BIOTECHNOLOGY REGULATION IN THE EUROPEAN UNION AND FRANCE: *UN DIALOGUE DES SOURDS*

by

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Abstract

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In the early 1990s, France was at the forefront of agricultural biotechnology innovation and implementation. Yet, by the end of the decade, France had become one of the most vocal opponents among the European Union member states to genetically modified organisms and genetically modified food. France's continued resistance to implementing EU agricultural biotechnology legislation has created a regulatory impasse in this issue area. This study examines the triggering events that led to the reversal in the French position on GMOs, as well as explores the institutional development of the EU and French regulatory frameworks. Using a historical institutionalist approach, this work demonstrates that triggering events in the 1990s led to policy changes and institutional development in the fields of public health and food safety, both at the EU-level and within France. The main argument put forth in this dissertation is that the differences in the institutional evolution of the French regulatory framework for GMOs when compared to the evolution of the EU's regulatory framework has created the regulatory deadlock, which can be characterized as *un dialogue des sourds* between the EU and France. Furthermore, this impasse will continue to exist as long as the EU disregards the core concerns of anti-GMO sentiment in France.

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Introduction

In 1996, the French plant registration office issued a license required for entry of genetically modified maize (Bt maize) onto the market in France. After French national authorities approved Bt maize for cultivation in France, they supported its approval for cultivation in all European Union (EU) member states. Yet, by the time the EU issued its approval for cultivation in its member states two years later, France had suspended commercialization of Bt maize over concerns about its potential risks. What happened to cause this reversal?

French authorities had backed the application from Novartis, a multinational pharmaceutical corporation, for EU approval of commercialization of three Bt maize varieties in 1996.[1] However, shortly after France had passed the dossier to the EU for approval for the common market, the environmental non-governmental organization Greenpeace challenged the French government's risk assessment of Bt maize, which had been performed as part of the domestic approval process. This challenge led the French *Conseil d'État* to suspend commercialization of the maize in 1998.[2]

In the meantime, though, the EU had completed its own assessment of Novartis' application and approved the Bt maize for cultivation in all member states in 1998. The suspension of commercialization of this maize by the French *Conseil d'État* was thus in direct violation of the EU's decision. When pressured to allow the cultivation of these genetically modified (GM) crops within its borders, France invoked the "safeguard clause," originally included in Directive 90/220/EEC and now preserved in its replacement, Directive 2001/18/EC.

[1] Sabine Louët, "EU Court overrules France's Bt maize ban," *Nature Biotechnology* vol. 18 (May 2000), p.487. Bt maize refers to a genetically modified form of maize that has a gene that codes for the *Bacillus thuringiensis* (Bt) toxin. Maize altered in this way will express the Bt toxin, which is poisonous to corn pests.
[2] Louët 2000.

While the EU had become the locus of legislative activity in the domain of agricultural biotechnology under which the regulation of genetically modified organisms (GMOs) falls, it also had provided the "safeguard clause" through which the individual member states retain some power. This clause allows member states to "provisionally restrict or prohibit the use and/or sale of that product on its territory" if they have "justifiable reasons to consider that a GMO, which has received written consent for placing on the market, constitutes a risk to human health or the environment."[3] Because of the suspension of and the subsequent lack of approval for these GM crops through the revamped assessment process in France, French authorities found themselves stuck. On the one hand, they could not implement the EU decision to allow GM maize onto their market without violating their own domestic judicial decisions. On the other hand, if they continued to not implement the EU's decisions, or if they were unable to provide new evidence justifying invocation of the safeguard clause, France would be penalized for non-compliance with EU law.

In order to resolve the situation, the *Conseil d'État* asked the European Court of Justice (ECJ) to rule on the issue. The ECJ decided that:

> …Member States which have forwarded a dossier to the Commission with a favourable opinion for placing a GMO on the market are bound by their opinion and must apply the Commission's decisions. However, new information indicating that a GMO constitutes a risk for human health and the environment allows the procedure for placing a GMO on the market to be stopped pending a fresh Commission decision.[4]

This decision referred specifically to the invocation of the safeguard clause: new information illustrating risk was required in order for the prohibition of a GMO to be legal. However, in the

[3] Directorate General for Health and Consumers, "GMOs in a nutshell," *Food Safety – From the Farm to the Fork*, http://ec.europa.eu/food/food/biotechnology/qanda/d1_en.htm#d (accessed July 2011).
[4] Press Release No. 18/00 on Case C-6/99 *Association Greenpeace France and Others v Ministère de l'Agriculture et de la Pêche and Others* [2000], http://curia.europa.eu/en/actu/communiques/cp00/aff/cp0018en.htm (accessed July 2011). Full text of the decision can be found at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:61999J0006:EN:PDF.

case of rescinding its approval for Bt maize, the ECJ found that France had not, in fact, presented new evidence to demonstrate that the crops were unsafe. Instead, the French authorities had only changed their process for assessing the original data. Thus, France was required to consent to placing the maize on the market because it had already approved the initial dossier.

Instead of opening its market to GMOs, France has remained entrenched in its resistance to implementing EU approvals of GM crops. At the same time, the EU has named biotechnology as one of the key technologies needed for sustainable development, particularly in areas of economic growth, environmental protections, and public health.[5] Consequently, because of its persistent refusal to follow EU regulation in this issue area, France has become a target for legal action, both at the EU-level and in global forums such as the World Trade Organization (WTO). The brief account of these events captures the discord that can occur between the EU and a non-compliant member state. But why and how has France managed to stay resistant to GMOs in the face of such pressure?

In this work, I use a historical institutionalist approach to demonstrate that triggering events in the 1990s led to policy changes and institutional development in the fields of public health and food safety, both at the EU-level and within France. However, because of the differences in the institutional evolution of the French regulatory framework for GMOs when compared to the evolution of the EU's regulatory framework, regulation for agricultural biotechnology has become deadlocked. This impasse can be characterized as *un dialogue des sourds* between the EU and France. Literally translated as "a dialogue of the deaf," the phrase encapsulates the nature of the European GMO debate: two sides that do not understand each other, though both sides believe that they are talking about the same thing. In this case, EU and

[5] European Commission (2007) EUR 22728: A Joint Research Centre Reference Report - Consequences, Opportunities and Challenges of Modern Biotechnology for Europe.

French public authorities are both grappling with the issue of GMOs, but the core concerns of the debate are different within each level of governance.

