to the target organisms, animals are unintentionally negatively affected. These two risks are equally applicable to the use of pesticide. Bullock et al. (2000) add cross-pollination of a seed-producing plant by the pollen of a plant of undesirable variety and Wolfenbarger (2000) takes this a step further by listing the "degradation of natural ecosystem functions and structure" as an environmental concern.

Until now there has been little evidence of negative impacts on human (animal) health associated with the consumption of GMOs by researchers[2]. However, authors do list *theoretical* risks. Dona & Arvanitoyannis (2009) point out, "The results of most studies with GM foods indicate that they *may* cause some common toxic effects such as hepatic, pancreatic, renal, or reproductive effects and may alter the hematological, biochemical, and immunologic parameters. However, many years of research with animals and clinical trials are required for this assessment". Furthermore authors list the potential

[2] A study by Séralini et al. (2012) that proofed detrimental effects was invalidated due to methodological shortcomings (EFSA, 2012).

transfer of antibiotic resistant genes into bacteria in the human body or the human genome itself (Baetens, 2007; Dona & Arvanitoyannis, 2009; Feldmann et al., 2000; Keese, 2008; Qureshi, 2000), and new allergic reactions (Dona & Arvanitoyannis, 2009; Feldmann et al., 2000) that *might* occur.

As to ethical concerns, Qureshi (2000), Zerbe (2007) and Keese (2008) all relate these to the interference with nature, 'God's design' or the "concept of natural order and the integrity of species" and "the integrity of the ecosystems" as Keese (2008) elaborates.

The discussed benefits and more importantly the risks (since trade is rarely disrupted due to product benefits) directly influence the views of all involved stakeholders about GMOs, which will form the basis of their attempts to shape TTIP and its effects on GMO policy change. However, what do the current GMO policy frameworks in both regions look like? This is the question, which the next section will address by laying out the two different policy frameworks and their historical development.

Present GMO Regulatory Framework

Since it was only in the second half of the 20th century that the DNA was discovered, opening the door for genetic modification, the need to regulate these new agricultural products arose quite recently. Pollack (2013b) describes the EU system that is in place to regulate biotechnology today, as a "far more cautious approach to GMOs". However, Lynch and Vogel (2001) emphasize that until the 1990s, the EU GMO regulation system was less restrictive than that of the US.

Lynch and Vogel (2001) describe how first developments were evolving quite similarly within both executive branches across the Atlantic. Tensions quickly arose between the more critical environmental departments on the one side[3] who advocated a profound risk assessment procedure, and the research and science departments on the other[4], focusing on the great potential that this new technology had from a commercial perspective. Morris and Spillane (2010) describe the next period, from 1983 until 1986 as the reorganization period in the EU, although equally applicable to the US since both sides created new bodies responsible for the development for regulations of biotechnology (Lynch and Vogel's, 2001). Here is where the EU and US chose different paths. In the EU a gradual shift of policy leadership towards the DG Environment occurred that initiated setting up strict guidelines that peaked in the 1998 de facto moratorium on new GMO approval. In the US, on the other hand, the working group aimed at "maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry" (Office of Science and Technology Policy, 1986). The current regulatory systems across the Atlantic will now be discussed.

[3] Directorate General (DG) on the Environment, Consumer Protection, and Nuclear Safety (DG XI) (*EU*); Environmental Protection Agency (EPA) (*US*)

[4] DG Science, Research, and Development (DG XII) (**EU**); Office of Science and Technology Policy (OSTP) on behalf of the White House, US Department of Agriculture (USDA), FDA (**US**)

Present GMO Regulation in the US

In the US two documents remain the primary sources that regulate biotechnology today (Farquhar & Meyer, 2007).

1. Coordinated Framework for the Regulation of Biotechnology (1986)

Firstly, the Coordinated Framework for the Regulation of Biotechnology (Office of Science and Technology Policy, 1986) appointed existing bodies, namely the EPA, USDA, and FDA as the three primary responsible regulatory agencies for GMOs, each with distinct areas of responsibilities.[5] Secondly, a product-based approach was chosen when looking at foods, making the method (genetic engineering) of obtaining that food irrelevant. By doing so, existing legislation was, thirdly, considered sufficient: "Upon examination of the existing laws available for the regulation of products developed by *traditional genetic manipulation techniques*, the working group concluded that, for the most part, these laws as currently implemented would address regulatory needs adequately" (Office of Science and Technology Policy, 1986).

This framework copes with the regulation of biotechnology as a whole. Regarding the safety of foods derived from such a technology – the focus of this report – the FDA was appointed to be the responsible authority. Hence, the most important and still valid document concerning US GMO regulation, was published by the FDA, namely the 'Statement of Policy: Foods Derived from New Plant Varieties' (FDA, 1992).

2. Statement of Policy: Foods Derived from New Plant Varieties (1992)

Building on the product-based approach this statement of policy adds two essential principles to the US GMO policy framework. Firstly the food category that GMOs shall be placed into is defined: "Foods [...] derived from plant varieties developed by the new methods of genetic modification are regulated within the existing framework [...] utilizing an approach identical in principle to that applied to foods developed by traditional plant breeding" (FDA, 1992). Thus, the FDA decided not to create a specific category for GMOs.

The second principle this policy statement lays out is the principle of substantial equivalence. The FDA states in this document that "in most cases, the substances expected to become components of food as a result of genetic modification of a plant will be the same as or substantially similar to substances commonly found in food [...]" (FDA, 1992). The principle of substantial equivalence is

[5] The FDA as the responsible agency regarding the safety of biotechnologically derived medical products and foods; the USDA in charge of regulation with respect to cultivation and farming of GM crops, and the EPA regulating pesticidal plants and genetically engineered microbial pesticides, thus dealing with environmental aspects of GM crops.

why labeling is not required in the US and Hansen-Kuhn and Suppan (2013) add that this principle is the reason for "no applications to commercialize GMOs hav[ing] been rejected".

To summarize, in the US GMO assessment takes place within existing authorities and is based on a product-based approach (Office of Science and Technology Policy, 1986). GMOs are regarded as being substantially equivalent to their non-GM counterparts and thus do not require a new food category (FDA, 1992). They are regulated within the existing framework of legislation related to foods developed by traditional plant breeding. Perhaps unsurprising, by the year 2002 already 60 percent of all foods in supermarkets in the US contained GMOs (Guruswamy, 2002). We shall now turn to the evolution of the regulation of biotechnology in the EU.

Present GMO Regulation in the EU

An extensive list of (amended) directives and regulations have been issued that the EU uses to regulate GMOs which Member States have to adhere to (Cantley, 2007) and Pollack and Shaffer (2009) acknowledge that a "complicated, multi-level approval process of GMOs for the release and marketing of GM foods and crops" now exists within the EU. This approval process is also laid out in two legislative texts, which shall now briefly be discussed, and is divided into two stages, the risk assessment and the risk management stage.

1. Directive 2001/18/EC

Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (EP & Ministers, 2001) repealed Council Directive 90/220/EEC and builds on the following principles. Firstly, a process-based approach[6] was chosen to assess GMOs. Secondly, a safeguard clause allowed Member States to provisionally ban or restrict "the use and/or sale of that product on its territory" (Council of Ministers, 1990). Thirdly, the requirement to label GM products had been introduced in the so-called Novel Foods Regulation (Council of Ministers, 1997). Lastly, a Council resolution (Council of Ministers, 1999) resulted in the adoption of the precautionary principle (as discussed later), of which authors say that it has strongly determined the nature of EU GMO risk assessment and specifically management (Alemanno, 2014; Pollack, 2013b; Vigani, Raimondi, & Olper, 2010).

[6] As Zerbe (2007) points out, this approach considers GMOs as essentially different from their non-GM counterparts.

New within Directive 2001 is the creation of an independent, scientific risk assessment body, namely EFSA, and a different authorization procedure for GMO cultivation, which will be important later when stakeholder critique on the EU process is discussed. As was provided EFSA (2014b), an overview of this procedure is illustrated in figure 4. As can be seen, first the applicant applies to the competent authority of the Member State he wants to sell his products in, who then carries out the risk assessment within 90 days. As soon as this is completed, it is send to the EC who forwards it to all Member States who in turn have a right to – in a 'Community period' – raise objections and comment on that risk assessment. No objection means that the Member States now vote on the authorization of the product in the role of risk managers. EFSA only comes in if there were objections raised, which were not able to be resolved between the Member States. In that case, EFSA has to provide an opinion within another 90 days. This opinion forms the basis for the decision the EC and Member States take on the authorization. Whenever no qualified majority is reached between Member States, the EC may decide whether to authorize the GMO (EFSA, 2014; EP & Ministers, 2001).

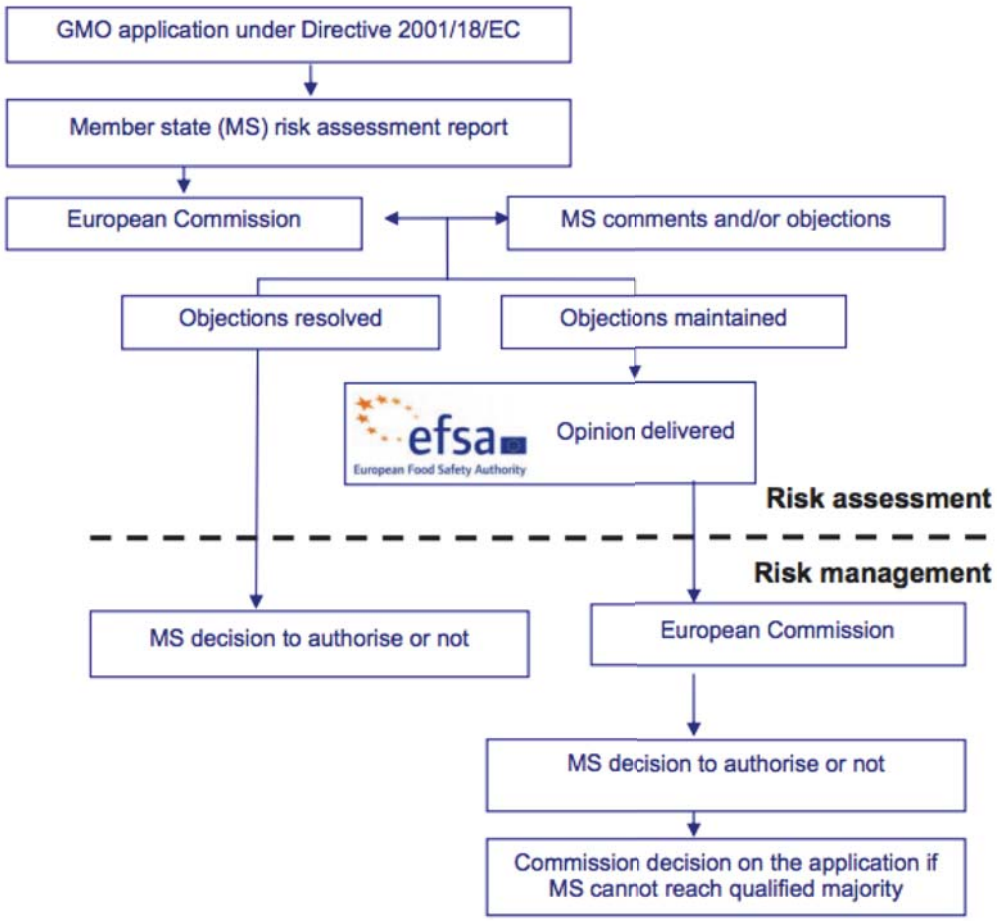

Figure 2: Authorization procedure under Directive 2001/18/EC

2. Regulation (EC) No 1829/2003

The second important document still in force in the EU today according to which GM food and feed are regulated is Regulation (EC) No 1829/2003 on genetically modified food and feed (EP & Ministers, 2003). Here EFSA plays a more prominent role since the GMO application is directly forwarded to the latter as opposed to the Member State. EFSA is asked to give an opinion within six months and may request additional information from the applicant, which extends the process (EP & Ministers, 2003). If a positive opinion is delivered by EFSA, the risk management takes place, starting with a 30-day public consultation period after the publication of the opinion. Based on that the Member States must take a decision on authorization. Whenever no qualified majority is reached within three months, the EC has to organize another vote within two months. If again no qualified majority is reached, the EC may authorize the GMO (EFSA, 2014; EP & Ministers, 2003; EuropaBio, 2013a).[7] This procedure is also visualized by EFSA (2014b) in figure 5.

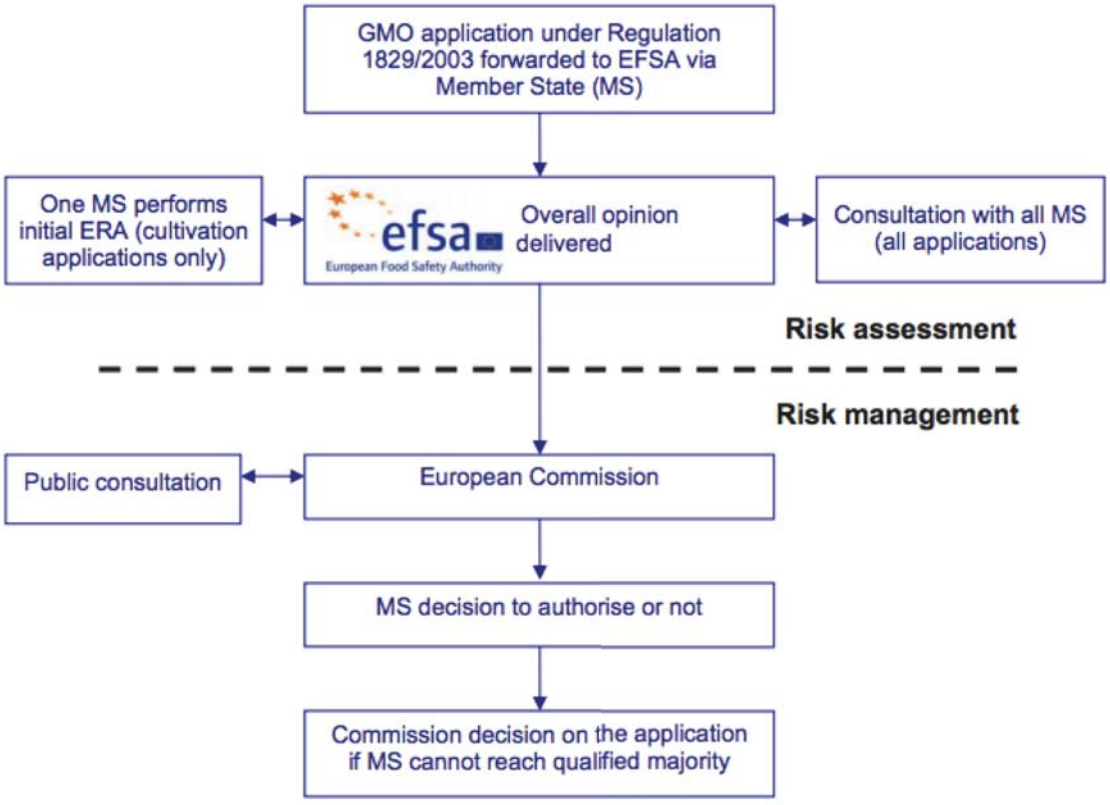

Figure 5: Authorization procedure under Regulation (EC) No 1829/2003 (centralized procedure)

[7] Once approval has been obtained through either of the two procedures (under either the directive 2001/18 or regulation 1829/2003), it is automatically also approved under the other one. Alemanno refers to this as the "'one door-one key' principle" (2008).

Recent Developments in the EU

Reacting to US and WTO litigation threats, the EC has attempted to speed up the existing GMO approval process since the end of the moratorium in 2004 and has approved 37 new GM varieties for marketing as food or feed (EC, 2014a). However, in respect of GM crop cultivation, the EU is still very reluctant to grant approvals. To date only one GM variety has been authorized for cultivation on European soil, namely MON810[8] (Reuters, 2013). In 2011 a second GM crop engineered by the German chemicals firm BASF, was also approved. But due to many Member States declaring safeguard bans and a general hostile environment, BASF announced in 2011 that it would stop planting and marketing that product in Europe, and move its biotechnology R&D operations to North Carolina (Trager, 2012).[9]

Member State's concerns remain, and therefore the EC initiated two developments to "revise the reoccurring 'stalemate' between countries", as Seaton (2014) puts it. The first was the identification of best practices to avoid unintended mixing of GM and conventional crops by establishing isolation distances necessary for a reduction of cross-pollination (EC, 2010a). Secondly, in July 2010 the EC proposed the addition of an article to Directive 2001/18/EC (EC, 2010a), which would explicitly allow Member States to restrict or prohibit cultivation of GMOs on their soils, based on other reasons than those covered by the risk assessment of the EU authorization process.[10] This Proposal has passed through the Parliament and is currently at the Council of Ministers (EP, 2011).

The following is another example, which illustrates this frustration with the application of the European GMO authorization system and occurred after the discussed EC's mitigation measures. In 2013 the General Court of the EU (EGC)[11] ruled that the EC failed to act on an application issued by the developer and supplier of plant genetics DuPont Pioneer under Directive 2001/18 that had been submitted in 2001. EFSA had delivered several positive opinions after being asked to revise assessment in 2005, 2006, 2008, 2011 and 2012. When in February 2014 there was a split-vote among the Member States, the EGC ruled that the EC is now obliged to take action and approve the maize, 13 years after the initial application (EGC, 2013; Seaton, 2014).

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[8] This is Monsanto's 'YieldGard maize' carrying genes resistant to the corn borer pest, which is grown mainly in Spain.

[9] Stefan Marcinowski, member of the BASF executive board, explained, "We are convinced that plant biotechnology is a key technology for the 21st century. [...] However, there is still a lack of acceptance for this technology in many parts of Europe - from the majority of consumers, farmers and politicians. Therefore, it does not make business sense to continue investing in products exclusively for cultivation in this market".

[10] E.g. ethical, moral or any other criteria could hence also justify the non-authorization of GM crop cultivation and the safeguard clause would thus be extended beyond its initial purpose (EC, 2010a).

[11] The EGC and the European Court of Justice (ECJ) together form the Court of Justice of the EU (CJEU). The EGC hears actions taken against EU institutions by individuals and Member States, in this case by DuPont Pioneer.

Pollack (2013b) states that a "Continuing Politicization of the EU Regulatory Process" has taken place in the EU institutions. He bases his assumption on two external evaluations that were published in 2010 and 2011 (European Policy Evaluation Consortium, 2011; Food Chain Evaluation Consortium et al., 2010), commissioned by the EC to evaluate the GM food and feed, and GMO cultivation regulatory frameworks in the EU. In the evaluation the assessors are generally happy with the risk assessment conducted by EFSA, however, strongly criticize the risk *management* procedures, and especially so in the approval system of GM crops for cultivation, stating, "The environment and human health are being protected from potential adverse risks of GMO cultivation not by a timely, efficient process that screens out of 'unsafe' products, but instead by the absence of decisions on applications" (European Policy Evaluation Consortium, 2011).

EU-US Trade Relations over GMOs

The EU's GMO regulation framework is so important in the international trading environment, since the EU is the world's largest importer of agricultural products (Cantley, 2007; United States Department of Agriculture, 2012), and exporting countries like the US thus have to meet EU GMO standards in order to sell their products in this large market. Already between 1995 and 1999 the European maize import share from the US had dropped from 86% to 12% (Lynch & Vogel, 2001) and more generally different authors note that it is due to GMO standards differing strongly internationally, that a "market fragmentation [...] currently challenges the international trading regime" (Isaac, Perdikis, & Kerr, 2004; Vigani et al., 2010). Pollack (2013b) emphasizes that the GMO conflict is one "of the most bitter and intractable conflicts dividing the United States (US) and the European Union (EU)".

Next to these obvious implications for exporters from the US, the EU is also affected by its strict framework. Lynch and Vogel (2001) argue that if it had been up to European farmers to decide on the import of GMOs, they would have gladly embraced them. They go on arguing that the posed restrictions have made farmers "worse off", with less choice available and consequently higher feed prices. This is equally applicable to end consumers regarding product choice and prices (Alemanno, 2008; Lynch & Vogel, 2001). More broadly the strict regulatory framework in the EU affected the whole European agricultural sector. In the light that historically most biotechnological development actually started in Europe-based companies, such as Novartis, Rhone-Poulenc, and Zeneca, the stringent environment for GMOs is, and Alemanno affirms that, "harming the long-term development of Europe's agricultural biotechnology sector" (Alemanno, 2008; Lynch & Vogel, 2001).

In short, Pollack (2013) describes the current US and EU regulatory systems for GMOs as being "strikingly different in spirit as well as in detail", and Alemanno (2008) agrees more symbolically portraying the current situation: "The US is from Mars and Europe is from Venus when it comes to the regulation of genetically modified organisms, notably GM food and crops". In this section first

reasons for diverging policies will be examined, followed by proposed solutions to the conflict. As Zerbe (2007) does, we assume that the objectives related to the regulation of biotechnology, e.g. "ensuring a safe and plentiful supply of food, encouraging rural development, and promoting environmental sustainability" are shared.

Reasons for Diverging GMO Policies across the Atlantic

Zerbe (2007) argues that the problem of GMO trade itself is a 'wicked' one. 'Wicked problems', according to Rittel and Webber (1973), whom Zerbe refers to, meet the following criteria:

- Different stakeholders have different definitions of the problem;
- There is no common sense solution to the problem;
- Judgments differ from stakeholder to stakeholder depending on his values and preferences; and lastly
- The problem is rooted in social dynamics and contexts.

We shall now have a look at some of these aspects, starting by discussing social dynamics and contexts, taking into account differing values and preferences, and lastly analyzing risk perceptions across the Atlantic, which reveal a general different definition of the problem.

Anti-Globalization Sentiments in the EU

Lynch and Vogel (2001) argue that the European public opposition to GMOs "has assumed an anti-American or anti-globalization flavor". The authors state that the impetus for this development is threefold. Firstly, the mere fact that the first GM crops that arrived in Europe were not grown in Europe, but rather exported by the American multinational Monsanto (who additionally chose not to label them), fostered European mistrust. Secondly, to the public it might have seemed that the American strategy was to regulate European agriculture, partly due to Monsanto's acquisitions of many seed companies. Thirdly, the timing of the first GM crop imports coincided with $100 million of punitive tariffs that were imposed on European exports (including many agricultural products) to the US (Lynch & Vogel, 2001).[12]

Somerville (2000) agrees with that notion and adds to it by stating that much of the transatlantic GMO debate is biased by the "industrialization of agriculture and control of the food supply by [American] multinational corporations". He argues that "the [GMO] technology [in itself] is inherently green" (2000) and believes that had it been any other sector who had introduced GMOs besides multinational

[12] These tariffs were imposed on European exports due to Europe's non-compliance of the WTO dispute panel's judgment related to the import of hormone treated beef. According to the panel, the EU was violating the Sanitary and Phytosanitary (SPS) Standards of the Uruguay Round Trade Agreement.

chemical companies, the environmentalists' reactions to them might have been as positive as they were to windmills and solar energy. It shall now be turned to differing cultural values and preferences.

Cultural Factors

Alemanno (2014) sees it as a given that "public perceptions are culturally determined" and goes on arguing that these "often mature into public concerns which, in turn, inform national risk decision-making and eventually crystalize into regulations". Thus, next to an anti-American attitude, cultural factors play another big role in the transatlantic GMO trade dispute. Swardson expresses the more traditional tendency of European consumers towards somewhat more 'natural' foods quite well, stating that, "the countries of Western Europe share a deep hostility to food fiddling of any kind. [...] To European consumers the idea of eating a hormone-injected steak or tomatoes whose genes have been reordered by science - *quelle horreur*!" (1999). Figure 6 shows an image that was published in an GM-adverse article by Sikh Archives (2011) and illustrates this hostility quite well. Lynch and Vogel (2001) agree that Americans are generally more open towards eating 'processed' or 'fast' food and Hoehn (2002) takes this even further by stating that Americans' "attitude towards GMOs is mainly indifference".

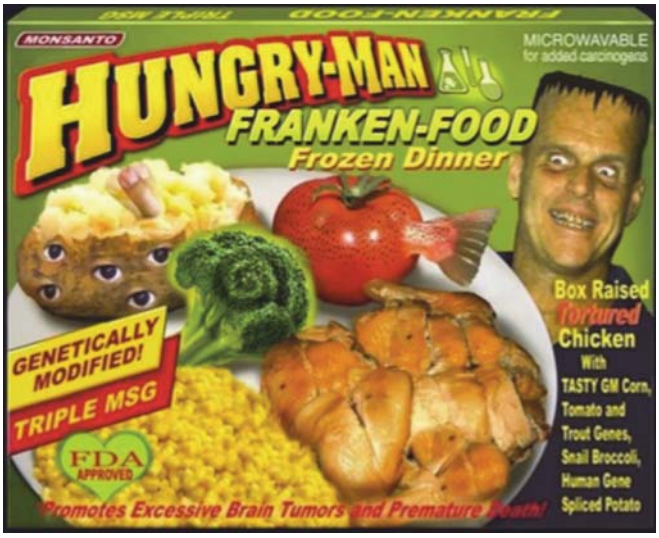

Figure 6: Frankenstein-food

Furthermore it has been argued that different cultural attitudes towards agriculture exist. While Europeans sometimes picture farming as being part of rural and wildlife environments, Americans tend to think of it as ingrained in their industrial system, and rather think of their national parks as rural and wildlife environments. Additionally, threats related to GM 'contamination' do not appear to them as fast as they do to Europeans, since their geographical size makes a separation of "agricultural heartland from rural playgrounds" (Lynch & Vogel, 2001) much easier than it seems to be in the smaller European countries (Hoehn, 2002).

While recognizing these cultural factors, Lynch and Vogel (2001) do partly question the legitimacy of some of them. Europeans do, for instance, also eat a large amount of processed foods, e.g. chocolate made with hydrogenated fats and food additives that can hardly be labeled 'natural'. Hence, rather than only blaming globalization or cultural factors for this trade dispute, Lynch and Vogel (2001) argue that nonconformity of EU and US regulations of GMOs is "part of a much broader political phenomena, namely the adaptation of more risk adverse policies in Europe". What is the source of this sudden risk adverse policy development?

Emergence of Risk Adverse Policies in the EU

Lynch and Vogel (2001) list three interrelated factors, "the emergence of a European civic culture, the growing regulatory role of the EU and a series of regulatory failures which have undermined public confidence in regulatory institutions and policies". With the emergence of a European civic culture, they mean the shift from once polarized European attitudes towards health, environment and general safety regulations to a more common culture, one in which NGOs and e.g. the Green party play a much bigger role than in the past. Pollack (2013) agrees, stating, "Activists and public opinion [is] far more mobilized over GM foods [in the EU] than in the US". Zerbe (2007) adds that media coverage to biotech opponents has been granted to a greater extent in the EU, "in ways which emphasized potential risks and downplayed potential benefits of GM foods".[13] The disaster in Chernobyl in 1986 might have somewhat triggered this sense of a shared vulnerability towards the dangers of modern technology, according to Lynch (2001).[14]

Next, the growing regulatory role of the EU has played its part in the evolution of greater risk adverse policies. Lynch and Vogel (2001) explain how the revisions of the Treaty of Rome subsequently granted civic interest greater importance in the policy process.[15] Furthermore, the EU institutions, especially the European Parliament (EP) that has gained more importance, have continuously laid more emphasis on representing diffused interest to a greater extent. Sometimes these civic interests were even represented better at EU level than in some national governments. Also, the single market has accounted for increased consumer mistrust towards non-national goods, which has further contributed to stricter regulatory standards.

Lastly, there are various examples of regulatory failures. Among the most famous is that of the mad cow disease.[16] The EC's reassurance that BSE (bovine spongiform encephalopathy) did not pose any threat to human health turned out to be wrong and only after about eight years after BSE was first detected in cows in the UK did the EC ban its consumption for humans. If the EC and scientists were wrong about the safety of the industrial food production technology in that case, might they also be wrong about the safety of GMOs now (Lynch & Vogel, 2001)? Pollack (2013b), Alemanno (2008), Zerbe (2007), and Hoehn (2002) all affirm that the food crisis of the 1990s and regulatory failures have contributed to more risk adverse policies. These policies reflect the diverging risk perceptions that will now be discussed.