As such a historical institutionalist approach, joined with multi-level governance and implementation studies, helps us understand the ongoing regulatory deadlock in the issue area of biotechnology.[6] At the EU-level, GMOs have been accepted as an integral part of the EU's economic development strategy and the debate now is over how to monitor, label, and trace GMOs and GM products. The EU regulatory framework has evolved so that the relevant EU institutions evaluate GMO risks using scientific-based risk assessments, which consider the potential impacts of GMOs on the environment and on human health. In contrast, the French have not accepted GMOs as an indispensable innovation; instead, they find GMOs to be unnatural and inherently risky for the environment and for consumer consumption. In addition, as a response to the public health and food safety crises of the 1990s, French public officials reformed their regulatory framework in order to include dissenting opinions on GMOs. This meant that public participation and the inclusion of anti-GMO representatives within regulatory institutions in France were institutionalized as part of the policymaking process. As such, French evaluations of the potential risks of GMOs consider a wider set of factors, including socio-economic impacts of GMOs, than EU risk assessments. The differences in the assessment processes have directly contributed to the regulatory impasse for GMO approvals and to the *dialogue des sourds.*

An alternative hypothesis to explain the regulatory impasse in the issue area of agricultural biotechnology could be offered through an analysis of the differing ways in which interest groups interact with the EU- and French- levels of governance. While this alternative hypothesis recognizes that there are differences between the levels of governance that affect

[6] The theoretical approach to this study is discussed in more detail in Chapter 1.

policymaking and implementation, similar to my own approach, it does not provide a compelling or complete explanation for this policy area. Agricultural interest groups and industry can have a significant influence on domestic politics at the French-level. However, in this case, the legacy of the crises of the 1990s and the resulting anxiety of the French public that the government was more concerned with producers' profits than protecting public health shaped the public authorities' response. A concerted effort was made by the French government to show its public that industry had not captured the policy domain. This was in part accomplished by the organization of public forums to debate GMOs and the government's emphasis on creating transparency in the policymaking process through reforms to existing institutions and the creation of new ones.[7] Consequently, the role of pro-GMO interest groups in the policymaking process was diluted within the French policymaking process.

At the EU-level, existing scholarship does explore the role of interest groups in policymaking processes.[8] In general, a coherent and universal theory of the role of interest groups cannot be created for the EU. Each issue area is different and requires a separate analysis. As Jonathan Smiles notes, "If you ask a question such as which institution [at the EU-level] is the main point of focus for lobby groups, the answer will always depend on the policy area being discussed."[9] During the time period studied, the agricultural biotechnology portfolio was moved between two Directorate Generals (DG): DG Environment and DG Agriculture. Moreover, other DGs, such as Research and Industry, and several EU institutions (the Commission, the Council, Parliament, etc.) also provided input during the policymaking process. This system of shared competence among different EU institutions prevented regulatory capture by any particular set of

[7] For a detailed discussion of the evolution of the French regulatory framework for GMOs, see Chapter 4.
[8] For an overview of the scholarship on interest groups at the EU-level, see David Coen and Jeremy Richardson, eds. 2009. *Lobbying the European Union: Institutions, Actors and Policies.* Oxford, UK: Oxford University Press.
[9] Jonathan Smiles. 2010. "Book Review: *Lobbying in the European Union: Institutions, Actors and Issues*." *The Journal of Politics*. Vol 72. Issue 4. p.1254-1255.

interest groups.[10] As such, the interest group approach as an alternative hypothesis does not provide as fruitful or as a rich an understanding of the factors contributing to the regulatory impasse in the same way as an institutionalist approach does.

Moreover, inherent to an interest group hypothesis in EU studies is the assumption that interest groups must interact differently within the two levels of governance because of institutional variation.[11] Thus, it is important to first understand what those institutional structures are and how they have evolved to produce variation. This dissertation traces the evolution of the regulatory frameworks at the EU- and French-level to produce that understanding. Interest groups are not ignored in the process, as anti-GMO groups are reviewed in Chapter 5; however, my focus in on how anti-GMO interest groups have played a role in GMO regulatory policymaking in the context of their institutional inclusion. As Jeremy Richardson states, though, it can be "a mistake to look for only one model of the EU policy process," because "particular policy areas may themselves be episodic, exhibiting different characteristics at different times."[12] Varying models of analysis may be useful to study different time periods of a policy area.[13] In this case, then, a historical institutionalism approach with conceptual contributions from multi-level governance and implementation studies (as discussed in more detail below) provides the best model of analysis for this policy area during this time period.

[10] "Regulatory capture" can be defined as when a particular interest group, such as business or industry, "capture" the policymaking process, leading to policies and regulations being designed and enforced primarily for the interest group's benefit. Jean-Jacques Laffont and Jean Tirole. 1991. "The Politics of Government Decision-Making: A Theory of Regulatory Capture." *The Quarterly Journal of Economics*, Vol. 106, No. 4 (November), pp. 1089-1127.
[11] It is important to note that while institutional variation is not a valid explanation for the differences in interest group behavior in the American tradition of interest group studies, institutional variation is considered as a variable in scholarship on interest group behavior in the EU.
[12] Jeremy Richardson. 2006. "Policy-making in the EU: interests, ideas and garbage cans of primeval soup," in J. Richardson (ed.), *European Union: Power and policy-making*, London: Routledge, pp. 4–30. Here, p.7.
[13] Richardson. "Policy-making in the EU." 7.

Biotechnology in the European Union: French Resistance to GMOs

Although agricultural biotechnology is a fairly new policy area (only attaining a position on the agenda in the last twenty-five years), the EU has quickly become the main regulator of biotechnology in Europe. France is one of several member states, however, that have resisted implementing EU policies on GMOs and GM food.[14] Eurobarometer polls reflect this resistance at the public opinion level; a special Eurobarometer report on the "Attitudes of European citizens towards the environment" showed that 70% of French respondents were opposed to the use of GMOs, compared to 15% in favor, 13% who did not know, and 2% who had never heard of GMOs.[15] Nevertheless, French popular resistance to GMOs has not always existed. A 1991 report on European opinions on biotechnology indicates the majority of French respondents were optimistic that biotechnology would "improve our way of life in the next 20 years."[16] Why, then, did France become resistant to implementing some policies that, at an EU-level, are deemed to be essential to progress in the areas of economic growth, the environment, and public health?

Theoretical Approach

Understanding the reasons why France has taken a more anti-GMO stance compared to its position in the early 1990s is only part of this study's research puzzle. Existing scholarship has already reviewed the food safety and public health scandals of the 1990s that acted as triggering events for precautionary policymaking in the issue area of agricultural biotechnology. These events set the tone for the policymaking environment at both the EU- and the French-level. But, although it is important to examine the triggers that caused the flip-flop in France's

[14] Eurobarometer surveys, for example, show that France, Italy, and Greece all have high rates of public opposition to GM food, as noted by Dave Toke, *The Politics of GM Food: A comparative study of the UK, USA, and EU*. (London: Routledge, 2004): 142-143. Austria has also emerged as strongly anti-GMO.

[15] Special Eurobarometer 295/EB68.2/2007 "Attitudes of European citizens towards the environment" in http://ec.europa.eu/public_opinion/archives/ebs/ebs_295_en.pdf.

[16] Durant, John, ed. "Biotechnology in public: a review of recent research." (London: Science Museum for the European Federation of Biotechnology, 1992): 9. http://ec.europa.eu/public_opinion/archives/ebs/ebs_061_en.pdf This report is a summary of data collected in the Eurobarometer Poll 35.1/March 1991.

position, the puzzle is not yet completed. Consequently, this research examines the persistence of France's anti-GMO stance in addition to the political context at critical junctures in the development of the French regulatory framework.

In order to understand French non-compliance in the domain of agricultural biotechnology, I conduct a historical institutionalist study of public policymaking and adaptation in this domain, pulling also from multi-level governance and implementation studies. Studies of the EU require this type of multi-pronged approach; in this dissertation, I focus on a single member state, which is embedded in the EU's structure as well as in the context of global trade. Singularly, each of these approaches would miss important layers of context that are needed to understand the issue area and the evolution of the regulatory framework created to address agricultural biotechnology. These approaches are used as complements to each other, as I explain in Chapter 1.

Historical institutionalism is the center of the multi-pronged approach, as it lends important key concepts to the study – timing, sequence, path dependence, and critical junctures. In addition, inherent in an institutionalist approach is the recognition of the historical legacy of laws, regulatory policy, rules, and institutions, which are not easily altered, thus contributing to the "stickiness" of institutions. The historical dimensions of this theoretical approach acknowledge the political and legal traditions that shape the context of policymaking in France and can set limits for interest group participation. While historical institutionalism provides the foundation for the study, multi-level governance and implementation studies provide additional theoretical and conceptual support to my findings. The multi-level governance framework allows me to address the influences and pressures external to the EU on the policymaking process, while implementation studies help me define important terms in the implementation process.

As such, this study adds to the historical institutionalist literature by showing how national and subnational institutions matter in the implementation processes of EU policy within member states. In addition, it helps reveal in more detail the domestic hurdles to policy implementation and enforcement that the EU faces in an issue area that it sees as a cornerstone for its progress and competitive viability. I have chosen the case of France for this study not only because is it one of the founding members of the European Union, but because it also continues to play an incredibly important role in EU policymaking, particularly in the issue area of agriculture. Biotechnological advances in GMOs and GM products have become central to discussions of improving agriculture, competitiveness, and trade at the EU level; yet, France resists EU promotion of GMOs and GM products.

An in-depth, single case study of France also provides a foundation for future comparative studies of EU member states. By detailing the evolution of the institutional structure of the GMO regulatory frameworks at the EU- and state-levels, I demonstrate not only that institutions matter in the case of French non-compliance, but also how they matter. While the particulars of the triggering events and the institutional structures in France may differ from the particulars of the development of the regulatory frameworks in other anti-GMO member states, the conclusion is the same: institutions matter for implementation. Although the populations of anti-GMO member states may exhibit high levels of anxiety about GMOs and GM food, domestic public opinion does not explain the non-compliance of the member states with EU public policies. This case study shows how public opinion became translated into institutions within France at critical junctures brought on by the public health and food safety scandals of the 1990s.

As a result, this study can be used to explore agricultural biotechnology regulation in other states in future, multi-case comparative studies. By studying these obstacles in the French case and the role of domestic institutions in adaptation, the approach serves as a template for studies on the implementation of EU legislation in other member states. Future studies can make use of the details from this work to discover how institutions matter in the implementation processes of other member states. For example, on one hand, research may focus on comparing other non-compliant states to France: were there the same triggering events? Is anti-GMO sentiment institutionalized in the regulatory framework? Is public opinion included in policymaking? On the other hand, future studies could compare the case of France to compliant or pro-GMO states by exploring the possible absence of triggering events or by reviewing the institutional structures of the domestic regulatory system.

While the lessons drawn from a study of France cannot be applied in their entirety to other EU member states due to variation across nations in their domestic institutions and potential triggering events, this study shows how institutions matter in the process of implementation, and thus must be studied when looking at issues of non-compliance among the member states. Conclusions from this study help us better understand how the EU should move forward in order to overcome obstacles to implementation. This work highlights the value of looking at the role of domestic institutions in the implementation phase, for policymakers and scholars.

The existing scholarship on French resistance to GMOs illustrates how public concerns about GMO regulation were originally linked to the European food safety and public health scandals of the 1990s. However, since the catalytic moment when American GM soybeans arrived on European shores in 1996, there have been no scientific analyses that have definitively

linked GMOs to major human health risks or to environmental destruction. In addition, the actual number of human fatalities from the mad cow disease outbreak[17] – considered one of the main triggering events of GMO opposition – has only amounted to a tiny fraction of the original predictions of up to 500,000 deaths. And, despite some small-scale food safety concerns, Europe did not experience any major crises between 2000 and 2010.[18] Yet, even without scientific confirmation of the public's worst fears, high death tolls from earlier crises, or new scandals to keep the public mobilized, French public opinion has remained overwhelmingly hostile to GMO approvals. Moreover, GMOs have maintained a constant position on the policy agenda.

The European public health and food safety scandals of the 1990s also allowed interest groups to frame agricultural biotechnology as they preferred: as a public health issue, as an environmental issue, and as a consumer rights issue. This work illustrates how the framing of the issue of agricultural biotechnology, the timing of the creation of the institutions responsible for regulating GMOs, and the frequent actions of domestic interest groups in France led to a reversal of France's position on GMO approvals at the EU-level and to entrenched opposition to GMO approvals by the French public. Thus, it examines both the triggers that contributed to France's reversal on GMO approvals at the EU-level and the persistent opposition to GMOs among French citizens.

[17] There were 226 confirmed cases as of 2011. NCJDRSU. 2011. "Variant Creutzfeldt-Jakob Disease Current Data (November 2011)." *NCJDRSU Site*. http://www.cjd.ed.ac.uk/vcjdworld.htm (accessed February 28, 2012).

[18] It should be noted that a major food safety event – "Europe's worst recorded outbreak of *Escherichia coli* infection" – occurred in late Spring of 2011. Germany first reported an ongoing outbreak of *Escherichia coli* (*E. coli*) infection on May 21, 2011, and France and other states reported clusters in the following weeks. In total, there were over 4,000 cases of *E. coli* infection, including 53 deaths. The infections were eventually traced to the consumption of contaminated fenugreek sprout seeds, which were imported from Egypt and cultivated in Europe. Marian Turner. "Reform falters after Europe's E. coli scare." *Nature*. Vol. 485. Issue 7400. May 20, 2012. http://www.nature.com/news/reform-falters-after-europe-s-e-coli-scare-1.10739 (accessed June 5, 2012).