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[13] However, even though social resistance may be greater in Europe, this public awareness and opposition to GMOs has also partly emerged on the other side of the Atlantic already in the late 1990s, to a great extent responding to developments in Europe (Blinken, 2001; Lynch & Vogel, 2001)

[14] It is exemplified by the recent decision of Germany, after the Fukushima incident, to ban the generation of nuclear power from its soil in the mid-term (BBC, 2011).

[15] To provide an example for this notion, the Treaty on the European Union (1993) first made precaution a guiding principle of EU environmental policy while previously that was not the case.

[16] Lynch & Vogel (2001) also name other examples, e.g. the dioxin contamination of food products produced in Belgium and mouth and hoof disease among sheep in several European countries.

Perception of Risk across the Atlantic

Alemanno (2014) argues that especially in the GMO case and more generally regarding new technologies, the stereotype of the US "being risk-takers and Europeans being more risk-averse" holds to be true. This relates in particular to the (until now) only theoretical risks associated with human consumption of GMOs. The EU has chosen for the application of the 'precautionary principle' to GMO policies (EP & Ministers, 2001). As EuropaBio describes, this implies that "where scientific data do not permit a complete evaluation of the risk, recourse to this principle may, for example, be used to stop distribution or order withdrawal from the market of products likely to be hazardous" (Europa.eu, 2014). In contrast to that Brom (2014) describes the US approach to risk as being based on a "familiarity principle", which leans on the idea that GMOs are substantially equivalent to their non-GM counterparts, thus *familiar*.

In essence, it all boils down to the question Taylor (2006) asks in her like-named journal article: "If no risk is proven, is there a risk?" Leaning on what has sometimes been accepted to be one of the laws of logic, Law (2011) further elaborates on this question, arguing that it is impossible to prove that something (such as potential risk) does not exist; Law explains that the absence of evidence does not result in evidence of absence, thus the non-occurrence of any given risk does not simply mean that no risk exists. The existence of risk on the other hand is only proven when there is evidence of its occurrence, which will consequently prove that there is a risk. Perdikis (2004) and Alemanno (2014) summarize that Europe takes the stance of the risk preventer that does not want to wait for proof if there is a possibility of risk occurring, while the US is typically more risk tolerant, waiting for damages to occur and then reacting to and dealing with them.

As Alemanno (2014) states, "Indeed, regulations are by definition dynamic: they change and adapt over time". He continues, "different societal and institutional attitudes towards risk may indeed prompt different regulatory answers and explain many transatlantic divergences over time". What are the proposed solutions to these transatlantic divergences and thus to the GMO conflict?

Proposed Solutions to the Transatlantic GMO Conflict

Pollack (2013) argues that while both players across the Atlantic are quite resistant to change their "deeply entrenched [...] domestic policies", a "pragmatic willingness of both sides to work together to minimize the disruptive effects of persistent regulatory differences" can also be noted. He adds an example of this greater willingness to negotiate rather than to litigate, using the conflict over hormone treated beef.[17] This combination of the reluctance to change policies on the one side and willingness

[17] While the EU would be able to keep its ban on hormone-treated beef even though declared unlawful under the WTO, it would in return grant the US a new duty-free quota for American high-quality, hormone-free beef. As a consequence the US would progressively remove its punitive tariffs.

to negotiate on the other, has not had a settlement of the dispute as a result; it has, however, somewhat led towards an "apparently lasting truce, in the transatlantic 'food fight'" (Pollack, 2013b).

Among other authors there is also general agreement that the transatlantic GMO conflict will not be solved through regulatory convergence in the GMO case due to the just mentioned change-resistance (Alemanno, 2008; Birnbaum, 2013; Pollack, 2013b). Nevertheless, "the two sides have largely succeeded in managing system friction between them during the Obama years" (Pollack, 2013). "No settlement but also no escalation", is thus the key phrase. Dan Hamilton[18] linked GMO regulation to a 'theological issue' for the both parties, arguing that US-EU negotiation on GMOs "is not about one side of the Atlantic converting the other to its religion, it's about finding a mechanism for religious tolerance" (quoted in Birnbaum, 2013).

So what do the parties expect from each other within this 'truce'? Pollack (2013) elaborates that the US wishes, rather than questioning the EU legislative framework as such, that the EU would implement the latter accordingly and politicize GM adoption to a lesser extent. The EU on the other hand hopes for the US to 'trade-up' at least to some extent, thus making their regulations stricter (Pollack, 2013b). While expectations on part of the US are more realistic since they do not include a change in policies, for the fulfillment of EU expectations it might have to take a "public health or environmental crisis attributable to a GM crop, of the type we have not seen during the two decades since the commercialization of the first such crop" (Pollack, 2013a).

Pollack gives many examples of American stakeholders, e.g. the American Biotechnology Industry Organization (BIO), Constance Cullman, head of U.S. federal government affairs at Dow Agrosciences, and even US President Obama, being fine with, or rather being able to live with, the EU legislative framework for GMOs, "including its rules on labeling and the political difficulty of approving crops for cultivation in Europe" (Pollack, 2013b). Now, the focus is thus, again rather reducing delays and "speeding up the EU's slow and politicized approvals process" (Pollack, 2013). Young adds to that saying that the EU already responded positively to such a wish, which consists largely in DG Trade trying to accelerate "the time that elapsed between the Commission receiving a positive opinion from EFSA and putting a draft decision to the SCoFCAH [the Standing Committee on the food chain and animal health], following the (inevitable) non-decision in the standing committee advancing a proposal to the Council [of Ministers] and in the wake of the (inevitable) non-decision in the Council approving the crop" (Young, 2011).

For those reasons, Pollack sees the only realistic outcome of the dispute in an "institutionalization of the current truce, in which the EC, on the EU side, would continue to struggle against Member State and public opinion to speed up the regulatory approval process for the import and marketing (but not cultivation) of commercially significant GM crops" (2013).

[18] Director of the Center for Transatlantic Relations at Johns Hopkins University.

Alemanno, however, goes a bit further. Instead of merely “speeding up the process” on the EU side and “institutionalizing the truce”, he is one of the authors that advocates more “regulatory cooperation” (2008). He argues that the EU framework for GMOs that is currently in place is increasingly unsustainable. Among the measures he names that would enable this regulatory cooperation are; the “sharing and exchange of information and best practices to improve mutual understanding” (rather than recognition); the “identification of alternative options which may bring close the regulatory approaches of both sides more gradually”; “structured dialogue” especially on risk assessment; and a “basic set of common transatlantic risk analysis principles” (2008).

In conclusion, this “bitter and intractable” (Pollack, 2013b) GMO conflict that is dividing the US and EU into two camps with very different regulatory frameworks, negatively affects both countries in different ways. It is rooted in anti-globalization sentiments, as well as cultural factors, the emergence of risk adverse policies in Europe, and fundamentally differing perception of risk across the Atlantic. As solutions and a way out of the trade disruption most authors do not suggest regulatory convergence, but rather propose mutual tolerance, enforcing the existing EU approvals process in a fair manner, institutionalizing the current truce, and enhanced cooperation on a regulatory level.

Research Methods

Due to TTIP negotiations being relatively recent, the literature review has illustrated a gap in the literature about the TTIP's potential effects on GMO policies. The research objective is therefore to contribute to closing that gap by exploring what the relevant negotiation stakeholders have to say about TTIP and its impact on EU GMO policies as well as a potential alignment with US policies. This chapter will describe the measures that have been taken to achieve this objective.

Research Strategy

This dissertation departs from the ontological[19] assumption that "people's knowledge, values and experiences" are "meaningful and worthy of exploration" (Bloch, 2004). Furthermore, it leans on epistemological[20] realism that supposes that claims about reality are either false or true and therefore things can be measured. This does not mean that hypotheses are formulated a prior. In fact, due to the limited knowledge of the topic an iterative research strategy has been chosen leaving room for explanatory (deduction) as well as exploratory (induction) elements (see figure 7).

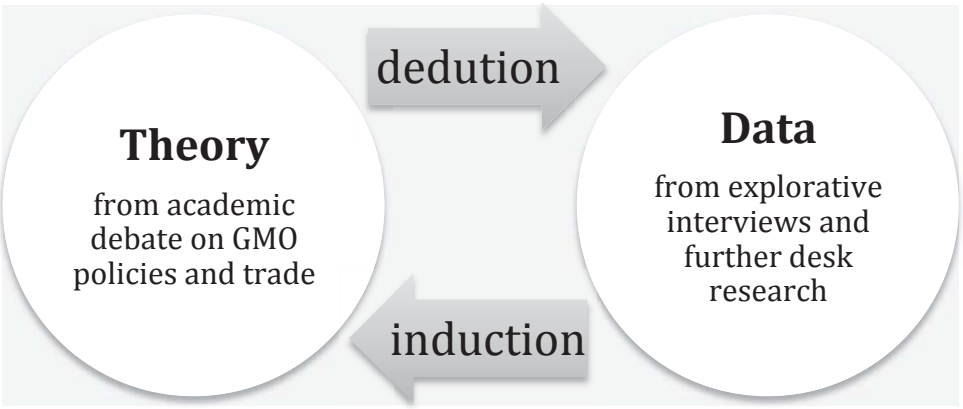

Figure 7 - Iterative approach

The literature review has aimed at capturing the most relevant authoritative discussion on the core themes. On the basis of these academic discussions, data collection through the vehicle of elite-interviews was chosen as the main research method. In addition to the literature review, relevant data from desk research was used in preparation of the interviews as well as to contrast and substantiate these. The findings of the interviews were then linked back to the literature to validate the latter but also explore possible new outcomes and to enable answering the research question.

[19] Ontology is understood as the philosophical branch that tries to address questions related to the existence or non-existence of things and their nature (Bloch, 2004).
[20] Being closely related to ontology, Bloch (ibid.) describes epistemology as the "philosophy of knowledge in general; it explores the possibility of knowing, the generation and evolution of knowledge, and its validity".

According to Mahoney and Goertz (2006) “Qualitative researchers are in some ways analogous to criminal detectives: they solve puzzles and explain particular outcomes by drawing on detailed fact gathering”. A qualitative rather than a quantitative approach was therefore justified, as the aim was never to obtain a representative view of a stakeholder group but instead to get a better understanding of the intricacies of the subject matter. Only the most knowledgeable members of the stakeholders were able to provide deep insight on the issue and thus are in essence all contributing distinctive pieces to a puzzle.

Data Collection

After having read the literature it became evident that many of the so-called interest groups do have a great interest in the outcome of the debate about GMOs and the regulation within TTIP. These range from consumers to farmers, seed producers, governments, the trading parties, risk assessing bodies, and activist groups. Figure 8 provides an overview of stakeholders and distinguishes between those

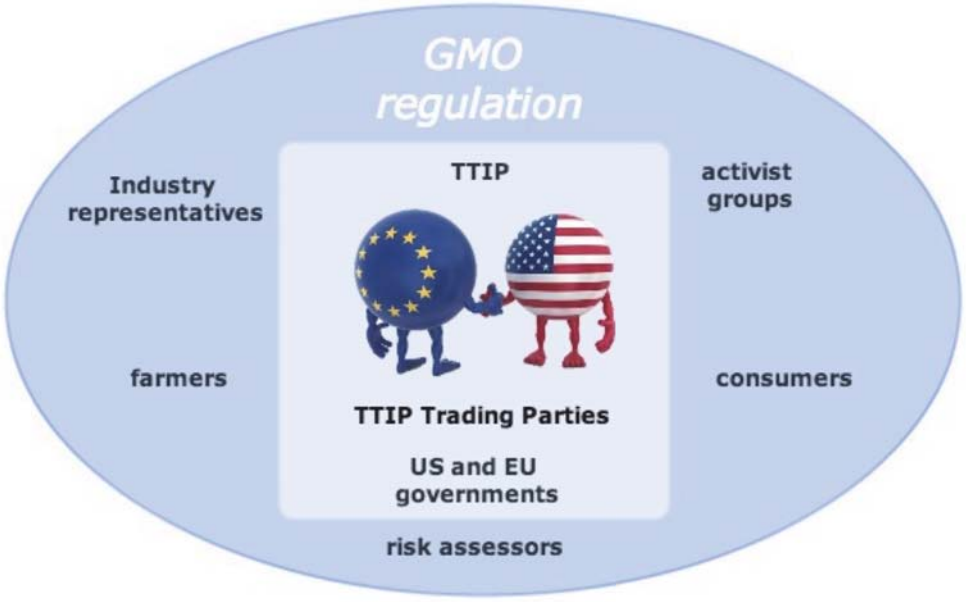

Figure 8: Stakeholders in the GMO debate

who carry out the TTIP negotiations (the trading parties and governments) and those who hold a stake in GMO regulation generally (industry representatives, activist groups, farmers, consumers, risk assessors). While the US government and the EU Member States are not directly involved in TTIP negotiations, they are in close contact with the trade representatives, since they constitute the parties that will eventually have to endorse the trade agreement. The main influencers being in charge of the negotiations are nevertheless the trading parties, with the EC on the EU side and the USTR on the US side as will be elaborated on later.

Interviews have been carried out with the following four of these stakeholder groups (for the first and last interest group, a distinction has to be made between stakeholders from the EU and from the US).

- *The trading parties*, who have direct influence on TTIP negotiations;
- *Industry representatives*, who constitute the group that has an economic interest in trade of GMOs and lobbies the trading partners;
- *An activist group*, the stakeholder group that represents public mistrust and influences the debate and TTIP via campaigns; and
- *The risk assessors*, the bodies that assess whether a given GMO is safe and thus 'tradable'.

Qualitative data has been collected conducting six extensive elite-interviews with representatives from the different interest groups. Each interview lasted an average of 42 minutes. The interviews were semi-structured, consisting of open-ended questions. This provided some structure whilst leaving room for elaborating more on certain issues and asking additional questions.

Due to the fact that all interviewees hold high positions within their organization, measures related to elite-interviewing were taken. For example, elites do not appreciate being asked a set of standardized questions (Aberbach & Rockman, 2002). Because of that and the fact that the interviewees formed part of different interest groups and were knowledgeable in different areas, the interview questions were designed individually and extensive preparation was completed e.g. on the organization and area of competence. Moreover, cues were given that the interviewer was familiar with the relevant key concepts and ideas so that the interviewee did not feel obliged to explain basics but could rather elaborate on more important matters within the limited timeframe.

Next to the elite-interviews, some desk research supplemented the findings of the interviews, which provided more extensive data on some of the discussed issues. This was carried out via the consultation of websites of EU institutions that have archives for relevant documents such as documents on the negotiation rounds of TTIP on the EC website, or via other stakeholder websites.

Sampling

As mentioned in the research strategy section, the interviewees, forming part of one of the identified stakeholder groups, were selected based on the knowledge they held regarding TTIP negotiations and GMOs generally. Randomized sampling was not desired as rather than obtaining a representative view of a stakeholder group, in-depth understanding of the issue was necessary to help the researcher solve the puzzle and answer the research question.

Interviewees were identified and contacted very early in the research process by searching for contact information on respective websites to ensure that enough time was given for scheduling an interview. E-mails were sent out and if no answer was received within a week, the person was called to see

whether conducting an interview would be feasible. Half of the interviews were conducted face-to-face at the office of the interviewee, namely those with Monsanto, EuropaBio and the EC, which is according to Gilbert (2001) "the best data-collection type for open-ended questions an in-depth exploration of opinions". The other half over interviews had to be carried out over the phone due to geographical limitations or interviewee preferences, thus those with the USTR, the two scientific officers from EFSA, and Greenpeace. Figure 9 provides a list of the interviewees.

Trading parties		
EU	**EC**	Member of Cabinet of Karel de Gucht, EU Trade Commissioner
US	**USTR**	Director for Agricultural Affairs
Risk assessors		
EU	**EFSA**	Scientific Officers
Industry representatives		
Monsanto		Government Affairs & Industry Affairs Lead Brussels
EuropaBio		Director of Agricultural Biotechnology
Activist group representatives		
Greenpeace		EU Policy Director on Agriculture, European Unit

Figure 9: Interviewees

Processing Data

The findings are presented in the chapter 'Data on impact of TTIP negotiations upon GMOs' and are organized under main themes identified through the processing of data. To do so, the interviews were transcribed in a denaturalized manner[21] (see appendix 2). Denaturalized transcription is used when studies are interested rather in the opinions themselves as opposed to how interviewees communicate (Oliver, Serovich, & Mason, 2005), which is the case in this dissertation. Additionally, off-topic conversation, which was irrelevant to the topic, was left out.

Common themes were identified through repeated reading of the transcripts and the creation of a concept map while closely keeping in mind the research objective, which was to identify a potential EU GMO policy alignment with the US system. To analyze the data parts of the transcripts relating to the various themes were collated enabling the researcher to better compare the various views. Themes are roughly, stakeholders' overall attitudes towards GMOs, stakeholder roles and opportunity/risk perception in TTIP, and TTIP Outcomes. It is important to remember that the different themes are not to be seen separately from each other, since they directly influence and relate to one another.

[21] This implies that idiosyncratic elements of speech such as stutters and involuntary vocalizations have not been transcribed (Oliver et al., 2005).

Framework for Data Analysis

As Strauss and Corbin (1990) point out, an analysis should result in codes connecting to each other in something that can be conceptualized as a "web of meanings". The task remains with the researcher to define the strings that establish this web. In order to define those strings, the data was analyzed, comparing it to the literature, merging key themes of the literature review with those of the findings and validating but also complementing literature.

The chapter was divided into two parts; one related to the stakeholders in TTIP and the other concerned TTIP outcomes. The first part compares the knowledge that has been obtained from the literature regarding GMOs and especially their trade with the first two parts of the findings section that discuss stakeholder overall attitudes towards GMOs and stakeholder roles. Thus, it firstly analyzes the stakeholders' attitudes towards GMOs and their level of risk perception and then the extent to which they can influence TTIP. These conclusions are brought together in a stakeholder map that will help the reader understand the positions of the different interest groups and forms the groundwork for the analysis of what TTIP outcomes are likely to be. The second part that analyzes the TTIP outcomes merges the third point of the findings – 'TTIP Outcomes' – with the data describing the EU GMO regulatory framework as well as proposed solutions discussed in the literature review in order to validate to what extent a policy alignment can and will likely occur.

Ethics

Gilbert (2001) argues, "Ethics say that while truth is good, respect for human dignity is better". The social researcher is faced with a number of ethical considerations, especially when the research involves human subjects, as it is the case in this dissertation. Therefore it was necessary that the interviews were conducted with the utmost ethical considerations to protect the participants' privacy, dignity and rights, as misrepresentation would have disrespected the interviewees' integrity. Hence, the research was guided by the principle of informed consent (Gilbert, 2001) and where anonymity and confidentiality was requested, special attention was given to ensuring that the privacy of the interviewee was safeguarded. All this was discussed prior to the interviews, and interviewees were given the opportunity to review transcripts and findings prior to submission. Explicit consent was received through an 'Informed Consent Form' (see appendix 1).

Limitations and Potential Problems

Despite the efforts that have been made to strengthen this thesis' validity through its choice of research design, the findings will still have limitations and potential problems that need to be acknowledged. First of all, even though interviewees represent the main relevant stakeholder groups, it is difficult to draw conclusions based on their views, since qualitative interviews generally only

project a “particular representation or account of an individual’s views and opinions” (Bloch, 2004). The realist tradition supposes that only recurring and controlled observations on a sample permit making generalizations. Considering the small sample, it is difficult to generalize and thus the research only allowed a substantiated estimation to the issue. This dissertation was, however, never meant to give an exhaustive account since that would have required more extensive resources. Evidently, the ‘depth’ of this research, which could reveal new findings on a potential GMO policy alignment, was only possible by sacrificing ‘breadth’.

Furthermore, a risk of bias exists, to the extent that unfortunately it was not possible to conduct interviews with all stakeholders due to the limited resources of an undergraduate dissertation. This means that no interviews have been carried out with farmers, consumers, the US Congress, EU Member States' governments, and a risk assessing authority on the US side. Therefore, the findings may be biased towards the involved stakeholders. Nonetheless, an attempt was made to fill these gaps by desk research on the lacking information.

Lastly, there is a limitation that relates to all research: one should question the researcher herself – could there have been any research bias? If anyone else had conducted the research, might different conclusions possibly have been drawn? To give two examples only, both the questions that were asked during the interviews as well as the choice of the interviewees themselves were a subjective choice made by the researcher. The answers that were thus obtained have influenced the conclusions, and might have been different if other persons had been asked a different set of questions. These are valid questions and the only answer that can be given is that one can comprehensively assess the validity of the outcomes since the research process is well documented. Hopefully such an assessment will prove plausible to the reader.

Data on Impact of TTIP Negotiations upon GMO Policies

The following section will present the findings obtained by means of six extensive elite-interviews. When referring to interviewees, the name of their organization will be used rather than their names to safeguard the interviewees' privacy. This chapter will meet research objective 3 by exploring high-level trade representatives', civil servants' and other relevant stakeholders' opinions on the impact of TTIP on EU GMO policy.

The chapter will be organized as follows. First, the stakeholders' attitudes towards GMOs will be presented. Such attitudes are significant in the sense that they are likely to affect stakeholders' views on the regulation and trading of GMOs and possibly impact the outcome of TTIP. Then the section 'Stakeholder roles and opportunity/risk perception in TTIP' outlines the extent to which interest groups influence the negotiations and how they look at TTIP as a whole. Finally, the section that is probably most relevant to the research question, namely 'TTIP Outcomes' will give an overview of the stakeholders' comments on the existing EU GMO policy framework and what change they would like to see be made, lastly presenting the extent to which the interest groups actually see this change occurring due to TTIP.

Stakeholders' Overall Attitudes towards GMOs in Agriculture

As could have been expected, the industry representatives standing behind their products held the most positive attitude towards GMOs. Monsanto (personal interview, April 25, 2014; ll.147f) pointed out, "Businesses only exist when they have something to sell and something to offer for a benefit for the people they're selling that to". In terms of benefits Monsanto (ibid.) highlighted those helping the farmer and those to the end consumer who is offered greater product choice and lower prices, when being able to choose between a GM and a non-GM product in the store. EuropaBio (personal interview, May 7, 2014, ll.5-28) added environmental benefits. Generally Monsanto (personal interview, April 25, 2014, ll.100ff) stated, "We don't defend GMOs, […] we defend our products and we defend risk assessment that is based on sound science. We don't favor regulatory environments". Monsanto (ibid., l.200) added that GMOs are no "silver bullet" but rather one of the tools in the toolbox. Underlining the strict EU GMO approval system, EuropaBio (personal interview, May 7, 2014, ll.27f) noticed that conventional coffee, would for instance, never pass through due to its allergenicity.

With regards to risks and the public being 'scared' EuropaBio (personal interview, May 7, 2014, ll.25-28) accentuated that there is "no evidence at all of any risks that would be greater than from conventional breeding". He (ibid., ll.129f) referred to GMOs as "something that nobody understands,

[…] something that is related to food, […] something that is related to big business", thus something that is qualified for being used in scare stories, which are "an old political recipe" that work and sell not only for the media "but for organizations" and "sociologically". He (ibid., ll.130-134) elaborated, "if you want to keep a group of people together, you have to position them against something, or against someone else". Moreover, Monsanto (personal interview, April 25, 2014, ll.61-65) argued that while activists present GMOs as being a top-of-mind issue for Europeans, the 2010 Eurobarometer revealed that only eight percent spontaneously say they are worried about GM in food (EC, 2010b).

As to the trading parties, the USTR (personal interview, May 5, 2014, ll.8ff) emphasized that the fairly long experience with cultivation and consumption of GMOs has so far been very positive in the US. The EC (personal interview, April 28, 2014, ll.122f), when asked about its general attitude towards GMOs, answered that it did not have one, stating that it was important to "keep things separated", arguing that this is EFSA's area of competence.

EFSA (personal interview, April 29, 2014, l.65), on the other hand, stressed that it did not look at benefits but exclusively at the risks of GMOs. Furthermore the authority (ibid., ll. 87-90) said that regarding the distinction of cultivation of GM crops vs. the marketing of GMO products, GMO cultivation was associated with higher risk levels during the assessment. This relates to the increased level of exposure to the environment when putting the seeds into the soil.

Being the stakeholder group that is most associated with criticism on GMOs, Greenpeace (personal interview, May 2, 2014, ll.12-15) firstly stressed that the organization is not against the use of genetic engineering in medicine, nor in industrial processes. However, they are against genetic modification of *living organisms* and releasing these into the environment, which resulted in contamination problems, also related with conventional breeding. Greenpeace (ibid., ll.89ff) pointed out that there were many alternatives[22] that were more sustainable. What Greenpeace (ibid., l.16-21) stressed was the lack of sufficient scientific knowledge about gene functioning and the inability to be 100% sure about the absence of eventual risks beyond those associated with the environment. Their occurrence would be irreversible and thus according to them, the risk should not be taken.

When it comes to how big the share of GMOs actually is in the potential TTIP agreement, The EC (personal interview, April 28, 2014, ll.3f) summarizes their slice of the deal by stating, "So, TTIP is pretty goddam big" and GMOs only constitute a "minor part of the whole package". How TTIP could and should, however, influence this minor issue according to stakeholder groups, will now be presented.

[22] A method called marker-assisted selection is one of these alternatives. Elaborating on that method would exceed the scope of this dissertation.

Stakeholder Roles and Opportunity/Risk Perception in TTIP

This section sets off by briefly discussing the roles stakeholders have in the negotiations with special attention to their perceived impact on the agreement that might in turn influence GMO policies. Then the opportunities/risks the interest groups associate with TTIP will be laid out.

Roles of the Stakeholders

Being the main negotiating parties of the agreement, the two trading partners have the strongest influence on TTIP negotiations. As The EC (personal interview, April 28, 2014, l.54) stated, the EC is "the single point of contact with the US". The USTR (2014), forming part of the executive office of the US president, "is responsible for developing and coordinating U.S. international trade […] and overseeing negotiations with other countries", which makes it the trading partner on the other side.

The trading parties noted, however, that there were other important stakeholders. After an agreement has (possibly) been made, the EC has to present it to the Member States and the EP and is thus in permanent contact with them "to make sure that the positions that we take are well-understood, the battles that we fight are the right ones and that the concessions that we give are within the perimeter of what can be accepted" (EC, personal interview, April 28, 2014, ll.63ff). For the USTR (personal interview, May 5, 2014, ll.134f) this point of contact is the US Congress, who has to be convinced of the agreement in order to adopt it.

On the industry side, when being asked the question how the interviewee sees his organization's influence on TTIP negotiations, Monsanto (personal interview, April 25, 2014, l.461) stated, "So I would think that the influence in the debate is, I would probably say 0". Similarly, EuropaBio does not see itself as influencing the GMO debate in TTIP, but rather informing it (EuropaBio, personal interview, May 7, 2014, l.234). At the moment, EuropaBio is involved in TTIP only in so far, that it is monitoring what is happening (ibid., l.243) and inviting negotiating parties to its events (ibid., l.252).[23] Ways in which EuropaBio tries to influence the debate around GMOs here in Brussels mostly relate to writing positioning papers or brochures[24] available to the public and also distributed to DG SANCO (ibid., ll.249ff).

Greenpeace (personal interview, May 2, 2014, ll.97ff), similar to the industry representatives, is also not directly involved in the negotiations and the organization's current activities related to TTIP are limited to monitoring. There is an intention to become more active as soon as specific negotiations on

[23] EuropaBio (ibid., ll.239f) added that in the US the biotechnology industry gets involved more in stakeholder conferences, which take place with every negotiation round. There, the vice president of BIO, EuropaBio's partner organization in the US, was able to express wishes and expectations for TTIP.
[24] As a step towards greater public engagement the organization has, for instance, made the brochure 'Science not fiction: Time to think again about GM' (EuropaBio, 2013b).