Resolving the Regulatory Deadlock

In an attempt to resolve the regulatory deadlock over GMOs, the European Commission announced an amendment in April 2010 that would give the member states "the freedom to allow, restrict or ban the cultivation of GMOs on part or all of their territory," while also leaving "unchanged the EU's science-based GM authorisation system."[19] The proposal would amend Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, and it has been working its way through the relevant EU institutions since July 2010. As of July 2012, the European Parliament has adopted its draft of the proposal, while the Council of the European Union (the Council) has not yet reached an agreement because of continued concerns about "the legal compatibility of some provisions in the proposal with WTO and EU internal market rules."[20]

Even though the regulatory impasse has reached an untenable position, both at the EU-level and within France, the Commission's approach to resolving it is wrongheaded. Shifting power back to national authorities will not successfully resolve the issues of non-compliance that the EU faces in this policy domain. For one, in most member states, the EU garners more trust and confidence in its ability to regulate biotechnology than Europeans express for their respective national authorities. Although Europeans' confidence in the EU authorities to effectively regulate biotechnology policy hit an all-time low during the wave of food safety and public health crises in the 1990s, public opinion polls have revealed a fairly steady, upward trend in trust since 1999. Moreover, Europeans have expressed a positive outlook on EU legislation in

[19] European Commission. "GMOs: Member States to be given full responsibility on cultivation in their territories." *Press Releases RAPID*. http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/921 (accessed July 2012).
[20] European Parliament. "Procedure File. Genetically modified organisms GMOs: possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory." *Legislative Observatory*. http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?id=586551#basicInformation (accessed July 2012).

the domains of biotechnology and food safety.[21] One of the main critiques of EU biotechnology legislation is not about its content, but that EU law is not properly enforced. Relinquishing power back to the member states would not address the public's concerns about the ability of authorities to effectively regulate GMOs; it would simply shift the blame for perceived ineffectiveness from EU authorities to national ones, leading to a further erosion of trust.

Secondly, shifting the power back to national authorities would not address the overwhelmingly negative attitudes towards agricultural biotechnology in Europe. Europeans are not anti-GM food because they believe that the EU does not have the ability to regulate it, although there are some concerns. While both optimism about biotechnology applications and confidence in regulatory authorities have fluctuated over the last twenty years, the European outlook on GM food has been persistently negative. Europeans reject GM food on several grounds; for example, they conclude that GMOs are unsafe for individual and public health and that they are harmful to the environment. The majority of Europeans also do not believe that there is an economic benefit to producing GM crops or food, due to fears about the consequences of an increasingly globalized and industrialized food chain. Environmental groups criticize the amendment as an attempt to sneakily (and perhaps illegally) push GM food onto European plates.[22]

Creating a way to fast-track GMO approvals at the EU-level, but then allowing member states to determine whether the GM crop will be cultivated and under which standards, not only ignores the many elements that make up anti-GMO attitudes, it plays upon one of the European

[21] TNS Opinion & Social. 2010. "Biotechnology." *Special Eurobarometer 341 / Wave 73.1*. Brussels, Belgium: European Commission. 29, 30, and 20. http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_en.pdf (accessed July 2012). 153-166; TNS Opinion & Social. 2010. "Food-related risks." *Special Eurobarometer 354 / Wave 73.5*. Brussels, Belgium: European Commission. 60-68.

[22] EurActiv with Reuters. 2010. "EU to overhaul GM crop approval system." *Agriculture and Food – News.* June 4. http://www.euractiv.com/cap/eu-overhaul-gm-crop-approval-sys-news-494896 (accessed July 2012).

public's fears about food-related risks. Over 40% of Europeans do not believe that public authorities see "the health of consumers as being more important than the profits of producers."[23] Recurrent statements by EU institutions based on economic arguments – that agricultural biotechnology is important for the EU's competitiveness in the world market and for economic growth – only bolster the image that the EU's promotion of GMO cultivation is founded on economic interests and ignores public health and food safety concerns.

Finally, the Commission's attempt to resolve the GMO issue is a solution to the regulatory deadlock only at the EU-level. It provides a way to streamline and advance the GMO approval process within the EU institutions, with the goal of approving more GMOs. The EU is not considering *if* it should allow GMOs to be cultivated, but rather *which ones* should be approved. Agricultural biotechnology is seen as a crucial part of the EU's development strategies.[24] Thus, the European Commission has accepted GMO approvals as a necessary part of its long-term economic goals. In contrast, at the member state-level, many Europeans are still debating if GMOs should be approved at all. The failure to recognize the difference in the core concerns of the debate at each level of governance has resulted in the *dialogue des sourds*.

In the case of France, the *dialogue des sourds* is happening in two ways: in the debate between the EU and France, and in the debate between the pro- and anti-GMO sides within France. As a result, the Commission's proposed amendment will not resolve the regulatory deadlock in France, if "resolution" means allowing GMO approvals. Due to the timing of reforms and the creation of the agencies responsible for GMO regulation, anti-GMO sentiment was institutionalized in the French risk assessment process. Currently, GMO opponents are

[23] TNS Opinion & Social. "Food-related risks." 65.
[24] Eleni Zika, Ilias Papatryfon, Oliver Wolf, Manuel Gómez-Barbero, Alexander J. Stein, and Anne-Katrin Bock. 2007. *Consequences, Opportunities and Challenges of Modern Biotechnology for Europe.* JRC Reference Report. The Bio4EU Study. http://ftp.jrc.es/EURdoc/22728-ExeSumm.pdf (accessed July 2012).

incorporated into the *Comité économique, éthique et social* (Economic, Ethical, and Social Committee – CEES) of the *Haut Conseil des Biotechnologies* (High Council on Biotechnology – HCB).[25] And, despite hopes that the HCB would resolve the domestic regulatory deadlock while allowing different opinions to be heard, consensus on GMO dossiers within the HCB has been scarce. The European Commission claims that its amendment will give the member states the "freedom" to decide whether to cultivate or ban GMOs based other factors outside of scientific assessment, including political and economic motivations or preservation of national policies on biodiversity.[26] But members of the Council, including France, question the legal compatibility of parts of the amendment with WTO and EU internal market rules.[27] Again, allowing member states to enact domestic restrictions or bans on approved GMOs would not relieve the impasse that has developed in the GMO approval process; it would simply shift the vulnerability to WTO complaints and proceedings to the individual member states that maintain GMO bans.

Dissertation Roadmap

This dissertation demonstrates why the Commission's proposed resolution to the regulatory deadlock would be unsuccessful, specifically in the case of France. The study begins in Chapter 1 with an overview of the historical context of the development of agricultural biotechnology as a scientific process and of the initial regulatory responses to that development. Chapter 1 also reviews the implementation literature, Europeanization literature, multi-level governance literature, and the historical institutionalist approach, before broadly addressing the

[25] The HCB is a two-committee council in France that provides opinions on GMO dossiers to the French government based on scientific and on socio-economic and ethical assessments.