GMOs take place. Their GMO campaign generally belongs to one of the most established ones (ibid., l.5).

Lastly, EFSA (personal interview, April 29, 2014, ll.9ff) sees its competence as solely being restricted to risk assessment. The authority does not see itself as being involved, neither directly nor indirectly, in TTIP negotiations.

Having understood the different influence levels of stakeholders, the opportunities/risks they see in TTIP will be presented next.

Stakeholders' Perceived Opportunities/Risks in TTIP

Both trading partners have are high, and the reason for launching negotiations on the TTIP, relate to "job creation and economic growth in the US and the EU" (USTR, personal interview, May 5, 2014, l.119).[25] Related to GMO trade, the USTR (ibid., ll.71ff) added as a main goal the "normalization of trade" since trade is "substantially disrupted, particularly in corn and corn products". What the US side of the agreement would thus like to see is that products and especially GMOs can flow in a more predictable way (ibid.).

Monsanto would like to see "a fair, proportionate assessment of our products and the ability to bring safe products to the market" (ibid., ll.474f), whether this is achieved through TTIP or not. In TTIP, the main opportunity the company sees is that "common interests of the EU across the board that are common with the US in terms of common values and risk assessment, common approach, respect of scientific methodology" would be strengthened. As an industry association, at the heart of EuropaBio's wishes are those of its members, and the 'green biotechnology' department of EuropaBio[26] sees an opportunity for efficiencies to be made within the GMO approval system the law that is already in place applied as we will see more in detail below (ibid., l.197).

Elaborating on the fact that the EU is already importing a variety of GM crops, Greenpeace (personal interview, May 2, 2014, ll.118f) states, "So that there is a trade issue is actually a myth"; thus, its overall attitude towards TTIP is rather negative. Generally, Greenpeace (ibid., ll.168ff) states that the organization does advocate eliminating direct barriers; however, when it comes to changing standards and regulations – one of the main elements of TTIP – he argues, "we believe it's per se a problem" and does not think the GDP growth is worth the effort. Greenpeace (ibid., l.155) generally calls for more transparency. The risk assessor EFSA (personal interview, April 29, 2014) does not express any explicit opportunities nor threats or demands regarding the trade agreement.

[25] In one of its recent reports the EC (2013) phrases this a bit more precisely in terms of GDP, stating that "an ambitious TTIP deal would increase the size of the EU economy around €120 billion (or 0.5% of GDP) and the US by €95 billion (or 0.4% of GDP)".

[26] EuropaBio has three sectors, green biotechnology (agriculture and food), white biotechnology (industrial), and red biotechnology (healthcare) (EuropaBio, 2014).

Now that the general context of stakeholder roles and the opportunities/threats that they perceive in TTIP are clear, findings concerning the outcome of TTIP and its effect on GMO policy will be presented.

TTIP Outcomes

How the interest groups view the current EU GMO policy framework might determine their recommendations for change with which they will try and influence the negotiations. This is what this section starts discussing, followed by a section that – structured similarly – sets out the predictions of the extent to which the recommended changes will be made as a result of TTIP. Firstly the stakeholders' critique on the system and their recommendations will be presented.

Comments on Existing EU GMO Policy Framework

The stakeholders' comments and critique on the existing EU GMO policy framework can be divided into the two GMO approval stages, risk assessment and risk management, and the precautionary principle, which affects them both.

Risk Assessment Stage

To clarify the risk assessment process, EFSA (personal interview, April 29, 2014, ll.25ff) described it as being guided by three principles. The first, "comparative analysis", means, that "throughout the evaluation process, we [EFSA] compare the GM to a non-GM comparator, conventional counterpart" and the "difference observed" forms the basis of the assessment. The second principle is "case-by-case" implying that "each GMO is considered independently", and the third principle is "step-by-step" and describes several steps that have to be followed to assess the risks associated with the respective GMO. EFSA (ibid., l.59) highlighted that the principle of comparative analysis is derived from international guidelines.[27]

Generally, the industry representatives were happy with the science-based risk assessment carried out by EFSA (Monsanto, personal interview, April 25, 2014; EuropaBio, personal interview, May 7, 2014). The way the EC (personal interview, April 28, 2014, ll.125f) views EFSA's assessment is characterized by trust that believes "that they [EFSA] do it properly, straight and correct and make sure that if something is not safe they tell us and that if something is safe they tell us. And I take that as a basis". The USTR (personal interview, May 5, 2014, ll.86ff.) also holds a rather neutral position towards risk assessment carried out by EFSA, stating that the two approaches across the Atlantic are "very similar in their basic approach, and then generally in their outcome" which EuropaBio (EuropaBio, personal interview, May 7, 2014, ll.205f) confirmed.

[27] EFSA elaborated that international guidelines concerning risk assessment have, for instance, been set out within the Organization for Economic Cooperation and Development (OECD) and Codex Alimentarius.

Criticism on the risk assessment of EFSA was expressed by industry and activist group representatives. Industry recommended mainly "process improvements" (EuropaBio, personal interview, May 7, 2014) since the process "takes quite a lot longer in Europe than in North […] America" (ibid., l.204). To provide one concrete suggestion to achieve better efficiencies, EuropaBio (ibid., l.208) named enhanced "communications with the applicants".[28]

Greenpeace (personal interview, May 2, 2014, ll.64f), on the other hand, criticized "that risk assessment [was] conducted in the past by an agency which was very much linked to industry". A positive shift has, however, been noticed according to Greenpeace (ibid., l.60), noticeable by several opinions issued by EFSA that "concluded that they [EFSA] don't have enough scientific evidence to conduct risk assessment". However, Greenpeace (ibid., ll.61ff) sees the problem of risk assessment less in the assessor and more as "part of a wider problem", namely that risk assessment is limited in itself and for "a technology that you cannot master yet [biotechnology] […] risk assessment is not capable of actually providing you any answer, which is valid in the long-term".

After a (positive) scientific opinion has been provided, EFSA (personal interview, April 29, 2014, ll.139ff) argued that the latter "is out of our [EFSA's] end, and with the EC and the Member States". The authority added, "it's really up to them [the EC and the Member States], […] and it's true that all the Member States may vote for any good or bad reasons, not to vote or to abstain. […] It's really political […] It's a very complex decision-making". This brings up to the next step in the GMO approval process, risk management.

Risk Management Stage

Most of the critique of the EU GMO approval system expressed in the interviews relates to this stage, thus the 'post-EFSA' stage. EuropaBio (EuropaBio, personal interview, May 7, 2014, ll.197ff) highlighted its discontentment, arguing that related to risk management "it's not just efficiencies. It's first of all just applying the law. […] it's not really that far-fetched". The organization (ibid.) goes on, "that would already gain some time without in any way impacting any of the safety standards".[29] When referring to "applying the law", EuropaBio implies the responsibility of the EC to approve a GMO when no qualified majority vote was reached; "they [the EC] cannot just say 'Member States don't agree so we don't put it to vote'. They are breaching European law, as a European public institution" (ibid., ll.86ff).

[28] More recommendations can be found in the report 'Approvals of GMOs in the European Union' (EuropaBio, 2011, pp.23-39).

[29] Here again, EuropaBio points out to more suggestions for this stage in the GMO approval system, referring to the report 'Approvals of GMOs in the European Union' (EuropaBio, 2011, pp.23-39). Another interesting report is named 'Science not Fiction: Time to think again about GM' (EuropaBio, 2013b).

EuropaBio (EuropaBio, personal interview, May 7, 2014, ll.96ff) furthermore argues that while there are already "illegal [approval] delays" for the import of GMO products, when it comes to cultivation of GM crops the EC is breaching EU law as a public institution stating, "they [the EC] just don't do it". This is part of the reason why some member companies, like Monsanto, have partly withdrawn from Europe and established their businesses abroad (ibid., l.100). The USTR (personal interview, May 5, 2014, ll.120f) confirmed this, and added that this "should be a concern for Europe in terms of the messages sent about the role of innovation in [the] European economy". The USTR (ibid., ll.64ff) also strongly criticizes the non-compliance with the established timelines by the EC.

Much in accordance with the views of EuropaBio, Monsanto (personal interview, April 25, 2014, ll.483ff) criticizes risk management in so far that there are "elements that are being brought in for political reasons" which are introduced to "have better buy-in for the Member States" but which have not led to a change in the voting pattern, especially regarding those of Member States that are frequently abstaining and "will not follow the opinion of EFSA" (ibid., l.488).[30] As to the implementation of the existing system, Monsanto (ibid., l.91) argued that if Europe is so fond of it, they should use it, stating "okay, well then use your system, respect your system, defend your system".

Referring to the 2013 ruling of the EGC mentioned above, even the EC (personal interview, April 28, 2014, ll.137f) itself acknowledged, "It's embarrassing that the Court is telling us that we are not even respecting our own rules". The EC (ibid., ll.161ff) goes on, "let's find a way to make that [speed up the approval process] happen whether that has to be within the context of TTIP, or whether it has to happen anyway". The USTR (personal interview, May 5, 2014, ll.102-105) holds the same view, pointing also to international obligations, e.g. under the WTO SPS agreement[31] and the WTO SPS plus discipline that was recognized within TTIP. The EC (2013a) states in a position paper on SPS issues within TTIP that this chapter shall "maintain an improved dialogue and cooperation should be established to address bilateral sanitary and phytosanitary (SPS) issues […] with the objective of minimizing negative trade effects".[32] The USTR (personal interview, May 5, 2014) stated that the way risk is currently managed in the EU is not in line with these agreements yet and that needed to be discussed.

[30] One of these elements is the introduction of the safeguard clause for Member States (ibid.). When asked how often this clause had been made use of, EFSA (scientific officers, personal interview, April 29, 2014, ll.166ff) replied, "we got over the last five, six years more or less two safeguard clause [sic] on average per year".

[31] This agreement concerns the application of national food safety and animal and plant health regulations in a way that does not constitute a means of "arbitrary or unjustifiable discrimination between Members" (World Trade Organization, 2014).

[32] The SPS plus chapter further emphasizes, "Measures taken, in particular, when relevant scientific evidence is insufficient, must be applied only to the extent necessary to protect human, animal, or plant life or health, must developed in a transparent manner and reviewed within a reasonable period of time" (EC, 2013a).

In contrast to other stakeholder opinions about this approval stage, Greenpeace thinks that the system is using EFSA for GMO authorization. Greenpeace (personal interview, May 2, 2014, ll.67ff) stated that the "problem is that the system is using EFSA and the risk assessment they produce as if the risk assessment was […] a perfect tool, as if the risk assessment could provide you with […] [an] assessment of long-term impacts of the technology […] which cannot be possible". Additionally Greenpeace (ibid., ll.75f) added that when EFSA flags "scientific uncertainty, you, as risk manager, in this case the EC, should take a specific decision, which is based on the precautionary principle".

Precautionary Principle

Interestingly when it comes to the precautionary principle there are also differing opinions among stakeholders. Firstly, when talking about societal priorities, the EC (personal interview, April 28, 2014, ll.42-45) argues that this principle constitutes "a more high-level policy vision, if you will, where we have said that you can even ban things, if you are uncertain and where the US philosophy is you can ban things when you have proof that there is a risk. And that principle is in our Treaty. And that Treaty will be there before TTIP and after TTIP".

The USTR (personal interview, May 5, 2014, ll.143ff) argues that precaution itself is not wrong and that it generally forms part of risk assessment. What it criticizes is, however, the allegedly inconsistent way that precaution is sometimes applied within the EU, stating that it is sometimes used "not to evaluate the risk in terms of best mitigation to address the risk, but to avoid making a decision" (ibid., ll.148f). The USTR (ibid., ll.152ff) argues, "it's always possible to say 'oh no, we need more scientific information!'". Both industry representatives confirm this notion, Monsanto (personal interview, April 25, 2014, l.442) even accusing the EU of 'abuses' of the precautionary principle. EuropaBio (EuropaBio, personal interview, May 7, 2014, ll.117f), for instance, criticizes demands for re-assessment of a product.[33] Monsanto (personal interview, April 25, 2014, ll.451ff) elaborated on that, making a comparison to the car industry; "if you're in a car industry and if you get a question about landing lights for your car, you're gonna [sic] point out 'Well, it's a car, it's not an airplane'. But what if somebody took your car and turned it into an airplane? We would say, 'Well, we don't understand'". Furthermore Monsanto (ibid., ll.445f) argued that one "can't prove a negative", elaborating that it is impossible to prove the non-occurrence of any given event.

All in all, most stakeholders believe that the debate around GMOs is a politicized one, mainly related to the EU system and this second stage of the GMO approval system (EC, personal interview, April 28, 2014; EFSA, personal interview, April 29, 2014; USTR, personal interview, May 5, 2014; Monsanto, personal interview, April 25, 2014; EuropaBio, personal interview, May 7, 2014). Now,

[33] In the Pioneer case that was discussed above, the EC demanded EFSA seven times to update their risk assessment based on slightly adapted EC proposals concerning the same product, and each time EFSA provided a positive opinion (EuropaBio, personal interview, May 7, 2014, ll.117f).

predictions as to the influence of TTIP negotiations on the EU GMO policy framework will be presented.

Predicted Outcome

Having had a look at the comments on the EU GMO approval system and what different parties suggest as improvement measures, this section will present what interest groups thought about the possible outcomes of TTIP, divided similarly into the assessment and the management stage. Broadly concerning legislation, the interviewees all agreed that a change or an alignment of EU GMO policies to the US is not to be predicted (EC, personal interview, April 28, 2014; Greenpeace, personal interview, May 2, 2014; USTR, personal interview, May 5, 2014; EFSA, personal interview, April 29, 2014; Monsanto, personal interview, April 25, 2014; EuropaBio, personal interview, May 7, 2014). This goes in line with the words of the European Commissioner for Trade Karel de Gucht, "the legislation with respect to GMOs will remain unchanged - that's not up for discussion" (as quoted in Schliess, 2014).

Risk Assessment Stage

EFSA itself (personal interview, April 29, 2014, l.127) stated, "In terms of risk assessment, I wouldn't see any drastic change" and furthermore elaborated that its key regulatory principles including the precautionary principle, are very unlikely going to alter. What EFSA (ibid., ll.121ff) could, however, see is an increased "exchange and flow of information between [the] US […] and Europe" that would facilitate the comparison and increase awareness of different approaches, and would hence indirectly affect risk assessment. The EC (2013b) confirmed this in a report stating that the trading partners see "TTIP as an opportunity to support this cooperation", referring to the already existing exchange of information on "policy, regulations and technical issues concerning GMOs".

When asked whether an alignment of risk assessment is going to take place through TTIP, Monsanto (personal interview, April 25, 2014, ll.120ff) answered, "So, I, I can't see one system aligning to the other system". While the company (ibid., ll.69f) affirmed that a weakening of risk assessment would most likely not take place, it emphasized that this would not be in its interest either. The EC (personal interview, April 28, 2014, l.196f) affirmed that despite some disagreements, the rules concerning risk assessment that are in place will remain, elaborating that "we are gonna [sic] think about it within the framework of making sure that the laws and rules and protection standards that we have decided in Europe, will be maintained in Europe". The EC (ibid., ll.186f) stated that within TTIP the 'GMO problem' will be "pragmatically solved without us [the EU] being forced to take different views as societies than we want".

Greenpeace (personal interview, May 2, 2014, ll.132f) agreed, stating that a change in legislation is highly unlikely. Nevertheless, "the way legislation operates" might change (ibid.). Greenpeace (ibid.,

ll.135ff) expressed worries that related to mutual recognition of risk assessment stating, “Instead of having less risk assessment, we just are accepting risk […] assessment that’s done by the US which is much weaker [than in the EU]”. EuropaBio (EuropaBio, personal interview, May 7, 2014, ll.155ff) contradicted stating that even though mutual recognition might be desirable, as it in the car industry where “everybody can understand [this principle] quite easily”, this is not “going to work in the short or medium term on GMOs”. The USTR (personal interview, May 5, 2014, l.84f) confirmed this, saying that mutual recognition has so far only proved to work in few areas.

Risk Management Stage

The EC (personal interview, April 28, 2014, ll.151-154) stressed, “we [the EU] do have the rules in place. We do actually allow crops to come in that are GMO. […] the Court has told us that we need to move forward more speedily”. He added that TTIP, like the EGC ruling against the EC, serves as an incentive to adhere to the timelines that are already established in the EU GMO policy framework rather than changing them per se. The EC furthermore emphasized that GMOs will not generally be approved because of TTIP, arguing, “which GMOs will be approved in Europe is an ongoing process” (ibid., ll.200-203). If a certain GMO that an US company wants to export to Europe does not meet EU standards – whether in the risk assessment or management stage – The EC highlighted that this non-approval should be guided by EU “policy objectives, not for protectionist reasons”.

When asked whether TTIP would likely result in a change of EU GMO policy or processes, the USTR (personal interview, May 5, l.76) agreed with the European parties, pointing out that the key element to successful negotiations would not necessarily be an alignment of policies but rather the fair application of the EU system in place. That would already lead to a normalization of trade and trade with the EU market being more predictable in terms of market access. Quite boldly The USTR (ibid., ll.131-136) pointed out that if this goal were not reached, this could pose a threat to TTIP negotiations. EuropaBio (EuropaBio, personal interview, May 7, 2014, ll.139-141) confirmed the necessity of having to be able to trust the negotiation partner regarding policy implementation stating, “if you are negotiating of course with someone who exports a lot of products to Europe, a powerful partner, and who sees that the Europeans are not implementing their own system, and their own laws, I would expect that this is something they talk about”.

Having presented the findings that were obtained by means of qualitative, semi-structured elite-interviews with all relevant stakeholder groups, these will now be analyzed and discussed, comparing them to the literature.

Discussion on Impact of TTIP Negotiations upon GMO Policies

As discussed in detail in the Research Methods' section on the 'Framework for Data Analysis', this chapter will be divided into two parts, one related to the stakeholders in TTIP and the other concerning TTIP outcomes. Thereby research objective 4 – *Evaluation* of the extent to which TTIP is going to impact EU GMO policies – will be addressed.

Stakeholder Positions on GMOs and Influence Levels in TTIP

Within the literature review the historical GMO context that now constitutes the environment in which TTIP is being negotiated has already been discussed. Among these are different cultures with differing attitudes towards processed food and generally toward agriculture, and anti-globalization sentiments that are linked to the fear that US corporations want to continuously gain more control over the overall agricultural sector. Risk adverse policies were the result that was reinforced by the food crisis and several regulatory failures. The EU and US now aim at strengthening the trade of products like GMOs within TTIP with their long-term effects and potential risks only known to a certain extent. The EU holds a rather negative perception of GMOs in this context. As was pointed out by Alemanno (2014) public perceptions eventually lead to regulations and legislation, such as the introduction of the precautionary principle. This was affirmed by the interviews that will now be discussed in the light of the literature with special attention granted to stakeholders' risk perception of and attitudes towards GMOs.

Stakeholder Positions on GMOs

The chasm between industry and activist group representatives turned out to be the widest regarding their attitudes towards GMO use in agriculture. Notably, their disagreement does not come from slightly different focuses or basing their opinion on different science. Instead, their conflicting opinions stem from fundamentally different world views, which as described in the literature review can be summarized in Taylor's (2006) question: "If no risk is proven, is there a risk?" There is no easy answer to the question, and the fact that the absence of evidence does not imply evidence of absence makes the problem even more complex.

The two parties are unlikely to agree on the matter, due to the commercial interests of industry on the one hand, and the worries of the activist group organization on the other. It is debatable whether they are only driven by a genuine concern or (as is suggested by EuropaBio) also by some kind of commercial interest in the sense that just like any other organization groups like Greenpeace need a 'raison d'être'.

Regarding GMO attitudes and risk perception, the two trading partners can be positioned somewhere in between the activist group representatives and industry. The USTR, representing the US, is more on the industry side, emphasizing the previous successes of genetic engineering in agriculture. This reaffirms the profoundly different risk culture in the US that the literature has discussed, one that supports the development and application of new technologies and likes to be at the forefront of research and development of new products, even if these are potentially harmful. The EC, while not expressing a general attitude towards the technology by pointing to EFSA as the competent authority to judge GMOs case-by-case, highlighted the precautionary principle and its steadfastness in the light of TTIP. EFSA's role remains restricted to the assessment of GMOs, taking into account all the available science and providing an opinion as accurate as possible. Regardless of its scientific expertise it is impossible to rule out all potential risks, as the theory of the absence of evidence has revealed.

What becomes clear is that it is not only the EU on the one side and the US on the other that hold fundamentally different worldviews concerning risk and its management, having established strong regulatory frameworks that reflect these. A polarization can also be noted with activist group representatives on the one side who exemplify the risk-adverse culture that Alemanno (2014) described and the industry on the other, representing the stance of the risk-takers that is more typical for the US. Essentially different risk cultures and consequently different attitudes towards regulatory management of risk can be noted amongst interest groups. The negotiations on TTIP can hence not be torn out of their context and any potential agreement on GMO trade has to be made within these constraints. The theories of risk perception across the Atlantic are thus validated by the interviews. To what extent the discussed stakeholder views and risk perceptions can influence TTIP outcomes will be discussed in the next section.

Stakeholder Influence on TTIP

It is important to differentiate between different influence levels that the stakeholder groups hold regarding the power to influence the negotiations and thereby affect EU GMO policy change. Clearly the two trading partners, the USTR and the EC, directly influence the outcome of the negotiations. Industry representatives, such as EuropaBio and Monsanto, and activist groups like Greenpeace, can only indirectly influence the TTIP negotiations by lobbying activities, such as being involved in stakeholder conferences and publishing reports.[34] EFSA, being in charge of exclusively assessing GMOs and not having a stated opinion on GMOs in general, does have neither interest nor power to influence TTIP.

[34] An in-depth discussion of the extent to which these lobbying activities actually influence policy outcomes goes beyond the framework of this thesis; thus, this section remains very limited and restrained, not being among the key questions of this dissertation.

Figure 10 summarizes these points synthesizing them with the findings about risk perception discussed above.

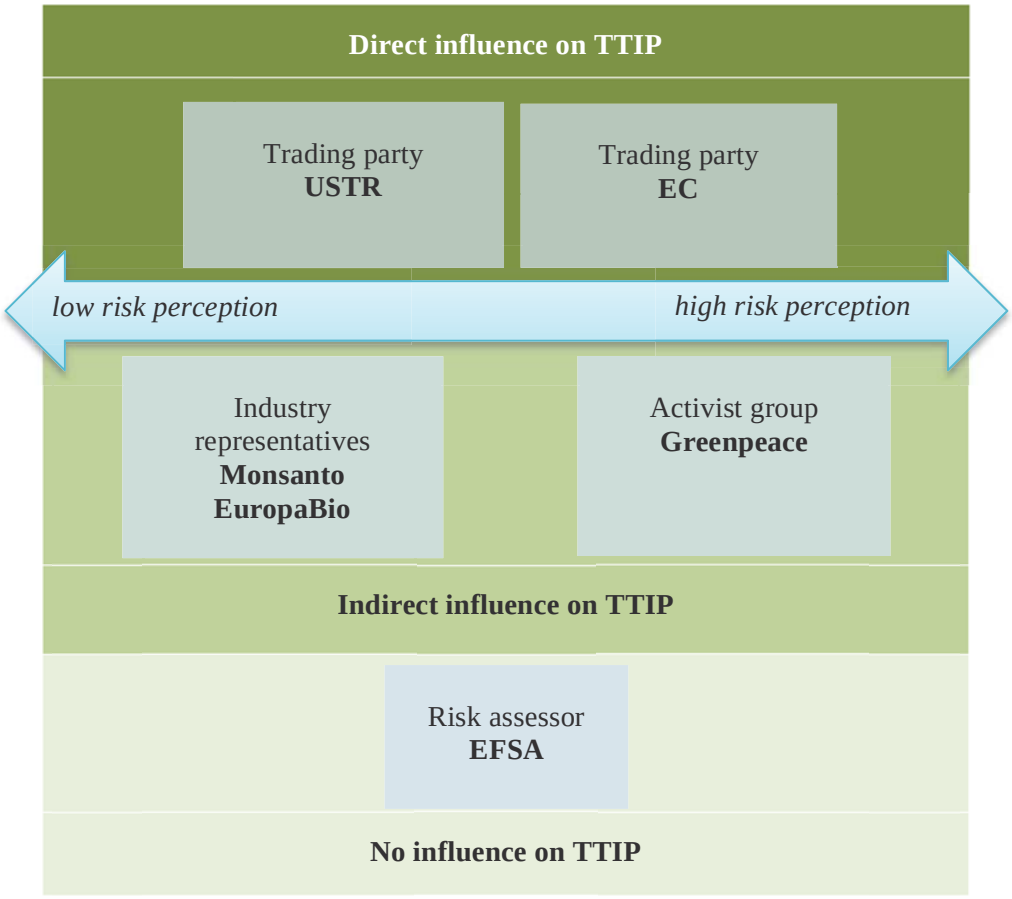

Figure 30: Stakeholder mapping

TTIP Outcome

The interviews have revealed that both trading partners have quite high expectations of TTIP as a whole, which they expect will result in significant economic growth on both sides of the Atlantic. This suggests that the parties are likely to try hard to find a compromise on the trade of all products within TTIP, including GMOs. As the latter only constitute a minor part of the agreement, which the EC has explicitly pointed out, it would be very unlikely that GMOs could endanger the overall agreement.

Nevertheless, the USTR has acknowledged that negotiations will only be seen as successful if they result in a compromise that will convince the US that is beneficial and useful. For the US, trade on agricultural products is among the focal points within TTIP, since this party sees trade especially in these products as currently being substantially disrupted. Thus, as the interview with the USTR has revealed, pressure from the US side to attain better European market access for GM products and higher levels of predictability appears quite high.

Does that imply, however, that an actual change in EU GMO policy is going to take place? This section combines the findings of stakeholder comments on the existing EU GMO policy framework and their predictions on TTIP outcomes and will start by analyzing potential changes in risk assessment and –management.

Changes in Risk Assessment and -Management

As presented, the EU risk assessment stage was viewed rather positively by most stakeholder groups, with only little criticism related to process improvements suggested by industry representatives. These would, however, not bring about a change in the policy of how risk assessment itself is carried out. It would rather impact the speed of the process, by e.g. improved communications with the applicants. Actual policy changes in the risk assessment stage of EFSA are thus highly unlikely. The guidelines on how to carry out risk assessment are well established, as pointed out by EFSA and the EC that stressed that TTIP will have to be negotiated within the laws, rules and protection standards the EU has established. Furthermore, the literature pointed to the guiding principle of precaution being deeply entrenched in EU legislation. As EFSA suggested, instead of drastic change occurring that would directly result in an alignment of risk assessment or weaken the latter, a more indirect change fostered by an increased exchange and flow of information between the US and EU is more likely. This suggests that the fear that Greenpeace expressed that TTIP would lead to possible mutual recognition of risk assessment is improbable to get confirmed, at least in the foreseeable future and within the first TTIP agreement.

Risk management in the ‘post-EFSA’ stage was the target of most of the criticism. While process improvements and greater efficiencies were among the suggestions, simple application of and compliance with the law and established timelines was seen as the key to solve the GMO conflict. This again, does not point to alignment of policies but rather to their stricter enforcement. It affirms what authors (Alemanno, 2008; Birnbaum, 2013; Pollack, 2013b) have written about proposed solutions that suggest that regulatory convergence is quite unlikely going to solve the transatlantic GMO conflict due to the reluctance to change entrenched domestic GMO policies on both sides. These conclusions are summarized in figure 11.

Hence, TTIP is unlikely going to result in an alignment on the EU side. Even less to be expected, however, will the US side ‘trade-up’. This is due to the deeply entrenched GMO policy frameworks on both sides and fundamentally different risk cultures. As the stakeholder groups have interestingly pointed out, convergence is not necessarily among their favored solutions. Dan Hamilton’s (quoted in Birnbaum, 2013) concept of finding “a mechanism for religious tolerance” rather than converting to either religion seems to be an appropriate metaphor to describe the outcome to the GMO dispute, as the willingness to negotiate does exists within TTIP.

The regulatory cooperation that Alemanno (2008) has pointed out, which exceeds compliance with the existing EU GMO policy framework that he described as "increasingly unsustainable" appears to have to stay a recommendation for the longer term. Increased exchange of information and risk assessments, and a structured dialogue that was also pointed out by EFSA, may lead to regulatory approaches coming closer to each other gradually; however, immediate identification of policy alternatives as a result of TTIP negotiations, remains unlikely.

	EU risk assessment	**EU risk management**
Policy Alignment	Highly unlikely	Highly unlikely
Changes	• Process improvements • Increased exchange and flow of information between the US and EU	Simple compliance with the law and established timelines
	Structured dialogue with US	

Figure 11: Expected TTIP outcome on risk assessment and management

These conclusions will now be applied to the concrete EU GMO policy documents that were discussed in the literature review, to identify opportunities of change.

Changes in EU GMO Policy Documents

It seems appropriate to discuss potential policy changes looking at the two EU policy documents, merging their content as was laid out in the literature review with the findings gathered concerning both recommendations and predictions to changes in risk assessment and risk management.

Directive 2001/18/EC

As discussed in the literature review, this directive concerns the deliberate release into the environment of GMOs, thus GM crop cultivation. It has also been discussed that EFSA as the European instance for risk assessment has a much smaller role under this directive when compared to the following regulation on genetically modified food and feed. The authority is only asked to deliver an opinion in the case that Member States fail to resolve objections amongst themselves if any were raised in the first place. This could be interpreted to hint to the conclusion that the smaller role of EFSA partially relates to the greater difficulties in the GM crops approval process.[35] However, both the EC and EuropaBio have referred to the EGC ruling that rebuked the EC for postponing a GMO

[35] One should not ignore the fact, however, that as EFSA has pointed out, any assessment on GMOs for cultivation result in increased levels on environmental risk due to their exposure level to the environment that does not occur when talking about GM food or feed.

cultivation approval for 13 years, after having received several positive opinions by EFSA. Therefore it seems that rather than EFSA having a smaller role under this directive, the EU is generally more reluctant towards the cultivation of GMOs than their marketing and therefore the EC has not shown a very fair application of the timelines established under this directive. This is confirmed by the fact that to date only one GMO is approved for cultivation. The increased environmental risk associated with GM cultivation that derives from higher exposure level therefore seem to be more important to the EU than general risks of GMOs related to their consumption by either animals or humans. Especially the US trading party will most likely focus on achieving efficiencies and fostering the application of the law under this directive through TTIP, since problems are the biggest here.

The EC has already made an attempt to speed up the EU GM cultivation approval process though the proposal for the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory on non-scientific grounds (see literature review). If the Council of Ministers should approve this proposal, the notion of national bans is likely to intensify. Whether that would lead to a faster GM approval process on EU level remains questionable; the introduction of the initial safeguard clause has not reached this goal as pointed out by industry representatives.

Regulation (EC) No 1829/2003

Nevertheless, under Regulation (EC) No 1829/2003 on genetically modified food and feed EFSA has a much stronger role as pointed out by EuropaBio. Although approval delays can also be noted within this regulation, at least a *more* lawful application can be noticed. This is confirmed by the 37 GMO varieties that have been approved for marketing as food or feed since the end of the moratorium in 2004. Trust that the EU will apply the law in a more accurate and timely manner also under this regulation will, however, be likely needed to be established as well, so that TTIP negotiations will be able to be carried out successfully as pointed out by the EC.

To summarize, it was interesting to see that almost all stakeholder groups agreed that policy alignment would most likely not be the solution fixing the trade disruption within TTIP. Rather, fairer and more accurate application of the existing EU GMO policy framework was the answer. Since on the EU side the EC agrees that in the past the system has been applied neither timely nor properly, TTIP is likely to be a good catalyzer for such changes.

Conclusion

This section will revisit the research objectives above, summarize the key steps of the research, provide conclusions based on them, and answer the research question. Furthermore, recommendations will be provided and indications made as to how to progress this study.

Research Objectives

The overall research aim of this dissertation was to answer the research question, 'To what extent will the Transatlantic Trade and Investment Partnership result in an alignment of European Union Genetically Modified Organisms policy with that of the United States?'. The introduction laid out four specific research objectives that made a systematic assessment of the question achievable;

1. *Investigation* of the EU and US GMO policies and standards and their evolution since the emergence of genetic engineering
2. *Examination* of the impact of these policies on GMO trade between the two parties, discussing reasons for and solutions to the trade disruption
3. *Exploration* of high-level trade representatives', civil servants' and other relevant stakeholders' opinions on the impact of TTIP on EU GMO policy
4. *Evaluation* of the extent to which TTIP is going to impact EU GMO policies

Objective 1 and 2 were met by giving an informed account of the literature that discussed central themes. To meet the third objective, the researcher gathered opinions of high-level trade representatives through the vehicle of six extensive elite-interviews, civil servants and other relevant stakeholders. An analysis that compared the responses of the different interest groups during interviews to the literature addressed the fourth objective.

In conclusion and to answer the research question, EU GMO policy alignment with the US is highly unlikely to occur as a result of TTIP. Both the literature and the interviews revealed that the deeply entrenched diverging GMO policy frameworks in the EU and the US originate from a wider context, and to truly understand the intricacies of the transatlantic GMO conflict one has to understand the fundamentally different risk cultures now clashing within TTIP. As a result of these, neither of the sides is willing to adapt their domestic policies; the willingness to negotiate, however, is likely to result in a trade partnership that aims at facilitating trade as far as possible within these constraints and fostering a mutual understanding of the diverging policy approaches, rather than mutual recognition of such. Because the two systems have to peacefully coexist, at least for the time being, and parties would be interested at resolving their differences, increased exchange and flow of information between the two parties is likely to occur.

In the short term, the pressure from the US and the industry side to normalize trade and put an end to the substantial trade disruption suggests that TTIP negotiations are only likely to be successful if the EU at least commits to genuinely comply with its established GMO approval system and the established timelines that are already in place. Only the fulfillment of this prerequisite will set the foundation of trust that is needed for both partners to negotiate. Therefore TTIP has the potential of being a catalyst to enforce a fairer application the EU system and make it work more properly, especially in the approval system that concerns GMO cultivation.

Recommendations

The negotiations on the TTIP are for the mean time at an early stage. To truly assess the extent of resulting regulatory cooperation in the area of GMOs, it is recommended to be patient and wait for more concrete discussions on GMOs to take place. This will make an assessment possible that can more accurately speculate about the extent to which the trading partners are willing to take a (small) step out of their culturally determined contexts and potentially approximate their regulatory systems bilaterally. Furthermore, the TTIP is meant to be a 'living' agreement that can be modified and even if GMO policies are not likely to align within its first draft, they might at a later stage do so.

If a *substantial* policy alignment were ever in the interest of any party, a bottom-up transformation would have to occur. As has been shown, national risk decision-making and regulations are a result of public risk perception. Due to the fact that risk perception is deeply rooted in cultural and societal preferences and experiences, this would need to change before any change in policy is likely occur. Obviously, experiences can only evolve with time, and if positive experiences were to enforce the benefits of GMOs, this would very likely contribute to a GMO-friendlier EU. As to preferences, activist groups try to convey the potential risks of GMOs to the public, while the industry naturally extols their benefits. To which extent these efforts will influence public perceptions and thus policy-making, is another extensive field of exploration that deserves research in itself.

Moreover, since within this study it was not possible to interview all the relevant interest groups, further research ought to focus on the views the Member States take on the issue and explore to which extent these would ultimately approve of an agreement that fosters the trade of GMOs. That kind of research would be useful to validate the conclusions of this dissertation but could also lead to new outcomes. The same can be said on a study of the US Congress that has to approve the treaty in the US. It is likely that these two players, the US Congress and the Member State governments are even more polarized in their views but this would require research to validate this hypothesis.

Finally, as briefly mentioned in the research methods section, this dissertation derived the findings from a very limited sample, which is why making generalizations remains problematic and future research of qualitative as well as quantitative nature is recommended. Thereby the scope should be expanded and hence the ‘breadth’ that was sacrificed for ‘depth’ within this dissertation complemented. Nonetheless, due to limited resources such limitations were justified within this undergraduate dissertation.

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Sources of the illustrations are available upon request.

Appendix 1: Informed Consent Form

This is the general form that was given to the interviewees who all signed it. Individual forms with the interviewees' signatures are available upon request.

Informed Consent Form

1. **Project Title:** "To what extent will the Transatlantic Trade and Investment Partnership result in an alignment of European Union Genetically Modified Organisms policy with that of the United States?"

2. **Project Description:** The dissertation first discusses literature on Genetically Modified Organism trade and then explores how European Genetically Modified Organism policies will be affected in the light of negotiation on the Transatlantic Trade and Investment Partnership taking place, and whether these will result in an alignment with those of the United States. Data will be collected by conducting elite-interviews.

If you agree to take part in this study please read the following statement and sign this form.

I am 16 years of age or older.

I can confirm that I have read and understood the description and aims of this research. The researcher has answered all the questions that I had to my satisfaction.

I agree to the audio recording of my interview with the researcher. I understand that the researcher offers me the following guarantees: f

- All information will be treated in the strictest confidence. My name will not be used in the study unless I give permission for it.
- Recordings will be accessible only by the researcher. Unless otherwise agreed, anonymity will be ensured at all times. Pseudonyms will be used in the transcriptions.
- I can ask for the recording to be stopped at any time and anything to be deleted from it. I consent to take part in the research on the basis of the guarantees outlined above.

Signed: _____ **Date:** _____

Appendix 2: Interview transcripts

In this section all six transcripts are documented, in order of the date they have been conducted, starting with the one that has been carried out first. Right-centered text, in slightly darker colored box, symbolizes what the interviewer said, left-centered text the words of the interviewee.

Government Affairs & Industry Affairs Lead, Monsanto Brussels

April 25, 2014. 11:15-12:33h. Face-to-face at Monsanto Brussels

Okay, maybe just before we start diving into the questions… so you are the government and industry affairs lead of Monsanto in Brussels and we know that this is an American Corporation maybe could you just briefly outline what Monsanto Brussels mainly does here in Belgium, Europe?

Sure. So, so, firstly I correct, I think originally - you know - I mean we were born in America but we operate globally and we are truly a global company; and by global I mean - you know - global in the sense, we outreach in various world areas and regions, but we are also a regional company. So, so for Europe we have a European business which is focused on our European farmers, and, and very much so, in fact, just because of the nature of our business - we're an agricultural business - the fit for agriculture needs to fit the local, regional needs and agronomic needs, climate needs, but the needs of our customers, our farmers and also as we've seen you know adapting to societal needs, policies, etc. etc. So, so that's one of the reasons why we have a government and industry affairs role here for the Europe, Middle East, Africa region. But specifically in Brussels, so, so this office deals mainly, most people in this office, nearly all of them in fact are regulatory colleagues, so they work on dossiers, files, making sure that we're compliant first and foremost, but also that we, we are presenting the information as necessary for our products here in Europe from a regulatory standpoint. So I think that's, that's a common sense place to be based.

[Interruption] Definitely [laugh].

I mean the European Union is, Europe is much bigger, so we also have a lot of activities if you look at growth markets, Ukraine, Russia, despite you know current events. These are key agricultural markets. We've also various Member States that are either applying, or haven't yet joined. Switzerland is not part of the EU. But kind of the big group is still part of, 28 countries are still part of the EU so it makes sense to have an office here and run some of our government relations from here. Maybe I should describe what industry affairs is, or industry relations: that's more dealing with the food feed chain. A lot of our issues, a lot of our products, what we're about as a company deals with other people also we are wider than, we are primarily a seed company that provides seed. But of course we are seen by society as being part of the food chain and that's maybe one of the things we haven't done a very good job and at representing, or we have avoided because we always say 'we are not a food company we're not a food company we're not a food company'; and it was probably a mistake on our, on our part to not fully engage in some of those wider societal debates so that's something we're really trying to change and in terms of what we do and how we communicate around these things, and how we show up in those debates. because people think you're a food company you're involved in the food chain and you just keep saying you're not that leads nowhere. You don't open any of these discussions and I think it's maybe contributed to some of those polarized debate, or feeling that we haven't been transparent enough. So that's one of those things industry, industry relations really goes for us – you know –it's 'farm to fork' and I guess it's probably the fork element we didn't do enough work on. in terms of farmers and how we communicate I think we've done a better job. You can always improve but I think certainly our customers and the industry understand what were doing, understand what we're trying to achieve. and I think that's reflected in our sales and that's reflected in our progress. But that's only one way of measuring success of a company. your focus is more on the government element of it so, it's very basic for us, I think at a very basic level we're, we try to explain what we do. We find that a lot of the stuff outside the technical regulatory products that's not unique to Monsanto or our industry. I think you always have people working, if you're in the car industry, working on what the particular regulation or directive does or how you apply your product, how you prepare your, your filing or your submission for a product. but in terms of the, what people consider lobby, or influence normally, – and I don't, I don't share the view that these are dirty words. I am from the UK myself – so, lobby was basically where people interacted when they didn't have direct access. in that sense we're not really lobbyists because– and I'm not a lobbyist because – I only really get a chance through official channels, I think there is a clear drive in Europe and other world areas for transparency, so if I need officials I, I request a meeting, and if I'm very lucky I get one, and then and then I use most of that opportunity to explain who we are as a company, what we do. It's really very, very basic, it's the same thing I would do introducing myself to new neighbors or colleagues or, or anything else. And that really takes up the majority of what we do, or I do in, in my role, and certainly where commercial people are interacting with officials. We do find we're spending a lot of our time getting back to basics, and just explaining who we are, what we do, and what we're trying to achieve as a company, because you don't have a lot of time to have these conversations, and I'm sure, apart from the very detailed research you do, Google is also a very good tool whether for yourself or myself and certainly wider society and that includes politicians and their advisers and everybody else so, and other search engines are of course available. But, you know, 'googling' is now, you know, a word in the dictionary so, as you know present continues activity. And if you look there it's fair to say that you are [gonna] see a lot of, a lot of stuff that's written, I wouldn't say it's information or [laugh]. And some of it is misinformation, and some of it is accurate and some of it's not accurate some of… And that's the sort of thing where probably Monsanto doesn't feature as much as we should in terms of what we actually do, what our business is, what our, what our, what our vision is.[Um] I'm sure you've been to our'.com-site', very basic research. You know, people visit our site and say, 'oh wow I didn't realize that your company was set up this way, I didn't realize you had this sort of corporate pledges, I

didn't realize that you were involved in these projects.' And there's a lot of stuff, and possibly that's our fault, we haven't shown up enough to get that across. I wouldn't separate that general information about our company with our government activity. It's really as simple as that. So I'll stop now because I'm going on a big monologue for you but I'll make sure we cover, cover your questions.

Thank you, that was very informative and good to know. my first question is actually a very big question and you could say a lot about it, I'm sure. It's actually my research question. I want to ask you, in your opinion, do you think that the TTIP negotiations will result in an alignment of EU GMO policy to that of the US?

[Um], so here is where, and we spoke earlier just about, you know, my views, company views, and as people who aren't a party to a trade agreement we are also looking at this from an external view and looking at the statements that have been made. Obviously, if you look at the, some of the public debate and expectations, you see a wide range from people saying this won't happen to this is Europe accepting US norms to… And, and then if you look maybe at the public statements from the chief negotiators, I mean GM has come up as one of the topics where they say 'we are not gonna [sic], we not gonna [sic] change our…', I think you will know the exact wording from your research, but I don't have it in my head, but it's something along the lines of 'we are not gonna [sic] weaken our risk assessment, our precautionary principle', etc.. As a company we are never looking for a weakening of risk assessment. That's, that's not in our interests in whether it be in Europe or the US or whatever. I think as a base rate if we look at the statements coming from Europe, there's a lot of defense of the European system. As, as a starting position or even a redline position, as it's being described. You know, that's their position so we can't really, we are not here to argue against this position or for this position. But I think, what most people would expect us perhaps to be challenged by that or upset with that, as a company who has struggled to get our products to market in Europe, and that certainly – just restricting this conversation to the GM piece for this stage – that has been a challenging environment for us. You know, there hasn't been a big real crop approval since 1998…

Yes, Europe has the most stringent regulations…

Yes. And we have made many public statements in the past years going back probably four or five years now, so after a decade of no progress just as a business our focus needs to be around what's doable, where our business is. And in Europe we have a really healthy business, we have a growing business. And it's for 99.9 percent or whatever non-GM. In terms of GM the big market is really in Iberian Spain; and that kind of makes sense because the only product available in the markets since 1998 is for the European corn borer. So if you look at where the product fit is, it's exactly there. And the planting's around a hundred thousand hectares, and slightly up, and it has been increasing. But that's pretty good market adoption by farmers there, who have a need for that product. Are there other parts of Europe we'd like to be in at this stage? Sure, you know, in the southwest of France there's a very similar problem. We'd love to offer the same product choice to farmers there as in Spain. But it hasn't been a reality, it's not a reality now, we, we don't see anything that's a game changer now. So we've really had to focus on our ongoing business, so in terms of that part of the product approval system, we'll have to be patient, we'll have to wait for Europe to move forward, and for people to be comfortable and following Europe's own process. But for the wider process – and I'm bringing myself back to the TTIP, but I thought that was an important caveat around where our focus lies… Europe has put out this stall of 'we're not going to move, we've got a great system, we've got the best system in the world', or whatever, or however they describe it, you'll have much better quotes than I do off the top of my head. My gut feeling, my immediate reaction to that is, 'okay, well then use your system, respect your system, defend your system'. It will never be up to Monsanto to defend European Union's system, I don't think anybody wants that, I'm not sure what the value of that would be. But if Europe is so proud of defending their own system as part of the new negotiations, as a redline issue, that they're not [gonna] change, fine. But we'd like them to use it then, and make sure that it functions properly. And by 'function', timely decisions, respecting their only timelines, and I think essentially because precautionary principle is used a lot in this context and level of risk assessment, the stringent nature of the European risk assessment. And we respect all of those values. But then the decision process doesn't follow what the best European science is saying about our products, which is that they are as safe as their conventional counterparts. That's not a blanket approval for us, it's product-by-product, case-by-case, I noticed again just looking at some of your questions, that people tend to talk about GMOs in general, as a sort of generic description. We don't defend GMOs, I mean we defend our products and we defend risk assessment that is based on sound science. We don't favor regulatory environments, you know, I'm a European, I defend Europe, I have a natural inclination to think about Europe first, because that's what I know best. we have other people, be it in India, other areas of Asia, Australia, South Africa, Burkina Faso, in West Africa who also see their world areas, they want that to be promoted first and have best science etc. But there are some holistic elements to risk assessments that we do believe in, and that's to base them on sound science, your best science and the science of the day. Most people agree with that, and I think Europe does, I think the US does. We would see, you know, things that we would like to improve or things that we disagree with as every system and every company does, and every industry does. But where sound science is no longer regarded as how you do risk assessment, it's kind of a binary decision., that's not a corporate view, that's just a world view, that's just common sense that… You either base risk, and how you assess risk on sound science, or you don't. And if you don't, well then you've already strayed completely off the path of sound science. And there are many people who believe in, you know, moon worship or stones or tea leaves, to predict safety, or what's [gonna] happen next, and that's fine, you know, that's their opinion. And we have to respect that, but I, I don't believe in that and our company wouldn't believe that's the way you should assess products.

[Yeah], definitely.

So I'm not trying to avoid to the TTIP question, and your question hints at a prediction of what will happen., you know, I think you have to tie in 'will the whole TTIP happen?', and again we have an external view, it seems to be slower, or the momentum seems to take a bit of a low from what you read in the press, from follow-up meetings and declarations, whether something will happen very quickly or slowly, your guess probably is better than mine, having a real focus on it. In terms of GM, will it lead to an EU adoption of the US…

Of an alignment, something that, that the policies are [gonna] adapt to those of the US or [their] regulation systems…

So, I can't see that happening, I can't see one system aligning to the other system. Can I see, and I don't know if I can see – and maybe I have to go back to tea leaves to do that [chuckles] – but I would hope, I mean our hope would be, that common interests of the EU across the board that are common with the US in terms of common values and risk assessment, common approach, respect of scientific methodology, I would hope that some of those principles can be, I think they're all there. Having been involved in this for over a decade and a half personally, I think the core approaches to science are sometimes, you know – coming from a different angle – but the core values are actually very similar. I mean science is science is science. So the approaches can differ, but I think the more that those core values can be put down and described and respected, and improved if possible, and, you know, whether it's a US improving system or the EU. We are not really worried about that. It's not something… We're often seen as an American company pushing for American systems, but that's not really the case, I don't think it would be successful, I don't think we would gain anything doing that. but the more, the more, you can reach those common values at least, in how you assess things, and common respect for, you know, scientific endeavor, scientific results and criteria, I think the better it is for both markets and certainly any industry would favor those. So that's kind of a holistic answer, but I'll stop now and let you probe that in your subsequent questions.

Yes, no, I understand that. Maybe generally, when talking about your attitudes personally and maybe representing Monsanto, how do you view, generally, free trade between the US and the EU? You don't have to say a lot about it just, do you think it's a good thing or not or… why?

In general I think for any business – and Monsanto doesn't differ at all in that case – things that can avoid duplication of process, and, you know, there are a few things that trade agreements – and they're not often talked about, and probably not talk about often enough – you know the generation of innovation, of having stable markets, larger markets, gives an ability to assess your investments, assess R&D for a wider market. So that's kind of a common principle. And the bit that's often forgotten though, is for the consumer and there I speak as someone who wants to sell products, of course, but also as a consumer myself. The ability to do that gives you a wider choice as a consumer, and I'm always up for different choices. You know, I think people sometimes forget that when they're, you know, ordering online or something, the ability to do that really does accelerate. And I know that people complain about globalization but usually using global tools. You know it's great to have Facebook or Twitter ramped about global trade, but it's kind of ironic and people see that. I think that ability just to see options and other options is good for consumers. I think it can, it can reduce costs, and overall costs, that are passed on at the end of the day to consumers and, or customers.so I think a lot of these good elements are sometimes missed by people thinking this is all about big business and governments, etc.. Businesses only exist when they have something to sell and something to offer for a benefit for the people they're selling that to. That's kind of how things function. Rightly or wrongly they get lumped into, you know, free trade agreements that look like it's one solution, it's, it's a kind of one-way stream capitalist ideology. And I think that misses the point, that this widening of markets, availability of information, availability of similar information, marketing and comparisons that can be made by consumers across regions can keep diversity of cultural identity and products in Europe or regions of Europe, and I'm from Northern Ireland, so regional identity is very, very sensitive to me, I'm from Belfast originally, so I like my cultural heritage, I like to correct people whether I'm from the UK, Great Britain, Ireland, England, and I constantly correct people until I bore them. but that is important to me as a person, as an individual, and I don't want to change that. But at the same time, I don't want to limit my options to, you know, buying comber potatoes, I [wanna] be able to have Cyprus potatoes and if there is other potatoes from other world regions that might be even nicer, I'd like to know what these options are, just to be able to choose those, so that's kind of how I see it and I feel our company looks at it in a very similar, similar way.

And I think that's something that most people can agree on, that free trade in itself is actually very good, and helps consumers as well as people who sell, and… [ya], actually benefit people in general., like you've said before, a lot of people don't really differentiate and just call it GMOs, and we know that you as Monsanto are one of the companies that have engineered these crops that are genetically modified, for example to be pest resistant. So I would guess your attitude generally towards GMOs is rather positive, is that right?

Yes this is kind of a basic answer, but again GM technology and biotechnology in plants is, we see it very much as one tool in the toolbox. I think that we've also not done a good job as Monsanto and possibly the wider industry but certainly as Monsanto. We're kind of seen as having a focus, an obsession with biotechnology, and I think we probably do have an obsession with plant breeding, because it's core to our business, and biotech for us really is one of those tools and, what is Biotech, what is GM, well GM itself is defined in legislation, so what is a GMO has legal and regulatory definitions etc. etc… But I think the way our R&D

and our technology platform looks is, is much wider than just, you know, it's not the simplistic sort of 'we wanted to take a gene and put it in a plant'. It's really, it starts with looking at, what are the challenges in agriculture, what can our R&D platform, what areas should we be looking at. So when it comes to weeds and insects, or 'weeds and bats' as our CEO likes to say, it's really simple, I mean those are two big, big challenges that farmers need to address, because if you don't address them you don't have a crop and that it's as simple as that. If you do nothing for weeds you won't have a crop. If you want to have wheat, and pull them out by hand, it's doable, maybe in your garden, on a very small scale, very few people will have food to eat. That's as simple as that. If you let bugs eat everything, it's the same again, you have crop loss. So what can you do? Well you can do what man has done before, you can introduce other predators for those bugs, that will be beneficial insects as they're usually referred to, who will eat the other insects, and that's great, and we use some of those biological controls and planned production, and our seed production, and… for big crop production, and to feed a growing population, or even to feed the current population, we think that you need to use every technology you know about, that is proven and apart from that , first and foremost that it's safe. It's very much at the heart of, it should be at the heart of every company, but I can't speak for everyone but for our company, that really has to be the key driver, it's safety. But very close up in our list of course is the benefits that it brings to the farmer, because if it doesn't bring those benefits to the farmers, they're not [gonna] buy it. It doesn't make sense as a product, it doesn't make sense as an avenue of research. And then something that we always believed in but that we haven't communicated very well and I think we sort of struggled because it looks like, it's hard to get that balance where you don't look like you're being arrogant and say we're [gonna] change and have a societal benefit. It's kind of hard to say but I think that something we need to do a better job with is explaining why, what our role is, in food production, in food security, and benefits to the consumer at the end of the day, and maybe there is a societal debate that we avoided for too long and why we exist, why does a seed company exist, why do people do research, why is it important to have seed quality, and I'll just do a little anecdote: if we look at the things that drive our company in terms of what we can do as a small, you know, as a fairly small player in the world scale at the end of the day, but is a big, big player in the seed industry and with huge research engine, and people understand finite at resources – water, land, etc – the challenges of agriculture and if you're driving along - you don't have to be a farmer - if you're driving on the road and you see an irrigation pipe that has a hole in it, your car splashes through it, it's very obvious to you that somebody is wasting water. About 70% of fresh water goes into agriculture, so, should it be addressed? I think everyone would agree yes. If you got a great system and all your pipes work and you recycle water, and you've got great water management, that may be fine, you've addressed a lot of those problems, but if you put that water, whatever, you need a better irrigation system, you've got the best in the world, everything's first in class. If you then put that on seed that's inefficient, we think that's just as sinful in a way [chuckles], it's just as wrong because you're also wasting out water if you're not driving yield from that seat. That's really where we approach seed technology and seed breeding. And biotechnology for us, in the GM question, has been one of the ways we protect that yield, so we, we strive for the best GM in the seed, but it's not limited to GM, GM is not a silver bullet, it's "a" tool in the toolbox. We have a lot of investments and nondestructive seed analytics we call it – not a very sexy name – but basically for millennia you can find out a lot about a seed by, by crushing it up and looking at the oil content, stuff like that, the problem is you can't replant them, because you say 'Wow that was a great seed' but it's gone [chuckles]. And the way plants have sex, well, you get multiple parentage, so if you get a nice corn crop – the hairy part that you peel off before you, people used to put it in boiling water and others put it in the microwave, well, I do anyway [chuckles] – I mean, but the pollen flow, and how those seeds are produced [...] that can be very different, so you can get different genetics. So if you think how many kernels are in that…what we're looking for as a seed company is trying to get those best breeding tools out of those, so what we can do is take a tiny chip off the seed that doesn't, that doesn't affect breeding, so whereas in the past what you had to do was plant those seeds, grow a plant until it's half the height of that [shows height] – which doesn't come across in the recording – but that's probably about three months growth which doesn't include the planting, the transport, all that, and you have to get a whole lot of people to go out and take a little punch hole out of the leaf, do the analytics, extract the DNA, with, you know, PCR techniques and look at their functioning and see what the genome looks like and look for characteristics… We can now do that before planting the seed. So in terms of time, in terms of knowledge, that really is one of the major drivers in our platform, that… What we describe as biotechnology, probably it's genetics, certainly it's advanced seed breeding. I think from our scientists' point of view, they, if they're very honest they don't really see much difference, but the world does, so introducing new genes or what you do with those genes is very different but certainly identifying those genes or marking them out so you can track them, and what you're promoting is really core to our business. So that's really where we see GM fit again, as, as just one of those tools. It's a decade and a half old now, over, it's coming up to two decades of wide scale planting, and research goes further back, it's probably three decades or more of real… what people called GM. In terms of benefits they're well-documented, if you look at the risk which I'm sure is your other question, in terms of our products and the products that have been approved and gone through a regulatory process and been placed on the market, I would point there I mean, I mean the fact that there is no evidence so far. But, a company saying that is one thing but I mean, recently the European Union published all of the scientific research and I forget how many papers it was, and that was a huge amount, a HUGE amount, much more than anything else that has ever happened in agriculture food and there's not one single evidence of harm, and, and the benefits are very, very clear. Does that mean that, again, it's a silver bullet technology and we're campaining for a no-regulatory system, absolutely not. We like safety, safety is our friend, but in terms of why we do the technology, why we still think it's important, it comes from the benefits we bring to growers, benefits we bring to agronomic systems, and then benefits to the environment that are, that are widely forgotten about, in terms of why we would be interested in that, and it's a good thing to do but it's also good for business, it is our business and what we do as a company… So again I'll stop, I'm trying to give you as much information as possible [chuckles] but interrupt me at any stage.