[26] European Commission. 2010. "Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on the freedom for Member States to decide on the cultivation of genetically modified crops." July 13. Brussels. COM(2010) 380 final. http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=EN&type_doc=COMfinal&an_doc=2010&nu_doc=380 (accessed July 2012).

[27] European Parliament. 2012. "2010/0208(COD) - 09/03/2012 Debate in Council." *Legislative Observatory.* http://www.europarl.europa.eu/oeil/popups/summary.do?id=1196575&t=e&l=en (accessed July 2012).

multi-level governance aspects of EU policymaking and member state implementation in this policy domain. Chapter 1 concludes with a more detailed discussion of the project's hypothesis and its methodological approach.

Chapter 2 reviews the triggering events that framed the debate on GMOs and shows that, before these scandals, there was significantly less opposition to GMOs in France. Chapter 2 examines three major public health scandals in Europe during the 1990s: the tainted blood scandal in France, the mad cow crisis in Great Britain, and episodes of dioxin contamination in Belgium. By reviewing these cases, the chapter establishes the environment into which the issue of GMOs was introduced. The chapter also connects the concept of "blame," and the role that it played in these crises, to the development of the policy linkage between GMOs and tainted blood, mad cow disease, and dioxin contamination.

L'affaire du sang contaminé (the HIV-tainted blood scandal) was the first of a series of triggers that elevated the domain of public health to a prominent position on the policy agenda. The scandal also provoked the French public's fears about the government's ability to regulate issues of public health. Furthermore, it raised concerns about the influence of industry in governmental regulation. In the mid- to late-1990s, the mad cow crisis presented as another triggering event that pushed French public opinion toward an anti-GMO position. The crisis raised the profile of food safety as a salient policy domain. And like the HIV-tainted blood scandal, it reinforced concerns that the French government could not effectively regulate food safety issues. Coupled with the dioxin contamination episodes, the mad cow crisis bolstered claims that industry interests were more heavily weighted than the greater good in regulatory decisionmaking. In addition, these food safety scandals raised concerns about the EU's ability to

effectively regulate food safety for the Common Market. And, the dioxin contaminations kept food safety at the forefront of the public's consciousness.

After these triggering events, public perception of public health and food safety as salient policy domains was elevated. It was into this anxiety-ridden environment that the issue of GMOs was introduced. Chapter 3 provides the context of GMO regulation at the EU-level, including a review of the EU institutions and legislation relevant to the EU regulatory framework for agricultural biotechnology. The chapter also reviews the international agreements and trade relationships that shape EU policy development, including how the European regulatory framework has developed in contrast to the American framework. Together, the review of the legal framework and the regulatory system for agricultural biotechnology illustrates the EU policymaking process for the regulation of agricultural biotechnology.

While the authority for biotechnology regulation cuts across several EU institutions and policy domains (like the environment, health, industry, and agriculture), the EU regulatory framework for GMO approvals and monitoring is heavily based on scientific assessment. Less weight, if any, is given to environmental and socio-economic concerns. The regulatory framework in France, however, considers more than just scientific data in its risk assessment process. As a result of the triggering events, anti-GMO interest groups challenged GMO approvals in France on environmental, consumer rights, and public health grounds. The French government then validated these positions when it created institutions with channels for "democratic inputs," through which the public could provide its feedback on the issue. The decision to include public input in the policymaking process not only gave credence to the opposing side as a legitimate position, but it also validated the inclusion of public opinion and non-scientific expertise in risk regulation. As a result, the French institutions that were

subsequently created to regulate GMOs all provided space for public opinion to be incorporated. This means that the French government has formally created channels for GMO opponents in the decisionmaking process.

The resulting differences in the risk assessment processes at the EU-level and in France contribute to French non-compliance with EU biotechnology regulation. French regulatory authorities consider other factors, in addition to scientific data, in their risk assessments of the possible effects of GMOs. Because the EU does not consider those factors in an institutionalized manner, the French see EU assessments as incomplete, which has lead to France's repeated invocation of the safeguard clause. The problem then gets reproduced in the international forum of the WTO.

Chapter 4 focuses on the development of the French regulatory framework, and how it came to incorporate non-scientific expertise in its risk assessment processes. In this chapter, I review the role of French officials, organizations, and institutions in the regulatory framework for agricultural biotechnology. While France has effectively resisted implementing the EU legislation in this domain, a look at French domestic actors reveals that they are not unified in their stance on GMOs. Chapter 4 explores the varied positions of the different domestic actors, and the role that these actors play in the policymaking process at the EU-level and the transposition process at the national-level. It also traces the development of the domestic institutions responsible for agricultural biotechnology regulation. The recommendation that non-scientific expertise be considered as an input in the risk assessment of GMOs in *la Conférence Citoyenne* led to later, more permanent institutions being formed with a place for social and ethical considerations (rather than just scientific or economic), laying the groundwork for continued conflict between the EU approval process and the French approval process.

Chapter 5 delves into the elements of French resistance to agricultural biotechnology and GM food. To do so, it examines public opinion surveys on biotechnology and food-related risks administered by the EU. The survey data illustrate French awareness of and attitudes towards agricultural biotechnology and GM food over time, which in turn reveals that the French are fiercely anti-GM food and highly worried about food-related risks. From the survey responses, I conclude that efforts to resolve the regulatory deadlock that focus narrowly on scientific assessment or economic arguments will be unsuccessful, as they will never be sufficient in addressing all of the issues raised by the anti-GM movement. The legacy of the scientific failings in the HIV-tainted blood scandal and the mad cow crisis remain. Europeans harbor concerns that scientists cannot anticipate unexpected problems or accurately assess the long-term effects of GMOs. There is also a general distrust of the government's motives for promoting GMOs, anchored in the belief that public authorities care more about producers' profits than they do about the protection of public health.

In addition, Chapter 5 reviews several anti-GMO interest groups[28] that have been at the forefront of French resistance and the varied conceptualizations of the issue of GMOs: as an issue of safety and health, consumers' rights, farmers' rights, and globalizing forces. The early linkage of GMOs to other food safety scandals helped anti-GMO groups frame the issue in the way that they desired. These interest groups have contributed to the entrenched opposition to GMOs among the French public, in part because they have been able to maintain continued support for their positions with frequent, highly visible actions. Their respective messages are not only appealing to the French public, but they are compatible among the different interest

[28] Chapter 5 reviews a consumers' rights group (*Association Consommation, Logement, Cadre de vie*), an independent research organization (*Comité de Recherche et d'Information Indépendantes sur le genie Génétique*), an environmental protection organization (Greenpeace France), and a farmers' union that has also been involved in the anti-globalization movement (*Confédération Paysanne*).

groups. In this way, environmental, consumer rights, and public health interest groups are not competing for support; rather, they can collaborate with and support each other's efforts. The public opinion surveys reflect the anti-GMO message of the interest groups.