Earlier you've talked about sound science and that it's important that everybody, globally, that it's something everyone should respect, and Europe as well as the US, and it's not about a single country getting their regulatory system across. This might even help me for my further research and I don't know if you know right now but I'm just gonna ask you: do you know, or what are actually the facts that you base this attitude towards, is there any scientific research you would like to emphasize or opinion polls, social studies, or something…

I think there are couple of things that are really interesting to me, so, me personally but I also think as a company, as an industry, would be well there a few things but on the science it's kind of a slam-dunk in a way – to use an American phrase in sports, well, German originally – there's nothing, I think that the one thing I would point to is we have a lot of claims coming up and, and that's fine. Certainly any claim against our product and safety we take, I mean 100% seriously, we report any claim, we urge the people that have these claims not, you know, rather than going to have a press conference and sell a book, that does give you a certain flavor of, of, you know, a certain cynicism that's crept in about, these claims coming from the same people, making the same claims over and over and... What we would urge people to do with any claim is to go to the regulatory authorities, go through the proper channels, and have them assessed. And the only thing we would want any claim, just like our product portfolio, we put the product in to assess them and we have it evaluated. So if we take the European Union, the competent authority, here there are the experts, and we don't always agree with everything they do or their approaches, I'll say that, but that's the system. We don't, I don't know what they would do to us if we just went out and tried to launch a product without going through the system or we made claims about the product that we couldn't back up or hadn't been approved by the regulatory authorities, I think we would be in a lot of trouble. And that has to be balanced by the other things that have been claimed, and again, they are the usual suspects, that comes out of, and some have made repeated claims and every time those claims have gone through the process, not our processes, the European Union's process, for example, or other world regulatory bodies, they've been rejected as not being sound, being misleading and various other things, so, I think any of these studies... science,, I really there has been nothing out there that has been a claim, that has been backed up by the science. I think that's disappointing. So moving on to the political or maybe societal studies that are done, I think there are a few interesting things. One is the impact of these studies sitting out there without having a strong defense and that maybe comes back to the TTIP and how Europe defends its own system. You know I don't think anyone is expecting Monsanto to defend the European system, I am not sure if that's helpful. But it would be helpful if Europe would defend its own system, in terms of backing it up but also emphasizing these sort of abusive-nature systems where people don't enter into, they don't want their science judged by the European regulatory system, their claims against our products so they just issue wild claims through the media or books or whatever. I don't think that's a good way to do risk assessment. And I think that has a negative impact on the lack of support, vocally, by institutions, and I think that has an impact on the societal. But I would go back I think the most interesting study, I really think the most interesting study was a Eurobarometer study, I forget which year it was in, but it was still around the time where there was a lot of activists activity around GM, GMO's there was certainly a lot of debate and media debate, and they questioned what people in Europe, what were their concerns in food safety. And only 8%, despite all that campaigning and the press articles and everything, only 8% even listed GMO as a potential concern that they had. With all of the debate in the media articles and the crazy claims and the horrific emotive challenges and sort of, some of the anti-global of that was around even then, 92% when asked about food didn't list GM as one thing and I think it's very telling. And what's also telling is when, when asked directly about GM, that percentage of worry went up. Similar to questions about 'would you like H2O on your food?' and H2O people say 'No, I don't want that, what is that? It's a chemical, no I don't want that on my food', so, people will also be survey that they don't want water in food. So how do you get out of that? Well information is probably the way out, and that's where our industry probably needs to do a better job of explaining what we do and why we do it, and the role we have to play in a consistent and fairly only humble approach to what we do and what we can do. But interestingly, when asked, and, the reason I used a Eurobarometer is because as they are huge, huge surveys, across the European Union with a lot of data and they certainly got nothing to do with us. When asked what would improve attitude towards biotech, there are own various things that are listed like producing pesticides for example. And if we look at the product that's available in the market since 1998, it reduces insecticide. Clearly all studies show that it reduces the use of insecticide.

What is this product?

It's the BT. So it's resistant to European corn borer, and the European corn borer will be addressed, you can't grow corn in areas with European corn borer without addressing it, so people, you know, whether it's GM, and that's one tool, if you're not doing that you're doing something else. Could you find ways of doing it by hand or other things? I don't think so, for European corn, because you can't see them [...]. So it's chemistry, that's used and insecticides, so it's a kind of 'either/or'. And then there are… it's not used in maize because I don't think there is much maize, organic maize grown at all in Europe. I mean there's some, I guess there's some sweet corn, I don't know what the stats are, but if you look that up it will be interesting, but I am not aware of any, because I don't think people grow it. But organic ways of addressing that actually use the same approach, use the BT. So organic farmers use the same chemistry basically as we use in our biotech option [...] you use granules and put it over the top of crops, but the way that works for, whether of human digests that, or a bug, the European corn borer, it has the same effect. So for human it doesn't have an effect, because we don't have the same receptors, and if you're the European corn borer, well, it will kill you. So that's, that's, kind of one of the societal problems we have… the things people say we want are actually the things were delivering, so possibly we haven't told our story as well, well, definitely we haven't told our story as well as we

could… But also is that, that's angst real? Are people, is this top of mind for European citizens? I'm not so sure, I don't think the evidence is there, from, you know, 8% percent, when really asked to list concerns in food. I'm trying to think of other data that's out there that we find…

[interrupting] Maybe that relates to the benefits of GMOs?

I think, I think, in a way that's true, that's true, I think when you don't have a direct consumer benefit it is harder for consumer to list it as a benefit because they don't see it. I think sometimes it's a bit of a red herring, because if the consumer says the benefit I see is not a direct benefit of price, etc… And taste and nutrition, people may see it in the final product but wouldn't have attribute it to the original seed company. So, when they list, you know, reducing insecticides and you have that available, does that get you over the line in direct consumer benefits? I'm not sure that direct consumer benefits is easy identifiable. We have certainly been working really hard on healthier oils - and those are coming to market, they're already available in the US, and they're available in Europe too but just not with GM technology, with other other ways of improving through breeding… Again, does a consumer see those as direct benefits, do they link that to the farm gate? Probably not. So we have to do a better job with explaining that, but it's not the same as having, you know I'm not really sure what people mean, you know is it a square banana that's easier to package, or… What are those things? [laugh] Not that were working on that at all, [laugh], but we have other products that we look at, I think when it comes to taste and nutrition those are certainly key focuses in our food and vegetable business, we spend a lot of time with that, for commodity crops it's about the oil content, it's about the impact on nature. But then also healthier oils, that we're developing. So we are listening in that aspect. I'm not sure it's a game changer in consumer attitudes, that people think, I think it's a kind of a red herring saying "Well, we're not really against the technology, but wait until you get something on the shelf". I'm not so sure because we also don't see consumers avoiding GM where it's labeled, there are products that are on the market and labeled, like Hershey chocolate bars and stuff, we're always careful of just identifying and picking out names, but if I go back to a product that not no longer exists, the first of which is the flavor Savor tomato, that actually had a big yellow labeling on it, on the front - again you can Google and, make sure you have the rights to copy the photo or whatever, or else I can try to get you one that we've taken - but it has a big yellow thing saying "Contains genetically modified organisms", I forgot the exact wording, but it's really clear, there was no …

People bought it…

Yeah, people bought it, there was no consumer reaction, with no indication that anybody through the retail channels had any questions. Certainly in the time when in the UK menus used to say "If you have any questions, we try…" I think the wording was something along, most restaurants put on "We try to avoid GM as much as possible [blah blah blah]" – this was back in the 90s – "if you have any questions please ask your waiter". And I always enjoyed asking the waiter and said "Could you tell me more about this?" and they just said "… you know, you're the first person who's ever asked" you know, they always said that, it was the first thing they said, "No one has ever asked us about this". Which I think is really telling, and that's anecdotal, not scientific research, but I've never had a case in any restaurant, or any fast-food place or cafeteria where there'd ever been asked the question, despite having this text on their menus, no one had ever asked. And secondly, they didn't have any information. I was asking – well that wasn't always very polite, I was slightly teasing them in a way, but I always explained, while I was asking, who I was and… [Interruption by colleague] Where was I… Well you know it's anecdotal rather than scientific but, yeah…

Okay do you think there is a need to differentiate between the import of GM foods from the US and the growing of GMO seeds in Europe or importing the seeds?

So, do I think? No. Because I think it's about, I think it should be about safety and scientific decision-making and risk assessment. Is it different? Well, yes. It's shown, I think, from a societal reaction I think, I think it maybe… will take longer for people to, to to have the right information about why these crops are grown, I think the level of misinformation about what… You know if I think back to, so that big first crisis and sort of the tabloid pressure in the UK of the 90s we had a lot of calls from, and part of my job way back then was answering a lot of these, we established hotlines and stuff. And a lot of it was questions from people, or either attacks or criticisms, are genuine questions about why foxes didn't visit their gardens anymore since introduction of GM crops in England for example, and, you know, it was really hard to answer that question, given that there were no crops growing… and I don't really see what the effect on the foxes would be anyway… So it was hard to see where people were coming from. So I think the issues are more wide ranging for society at large because they're thinking of it in a different way, I think, when anybody thinks there's something on their doorstep, they just have a different approach to it, and it's maybe something we weren't sensitive enough to, we didn't explain well enough and also, we were explaining a lot about the safety and facts, and I think we forgot that a lot of this was driven by emotion, and I think we also looked at some of the crazy claims, and the activist claims, and then facts over here… It was kind of a polarized debate, we probably contributed to the polarization of the debate, by our own lack of judgment and analysis. And we really forgot about people who had genuine concerns, but genuinely wanted to find out, you know, the concerns is genuine number one, it's not just the crazy stuff for propaganda, the concern is real and not everybody's just empty. They, they, a lot of people really do want information. And I think we get sucked into, you know defending our products, defending the science, giving facts and we gave a lot of facts about our stuff and facts about biotech and facts about GM. And I think we forgot to readdress some of the, you know, why, why we do any of this, why why would we invest money in biotechnology, why do seed companies exist, why are seeds important, and a lot of kind of basic stuff, and maybe because we're looking from a very technical and scientific view, we really forgot to address some of those

needs. And I think that ties into the attitude towards cultivation and imports. But should you have a different approach? I think recently one of the… there was a Council legal opinion on the differing approaches, or ethical, ethical, ethical differences between cultivation and imports and they likened it, at least one of their spokespeople, I'll try to find that, it's not one of our quotes, and I don't want to misquote somebody, it was something I think the reference probably inappropriately, so please don't quote me on this one, it's not my words, but I think they, they they used the example of slavery, and said that would be a bit like saying like you only use slavery outside the EU. You know, either you're for or against, either it's ethically right or wrong, so I think they were really trying to challenge this idea that it's okay to import stuff, you know, it's pretty fundamental. But I do think there's a difference in people's minds, for some product there may be differences in farming practice. If this is European farming, the second farm scale is different, farm size is different, for a lot of biotech products it's scale-neutral so the advantage for small farmers is beneficial just as it is to big farmers, but not all technologies are like that, not all harvesting equipment is like that, not all farm machinery's like that, and you know, people with big open fields and large scale farmers will address their farming in a different way than small-scale farmer so there are certainly differences but then not fundamental.

Okay maybe that also relates to this, in Europe there is one of the principles that's called Coexistence of non-GM and GM crops. What is your opinion on this, do you think this is really sustainable or is there some threat that somehow the seeds will also go to the other side and…

No absolutely, I mean, Coexistence is a extremely important in farming because farmers have neighbors, farmers have neighboring fields, that are their own fields, but two different fields, it's, I think it's been very disingenuous, and a very smart tactic by activist campaigners to single us out as a GM issue, I mean essentially it's not a GM issue if you look at northern Europe we have the ability and farmers know how to grow two different oilseed grape's on their own farm, and one oilseed grape which has toxins in it, which is not for human consumption, it is for biodiesel and they can grow that on the same farm even as oilseed grape for human food consumption. And the reason I use that is because the cross-pollination, we know that the pollen flow for oilseed grape, it's very light pollen, a lot of pollen… the pollen flow is in kilometers not meters… But they know how to manage that… It's a sensible approach, it's good practice, farmers really know how to do this. It has nothing to do with our company, our recommendation… Farmers make their crop coexist. Other techniques such as spraying of anything, farmers know how to do this with good practice. So, I think on the pollen flow that's one thing, they know how to look at prevailing winds they know how to minimalize, if you are spraying a crop rather than… if you're using insecticides rather than, you know our BT maize product, you know when to spray on when not to spray, they know about prevailing winds, high winds, they know about the neighbors fields, good farmers know how to communicate with their neighbors on time of the crops. So coexistence is important, it's also not really much to do with GM. However, GM is more emotive, so if people want to pay attention to that, great, that's good, but I think it has to be proportionate. GM crops that are approved and approved and demonstrated to be safe and beneficial for farmers so that's what they choose them that's why they would plant them. You have to look at it in the proportionate way, of, of, of what that is, these are plants, plants repopulate, plants have sex, but some plants have sex with themselves, so soybeans etc… are self-reproducing plants. Farmers also know how to deal with those. Is it an issue? Yes and no. How big an issue is it? We found that we are entering this debate and talking about coexistence with many politicians and journalists. This is my own, again, this is anecdotal but it's my own personal experience, it actually took a few years for me to realize that the problem they had was not the problem, the solution I was explaining, so when I talked about this, one element of the farming that they had forgotten about was harvesting. So at the end of the season, you harvest crops and you actually kill all the plants. So… with any crop structure you can have outcrossing and weedy, weedy relatives, of which, for our technology is an product that we had available and that we were offering at the time and throughout the last 15 years have tended to be, you know, it's been sugar beet which we're no longer involved with, we're currently involved in maize and, maize which is a hybrid, and oilseed grape which are variety lines and hybrids. These are crops that, people do manage and they manage how they reproduce, how they, how they cross-pollinate. It's also fairly easy to track where these things are because after you harvest, you clean the fields or whatever method you use to do that, then you want to either plant something similar or something different or rotate your crops, but the farmers know what other stuff shows up. And what I didn't realize was that a lot of people were thinking of this, like "GM is an invasive species or gave some sort of competitive advantage over the other crops and we didn't understand that because that's just not how farming works, and how plants grow. So it really took us a while to realize that it wasn't so much that people saw that, it was in the psyche, in the back of people's minds and of course when we realized then when talked people through, talked about harvesting, you know we saw this sort of people saying "Oh yeah of course!". What they were thinking was that maize growing like [...] something where a farmer picks corncobs, and these fields get bigger and bigger somehow, and GM keeps expanding and that's not really how it happens… Not really how it works. So is coexistence important, yes of course, it's important. Is it GM specific? No. Is it manageable? Definitely.

Perfect. I think it's a question we can almost leave out because it's about, the question about the debate about GMO is very politicized and often not very science base and I think we all agree on that right?

I would think that's a given. I would point, there was a recent there was an interesting one, a research which astounded me in fact, it was a parliamentary question and I might forget but you can remind me with an email, because I will be able to find it somewhere, the parliamentary question that was along the lines of, you know "Why don't things move in the system? Is the commission fully aware of the potential for trade disruption?" and I was quite astounded that the, the written answer - because

it was a parliamentary question - came back citing that when there's a potential for big trade disruption the commission had the ability to speed the process up. And I think that really summarizes not just a political element to the system, but the nonsensical political element, I mean, why would you accelerate some thing, because of a, I mean, that's not a way, I mean, as a European I found that one of the most disappointing things on the debate over the years because it was probably brutally honest [laugh] but it really makes a nonsense of the political elements. I mean, why do you do it, why on earth would you make your system actually obey your own rules in a certain trade environment and not another one. It looks like Europe is not controlling its own system, or able to do that, that saddens me as a European.

Yeah, I understand. Maybe coming back to TTIP negotiations, with regards to GMOs a bit more. Is there something that you may be – even though we are aware of the benefits - but something that view as particularly controversial regarding GMOs in these negotiations?

[um] I think may be the piece that's controversial is, the lack of explanation from, from the trading blocs in terms of systems. I think… I don't think there's any particularly controversial, I mean the controversy out there is already known, different attitudes towards food, and stuff like that, but I think, I don't think - and again this is a personal view as a European more than anything else - I think I'm very happy when I can, you know, visit the States or visit other world areas, I enjoy going to the world areas. I don't bring my own food. I've been on the plane, and I usually don't get as good a seat as some of the activists [laugh], but they travel too and I have never seen them bring a pack lunch with them or worry about food as much. I think it's kind of controversial for me, just really personally that we accept some of these sort of things about attitude toward foods and in reality that's not what we see in terms of what consumer habits are, and, and people sort of, kind of skipped that, on any hard data or facts on consumption data, on purchasing data.. It's based a lot on pretty subjective polling sometimes, or attitudes or interest groups and lobby groups and how much noise is being made by certain parties and I think that's sad that, that, that for me is a controversial aspect. But in terms of GM, I don't know, I think people's, I think it's controversial again that people assume that there's no regulatory system in the US. There seems to be some sort of attitude that, you know, Monsanto for example is a US company that gets, just launches products, that the US isn't concerned about risk, or the US isn't concerned about food quality. I think it's quite astounding that people can still make those declarations…

Maybe directly connecting to that, why do you think there is such a big difference between the regulatory system - we know that in the US they also have a regulatory system - but if you look at it it's very different from that of the EU if you look at risk assessment and precautionary principle for instance, why do you think that is?

I think some of the fundamental things aren't that different. You know, what you're trying to look for and aim for is healthy, safe food, [...] I think those principles are in both systems, I don't think that's any different. I think the timing and how things were set up in the legislation, and the activist campaigns obviously had more impact on how products were assessed in Europe. But a lot of the products have been waiting out of the risk assessment piece and actually the regulatory piece for a long time in Europe. Or get brought back in, and not on the request of the risk assessments body but through the political channels. So I think that's where there is a big difference that there doesn't seem to be this backing up by Europe of their own system, and that's, again, that's very different.

Although generally, if I'm correct and my research was correct, it can be said that in the US it's rather based on risk assessments – and so far that if there's nobody that has evidence that it is really bad, it can be marketed, whereas here if somebody says it might be bad, somebody has to back this up with a positive "No, it's not".

Yes in a way. And the precautionary principle, I mean, as defined, is fine. It's abuses of the precautionary principle that are problematic. So, I think the fundamental approach is, while different, can lead to to a very satisfactory and workable and functioning regulatory system, so it's not really about one or the other when you approach it, it's when you get down to the detail of what you have to demonstrate that it's problematic sometimes, that you, I mean, everybody accepts that you can't prove a negative. I mean it is just scientifically impossible. So if you bring in elements that, just, you can't prove or demonstrate, it's just scientifically impossible. Those make it very difficult. And predictability of the system is another thing. And I'm always cautious to define 'predictable'. Predictability is really functioning, the systems is used the way it's described. Predictability is often thrown at us if, you know, companies like Monsanto or any other, we wants a system where we can put it in and guarantee the outcome at the end that our product's okay. That's what we mean by predictability. We just want a clear, transparent system that we go through. But if you're in a car industry and if you get a question about landing lights for your car, you're gonna [sic] point out 'Well, it's a car, it's not an airplane'. But what if somebody took your car and turned it into an airplane? We would say, 'Well, we don't understand' sometimes questions on our products are scientifically similar to that sort of question where people would ask, you know, 'What if your product was used for X, Y or Z?', all we would ask for is that our product is safe as a conventional maize. 'Is maize safe?' - 'Yes/No.' If, if, you know I was gonna say 'If I took a corncob' but I should say 'If YOU took a corncob and beat me to death with it or hit me on the head with it…?' Is it, is… is it what maize is for? I would say no. So what we're really trying to demonstrate in all systems and certainly EU and US is we are as safe as our conventional counterpart and I think those can be achievable in both systems. [...]

Maybe just the last question then, so coming to your organization again. How do you see your role in negotiations on this debate, and are you planning to take any actions to influence the debate or do something similar?

So I would think that the influence in the debate is I would probably say 0. I mean we're not government body, we're not part of the negotiations. If you look at the side of the trade agreements, you know agriculture's part of it and within agriculture we're part of that and we keep getting subsets of subset's so, I think even if we wanted to I'm not sure that those are, there are levers or mechanisms to influence. Having said that, you know agriculture is still important and, and general approaches to technology are important. So… I don't think TTIP changes any of our messaging, or who we are, or how we approach the EU or the US in fact. It comes back to basics of explaining who we are, what we do and why it's important and why it's important on two levels, I think. These are the bits that hopefully, by, not just ourselves, our industry, wider industries, the food feed chain, I think agree on those principles we started this conversation out on, which are, how does this benefit the industry and the wider impact on the food feed chain and the importance of agriculture and innovation of agriculture. Do we believe it's important or not? Should we try and expand our ability to cooperate in some way or another across these markets? I think we would've always said "yes", whether it's TTIP or sensible approaches, non-discriminatory approaches, not have trade barriers in place… I, I think that's, that's… nothing that's in TTIP changes that approach. And secondly, it's of course the regulatory framework, you know, TTIP I don't think changes what we've been saying, we would like, whether - and this is for the US as well as for the EU - we would like a fair, proportionate assessment of our products and the ability to bring safe products to the market, that's what we want. But it's not about, certainly our positioning whether it's be directly as Monsanto [cough] and we do, we we meet as many, and as few US counterparts as we do EU counterparts. We're not party to the, the talks, the meetings, the documents or anything like that. So all we can do is do what we do, and anything we would put in the letter to a senator, or an MEP, or a Commissioner is pretty much the same that we'd put on our website, or we would explain to you coming to do a research for your thesis, or the general public or anybody or journalists or anybody who would ask us.

Okay, just something that comes up really fast in my mind: do you feel like the regulatory system in Europe right now is not really fair and appropriate for the marketing of your products?

[um] You know it's always to say unfair is like "boo-hoo". We… There are elements that are being brought in for political reasons and risk assessment that we're constantly told are to, to improve the process to, have better buy-in for the Member States and I think if you look at the voting patterns that are, that are public or gleamed or whatever, and certainly, I think Europe, I think they still have that on their website but pretty much that hasn't been much change in voting behavior in the last, you know, decade and a half, apart from the Member States joining but, there are people who consistently, in this area, will not follow the opinion of EFSA and there are countries that back up sound science. And… I wish there were a rule change that, that would fix that, I don't think it's by continually raising the bar beyond sound science and, and introducing elements that are beyond sound science that, that's EFSA's not requiring that are actually coming in and being driven by the political side… I, I don't think… I would fear a world where politicians would regulate safety and I don't think… I mean, they need to reflect civil society but the risk assessment should be done based on sound science. That's why I hope, when I eat food, as a consumer, I would hope that at the end of the day I can't think of a better way than the best scientists in Europe who are qualified to analyze to tell me if something is safe, that's really where I'd like to not, not elect an official who says "yes" or "no" [...]. I think they could potentially block really cool products coming to my shelf in the supermarket, and they could potentially have unsafe products. I think those are equally or probably, first and foremost, to stop unsafe things from coming to the market. But it's also important to make sure that choice is available for people and I think this will be the final bit on the system, is that… It, it, it really is about choice. I think, people sometimes confuse risk assessment with putting up with selling stuff. Risk assessment is about the risk of your product, it's about making sure that no company launches a product that's unsafe, or that is, a safety factor, I mean we still have coffee and cigarettes and all sorts of things on the market that we know are unsafe but in terms of us, it's a really stringent process, I don't think any other agricultural product or food product has ever been analyzed and go through a process as strict as us… That's just about the safety. That doesn't mean that if Monsanto or one of our competitors you get that, that means that, suddenly, you know the product is is alone. And the next stage is, we have to sell it, it has to have a benefit and that's why we invest money in R&D, it's not "either/or" for farmers. Farmers have a lot of seed options, and they have seed options not just every year but a few times in that season, or a few seasons out, or how they want to plant, what they're going to plant, how successfully it is, what the weather conditions are, how they want to rotate their crops etc. etc. So, even if you, you know safety is the first thing, the most important thing but, but I think sometimes forget the people that the other things are just as important, so the safety is only so you can offer choice. And the next stage is that choice needs to work and fit for Europe, for European farmers, and European farmers also have to sell, to you know whether it's grain handlers or whatever the middle person is or whether they are directly contracted with supermarkets or farmer markets or whether they sell it themselves in their own farm shops… So at the end of the day, the consumer always decides the consumer eats stuff and they buy it and they have purchasing behavior and It's not as if… I think what we… We sometimes… The failure of the system is that all of the highlight comes down to the EFSA, the European Commission and what happens in Brussels in terms of product approval but the approval is really to demonstrate that you're placing a safe product in the market for a choice. One of other products on the market, and that's maybe one of the facts that's not highlighted enough. We also again have failed to communicate enough on that.

Okay I think it could be interesting to see how TTIP negotiations go on and also how far Member States, we haven't talked about that at all now, but it might come to a point where Member States are going to gain the ability to say "Stop we don't want it", or "We do want it" so… We will see.

Sure that will be a very interesting thing to see how products will flow or how… if you're a seed company how would you develop a product in a market that… how do you invest some more where your product could be banned at any stage for any reason?

True

Who's going to be making that investment because, certainly for our company we just don't see how you would operate. How do employ people, how do you give people jobs? And that's what we want to do, we want to, we like creating jobs, we like creating innovation, we like creating markets, wealth in regions, improving lives, you know, making our company a great place to work for people and you know we've had a lot of angst with people, people who have invested their lives in breeding technologies and biotech who, who now in Europe just, you know they see their lives work as Europeans they want to see their products choice here and they see that it's not completely the case but I… We don't understand how that would work in a, you know never mind the trade agreement, we were supposed to have a trade agreement, at least within the EU that we had a common market for many, many years… Even before it was the EU, it was the ECC and the EEC and the… that was supposed to be one of the fundamental principles. That What we've seen was a really challenging and disappointing development and this approach it's really sad…

Thank you very much.

No thank you.

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Member of Cabinet of Karel de Gucht, EU Trade Commissioner, EC

April 28, 2014. 11:00-12:34h. Face-to-face at Berlaymont

My first question is much [related] to the role of GMOs in TTIP negotiations. I wanted to ask you: "Do they actually play a big role in the whole negotiation package or what would you say about that?

So, TTIP is pretty goddam big. And it really touches on many, many, many issues. So, in terms of all the different things we need to, to deal with, this is a minor part of the whole package I would say. so if you ask what the negotiators are, what keep[s] them busy, it's many, many other things than just GMOs. Of course in the public it's a little bit different because the public focus on a much smaller set of issues that have prone to raise attention, if you will, and they are of course one of the areas that attracts a lot of attention. Not the only one, but one of them is the whole SPS issue, so the, the quality of food protection or the protection of, of agricultural production, the safety standards there and how they differ with the US, so vis-à-vis the public and the questions we get, the GMOs have a slightly bigger market share than in terms of the difficulties that we, or the challenges we have with getting a deal.