The final section summarizes the findings and offers conclusions that can be drawn from this research for future projects. Although lessons learned from the case of France cannot be wholly applied to other member states, the recognition that the GMO debate is happening on two levels, each with different core issues, is an important conclusion, which can be explored in other member state cases. Finally, I offer suggestions for future research projects that can build on this case.

Chapter 1. The Conceptual Framework

Before delving into an analysis of the contemporary European regulatory framework for agricultural biotechnology, it is important first to provide a historical context of the development of agricultural biotechnology as a scientific process. To that end, this chapter defines basic concepts of agricultural biotechnology and of risk assessment, and it details the initial regulatory responses in Europe and in the United States to the development of agricultural biotechnology processes. Chapter 1 then presents a more detailed discussion of this project's hypothesis and a review of the relevant literature in implementation, Europeanization, and multi-level governance studies. These literatures provide a foundation on which the methods of this project are built, and a discussion of the historical institutionalist approach and methodological framework is included. Finally, this chapter broadly addresses the multi-level governance aspects of EU policymaking and French implementation in this policy domain.

The Development of Agricultural Biotechnology Regulation

Policymaking in the European Union occurs within a continually developing system of multi-level governance. While some policy domains have remained under the direct control of national institutions, member states have ceded sovereignty over a number of different issue areas to the institutions of the EU. In addition, the Europeanization of national policymaking has led to adjustments in domestic institutions and governance structures. These adjustments, however, do not represent a complete integration of domestic policies into EU governance structures and systems. This remaining divide is readily apparent in the phase of policy implementation. During this phase, national institutional differences lead to variations in the adoption of EU policies among the member states. Moreover, variation in implementation can appear within individual states when policies in a single issue area are compared. Why is it that

the implementation of some policies by the member states meets the standards set by the EU, while seemingly similar policies do not? In order to understand this variation, one must look at the national institutions responsible for policy implementation within the context of their interactions with the multi-level governance structure of the EU. The issue area of biotechnology illustrates how this variation within a state can occur.

What is agricultural biotechnology?

Biotechnology refers to the process of genetic engineering, which, broadly defined, is the manipulation of heredity or of hereditary material with the goal of altering cells and organisms so that they produce more or different chemicals, resulting in new or "improved" functions.[1] Such manipulation has occurred for as long as humans have cultivated crops and bred livestock. However, since the end of World War II, scientific breakthroughs have evolved into the "molecular revolution" of genetics, leading to the microgenetic engineering that has distinguished late twentieth-century and early twenty-first century genetic engineering from earlier methods.[2] Combined with innovations in electronics and information technology, this contemporary form of genetic engineering undergirds the development of a new "expert system" known as the "bio-industrial complex."[3] New techniques, scientific knowledge, systems of classification, professions, and professional specializations come with this new system. And, as a result, public policy makers are faced with handling these changes, the uncertainty of the impacts of these advancements and their products, and their potential risks. Policymakers must therefore

[1] Peter Wheale and Ruth McNally, "The Social Management of Genetic Engineering: An Introduction," in *The Social Management of Genetic Engineering*, Wheale, von Schomberg, Glasner, eds. (Aldershot, UK: Ashgate Publishing Ltd, 1998): 1.
[2] Wheale and McNally 2. Microgenetic engineering is genetic manipulation at the molecular level, which makes it possible for scientists to combine genetic material from totally unrelated species.
[3] Ibid 2.

deal with public concern over potential health and environmental hazards, while also balancing the commercial and research interests of the scientific community and of industry.

The EU has named biotechnology as one of the key technologies needed for sustainable development, particularly in areas of economic growth, environmental protections, and public health.[4] The EU divides current applications of biotechnology into three main fields: medicine and healthcare; industrial production processes, energy, and the environment; and primary production and agro-food.[5] Yet for policymakers, these categories are not strictly bounded. While regulation of biotechnology processes can be divided into these three groupings, the overlapping nature of the ever-growing fields of biotechnology is reflected in the numerous policy domains that claim the right to regulate biotechnology and its products. Biotechnology can be thought of (alternately or simultaneously) as a trade, agricultural, environmental, or public health issue. Applications of biotechnology in the field of primary production and agro-food are often characterized as having economic, environmental, and public health significance.[6]

The policy issue area of primary production and agro-food biotechnology has been established as important to the progress of the EU. However, the EU has recognized that implementation of legislation in this particular field has "proven to be difficult," in part because of reluctance on the part of member states to transition between the former legal framework on genetically modified organisms and the new framework, and also because of the negative public perception of GM food.[7] While the European Commission has acknowledged that the issue of governance is central to implementation of these policies and has tried to improve

[4] European Commission (2007) EUR 22728: A Joint Research Centre Reference Report - Consequences, Opportunities and Challenges of Modern Biotechnology for Europe.
[5] EUR 22728. The different categories of biotechnology applications may also be referred to as "red biotechnologies" (medical); "white biotechnologies" (industrial); and "green biotechnologies" (agricultural).
[6] European Commission (2007) SEC 441: A Communication to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions on the mid term review of the Strategy on Life Sciences and Biotechnology.
[7] SEC 441, 6-7.

implementation by developing applications specific to individual member states, the EU continues to meet resistance to implementation and to have problems with policy enforcement.[8] The Commission has noted that this "gap between public perception and the agreed legal framework on GMOs has to be addressed" in future EU initiatives.[9]

Thus, this "bio-industrial complex" has been created as a consequence of advances made in microgenetic engineering research. With this new system have come new uncertainties about the impacts of these advancements and potential risks. As a result, public policy makers must manage these new changes. As Smita Siddhanti points out: "Social management of technological development faces the essential requirement of balancing the benefits of the technology to the public against the potential harm of its application."[10] Accordingly, policymakers must deal with public concern of potential health and environmental hazards, in what is termed "low-probability-high-consequence" technological activities. Because new technologies could possibly create many risks, determining which risks are socially acceptable becomes an important national issue. In order to regulate the genetic modification of plants, animals, and human genetic material, particularly with respect to those products that are deliberately released into the environment, policymakers have had to respond to this new area of advanced biotechnology with systems of risk assessment and risk management.

The concepts of risk

The concept of risk is not limited to the issue area of biotechnology, or more specifically to GMOs and their inclusion in food sources. Risk may be similarly considered for policy decisions in security, environment, health care, and other technology issue areas, for example.