[Ya], ok. That's interesting because I also read something that actually GMOs only account for about four percent of the whole negotiations. But, if you look [at] the public, the debate is very controversial and that actually relates to my next question, which relates to Alemanno's report, that he published I think in March this year about the parliamentary role of regulatory cooperation. And one of the things he says in this report is that "this", so it's about the different approaches towards GMOs in the US and Europe, "is an example of an area where the source of divergence is, however, not regulatory in nature, but appears rather ingrained in European societal preferences" (Alemanno, 2014). And a lot of other stakeholders also say that the debate about GMOs is very highly politicized and [ya], maybe, what do you think about this? Do you agree? And…

I think it is, it is true that, no GMOs is clearly something that raise people's attention and evokes strong feelings and in that respect it is something that should not be ignored or underestimated in terms of, of the issues ahead of us. And it's also obvious that there has been a historical different approach in the US and in Europe in terms of how non-receptive Europe has been to, GMOs. But it is a debate that has many different layers, if you will, because I think you can discuss to what extent the public debate is really informed about the science underneath but you can also discuss whether the public debate is really related to how the policy is actually implemented already, this idea that we already do accept GMOs in feed stock, for instance, and also in a couple of [GMOs] for human consumption, that we have a legislative process in place that could, imprints of who allow it. But you have similar debates in the US, you have many initiatives at the state-level trying to promote, for instance, labeling of GMO products on the US side also. So it's a, it's a debate that, it's true, that maybe the outcome in Europe and the US are not exactly the same but it's a debate that is also alive in both our societies I'd say.

Ok, yes. That's true, very true., since they have kind of different starting points, the US and Europe, when it comes to GMOs and Europe, as opposed to the US, is more, like the precautionary principle we have, for example, and it's more hazard-based as opposed to risk-based in the US. Do you think this approach, this hazard-based approach towards GMOs, plays a role in TTIP negotiations? And how big of a role?

I think it is true that this goes to a more broad point about TTIP negotiations, that one of the ambitions we have is to try to see whether we can not make our regulatory systems more coherent so that we don't create unnecessary trade barriers in those areas in that we want exactly the same. So, if we think about car safety, we want exactly the same as, as our US counterpart, and should we then try to find a way to make sure that when we then implement these ambitions, we get to the same, do it in a way that does not obstruct trade. That's kind of the vision of things. But there are different areas where this will be easier and different areas where this will be more difficult and one of the…Sometimes it will be difficult because we have entrenched how we do things. So they are different but not because we really want different things. We are just convinced that the way we do things is better than the way the other side does things. And that creates a difficulty in getting a deal done. But there are other areas where we do want different things. We our societies have taken different priorities.

Like GMOs, right?

Yes. Or, I was going to say like the precautionary principle, [cuz] this is really, if you will, a more high level policy vision, if you will, where we have said that you can even ban things, if you are uncertain and where the US philosophy is you can ban things when you have proof that there is a risk. And that principle is in our Treaty. And that Treaty will be there before TTIP and after TTIP. And there is no, that's just how it is, right?, so this will obviously constrain what you can do under the heading I mentioned before about seeing what kind of barriers you can, can eliminate. But of course even if you then administer the precautionary principle or the US system, you can still think about whether that within these constrains of having different ambitions, are there not ways in which we can achieve our ambitions without unnecessarily posing restrictions on trade. And so of course that should be part of the exercise.

Ok, yes,. Maybe moving on to the role of Member States. We've seen that particularly some of the big players like Germany abstained totally from voting on any GM-related matters and this is also a reason why there has not been a qualified majority to adopt a decision of authorization., so what would you say [that] the Member State role[s] in TTIP negotiations in general are and also especially related to GMOs?

So,, so of course we negotiate with the US. So we are in a way the single point of contact with the US with respect to the…

The Commission being 'we', right?

Yes, the Commission. But, it's also obvious that as soon as the negotiations are over, then the parliament and each Member States will have to give it's opinion about the agreement and so if we don't have the support of the Member States and [parliament], or sufficient support, if you will, to get the agreement voted, we would be wasting our time. So of course we are in very, very close contact all the time with the Member States and with the parliament and the Member States are even given, as to negotiating, mandate on where they have laid out the expectations about what kind of agreement we achieve, where they have also clearly said that we should not have an undermining of the standards for health and safety in Europe, that if we come back with an agreement that produced that outcome, we would have, if you will, violated our mandate and then the Member States, would, and the parliament, would be right to say "bugger-off!". , so of course we have to stay in permanent contact with the Member States and with the parliament to make sure that the positions that we take are well-understood, the battles that we fight are the right ones and that the concessions that we give are within the perimeter of what can be accepted., so that's and ongoing process. Now this is about what happens within TTIP. The other part of your question is what happens to implementation of GMO legislation because we have this process in place where EFSA makes its scientific assessment, the Commission on that basis makes proposals and then the Member States have to or I'm not even sure [...] [looking at the EFSA chart of risk assessment together] I think, of course there is a process that has to be respected, then in that the Member States have to play their role. and so, I don't think, it's not the Commission's role to substitute their opinion for that of the Member States or the other way around. They have their role to play and they do that.

Could you maybe give some concrete examples of how that looks that you have this contact the Member States all throughout the TTIP negotiations?

Yes, so we have these negotiation rounds with the US Trade Representative and they take place roughly every two, three months. And so before each round and after each round we meet with the EP, we have a permanent contact with the Member States in, what we call the trade policy, TPC it's called, where a permanent representative from each Member State is sitting around the table, the Commission is sitting at the end of the table and they are discussing whatever matters come up on a, on a very frequent basis. So they know in great detail what is, what is being negotiated.

And how would this look if we, for example imagine now that such an agreement as the TTIP is [gonna] get…both parties want to do it and there is some regulatory similarities that are [gonna] be established within the negotiations also regarding GMOs that, for example, we have the same procedure somehow, we somehow manage to find a way that we both agree [...]. How would that look then if some Member States would say, "but we don't want this" because in Europe you also have the principle of mutual recognition, where if a product is valid in one Member State, ever Member State has to accept it.

Yes. I think with respect to…now there's a difference there to be had between trade in GMO products and then the permission to grow GMOs in a given Member State because with respect to the latter, so far there has been…because in some Member States there is a very, very strong resistance or hostility towards having GMO crops on their soil; Austria being one of them, for instance. And that has led to the situation that because this, I think, historically has been on the unanimity of, I'm not 100 percent sure about whether it was under unanimity, but as a result, no GMO has been allowed for cultivation in Europe. And so, what the Commission has proposed is 'let's create a new procedure whereby you allow, even if it is generally permitted to, a give crop is allowed to be cultivated, then let's allow individual Member States from taking an exception and say 'we will prohibit it for other reasons than the scientific rules that EFSA has…''because EFSA will still make the assessment that this is safe and produces no risk and that will of course be the first step in ever allowing a crop for cultivation. But then you would then allow Member States to say 'ok, I prohibit it anyway because, for instance, fields are too close to each other in my country' or whatever you would assess, and so that will in the end pave the way for different Member States to having different rules for cultivation, which is of course something very different from the rules on trade in the goods.

Are you relating to the Regulation for the possibility for Member States to restrict of prohibit cultivation?

Yes. And if my understanding is correct this one has left the Commission, we have made this proposal, but it is still under consideration in the Council.

Yes, exactly, that's what I also saw., so you have already talked now about the difference of the import of GM foods to and the growing of GMO seed in Europe. Do you see some, a difficulty there, because isn't this kind of applying that ok, we still, for example, import a product, but we don't [wanna] grow it ourselves. You could even say this is kind of slavery is allowed somewhere else but we're not [laughs].

[Um] I think there is…I don't think that this is the right way to characterize it. Because of course, part of the concerns that you have about GMOs is that the crop, once is has been put in the ground, can transmit properties to other crops. That's kind of part of, at least the perceived risk of why GMOs might be bad. That's a risk that you take upon you if you grow it. It's not a risk that you take upon you if you eat it. And so of course whether you want to eat it and whether you want to grow it, I think it's natural that that assessment is…that it's two different assessments. If somebody else, because they don't have the precautionary principle or something else, than that is their democratic right in their society to take that decision and in principle Europe should be allowed to take its own decision on that. So I don't…I think it's perfectly logical that you, you distinguish between those two.

Ok, and do you, do you know if that in the TTIP negotiation there is a difference made between those two things, so either growing or importing GM products?

Yes, I would imagine so, because it is two different issues and it's also two different sets of stakeholders, right? If you are…the issue of cultivation is mainly an issue for those in the US that sell the crops whereas the trade in the GMO product is for the farmers that grow the crops. [...] So it is at two different levels.

So do you think that in the end we might come to a point where we import more GMO foods than that we allow to grow them?

No, but that's already the case today.

Yes, for feed, [ya].

So, yes, so that is GMO crop that comes into Europe., so that distinction is already there, if you will. [...]

Maybe personally, and also representing the opinion of the Commission, what is you general attitude towards GMOs, or your gut feeling regarding this issue?

I honestly…I don't really have any because, I think, at least from my point of view, it's very important that we keep keep things separated that should be separated, right? It's not, it's not for me to, to…

Judge?

Yes. So I trust that EFSA, when they do their scientific assessments, that they do it properly, straight and correct and make sure that if something is not safe they tell us and that if something is safe they tell us. And I take that as a basis. If it is safe then I think it's very important that the subsequent debate of whether we should allow it or not, is based on that. [...] If it is not safe then I think of course it's a no-brainer, then it should not be brought on the market. But what we have seen is that we have, we have this procedure in place that allow us to to allow, to permit GMO products to come into Europe, and we have had a tendency to sit on it, right? To extent that the Court has told us that we are not respecting our own rules and that I think is a problem. I think we should respect our rules, we should own up to our responsibility and take the decisions when the decisions have to be taken.

So in the sense that if EFSA approves something, we shouldn't wait very long to adopt it, if it's safe.

Yes. That I think, then I think we should move the process forward and then take a decision on whether we want to allow it or not. But whether we want to allow it or not is not, I'm just a civil servant, that's not my responsibility, that's the responsibility of those in your flow chart [referring to the EFSA chart Isabella brought] that has to make that decision. But at least when we have created the rule of how to to move forward, we should respect it and we should not…It's embarrassing that the Court is telling us that we are not even respecting our own rules.

[Ya], ok.

And I think once you do that, then a lot of the conflict also with the US will go away.

Definitely. And to what extent do you, as the, so like, in trade negotiations [since] you are involved there, to what extent do you cooperate with the DG Health and Consumer who after EFSA gives an opinion has to deal with that opinion and do other risk assessment?

No, we are very closely and I mean they are involved in the negotiations. So, they are at the table because we end up discussing things that are very detailed not only on GMOs but on everything in the negotiation and those poor lead negotiators they would not be able to cover all these issues if they didn't have the expertise of all the people, including in SANCO. [...]

My last question, do you think from recent developments that you have seen in TTIP negotiations that these negotiations will result in an alignment of EU GMO policies with that of the US or the other way around? And what specific elements would that alignment comprise, for instance, if it would result in an alignment?

As I said I think it's an area where tension between the EU and the US ought to be much less than what it's sometimes laid out to be. Because, as I said, we do have the rules in place. We do actually allow crops to come in that are GMO., the Court has told us that we need to move forward more speedily and so I think that in itself is…and then we have this proposal before the Council which would also allow us to move out of the dead lock where countries that actually do want to grow GMO can grow GMO., and so I think that we already, even before the negotiations started, if you will, we have a lot of ingredients already to diffuse a lot of the tension that has been there in the, in the past.

So you think that the tension anyway is diffused but do you also think that concretely something is really [gonna] change regarding the regulatory…you said already the precautionary principle is something that's in the Treaty and that's going to stay there. But you don't see anything that is going to align in the policies regarding GMs? Or maybe the speed that is [gonna] align?

No, I think that if you look within the existing legal framework, I mean everybody who uses the system as applicants are frustrated with the speed. And so, whether there is something there that can be done I don't know but it's obvious that when the Court is telling us to move faster, the applicants are telling us to move faster that seems to point towards let's find a way to make that happen whether that has to be within the context of TTIP, or whether it has to happen anyway, I suspect that if the Court is telling us something then that counts even more than if the Americans tell us to do something, right? [laugh] So, so, well we have to see where things end in…It's not something that keeps me awake at night.

But there is…isn't there a problem if, because right now in the US there are far more products that are sold that contain GM than in Europe. And I thought, in my…I see the TTIP as that trade really is [gonna] go to a same level where everything can sort of cross boundaries without these restrictions. So, do you think that in that sense maybe GM or GMOs might be a critical factor or maybe might be excluded? Because those that are not allowed in the EU but, however, are allowed in the US, what is [gonna] happen with those products?

I don't think that it will be excluded but the fundamental principle that I mentioned in the beginning is – I really mean it – that we will look at what is the regulatory level of protection that we want in Europe. And that we decide first. And then maybe it's different, or higher or lower, than in the US. If it's exactly the same, then we can do a lot on trying to make sure that trade flows exactly freely. But if we end up in some areas where we have a different, our democracy has decided a different level of protection than in the US, then our ability to make trade flow would still be such that the European regulation will have to be respected in Europe. So, for instance, this issue of hormone in beef. There we have a very different approach: The US allow it, and we don't. That was true before the TTIP and it will be true after the TTIP. And so we will be able to facilitate trade of hormone-free beef, not on the beef that contains hormone. So of course you would look at whether there are things that we do that doesn't make sense in the way we implement our wishes. But if our, it's the same with a lot of our…data protection, for instance. We make rules in Europe about what is the level of data protection that we want on European soil. And then, based on that we try to find ways to not obstruct trade. But still respecting the level of protection that we want. That's how it has to be, right? And so once you, once you trust that that is really the concept of what we are doing, a lot of the tension goes away. But of course there is some people that don't trust that this is what we will do. You'll have people that keep saying this will mean that hormone beef will come to Europe, and we can tell them 'no, it will not' and they will say 'yes, it will' and then we have that debate in public for two years. But, that's how it is. As the Commissioner said at one press conference, 'is it my English, that is not good enough?' [laugh] 'There will be no hormone beef.' And so, so I think, of course there are many issues where we, and also where we disagree and have big conflicts with the US but this GMO thing, I think it ought to be pragmatically solved without us being forced to take different views as societies than we want.

So, if I get you right, basically TTIP is supposed to make trade easier on those products where the US and Europe can agree on a regulation system that is exactly the same, like cars and a lot of other things. But those things where they do have different policies in place and different products allowed on the markets, those will not merge because of TTIP negotiations, those will still have their own things and we might import some GMOs but not all of them and you think that these negotiations might speed up the process of allowing those that Europe allows, but in general will not change the system in Europe, right?

No. That, [ya], roughly speaking. What I'm saying is that even if we have different views, there might be things you can do. Because you might have different ways of ensuring that companies get to this level of protection in terms of certification, of all kinds of things, so it's not that as soon as we have different ambitions we take it off the table and we are not [gonna] think about it; we are still trying to think about it but we are [gonna] think about it within the framework of making sure that the laws and rules and protection standards that we have decided in Europe, will be maintained in Europe.

But up to this point, there are no concrete examples of how the US and Europe have talked about GMOs in particular and how they might kind of come to…

No, because, and that's the other part of it, right? Which GMOs will be approved in Europe is an ongoing process. And the process is there and so the Americans are making applications and that process will continue and we need to make sure that when they make their applications we are not saying no just because they are Americans, we are saying no because they are, they don't meet whatever standards we, we put in place.

So, it's more a case-by-case…

[Yea], you can say, it's about going through all our regulation, making sure that when we implement it we do it with a view to our policy objectives, not for protectionist reasons. So leaving out all the part of it that has to do with protectionism, if both sides can do that, we can make a lot of gains without any cost, because we are still preserving our level of regulation.

Ok, yes. I think that's it so far, and we are a bit overtime. Sorry, I hope you don't mind [laugh]. Thank you very much.

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Scientific Officers, EFSA

April 29, 2014. 15:00-12:41h. Conducted over phone

I am writing my thesis on [...] Wen we are talking about GMOs and policies in Europe, I realized that you, EFSA, is really a big stakeholder in that debate since in the directive and in the regulation of 2003 there are procedures laid out as to how you do risk assessment, so you really play a big role. And that also relates to the first question:, you role is to independently assess possible risk of GMOs to human health, animal health, the environment. But, I've already talked to a couple of stakeholders by now and all told me that Europe is not really respecting it's own system in the sense that sometimes timely implementation is not carried out and the Court even has issued a complaint regarding that. Do you feel like the Commission is taking your risk assessment into account timely or do you agree and do you think that the debate around GMOs is highly politicized and not really following the way it should?

[Um], it's a quite tricky question [laugh] in the sense that we don't have any particular opinion on that. [...] EFSA is one of the main stakeholders in terms of risk assessment, I mean one because we have all the EU Member States involved. And so through the scientific opinion, statement or any type of prove that are delivered by EFSA, and in our case the GMO panel, indeed we give to risk managers, so to Commission and Member States or advice [...] but I would say that after that it's really up to them. [...] And in addition to the risk assessment, the risk managers also take into consideration other factors, [...].

Yes, they also take into account, for example, the I think the public consultation or they let public actors speak as well.

Yes, indeed, they do.

So, do you have the impression that your role as risk assessors is really taken seriously and to what extent do you, do you think that they really do take it into account?

[Ah], I think that EFSA's work, and the GMO panel's work, yes is taken seriously. Actually, if you think that all this, all, I mean most of the output issued by the GMO panel are upon request from the Commission., but as I told you once, it's out of our hands it's over for us, I mean we have really no control on what they do or don't do [...]. We could think that they don't take anything into account for good reasons, ethics, socio-economics, who knows. [...]

I understand that your role as risk assessors is probably still respected, since you are the main authority. But could you maybe elaborate a bit on what this risk assessment procedure actually looks like concretely, how long it usually takes and in how far, to what extent hazard-based assessment affects it? As opposed to risk-assessment in the US, for example?

Yes, so. Actually we print a few slides before [...] so the key principle of the risk assessment are set up by, so actually the regulation and the directive you just mentioned before. And we strictly follow these principles [...]. So by the key principles I have in mind the case-by-case approach, so meaning that each GMO is considered independently [...] then, I would say the first, I should have started with that one, the first principle in my opinion in the risk assessment is the comparative analysis. So it means that throughout the evaluation process, we compare the GM to a non-GM comparator, conventional counterpart, it would be called that way. And we bring the risk assessment of the difference observed between the GM and the non-GM, if any differences are observed. And the third principle is step-by-step [...] it's made of six, seven steps, and it starts by consideration, identification of hazard, identification of the exposure, a proper combination of both in order to characterize, to identify and characterize the risk, and then if risks are identified the risk assessor may propose to its manager mitigation measures or management measures so to limit the risks, and finally, what we expect from applicant and from risk manager is an overall conclusion of the risk assessment when the mitigation measures are properly put in place, so all the risk is reduced.

Alright, how long would you say going through all these seven steps usually takes in order to have a scientific assessment of one GMO?

Look, we have statistics on that, that I don't have in mind of course, but I would say that it probably goes from…I mean it really case-by-case in the sense that it highly depends on the quality of the dossier we received, first of all., then throughout the risk assessment process, so the panel, and it's basically the working group, have the possibility to go back to the applicant, so to seek new information., so based on that it means, it also highly depends on how long the applicants need to produce the new data. So you may imagine, that in the case that we would ask for new feed trial, it may stop an application for at least two years. [...] It takes quite some time. Also because, I mean the objective is really to give a comprehensive advice, so comprehensive risk assessment.

[Yea], definitely., maybe can you, do you have the data or knowledge about the difference of the assessment that you carry out and that, for example, in the US your counterpart, the FDA, carries out, because I read something that there it goes much faster and that might be based on the fact of substantial equivalence, maybe, or – I don't know – the different approach, do you have anything, an opinion about that?

[...] [Yea, um], look I'm not really aware of the last figure of the US, but, [yea], I think that I am not mistaken that I think that yes, they are much faster., as far as I know they also follow this…No, actually they don't strictly follow the same principles, because, so they don't follow this – wait a minute – there's a difference between product-based and process-based.

Ok, product-based and process-based.

Yes, so in Europe [...] [in the Directive 2001/18] it's defined what's a GM, what in Europe is considered a GM. And it's based on the techniques used to obtain the new crop, I say, the new plant. But as far as I know, but I hope I'm not mixing with the Australian system, [...] but want to move on the product-based.

Ah, I see, so you are differentiating between, for example, if you use this gun to insert the gene, and if you use that for different products, then they might be assessed similarly because the same method is used rather than saying it's another product [...].

Yes, and in terms of the key principle if we share the same, I mean this comparative analysis, as far as I know, it comes from internationally agreed guidance. So it certainly comes from OECD and Codex to which US and Canada adhere to so this comparative analysis is followed. [...]

Maybe we can move on to the next question, which is your general attitude towards the use of GMOs or GMOs, the benefits and risks you see and whether you can actually give a generalized answer or whether, like you said before, you have to look at different risks case-by-case, and differentiate between imports of GM foods and the growing of GMO seeds.

So,, first of all we only look at possible risk. So we don't take into account benefits. So, there is, I mean, for the last years quite a debate on the risk-benefit balance, and that's not something we check. [...] So the attitude from the EFSA side is quite neutral. And then yes, I would stick to the case-by-case, case-by-case risk assessment.

So no, you cannot just say GMOs generally have these risks because it really depends on the product, on the process?

No, you know, I mean, back to question 2 and also your question 'how long can we take for an application?', so I wouldn't know how many GM maize we have in the pipeline with similar traits, let's say herbicide tolerance traits, and we always start from scratch, we always start from scratch with all of them. And that's what I meant by case-by-case. So, we don't really…of course, I mean we have expert knowledge [...] which will be valid across, but it's…each GM is a new GM that needs to be looked at.

[...] Could you differentiate a bit between what you think about the import of GM foods and the growing of GM seeds, or the cultivation of GMOs?

[Um], yes. So, I mean strictly speaking, we need to differentiate? Not really. In the sense that we have clear guidelines, so sets in our guidance documents, and so applicants and risk assessor are asked to follow these guidelines. So let's say that it applies to all types of dossier. [...] But there is a differentiation in the sense that the exposure is different. So, one of the principles of the risk assessment we have seen is hazard identification, hazard characterization, exposure and at the end the risk is, let's say the sum or the combination of hazard versus exposure. So, the risk assessment is a bit different in the sense that exposure is different. So in the case of import we consider possible accidental spillage of grains that are transported by trucks or…and in case of exposure, ah sorry, in case of growing, cultivation we really consider deliberate use of seeds or crops by farmer. So for me the difference is mainly in the exposure level.

So you think the exposure to GM seeds, for example when they get spilled is different than non-GM, so that there is more risk in the spillage of those?

No, no, no. I mean the risk is really the exposure and the hazard. [...] To identify the risk, first we take into consideration hazard. So, the possible adverse characteristic of the GM that's more or less, you know…And we need to put that into context. So in the case of cultivation, the exposure to the environment to, to other organisms is going to be high. And then this is going to be translated into risk, yes or no. But in case of import and processing, the exposure is going to be much lower. So we only see exposure in the case of a few seeds spilled from the truck, going from the harbor to the processing facilities. And that's the difference. And in deed, it can be translated to different levels of risks. [...] And it's still case-by-case.

So if I understand it right, then it's probably easier to import GM foods than to really grow that, because you just don't have, or you really have a much lower level of exposure, right?

It's easier, you're right. In that sense it's easier in terms of impact on the environment. But you know that the objective of the risk assessment is to consider the impact on the environment, but also on human and animal health. And the impact on human and animal health is probably the major pillar of the risk assessment in the case of import and processing.

[...] We have already talked a little bit about the impact on animals thus, so this is relating to my next question. EFSA says that the safe animal feed is important for foods of animal origin and that there are many examples of the close link between the safety of animal feed and the foods we eat. Can you maybe give a concrete example of this link and say, or elaborate on…Because for me as a consumer, it's a bit strange to understand that maybe I'm not allowed to eat one GMO, but then maybe

the cow that I'm going to eat tonight is allowed to eat this GMO, so in how far does this secondary inflow into the food chain affect consumers?

I mean honestly, as far as I know, but that's something that we need to check with the Commission, who is in charge of the approval, I cannot recollect any example of having a GM maize, for instance, that would be authorized for feed and not for food. But that's really something to check with DG SANCO. [...] They have on their website what they call the EU register. [...] First of all, when we receive an application, it's up to the company to define what they want on the market, [...]. And most of the time it's food and feed. [...] They might ask only for food or only for feed. So far, I think they always ask for both.

[...] Yes, I will check that with DG SANCO as well. But then, [...] in general I have the impression when it comes to consumption of consumers, that we eat not so many GMO actually, and that a lot of animal food or feed is actually imported from countries like Argentina, Brazil or the US where they use GM crops. So…

Yes, you know probably, I wonder if it's if it's…in my opinion it's more a market dynamic. But if you look through the register and you check some of the GMO, if they are authorized for food and feed, ok, it means that they could be legally commercialized as food or feed, then it's more the market ruling. [...] But it's also up to the Supermarket and answering to the consumer who is not really keen to have GMOs. They need to follow some traceability and labeling rules, which is probably less the case in feed. [...]

Ok, [ya], perfect. Thank you for answering that. [Question of elements of alignment]

What could specific elements of alignment comprise with regards to a change…[um] actually I'm not sure if it's directly related but I have something that comes to my mind, and it's about the guidance we developed on GM animal. It's a quite new guidance. [...] So when we started working on that, upon request from the European Commission, we really started from scratch, we had…and we grabbed quite a lot of inspiration from guidance that were available in the US. [...] In the risk assessment world, so like the trade or political, I really think that for sake of good risk assessment and let's say good science, there is some, I wouldn't say an alignment, but an exchange and flow of information between US, Canada and Europe. So trying to – and Australia [...] – to, to compare the different approach, but to be aware of what has been done by others.

Ok, and you do think that for example…I mean you have already talked about this hazard-based assessment. And I mean the precautionary principle is actually laid out in the EU treaties, so you would say that in sense of this and maybe in sense of the seven step procedure, nothing will really change because safety standards are maintained on the same level, do you agree?

In terms of risk assessment, I wouldn't see any drastic change, no. Because as you say, it's put black and white in the Treaty, and back to the key principle of the risk assessment, we simply follow them, those, that are also endorsed by regulatory framework.

Ok, good. That's what I thought and hoped [laugh]. Good, maybe let's come to the role of Member States; I've read on your website that you, a couple of thing where Member States are really involved. First of all, during the GMO assessment process, you say that you have thorough contact with Member States and a hug expert network. Then also, secondly, when I looked at how Directive 2001 and the Regulation of 2003 lay out the procedure and your role in the risk assessment, the Member States are sort of always the last instance to approve or authorize those GMOs. But then there is countries like Germany who are now systematically abstaining from GM related votes and, thus, no qualified majority has been adopted, I mean no decision on authorization could be adopted. So what do you think about this and do you think or feel that GMO adoption and restriction after your risk assessment is and should be a Member State issue, or should it be regulated on the EU level?

[...] So first of all the risk assessment that is carried out by EFSA is EU wide, [...] So the risk assessment really consider all condition encountered by the different Member States. But then, I mean it's almost back to the first question, I mean once a scientific opinion is out of our end, and with the Commission and the Member States, it's really up to them, it's really…and it's true that all the Member States may vote for any good or bad reasons, not to vote or to abstain. [...] It's really political, [...] even if it's approved, then at the national level, I don't know, a country like Austria or France may completely say 'no we don't want to plant any GM here' [...] It's a very complex decision-making. [...]

So you do think that somehow the Member States do have a big role, and they actually have the last word to say it right?

Oh they do, but actually, so this approval process is called comitology [...] it's defined in the Directive 2001/18 and the final word is really with the Member States. Nobody else. No, initially with the Member States. If they don't manage to find an agreement, it goes to the Commission. But it's really up to Member States [...].

[Ya], and this majority somehow hasn't been reached yet because countries like Germany abstain. So how does that influence the whole debate?

[...] But not much in the sense that…in deed, Germany is I think one of the most involved Member States, during the risk assessment, in terms of commenting the application when we receive them, in terms of volunteering to carry out initial risk assessment, Germany attends the network meeting that is organized by EFSA for the Member States, Germany is attending all the European Commission Committee where EFSA is invited to present, so they are quite active. [...] They [Germany] have

different ministries involved in the GMO context. And my feeling is more that it comes from discrepancies or disagreement between different ministries. And it's reflected at the political level by a no-decision.

That's interesting that Germany on the one hand is very involved in risk assessment and then, when it comes to a general vote on GM products or GMOs, then they abstain. It's interesting to see.

[Ya], but actually it's true, I'm listening to you, it's really, for me it's really a, let's say the good proof, or a good example of the gap between science, I mean let's say risk assessment, and the approval process, which is more about politics.

[...] Then, what also relates to Member States is the specific safeguard clause, that I've read about, where a Member State can provisionally prohibit the cultivation or use of a GMO based on scientifically-based concerns, and then the Commission may ask you, the EFSA, to provide a scientific opinion on the information presented by the Member State. Now my question is,, how often does this generally happen, because mostly what I've read, the countries that have used this safeguard clause, in the end you kind of assessed a product and you said the product was actually safe. Could you maybe…Is that true, or how often does this usually happen and successfully or not for the Member States?

Ok, so, let's see, we got over the last five, six years more or less two safeguard clause on average per year. [...] So we have Italy, we have Luxembourg, we have France. But the thing is that when a Member State invoked a safeguard clause, it means that so this prohibition is let's say acknowledged or officialized in a national decree for a certain period of time. And their national law implies a renewal or an extension and that's when the risk submits let's say new evidence to support the extension of the clause. So that's why we are recurrent clause (?), which has to be always the same, on the same GMOs, from France, from Greece, from Luxembourg and Austria. [...] What we call emergency measures, because safeguard clause was under the directive and emergency measure is under the regulation. But the principle is the same: it's a Member State willing to prohibit the commercialization. So we have France, we have Greece, we have Italy, we have Luxembourg, we have Germany, we have Austria, Hungary, and it will be it. [...] And so it means that, so first of all, those Member States invoked this safeguard clause to the European Commission, not directly to EFSA. [...] their evidence to the European Commission, the other Member States are informed, and then it's really up to the Commission to decide whether or not they want from EFSA a scientific opinion on the evidence that are provided by the Member States to support their case. [...] So what is provided by the Member States needs to be scientifically based, which is not always the case, and new. So that are the two strict conditions that we look at. And, you are right, because I really, you are right in the sense that so far having assessed this different supporting documentation provided by Member States, we couldn't find new, science-based information supporting a revision of a previous assessment.

In all cases?

In all cases, [ya]. [...]

So none of these, none of these safeguard clauses were in the end proved right, and the Member States was not allowed to keep this prohibition of the market, in the end they…you proved them wrong, basically, and they had to reintroduce the product to the market.

If they have to, honestly, I wouldn't know, because I think they never did. But, you are correct; we never really found new scientific evidence that would invalidate previous conclusions on the safety of a product. [...] In terms of risk assessment it [the 1998 moratorium] simply, simply strengthened the requirements. [...] The key principles, I mean case-by-case, step-by-step and so on, were already there, they were already in the Directive 2001/18 and they were even in the previous directive, which dates 1990. But I mean more stricter in the sense of data requirements, probably [...] for proper risk assessment, asking for more, more information. [...]

Well, that's already it, I think the 40 minutes are also over, so we should come to an end probably. I want to thank you again, very much for taking the time.

Ok, thanks to you.

###

EU Policy Director on Agriculture, Greenpeace European Unit

May 2, 2014. 14:30-15:02h. Conducted over phone

My first question relates to the role of GMOs in Greenpeace itself, so, is it big of a deal, is it a lot of discussion that's focused on GMOs?

Well, it's a very let's say old and consistent campaign. We've been working on this issue for many, many years. about a decade and a half, basically. we built a lot of knowledge, scientific knowledge, economic knowledge, agronomic knowledge on the issue and on European level, on national level, but also at global level, so, it definitely is a well-established campaign where the organization has put resources on. And I assume it will continue to be so in the future.

Ok, good. Well, in the light that it does actually constitute quite a big part of your activity, was is your attitude towards the use of GMOs if you would have to summarize that in a few words, is it positive or neutral or negative and what are the main benefits and risks you see? I've already looked at your website, so I know some of them, but could you maybe just briefly summarize that and also say…

[Ya], first of all its important to clarify that we are concerned about genetic engineering when it comes to the deliberate release into the environment of GM crops. We are not against genetic engineering when it's used in closed systems, in controlled systems, we are not against GM use in medicine, we are not against the use of GM in industrial processes, so what we are against is the deliberate release of plants, which are living organisms, into the environment, because of the [...] contamination problems. Because these are not just products, you cannot take them off the shelves. Because the crops with the natural plants...so in case there's a problem that probably won't be able to be stopped., it's irreversible. This makes this, this is one of the characteristics that makes this technology peculiar. The other one is that it interferes with the genome of living organisms, these are the main risks. In their way there is no sufficiently scientifically robust. What do I mean from that? I mean that, we are managing; we are altering the genome of living organisms. We are not having a knowledge about the very complex network the way in which these genes are actually functioning, whether they are switched on or switched off, the kind of rearrangement that happens in the DNA of a plant that's subject to genetic engineering. The fact that there are fractions that remain there, they used to be called junk DNA. [...] We had scientists observe that sometimes a plant exposed to higher temperature… one gene gets expressed while it was thought that this gene would never get expressed. This can be, you know, good or bad. [...] The most widespread GM soybean in the planet [...] when exposed to optimal conditions it actually gets much less yielding. The yields are much lower. Why? Because a specific gene gets expressed. Nobody knew it before it happened actually. These are just examples to clarify that there are problems. Problems caused in the environment, we have plans that release toxins, and these toxins affect living organisms [...] and the problem is also related because of the way in which this technology is used, first of all because two thirds of GM crops out there are tolerant to herbicides, which means that they require more herbicides to use. And the development of herbicide resistance is an issue, since a decade now, acknowledged by everybody, including the United States department for agriculture and Monsanto and DuPont, so it's not anymore us saying that this happens but it's clear. but it's also that GM, due to the costs involved in developing one plant, which are massive, 200, 300 million dollars depending on the kind of plant we are talking about. only corporations can spend 300 million dollars to develop one single plant. And, and that's why the six companies are dominating the market on global level, and one, Monsanto, is dominating it within those six., the kind of agriculture we need, is not the kind of agriculture that suits perfectly GM technology and the package GM and agrochemicals like herbicides. These are, in a very short time, the kind of problems we see. [...] it is known that, Roundup ready soy one, the most widespread GM crop on the globe, has like 11, 12 percent lower yields than commercial varieties, and that has been accepted even by Monsanto, [...]

So what I got them from what you said is that generally have to make a distinction between GMO food and GM feed because the impact that the growing, or the cultivation of GM crops has on the environment is very big due to nontarget effects and things like that basically when it comes to human consumption all you say is that there is not enough research conducted on that topic. So you do think that there has to be a distinction made, also when talking about trade, but you do also – if I get you right – to also reject the consumption of GMO products, is that right?

[Uh], yes, yes. Of course when you work in Europe…what we are willing to get us to establish the most robust system in Europe. we cannot, of course, lay any hope in establishing any systems abroad. We would not like to see 53 percent of the Argentinian territory being used to produce GM soya beans, for example. This is not at all sustainable. But who is Europe to dictate what other nations should do? What Europe says is, I have the system of GM and I authorize them in a specific way and if you want to sell products to Europeans you have to respect those rules. [...]

What do you think about the risk assessment that's done by EFSA because they, for example, conducted some research on, I'm sorry I don't have an exact name, but I also spoke to them a couple of years, um days [laugh] ago. so they have done research on GMO products, and they said that some of them were fine and not dangerous to the consumer. So what about those GM ingredients in food, do you agree that they can be eaten?

[Uh, ya] no, the problem we have with EFSA is a bit more, more… we have a number of problems let's say. First of all, EFSA, in the past, and specifically the panels dealing with GMOs, [...] were having a problem with being representing far too many scientists with close links to the industry. Not only, also, far too many scientists of the same kind. If you ask a microbiologist to have a say on molecular biology as a science, they all are going to defend it, of course. It's like, you are specialized on an issue, and then you are asked to say whether the issue is good. You spent the last 20 years of your life working on that. You are not going to… it's human, it's absolutely normal, you're not [gonna] be moved to put questions into that. So the problem we had was that when… the panels were actually shaped, the way in which actually the whole EFSA was also shaped. Due to a number of fights and discussions on public level, I have to say that I have seen a shift in EFSA to an extent that last year EFSA leaves four opinions, where they actually concluded that they don't have enough scientific evidence to conduct risk assessment. But this is part of a wider problem. Risk assessment is valid to provide some information. But the problem is, that if you have a technology that you cannot master yet [...] risk assessment is not capable of actually providing you any answer, which is valid in the long-term owner which is, you know, very solid in terms of what could be the long-term impact of that specific technology because risk assessment is limited. What we criticize, is the fact that risk assessment conducted in the past by an agency which was very much linked to industry, the panels, not as an institution of course, was used as some sort of official green light on the safety of this crop. This is not fair, this is not scientific. [...] we are constantly attacked because we're not scientific, but the problem is that the system is using EFSA and the risk assessment they produce as if the risk assessment was, you know, a perfect tool, as if the risk assessment could provide you with long-term evaluation, assessment of long-term impacts of the technology [...] which cannot be possible, as if EFSA was absolutely independent and balanced, which was not the case, and without taking into consideration all other independent scientists, all scientific research being conducted, [...]. In evaluating a technology one aspect is the risk evaluation, the other one is the risk management. And the risk management is an activity, which is as problematic and complex as risk assessment. We should take into account all different factors and come to the conclusion whether or not the precautionary principle or the prevention principle should be put in place. In the case of GM we constantly saw the Commission say '[Ah], EFSA delivered a positive opinion so we need to authorize this crop'. No, EFSA delivered an opinion, but they also flagged scientific uncertainty, for example. When there is scientific uncertainty, you, as risk manager, in this case the European Commission should take a specific decision, which is based on the precautionary principle. I have a technology, which can provide an irreversible effect, which is also unpredictable; I have scientific, evidence from scientific uncertainty; I have public demanding for that; [...]

Okay, that makes sense. So, if I get you right, then you would say that, you don't have a problem with the technology when it's researched indoors. Where the problem lies, is that right now there's not enough evidence to support the release of GMO products onto the market, nor the environment. But the research can still go on, because the technology in itself can maybe get developed and can at one point be more safe, is that right?

So, [ya] the core of the topic is the use of the technology needs to be clarified. We are only against one kind of use of this technology, and it's the use on agriculture. Why? Because it deals with living organisms. We are not against controlled use of GM crops, of GMOs, such as possibly in agriculture, but also in the medical sector or in the industrial sector. Second, it's also a question of the kind of technology. GM is modern biotechnology, but there are other modern biotechnologies, which are even more advanced than GM and do not pose the same kind of problems and risks of GM.

Do you have an example of that?

Marker-assisted Selection, MAS, [...]. We have an entire report on that, you can check online. [...] This technology is brilliant because it uses technology we have about genomes and genes and it's used to speed up enourmously conventional breeding. [...]

I think we could talk about this for a long time, it's also really interesting.

[Ya, ya, ya], let's go into TTIP.

It sounds great. [laugh] [...] but [ya], let's maybe get not too far off-track., related to you as Greenpeace, how do you see your role in the negotiations on this sensitive debate, and also, are you taking any actions already, or [are you] planning to do that to influence the debate on GMO trade between the US and Europe?

Well, we have been discussing about GM trade in the past for decades. If you are referring specifically to the TTIP, we are…for the time being we have not been particularly active., we intend to become more active, we are monitoring what is happening, what are the positions being expressed,, but [ya] for a number of reasons, for the time being we haven't been extremely active.

Ok, so, that sounds like it's not on the top of your agenda right now. There is more important issues that have to be dealt with at the moment?

Well, I would say not urgent, but this is clearly one of the most important ones. So, we will definitely, together with a lot of other NGOs, keep focusing and looking into that.

Ok. Regarding everything that you have already said about risk assessment and EFSA and things that are just in Europe already not quite working, regarding GMO regulations, is there any, any fear you maybe have, that really relates to this new transatlantic trade and investment partnership, that might…where GM trade or GMOs might get worse or something that you view as particularly controversial in those negotiations?

Well, [ya], definitely, definitely. I mean, the whole purpose of this negotiation is to basically weaken standards and regulations. The US government is willing to, to do two things. On the one hand, to convince Europe to leave its zero-tolerance policy on, on basically unauthorized GM material in food or feed and they are willing to have basically a harmonization, something that could be called mutual recognition even. And if the FDA has found that a specific crop is not…provide any problem, that Europe should accept the risk assessment provided by the FDA. But the problem is that there are different rules. The FDA is not supposed to do all, what is required for EFSA [...]. Plus, the regulation is a deregulation in practice. [...] So there is no chance to harmonize an absence of regulation with a strict regulation. Their aim is to water down, to weaken Europe's regulations [...]. The other problem is that basically they are also presenting the issue as if it were a big problem, but from a trade point a view, [...] we already authorize and we are importing 52, 53 different GM crops, and we are, I think, on the top 10, probably number five or six, in terms of countries in the world that have allowed the highest number of GM crops. So that there is a trade issue is actually a myth. What the US wants is to put pressure on Europe to start authorizing more GM crops for cultivation so that it will stop to give GM technology a bad image and other countries in the world, Africa, India, China, will start also cultivating GM food [...].

When you refer to the zero tolerance policy, can you just explain that very briefly, what you mean, [cuz] I wasn't?

Yes, so, if a GM crop, non-authorized in Europe, is found in a shipment from the US to the EU that shipment gets sent back. [...] The same is happening with China, for example. China already sent back many, many shipments this year creating an enormous problem for the US industry. [...]

When I ask you the question, that if you think if the TTIP will result in an alignment of EU GMO policy with that if the US, what I heard until now, was…so maybe this zero tolerance policy will get weakened and some regulatory standards as well, but, I have also just spoken to the Commission a few days back and what they told me is that, for example, the precautionary principle is something that's laid down in the treaty and that's not going to weaken and, for example, the hormone beef that's also not allowed in Europe right now but in the US, will also not be traded just because of TTIP, so there are still restrictions.

[Ah], yes, well, of course. Europe cannot change the treaty while doing a trade deal. the institutions involved don't have the power to change treaties. [...] and I don't think there will be any change in legislation, but there will be change in the way legislation operates.

And how far so?

If you change the way, for example, if you have…instead of having less risk assessment, we just are accepting risk, well, analysis, assessment that's done by the US which are much weaker than those…and you consider them as equal, you know, that's it. That's the same ask about the mutual recognition of diplomas, you know? [...] There are differences where you cannot have mutual recognition because things are different because there is one mutual recognition of two different things. If we were talking about very similar things where only bureaucratic or administrative issues are creating problems, then of course nobody's against. But if you're talking about two substantially different things, there is no way or possibility to harmonize them.

So you think that maybe…EFSA is still going to carry out risk assessment, but they might take into account to a greater extent the assessment that has already been done by the FDA for example, is that right?

No, the problem is that EFSA is actually doing a completely different risk assessment, a real risk assessment I would say. [...]

But do you think that, EFSA will then at some point not carry out risk assessment on specific products because the US has already done so?

No, I, I definitely hope this will never happen because otherwise it would mean we had mutual recognition of assessments done by, you know, in two different ways.

[Ya], so your fear in regards to that is…or you don't think that this is going to happen but the possibilities is there, [so that's] what you are afraid of.

Yes, absolutely, absolutely.

Ah, ok. And, maybe to wrap everything up a little bit, I see that you do have strong opinions on that and they are also supported by science and scientific reports. So, are there any ways that you are planning to have a say in these negotiations, or that you want to influence that debate?

Well, we first want to see whether there will be…what we want or what we're calling for in the time being is transparency. The debate has been quite intransparent and…on many issues of course, on GM as well. And it's, one the one hand it's

understandable because it's a trade agreement, but on the other hand in our opinion it's not acceptable because you are in a nondemocratic way trying to change policies that have been created democratically many decades [...]. And once we see that these issues, and issues like GM, will be the subject of specific negotiations [...] but specific negotiation on it still have to happen, so to say. So we wait, we are monitoring.

Ok, monitoring for the time being. Okay, is there anything else that you would maybe like to add or emphasize again?

No, I mean, the process is, is still, I'd say long., overall, the major concern we have on TTIP is that the figures [...] that try to promote the benefits of such an agreement have actually been…the most realistic scenario have been very, very worried. In the European Commission, the most realistic scenario says that there will be a 0.1 percent increase in GDP, which is actually, a final total increase, which is a 0.01 percent per year basically. And a 0.01 percent of GDP per year increase compared to the amount of changes the European citizens will have to swallow, and the wins and the fights of the last two, three decades on all sorts of issues, from chemical legislations [...] to GM, two other agricultural issues, to the, to the quality of food, to, you know, labor regulations, I don't think any of this even alone is worth a 0.01 percent increase in GDP, let alone altogether. [...] So, [it's] fair to change direct barriers, to drop some of these barriers, no problem at all, but going for a change in standards and regulations, we believe it's per se a problem.

Where do you have this figure from, with the 0.01 percent, is it from the Commission website?

[Part of the European Commission statics from what was last year on the, they built a number of scenarios. And the credible scenario number one quotes that figure. → Corporate Europe Observatory were quoting them.in general report CEO TTIP GDP 4, 5 months ago]

Ok, thank you very much for answering my questions, was very helpful and I'm [gonna] send you the transcript as soon as I have it and [the] quotes I will use. [...]

Send me the thesis; that will be more interesting.

Ok, I will do that.

###

Director for Agricultural Affairs, USTR

May 5, 2014. 14:00-14:33h. Conducted over phone

Okay, let's just start then., my first question relates to your general attitude towards GMOs, just to sort of set the scene a little bit and see where we stand. So I would ask you to tell me whether your attitude towards GMOs is rather positive or negative and what facts you base your attitude on.

This is from the perspective of the US government?

Yes, exactly.

[Um], right. I think that our view is, that GMOs are very much like any other agricultural technology, that they have the potential increase returns to farmers, reduce the use of pesticides, improve the way that farmers can farm, [...], and that they can contribute to global food security. So from that regard,… and also, in the United States we have a pretty long experience with the cultivation and consumption of genetically engineered crops, and that has been a positive experience, which you can, if you want to infer that from the adoption rate, that there is a very high level of the adoption of the technology.

High-level adoption rate, okay, great, so having that said, what is the role of GMOs actually, when it comes to TTIP negotiations? Does it constitute a big part of the negotiations that you have right now, or is it rather minor issue?

The trade between the US and the EU is disrupted because of problems related to regulatory approaches to biotech crops. So there are some biotech crops that have been approved and are being cultivated in the United States that have not yet been approved in the European Union. And because of that there is a disruption of trade. So that is, that makes it important in the context of our bilateral trade negotiations.

That's interesting that you say that, because while I was researching, I also came across some other products, which may be face similar regulatory trade barriers. One of these would be hormone beef in the US, which is commonly used and consumed, while in Europe not so. Would you say that in the light of that, that these kind of products, or GMOs would be able to pose a threat to the negotiations, or be a critical factor? Or could one just, maybe, ignore these insimilarities, or how is that?

They way we look at it is through the lens of our obligations under the WTO, in particular the SPS agreement [...] as part of a trade negotiation we are also having discussions about, well SPS measures, and disciplines related to SPS measures, and ways we can resolve trade barriers that are resulting from SPS measures. And if you have a look at some of the comments that the US and other stakeholders submitted, as part of the public comment period, before we launch negotiations last year the SPS measures and other regulatory barriers were identified as a key priority area, for US agricultural interests. So the regulatory issues related to biotech crops, so that's just one of a number of different regulatory issues.

If you would say that they wouldn't be able to come to a common denominator, to agree on that subject, could GMOs just be left out of the agreement possibly?

No, they are already in the agreement. So the agreement is supposed to cover all products, so that would include products where trade is currently disrupted, and it's supposed to build on, and strengthen our existing obligations under the WTO SPS agreement.

Okay, what about hormone beef then for example? Because that will probably not be something that Europe wants to change, or the policies around that.

Yes, I mean, Europe… they already have a WTO finding panel report indicating that the measure is not consistent with their obligation. So the fundamental problem is between measures that are not consistent with international obligations, so in both the case of the biotech crops, and with the beef from animals treated with hormones, those measures are not consistent. Well the WTO panel findings indicating that those measures aren't fully consistent with the SPS agreement.

So is that something that you think has to be agreed on, that hormone beef, for example, will also be exported to the EU?

I think that we definitely need to find some way to address that problem, [ya].

When looking at the differences between the US and the EU regarding GMOs, I came across a couple of principles and basic concepts, which would be the fact that in the US, the concept of substantial equivalence makes GM crops basically equivalent to their non-GM counterparts; then the more product- instead of process-based approach; and also the scope of the consideration of nonscientific factors, which is much bigger in the EU, while there are also more veto points in the EU. And, of course, one

cannot forget that in the EU you have to label GM products, and the concept of traceability is also very big. To what extent do you think that TTIP negotiations could impact any of these differences?

There is not really a difference in the area of substantial equivalence. So,, that's how both sides do their scientific reviews. They take a look at the GE product and then determine whether it's the equivalent to a conventional product. That's basically, at a scientific level we are both looking at the same thing., so you had… in terms of… I mean, there are differences in the way that the regulatory systems function., and I would say that on the EU side when you talk about the veto points in the approval process, I think that many of those veto points are not actually part of the process. So if the EU adhered to the established timelines in its approval process, then there would be much less of a problem with asynchrony in approval, and much less in terms of trade disruption.

In how far do you think that they are not part of it, because for example in the EU each Member State has the right to provisionally prohibit or restrict the use or, selling one product based on factors that might be evidence to the harm of the product. Do you refer to those vetoes or…?

No, I'm talking about the… there's an approval processes so once EFSA has issued its opinion, then there is a regulatory process, and establish timelines for drafting a proposed regulation and then putting it forward for consideration and then what happens with it next. [...] so what you talked about with the Member States, that there are, you know, provisional prohibitions generally on the cultivation of a product, that's after it has already been approved at the EU level.

Yes that's true, exactly. So you refer to the process itself then?

Right, within the approval process. once EFSA has issued its opinion, there are really sort of two decision points; and what tends to happen is that the Commission doesn't meet its own deadline for submitting a proposal for approval for consideration for the standing committee. And then once the standing committee has voted, and, you know, at this point in time it's fairly easy to project the outcome of the vote, and there is never a qualified majority in favor. Then there is a time in which it's supposed to go to the Appeals Committee, and often those deadlines aren't met. So there might be some other veto points that are not part of the process, but that's problematic, from a standpoint of good regulatory practice, when you have a process and it has certain steps, but then the way you implement the process, you add in ad hoc steps, or undue delay.

So what outcome would you like to see from the TTIP negotiations with regards to transatlantic trade of GMOs?

The key outcomes we'd like to see, a normalization of trade. So right now trade is substantially disrupted, particularly in corn and corn products. The key thing that we would like to see is that trade would be able to know and impeded and in a predictable way.

And in what way would that be met? Would it be by just speeding up the process that is already in place in Europe or would it be like changing some of the regulatory framework?

I think that the key element is just making the process work the way it's supposed to. But I think that the regulatory systems are… regulatory processes and regulatory requirements change all the time and certainly it would be important to see any future regulatory changes going in the direction that does not contribute to creating more trade problems.

Do you think – this is a question which is not, which I haven't put on your sheet because I just came up with it before and also during a talk with someone else – is mutual recognition of the regulation or the risk assessment actually something that's being discussed at all in the sense that, for example, if Europe has done risk assessment on a certain GMO product, that this risk assessment could be taken in the US as well or the other way around, and it wouldn't have to be done again, like when we're talking about cars, that's what we're aiming for, right?

[Um], There are some discussions taking place on an international level about how that could happen,, I think it makes sense from a trade perspective. Regulators tend to be very resistant to that, because each side has their own approaches towards risk assessment… even though the risk assessments are, you know, very similar in their basic approach, and then generally in their outcome; and also, since there are actually international like OECD and codex who have done some work related to risk assessment for genetically engineered plants. It's, it's difficult to get to that… it has a lot of promise, but in every area it's actually kind of challenging. There are very few areas, where that's been successful.

[...] When I look at the framework in the EU, we have actually these two steps that make part of the [approval process], which is first risk assessment and then always risk management. Is that something that you would say is also taking place in the US or is it rather based on the scientific risk assessment there?

Well, everybody does risk assessment and risk management. So, I mean, it's a general process, so…

So you think after you see for example the FDA sees, there's a product, if it's safe then it also goes to you for example or the government and… is there also something which is comparable to the public consultation period In the EU or not?

[Um] [...] Each of the reviewers is looking at it from the standpoint of their regulatory authority, and as part of the question of whether a genetically engineered crop could pose a risk to plant health, because these are things that you plant, and sometimes they're incorporating, say, potential plant pathogens, they are evaluated by the USDA. And as part of that evaluation there is a public comment period.

[...] I have also seen that the WTO has played a role in these… in trade of agricultural products and has told the EU that it should sometimes speed up the process. To what extent does the WTO also play a part in TTIP negotiations, or does it at all?

Well, I mentioned that our basic… we already have international obligations, both the US and the EU, under the WT0 SPS agreement, and as part of the the work that we did in determining, whether or not to have a trade negotiation, we agreed that we would pursue what's called the WTO SPS plus discipline. So we're speaking to build on the disciplines in the area of SPS, that we already have under the WTO.

[...] would you agree with stakeholders, like Alemanno, for example, or like other people who say that the debate around GMOs is a highly politicized one?

It is highly politicized in some places. I think it's highly politicized in the EU.

So you would say that in the US not?

It's not, terribly… No, not to the same extent.

Do you think there is a need to differentiate between the import of GMO foods and the growing of GMO seeds? Does there have to be a distinction between that in the agreement?

[Um], I think that they are two different regulatory questions, and, in… so, there is already a distinction, certainly. And then the way that the EU's regulatory process is possible to receive approval for import and use for food, feed and processing, but not cultivation. so in the WTO case that the US, Canada and Argentina… those cases that they won against the EU. It addressed problems both with the import of food for food, feed and processing and with cultivation. In terms of the greatest trade impact, the greatest trade impact is going to be in, not in seeds.

Okay, so the exportation of already processed foods, for example.

Or just bulk corn for animal feed. [...] The key goals in the TTIP negotiation, is job creation and economic growth in the US and the EU, and the problem is related to approval for cultivation. It should be a concern for Europe in terms of the messages sent about the role of innovation in European economy. And certainly all of the companies that have been developing biotech events in Europe have all left, and lose those jobs to other countries.

Now we have already talked a little bit about how you would like to TTIP negotiations to end, or what you would like to see and which adjustments should maybe be made. Are those realistic, and what do you think are going to be specific, concrete elements of alignment of policies in the US or in the EU?

Well, I think it's hard to say anything very specific, but certainly we would want to make sure that trade isn't disrupted. And this is a trade agreement; we need to remove trade barriers. And certainly in the United States for our stakeholders who are looking at an agreement and if it isn't able to resolve some of these very key problems, then there won't be very much support for the agreement on the US side.

In that sense, could the trade of GMOs really pose a critical factor to the success of negotiations?

[Um], yes.

So you say that maybe if you are not going to be able to have an agreement on the trade, facilitate trade and take down those trade barriers you have talked about, then maybe you won't be able to reach any agreement at all?