[8] SEC 441, 7.
[9] SEC 441, 7.
[10] Smita Siddhanti, *Multiple Perspectives on Risk and Regulation: The Case of Deliberate Release of Genetically Engineered Organisms into the Environment* (New York: Garland Publishing, Inc., 1991): 4

Academic interest in risk and risk management has increased in the last two decades. This may be attributable to increasing expectations of safety and security within these areas, or in light of scientific breakthroughs and the emergence of a number of large-scale, high-technology advancements.[11] Consequently, within such a broad range of issue areas, one can find numerous definitions and uses of the concept of risk.

Christopher Hood and David Jones address this inconsistency in the literature by looking at the use of the words "risk" and "hazard." Though often used interchangeably, Hood and Jones point out that the concepts are distinct. "Risk" is said to "comprise perceptions about the loss potential associated with the interrelationship among humans and between humans and their natural (physical) environment, biological, technological, behavioural and financial environments – a complex that may conveniently be termed the 'risk environment.'"[12] "Hazard," by contrast, in general means "a phenomenon or circumstance perceived to be capable of causing harm or costs to society."[13] Thus, while "hazard" more specifically addresses the cause of the perceived adverse consequence, "risk" is a broader concept that is concerned with the assessment of consequences or exposure to the chance of loss. In this way, hazard is a component of risk.

The questions of risk analysis and management differ based upon the discipline in which they are situated. No single comprehensive and integrated approach encompasses the three subfields of risk management, classified as natural hazards research, disaster research, and risk analysis.[14] Furthermore, these subfields are interrelated, which adds to the lack of clarity in the field. Risk management, then, becomes difficult to elucidate because of the variety of definitions

[11] Christopher Hood and David Jones, "Introduction," in *Accident and Design: Contemporary debates in risk management*, Hood and Jones, eds. (London: Routledge, 1998): 1.
[12] Hood and Jones 3.
[13] Hood and Jones 2.
[14] Hood and Jones 5.

for risk. But generally the management of risk is understood as "a process involving the three basic elements of any control system, namely goal-setting (whether explicit or implicit), information gathering and interpretation, and action to influence human behavior, modify physical structures or both."[15] In public policy, risk management typically refers to an analytical technique for quantifiably measuring estimated risks of a course of action, and then evaluating those risks against the estimated benefits.[16]

Additionally, there are a number of fundamental questions – which do not always have answers – that underpin these three elements:

> Who is to bear what level of risk? Who is to benefit from risk-taking? …Where is the line to be drawn between risks to be managed by the state, and those to be managed by individuals, social groups or corporations? …Who evaluates success of failure in risk management and how? Who decides on what should be the desired trade-off between different risks?[17]

As noted, not every question may be answered during the process of risk management, but each is likely to be considered. More broadly, risk management can be considered as all regulatory measures, or as the range of activities needed for coping with risk. Yet while risk management includes identification and evaluation of risk, it is not the same as risk assessment. Assessment may be construed as a more scientific process, while management occurs at a political or bureaucratic level,[18] but these spheres are too enmeshed to be cleanly separated out. Rather, we can think of assessment as part of the process of risk management.

Societies deal with risk in the form of regulation. Risk regulation, as a concept, can be defined as "governmental interference with market or social processes to control potential

[15] Hood and Jones 6.
[16] Hood and Jones 6.
[17] Hood and Jones 6.
[18] Hood and Jones 8.

adverse consequences to health."[19] Thus risk regulation is specifically the political aspect of risk management, meaning the moment that a government becomes clearly involved in the process. This does not mean, however, that risk regulation in the political sphere operates in isolation; the distinction is made simply for identifying risk regulation as an outcome of a political process. Some scholarship has focused on the development of the "regulatory state" in response to a "risk society" in looking at the social handling of risk; other works have addressed the development of an "audit society."[20] These works reveal that not only does the understanding of risk and of the response to it vary across policy domains, but it also varies across cultures.

In the domain of biotechnology, governments were first concerned with safety regulations for laboratory practices and field tests. But over time, as the products and innovations of those laboratory processes became market-ready, policymakers had to respond to the growing area of advanced biotechnology with new regulations, while balancing public concern of potential health risks and environmental hazards with the commercial and research interests of the scientific community and of industry. As a whole, European states have been much more cautious in their risk assessment and management of genetically engineered agricultural products than their North American counterparts.

Blame

In his research, Hood makes a connection between the development of risk regulatory regimes and blame. Inherent in the process of risk regulation is the personal risk that public officeholders are taking, which Hood labels "blame risk."[21] Hood takes blame risk into

[19] Christopher Hood, Henry Rothstein, and Robert Baldwin, *The Government of Risk: Understanding Risk Regulatory Regimes* (Oxford: Oxford University Press, 2001): 3.
[20] Hood et al. 4-5. See this source for a brief review of Majone's "The Rise of the Regulatory State in Europe," and also Power's *The Audit Society*.
[21] Christopher Hood, *The Blame Game: Spin, Bureaucracy, and Self-Preservation in Government* (Princeton: Princeton University Press, 2011): 5.

consideration as a variable in the decisionmaking processes of regulators. He defines blame as "the act of attributing something considered to be bad or wrong to some person or entity."[22] Hood goes further by breaking blame down into two elements. Perceived avoidable harm or loss (PAH) is "something that is seen as being worse for some person or group than it could have been if matters had been handled differently."[23] Whereas, perceived responsibility or agency (PR) indicates that "harm was avoidable because it was caused by acts of omissions or commission by some identifiable individual or organization or possibly some more abstract institution such as 'capitalism' or 'patriarchy.'"[24] These elements of blame may vary based on the case and the timing of an event.

Public officeholders may care about the risk of blame for different reasons, partially based on their position:

> Elected politicians will care about blame if they think it will reduce their chances of re-election. Managers will care about blame if they think it will reduce their prospects of promotion, bonuses, staying in their current jobs, or moving on to better ones. Professionals will care about blame if they think it will diminish their reputations in ways that could damage their careers or produce expensive lawsuits over malpractice. Front-line bureaucrats will care about blame if they think it will cost them their jobs or their bonuses or their chances of promotion, or bust them back down the ranks.[25]

Position, of course, is not the only variable in determining how an individual may address the possibility of blame risk. Hood notes that personality and psychological needs also motivate responses to blame risk. More importantly, though, is his assertion that social settings and institutional backgrounds play a part in responses to blame risk.

[22] Christopher Hood, *The Blame Game,* 6.
[23] Christopher Hood, *The Blame Game*,6.
[24] Raanan Sulitzeanu-Kenan and Christopher Hood, "Blame Avoidance with Adjectives? Motivation, Opportunity, Activity and Outcome." Paper presented at the ECPR Joint Sessions, Granada, April 2005, as cited in Hood 6.
[25] Christopher Hood, *The Blame Game,* 8.