One of the challenges we need to, on both sides, is once we negotiate an agreement it needs to be adopted. And to adopt an agreement, we need we need support from our stakeholders. The people we are going to go to, our Congress in the United States, and say that…yes, we need to adopt that agreement.

So that is where it might fail then?

[Um], that is going to be, that is going to be very important for us to be able to demonstrate to our stakeholders that, things will be better in terms of the predictability and the actual access for products.

The European Union has the precautionary principle, and the US is generally more based on the risk assessment not from a precautionary approach. Does this have any impact, or does this play a role in the negotiations, this general viewpoint of risk assessment?

Well, precaution is part of risk assessment. The reason that you do a risk assessment is because there is potentially a hazard that's going to be needed to be mitigated or managed. So, precaution is an element of how we make decisions, regulatory decisions on both sides of the Atlantic; and the… so in many ways that's similar on both sides. However, the way the concept, precaution, is applied in Europe seems to be somewhat variable.

In what sense?

[Um], that there is not consistency in necessarily the way that… sometimes precaution is used more as, not to evaluate the risk in terms of best mitigation to address the risk, but to avoid making a decision.

Could you maybe give an example of that?

Well, sometimes there is a whole lot of information out there, and there is sufficient scientific information to make a decision on what the likely sort of risk is and how the risk could be further mitigated, but it's always possible to say ' oh no, we need more scientific information!'. So that's not applying precaution as part of, you know, normal scientific approach, that saying that you don't want to make a decision.

Okay, so you think that the EU is generally a little bit more reluctant to, probably a little bit more afraid than the US in that sense of GMOs.

Well afraid in what sense? [...] Oh, there are two different fears. One is a general fear of certain individuals in the population. And then there is a fear in terms of bioregulators for politicians of making a decision. And the way precaution tends to be applied, or misapplied in Europe, is when regulators and politicians are afraid to make a decision based on scientific evidence that they have. [...] they have the information that they need, but they are afraid to make a decision.

Maybe just one last question in terms of the timeframe, I know you can't really tell me when these negotiations will most likely be done, but in your ideas, with regards to also other ongoing trade agreements that you have right now, for example with Asia, what is the timeframe of TTIP in your opinion?

Oh, well, on the US side, with our transpacific partnership we are much, much further along with that and close to closing it out. But TTIP we have only had four rounds of negotiations so far, so it's not as far along. But my expectation is that TPP would be completed before we complete TTIP.

How many rounds do you usually need for an agreement to be done?

I don't think it's possible to say [laugh].

Depends on the agreement probably.

I guess as many as you need [laugh] but few as you have to.

And would you say that the TTIP is a priority among the agreements, or…?

[Um], yes. It's certainly dedicating a lot of resources to… and we are only actually really negotiating these two, so in Europe I think that they are negotiating something like, you know, more agreements than we are. So at the same time that they are negotiating TTIP, they are negotiating with Japan, and India, MERCOSUR, so in fact I think that in the EU they have more negotiations than TTIP.

All right, good, I think that's it. Is there anything else that you would like to add or emphasize on?

No, I think that's fine.

Okay, thanks so much for taking the time and letting me ask you some questions.

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Director of Agricultural Biotechnology, EuropaBio

May 7, 2014. 9:30-10:11h. Face-to-face at EuropaBio office Brussels

Well, First of all thanks for agreeing to do this internship, internship, interview [laugh], my first question relates to you as an organization, I read on your website that you are involved in healthcare, in industrial biotech, and also agro-food, green biotech. Since you are the GMO person for the company, what is your attitude towards GMOs generally and do you think…what are the main benefits and risks you see?

So as an association but also personally, of course, so we… you are right that we have these three sectors, so biotechnology is wider than just GMOs and agriculture, but there is also other kinds of uses of the same type of technology, and in all uses there are obviously benefits, that's why people are buying these products, or industries in the other sectors, so there must be some benefits. In the case of GMOs and agriculture, farmers worldwide have been buying them increasingly, where they are allowed to do so and so benefits they have, the farmers…I mean it's products for farmers, so basically the seeds, the GMO seeds, they will only buy what they think helps them in their business. Buying seeds and buying other agricultural products is quite a big decision for farmers, so they don't… they are neither forced to buy that kind of seed nor do they just do it to try something you, but they really think about it. And so in the case of… first of all GMOs are not all the same, they are just bred in a newer type of way, with an newer technology, but that doesn't actually… that enables the breeders to do some new things, but it doesn't fundamentally really change any of the type of benefits that breeders of seeds want to deliver to their farmers. But in particular, the types of GMOs that are already on the market are mostly herbicide-tolerant, and or insect-resistant, more and more often combined. Benefits are basically easier work for the former, particularly on the herbicide-tolerant, he doesn't really need to plow the land for most crops. It's also good for the environment, actually, because [...] plowing takes a lot of energy and petrol and time for the farmers, but also it's actually bad for the soil and for the water as well, so you get a lot of soil degradation from it. So that's one benefit. And on the insect-resistant types of crops, one of which is actually allowed in Europe and grown in Spain, as an insecticide that's the main benefit, that's what it's made for. GM process such, I mean there's also lots of new, different types of products coming, now, onto the market, so you cannot generalize, but they do have, definitely, advantages for the farmers, otherwise they wouldn't buy them in increasing numbers, and well we also have a lot of evidence of environmental benefits as well.

Okay, good. Do you see any risks at all in trade of GMOs or GMOs [themselves]?

[Um] in the technology as such, actually we have not… I mean there are no, there is no evidence at all of any risks that would be greater than from conventional breeding. But of course, any type of plant, it doesn't matter how it is bread can have also some risks, I mean, certain conventional plants, old plants, like coffee or whatever, would never actually get through the GMO approval system.

Oh, really?

Yes, because it's allergenic. No chance, no chance. So it's a much more targeted way of breeding plants who insert normally just one specific gene, and you know much more precisely what you are doing then if you do it, for example, for the last 50 years, by mutagenesis, that was the main thing, the main conventional thing. Mutagenesis by chemicals or radiation, and you just expose the whole genome to, you know, to mutate, to mutations. You don't really control what is happening. Everything can change. And you hope that something good comes out of it. That is conventional breeding. [...] All the relevant institutions, scientific but also risk assessors, the government risk assessors, like EFSA, or BfR in Germany (?), the European Commission Joint Research Center, the European Academy of Sciences, including Leopoldina, I mean everybody says that GMOs are at least as safe as conventional plants.

[Um] maybe, just because, for example, when I was speaking to Greenpeace, one risk they mentioned was the emergence of super-weeds and super-pests.

[Ya], that is not specific to GMOs, but that is something that is actually there, yes. This is there in modern agriculture, so when you have pesticide use, so you have… That's linked to chemicals and not directly to the GMO technology. This is something we do see, yes, in North and South America, and it can be, it can be handled, [ya], as that has been done, also before the occurrence of GMOs by crop rotation and other good practices. And of course you should not overuse these pesticides. Also the people, the colleagues, from the pesticide industry will tell you that, so there are a lot good management practices with which you can avoid or limit that problem of well, super-weeds, of resistant weeds, [ya], against the pesticides., but it's, it's a problem you have, I mean, it's an issue you have exactly also conventional, modern agriculture, where they use pesticides.

Maybe, since we're already talking about the technology quite a lot right now,, since you, as EuropaBio, you represent the whole [biotech] industry, not only GMOs but also other alternative methods I think. [...] What to you think about alternatives, like the marker-assisted breeding or selection method?

They are not alternatives; they are parts of the same toolbox. I mean, every breeding company, also the ones that don't use GMOs, because they are too expensive, [ya] for medium-sized… it costs about 130 something million dollars to bring a new GMO to the market. Research & development, and there are a lot of regulatory costs, and marketing. Ok, but that you have for conventional crops as well. So, it's not a GMO, it's not a small business-friendly issue, also because of over-regulation. But every… so plant breeding is really a modern business, I mean, if you visit, you know, any KWS, for example in Germany, they don't do a lot of GMOs, but any modern plant breeding business, you will be amazed at how modern a business that is, it's high-tech, even without GMOs its high-tech. And so, of course, looking at the genome and to understand better what is happening in conventional breeding, that is already, I mean, also standard in all these breading companies, and that's marker-assisted breeding, for example. It's standard, it's not really an alternative. So, we are not, we are really not saying GMOs is the only way forward, there are also other techniques, but it just doesn't make sense to discriminate one technique, just because some people don't like it.

[Ya, um], do you think generally there needs to be, I mean I'm writing my thesis on transatlantic negotiations on GMO trade, so do you think in that sense there's a need to differentiate between the import of GM foods and the cultivation of GMO crops?

Cultivation in Europe, yes, I mean the two issues are in practice quite separate. There are different legal provisions for the approvals of GMO crops, depending on whether they are [gonna] be cultivated in Europe, or they are going to be imported in Europe.

Do you refer to the Directive 2001 and Regulation 2003.

[Yes]. And so in a number of other countries this is not the case, so there it's just the same, you have basically a big, encompassing, all-encompassing risk assessment, also for cultivation, and then of course you can also market it. But here in Europe basically what happens is that the, the approval system for cultivation doesn't work at all.

So you think that the biggest problem relates to Regulation 2003 and how it is implemented.

2001/18 [ya], you mean?

[Uh], that's the directive.

On sorry, [ya, ya,] no no, but the directive is for cultivation, so the problem is that, the directive is not implemented properly for cultivation. So the legislation is demanding, but not horrible, it would be workable. But what happens is that at the different stages of the process, it's not implemented properly. So, EFSA, ok, takes already long, but they do their job, it's largely science-based, and fine, okay that's a different story, but after EFSA has given a positive opinion on the safety of the product, then that's where a lot of problems start. The Commission doesn't stick to its own timelines to submit the products for voting of the Member States.

Which is three months, and then, if no quality majority has been reached, then another two months.

[Ya], exactly, so this is… they don't even stick in most of the cases to these timelines when it's for import, so it takes a bit longer but it gets done for imports. For cultivation, it doesn't get done at all basically. So you have the resent caught case of Pioneer, one of our member companies, September 2013 Pioneer against the Commission.

Oh, DuPont, was it that?

Yes, Pioneer DuPont, so you read about it. So they won against the Commission because the Commission failed. [...] And these are just procedures that are in law, there is explicitly… there are procedures foreseen for this difficult case where Member States don't agree. The Commission still has to put it to the vote; they cannot just say 'Member States don't agree so we don't put it to vote'. They are breaching European law, as a European public institution.

[Ya], so if we look at this process actually, you could say that when talking about cultivation of GMOs, first the Member State is the first instance to be involved and, then it goes to the Commission. So actually EFSA wouldn't even be needed in this procedure if they [the Member States] would agree.

But that is, that's a bit more centralized under the regulation for import actually, this system. So EFSA has a much stronger role in imports.

That goes directly to EFSA, that's true. But, so you say basically, which I also found out during my research, that here is actually where the problem arises, when the positive opinion is delivered and the Commission has these actually five months, do I get you right?

[Ya], I mean that's something, that is I mean… so there are illegal delays already for imports, but for cultivation they just don't do it, they don't do it. So that's also the main reason why two of our companies have withdrawn their products, or most of them, for cultivation, that were ending in the approval system.

Do you know which companies?

2013 Monsanto and BSF you will find press releases about that. [...]

Maybe just a question to clarify, because I know that most of the times there is no quality majority vote for the approval. But has there been, or if there would be quality majority vote against the product, then it wouldn't even go to the Commission. [...]

The Commission always has to propose the actual, the draft position, which is a legal act, and then it needs to go through the comitology, the Member States decision. Now, if there is a quality majority for, that is the normal case in all other products, because product approvals are usually comitology, where there is a premarket approval for products, so the usual case in all other products is that there is qualified majority in favor [ya] because in any other case, basically, there is a science—based approval system that is adhered to and implemented. So EFSA, or EMA, the medical, medicines agency or ECA, the chemicals agency, they say okay this product is as safe as, or they say in the chemicals maybe, 'this is okay, the risk is so and so' [...] and then you would usually get a, the Commission drafting product approval based on this scientific input and the Member States saying 'okay, well the relevant agency has looked through it, so we approve it, [ya]'. So if you have a quality majority favor, that's the normal case, just not in GMOs, and then it's immediately approved and there is no second vote needed. If there is a quality majority against, then that's the end of the process. What the Commission can do, like always, it has the right of initiative, so it can draft something new and different on the same product if they want. I mean, they could for example say 'huh, why don't we try to, I mean, we still have a positive risk assessment, so we should really do something. Why don't we say is can be approved under very strict conditions, maybe then the Member States agree.' [...] Often then the Commission asks EFSA to provide another risk assessment, an updated risk assessment. And not only when there was a bad…so on the 1507 case, when you read about it you will see that EFSA provided seven I think… well, they were asked seven times by the Commission, to update their own risk assessment again, and of course EFSA always said 'well, there is no new risk evidence [...] its still as safe as a conventional plant' and they have say that seven times and it's a lot of waste of time of all the panel members, who are renowned experts in the field, from universities and so on, and are really wasting their time. And in the Pioneer case, also the court has a very strong sentence saying that the Commission cannot just do that, they cannot just repeatedly put it to EFSA to waste time.

[...] Why do you think this is? In most other products there is a quality majority vote, why do you think this is such a sensitive debate? Do you agree that it is also politicized?

Oh, sure. That's the reason, I mean for, the impulse EFSA delays, or the fact that it doesn't work at all on cultivation, it's because of the over-politicization. And a lot has been said and written about why it is politicized. [...] You know, I mean people make money with scare stories, or they motivate their members to join their organization or stay with their radical NGO organization by scaring people pretending that the food is so horribly unsafe today. Which is obviously, I mean, it has never been safer, and particularly on GMOs there is absolutely no evidence on safety; but, it's something that nobody understands, it's something that is related to food, it's something that is related to big business, so it's a very good scare quote. [...] Scaring people, I mean it's an old political recipe. I mean, and unfortunately it works. A lot of people like to be a little bit scared. At least, you know, bad news, or even bad scare stories, even if they are completely unfounded, it sells well. And it sells well, not only for newspapers, for the media but for organizations [...] sociologically, if you want to, keep a group of people together, you have to position them against something, or against someone else.

To what extent do you see an opportunity to change all these delays, and all these problems we have in TTIP?

It's a difficult one. we don't really know exactly, personally I don't expect that the TTIP agreement will very much and very concrete things about GMOs specifically. I know that there are some talks, and some speculations about that, but there is no way that the TTIP agreement will say the European legislation on standards on GMOs have to be changed. I really don't think so. But still, if you are negotiating of course with someone who exports a lot of products to Europe, a powerful partner, and who sees that the Europeans are not implementing their own system, and their own laws, I would expect that this is something they talk about. How can you have an agreement, I mean, if some exports are effectively threatened, let's say, because of these delays that are illegal under European law even. [...] when you negotiate with someone, you should first of all be able to trust that they implement their own rules, but actually this is not happening, so I would expect that this is one of the first expectations that the trading partners have to each other. Because of course the European Commission always says 'yes, our rules are transparent [la,la,la]', and it's true that the legislation is transparent, but it's not implemented properly.

Would you think that the mutual recognition of science and risk assessment would be something that would be possible to implement. Since, I mean, when we are talking about cars in TTIP negotiations, that's what they want to do. They want to narrow the risk assessment to one procedure.

[...] indeed, they do talk a lot about this and about regulatory, what do they call it, streamlining, or whatever the word is, so that seems to be the new focus. [...] you know, a lot of this has been tried already in a lot of different fields, in the field of foods, I mean there is of course some global coordination, you have the FAO, you have the codex alimentarius, I mean there are actually rules, you have WTO as well. There are rules, it's of course not the harmonization of the risk assessment, but there are some rules also on the risk assessment, in codex alimentarius particularly. so it's an important field but it's not completely new, at

least in the field of foods it's not really new to find some intercontinental and even global harmonization, very difficult business, particularly where it is politicized. So I don't think this is going to work in the short or medium term on GMOs, even if it would be very desirable. [...] At least in the field of cars everybody can understand quite easily that, I mean I'm not an expert in cars, but what I understand from these news stories, there are just some slightly different technical requirements, the safety standard is probably the same, I would expect, I mean surely the Americans don't have an interest in people hurting themselves in the cars more or in getting hurt from food. So the safety standards as such are very comparable, but the actual requirements are very, are quite different; some of the stages that companies have to do are similar in what should be tested, but then the testing requirements, the details are different again, so they just have to do everything over and over again. They have to, for example, do tests with rats and so on in Europe, which is an requirement which also EFSA said is nonsense to require it for every GMO, but it was politically imposed that for every import also the authorization that has to be done. So the animal protection people were also against that.

And that's not done in the US with the rats?

It is not required on regular basis, in this type of format. Maybe they have some kind of rat studies as well, I don't know, but these 90-day rat studies which is…basically you feed the rats with your GM maize for 90 days and then you see if anything happens, like this it's just considered by the scientists, as far as I know also in America, but certainly by the EFSA scientists to be nonsense for most products. You could have a special product, where really you see a change in the actual food composition, so a different nutritional value or something where it could make sense, but the farmer input products that we talked about before, that are pest resistant basically… I mean, if there is no indication that a change is actually the chemical composition, the end product then it doesn't really make sense to feed the rat. But that is just an example, so I would say that just like in the field of cars we have really, very comparable safety standards, but different requirements, sometimes just because, you know, people may be want to make it different. [...] so these global harmonization measures they didn't work too well, unfortunately. [...]

Could you compare the codex alimentarius to, let's say a directive, that has to be transposed in the EU in a certain way and in the US, like some general rules that can be implemented in different ways?

[Yes], kind of, I mean, codex alimentarius actually does have a, I don't know exactly now how it is legally, but it has a relatively strong binding force in practice. But of course often the rules are quite with little details, then allowing of course divergence that is not regulated in codex, if you understand what I mean. [...] If you have, just theoretically, two pages about codex alimentarius talking about GMO risk assessment, then you'll just find some general principles in there. 'This has to be science-based, [da,da,da,da,da] but it leaves a lot of scope to still do things very differently, because the actual risk assessment requirements are put down, in Europe for example, on probably several thousand pages. The guidelines only and the actual dossiers are probably 50,000 pages, or something like that. So the guidelines, how do you do your risk assessment partly also went into legislation in Europe [...]. So there is a lot of possibility to fit requirements that are not at all mentioned by codex alimentarius, for example.

[...] I have read in one of the documents you have on your website, that one of the recommendations you list, is greater efficiencies in the processing of stacked products, so we have already talked about that a little bit. Concretely, how could we reach this, do you think?

Well, there are different levels of… so, the stacked products [...], a specific type of product, there are more and more of those and these combine several traits. So you could combine, they do already, for example in the, let's say maize product, herbicide tolerant modification together with an insect resistant modification, or two or three different insect resistant traits in one. So when these several traits get combined, stacked on top of each other, by conventional breeding usually even, so it's not, in America that's not considered to be a new product because you just, you one GMO, you have another GMO, you cross them conventionally, you have a stack. It's not a new genetic modification, really, but in Europe they think it is, so we have to, our companies have to submit an extra application for these stacks. But let's talk in general about efficiencies. It also applies to stacks particularly, but also to all the other products., so efficiencies could really be made, we think, in all the stages. We already addressed the post-EFSA stage, this is the one we have been focusing on quite a lot, because it's not just efficiencies. It's first of all just applying the law. The public institutions just need to just apply their own laws, it's not really that far-fetched. So that would already gain some time without in any way impacting any of the safety standards, so all they would do would just be to vote in a reasonable time.

So it is a bit more about the management than the assessment.

It's a management thing, it's the risk management thing that particularly, and in the risk assessment phase it is also the case that it takes quite a lot longer in Europe than in North and South America, for example, so the EFSA phase., we think, again, that the general safety standards are already very comparable, so there is also some process improvements that could be made in EFSA, and we wrote also about that [fetches report], this is our 2011 report on approvals of GMOs in the EU, is quite long but you find actually suggestions for improvements in the different phases, and also some improvements in the EFSA phase. So aside from the really scientific bit, what could really be improved is really communications with the applicants basically. So that

works very differently in the medicines, so the EMA, the European medicines authority, that is based in London, [...] and what happens there is that when you want to submit a product for approval at the agency, usually there is a possibility to have a pre-submission meeting to just say, you know, 'this is what we intend to submit, these 30, 40 different studies, you know. We just have these three or four questions, because we were not totally sure about the requirements, can we discuss it?' This is impossible in EFSA., so what EMA also does, is they give the applicant a kind of individual timesheet with the different phases, saying, 'so normally the timelines are like this, the first stage is [...]' they do give the applicants an exact timesheet [...] specifying timelines for several of the cornerstones in the process in EMA. So it would say something like, ' two weeks after you submitted, you will get our information that you submitted, and four weeks after, you will get our, another confirmation that we really checked that everything is there that we need to really assess it, and then after three months we will finish looking at the first pack of studies and if we have any questions we will get back to you'. So, you know, there is a kind of simple communication about what is happening with the data, the packages that the companies are providing. If there any questions back to the company, from the risk assessor, then there are also quite transparent procedures for that in the case of EMA. In the case of EFSA, what happens unfortunately more and more, is that EFSA submits an additional question to the applicant – so this is not just for GMOs also happens in other EFSA-regulated industries, we also talk to them – so, EFSA sends an additional question [...]. So the company does that, it may of course take a couple of months, if you really have to change a study, puts it back, and then they don't hear from EFSA, if the new information provided by the applicant is satisfactory or not. In some cases then, the next step that companies hear, is that an inconclusive opinion was issued by EFSA, saying ' we cannot judge the safety of the product, because we still didn't like all the exact protocols or something'.

So something that you would maybe like to see would be greater transparency and a better communication. So that EFSA tells them, 'look this is good but we need more information on this, and this was missing'…

So I mean risk assessment is, you know, a difficult job at EFSA, for these panelists also, and also the Secretariat of EFSA. But the process could just be managed little bit better to also save some time and avoid unnecessary steps on delays. That's not to say, we should have less studies, it's really just to say, managed the process like they do in EMA.

Maybe a last question, since I do not want to take too much of your time, how do you see your organization's role in this debate, and in TTIP negotiations. Do you intend to influence the debate there somehow?

Influence, I mean, I wouldn't say influence, but inform to some extent yes. You may have seen that we do have on our website also a joint position paper with BIO. This is our partner organization in the US. [...] we made a joint paper with them, it's about four pages long or so, and it also says what we would expect and hope for these negotiations [...]. But the first thing is, again, implement your own laws in Europe please, and there are a couple of other things there. [...] Both in Brussels and also in Washington usually at every negotiation round, there are also some kind of stakeholder conferences. Now in America they tend to involve industries like ours a little bit more in this, so I think already on two or three occasions a vice president, or whatever it is, of BIO was able to actually address one of these conferences to say what they would like to expect from the negotiations. We haven't really had the same opportunity in a formal way here.

Do you plan on something like that, for the next negotiation round maybe. Or anything concrete, that you have planned?

[Um], At the moment, to be honest, we haven't really planned on…Of course we try to follow a little bit what is happening there, and it seems, I mean, they do talk about, a lot about the regulatory coherence more in general, and the Americans have also, I mean, there are also public statements that various American governmental representatives made over the last few months, that they have a problem with product bans or delays, are whatever it is, […] when it is scientifically unfounded [...] It is a kind of national economic interest for them to get back to normal [the trade disruption], given that there is absolutely no safety issue.

[...] Do you for example submit your papers to DG SANCO as well specifically? [...]

I mean, for the TTIP, that we made with BIO, I don't know exactly is already three years ago I think, or two and a half, but… normally yes what we do when we publish something new, certainly also our 2011 bigger report, I mean… DG SANCO of course, I mean they have the main political responsibility for the risk management on GMOs, so of course we talk to them. [...] Of course we invite them to our events, to talk, like in January [...] there was also the director general of DG SANCO. I think the speeches are also online. [...]

Okay, well, I think from my side that's it. Do you have something you would like to add, emphasize?

No, not really, thank you very much.

Yes well, thank you very much!

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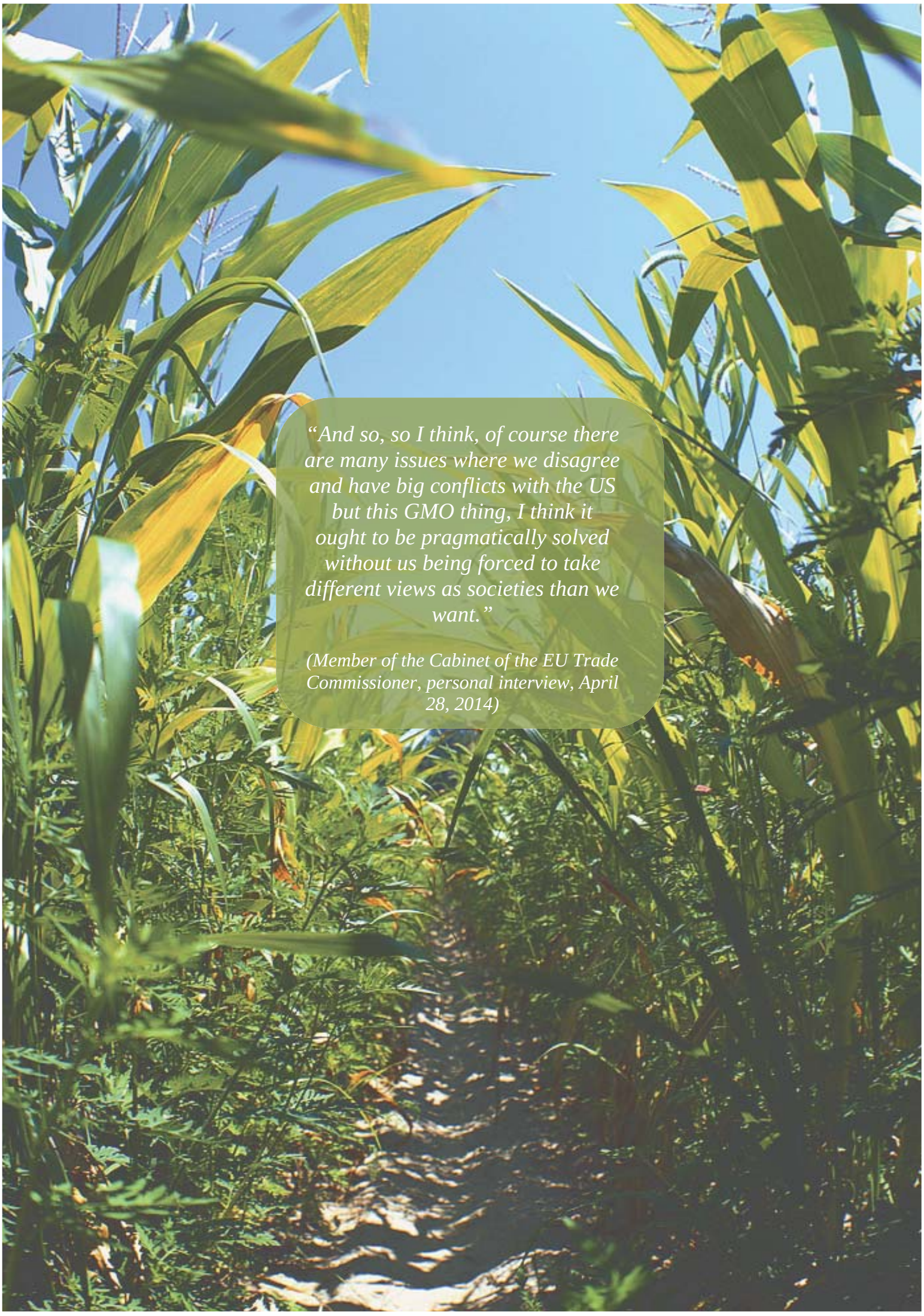

"And so, so I think, of course there are many issues where we disagree and have big conflicts with the US but this GMO thing, I think it ought to be pragmatically solved without us being forced to take different views as societies than we want."

(Member of the Cabinet of the EU Trade Commissioner, personal interview, April 28, 2014)