Hood outlines several different strategies to deal with blame risk for policymakers; however, I focus on the particular policy strategy of abstinence due to its particular relevance to the French GMO case. Abstinence is one approach to blame avoidance. Some "forms of blame avoidance are anticipative – they involve efforts to 'stop blame before it starts'…"[26] Abstinence is anticipative; it is a "just say no" strategy that "means choosing not to operate or provide facilities or services… that attract blame or have the potential to do so."[27] In short, policymakers or public officials refuse to provide particular services or make decisions on issues for which they anticipate a high blame risk. Although abstinence may avoid some blame, it can still leave public officials susceptible to blame from the opposite direction,[28] as we will see in the case of GMO regulation in France.

Initial regulatory responses to biotechnology in Europe and the United States

Recombinant DNA techniques were central to the microgenetic engineering "molecular revolution" in the early 1970s. While scientists were excited about the new opportunities for research available through this method, they were also concerned with the uncertainty around the level of risk and the potential for biohazards.[29] As a result, in 1974 the international scientific community accepted a self-imposed moratorium on certain experiments involving recombinant DNA methods that were deemed too risky, in order to engage in debate over the place of these methods in research programs.[30] The main actors in this debate, which centered on the use of antibiotic-resistant plasmids in the recombinant DNA process, were the United States and Great Britain. The differences in the American and British responses to the perceived risks of

[26] Christopher Hood, *The Blame Game: Spin, Bureaucracy, and Self-Preservation in Government*, 6.
[27] Christopher Hood, *The Blame Game: Spin, Bureaucracy, and Self-Preservation in Government*, 102.
[28] Ibid 104. The "opposite direction" refers to individuals, groups, institutions, etc. who do want action to be taken in the particular policy domain. Therefore, they argue against abstinence. In the case of GMOs, biotechnology industries and pro-GM farming lobbies come from the "opposite direction."
[29] Wheale and M^{c}Nally 40.
[30] Wheale and M^{c}Nally 42.

recombinant DNA procedures reveal the divergence in risk management between the United States and Europe.

In the United States, the National Institutes of Health (NIH), a federal agency, stepped in and composed a series of recommendations, which turned into and were issued as the NIH Guidelines for Research Involving Recombinant DNA Molecules.[31] The 1976 NIH Guidelines provided a classification schema based on the experiment type's potential biohazard level. They also prohibited some classes of experiments that were deemed too risky. In addition, the Guidelines outlined containment measures of how to "properly" handle certain pathogens involved in the processes.

Besides the procedures for the methods of experiments, the Guidelines also laid out procedures for adherence. Each institution wishing to engage in recombinant DNA activities was required to appoint a Principal Investigator (PI) and an Institutional Biohazard Committee (IBC) for the project. In turn, the PI and IBC were responsible for their project's adherence to the NIH Guidelines. Thus, although the NIH was the major regulatory agency responsible for all recombinant DNA activities, monitoring and compliance were left up to each research institution's own PI and IBC.[32] In short, implementation and enforcement of the 1976 NIH Guidelines were left in the hands of the scientists using the recombinant DNA methods.

Unlike the American experience, in which the NIH was responding to questions of potential risk in an ongoing debate, the British experience was shaped by public alarm resulting from the escape of pathogenic smallpox microorganisms from a laboratory that had left two people dead in 1973.[33] In response to this event, the British government formed an investigative committee to report on the safety of laboratories in 1974, followed by committees to address the

[31] Wheale and M^{c}Nally 47.
[32] Wheale and M^{c}Nally 50-51.
[33] Wheale and M^{c}Nally 51.

resulting recommendations. These committees included three working parties that were established in 1975 – the Ashby Working Party, the Williams Working Party, and the Godber Working Party – that in turn offered recommendations on how to create a regulatory system for genetic engineering experiments.[34] Like the NIH Guidelines, the recommendations that came from these committees also required a classification system of potential hazards and containment measures, though the Ashby Report pushed for more stringent criteria, meaning that only weaker strains of pathogens could be used for experiments.[35]

Also in contrast to the American response was the conclusion of the Williams Report; it proposed that the UK advisory body for genetic engineering not be composed solely of technical experts in the field. In 1976, the European Molecular Biology Organization (EMBO) standing advisory committee suggested that states that allowed experimentation involving genetic engineering should adopt either the Williams Report or the 1976 NIH Guidelines.[36] European states largely adopted the guidelines from the Williams Report. As a consequence, differences that exist today in American and European risk regulation can be traced back to the diverging American and British responses to the potential risks of genetic engineering of the 1970s. Risk assessment and management vis-à-vis the realm of genetic engineering during this time was directed at understanding and containing risks in the laboratory. But, as knowledge and developments progressed and scientists were ready to field-test and then market their products, the issue of risk was reassessed in terms of environmental and food safety as well.

Europe's more cautious approach to the regulation of genetic engineering was reinforced in the mid-1990s. As a result of the "mad cow" disease crisis, the dioxin contamination of chicken feed, the foot-and-mouth disease outbreak, and fears over growth hormones in beef,

[34] Wheale and M^{c}Nally 52.
[35] Wheale and M^{c}Nally 53.
[36] Wheale and M^{c}Nally 54.

there was a growing public distrust in food safety governance. Christopher Ansell, Rahsaan Maxwell, and Daniela Sicurelli trace the shift in perception more specifically to 1996, which they label as the *annus horriblis* of European food safety.[37] Over the course of that year, the UK announced that the human Creutzfeldt-Jakob disease (commonly known as "mad cow" disease) was most probably caused by eating beef infected with bovine spongiform encephalopathy (BSE); American GM corn and soybeans began to arrive in Europe; the world's first cloned mammal, Dolly, was born in the UK; the US and Canada filed a complaint against Europe's ban on beef raised with hormones with the WTO; and the American biotechnology company Monsanto took the European Commission to court because of a failure to approve a genetically engineered hormone for milk production.[38] Similarly, Damian Chalmers labels 1996 a "Year Zero," in which both the member states and the EU were forced to recognize past failures and the need to create a new "European politics of risk," in which food safety would become a predominantly European, rather than national, political concern.[39] Hence, market approval for GM crops appeared on the policy agenda during a period of heightened public concern regarding public health and food safety matters.

The precautionary principle

In order to understand the European approach to agricultural biotechnology regulation, we must first understand the principle that undergirds EU food regulation. Prompted by the European food safety crises, the EU turned to the precautionary principle for the cornerstone of

[37] Christopher Ansell, Rahsaan Maxwell, and Daniela Sicurelli, "Protesting Food: NGOs and Political Mobilization in Europe," in *What's the Beef? The Contested Governance of European Food Safety*, Ansell and Vogel, eds. (Cambridge, MA: The MIT Press, 2006): 97.
[38] Ansell et al. 97.
[39] Damian Chalmers, "'Food for Thought': Reconciling European Risks and Traditional Ways of Life" *The Modern Law Review* 66.4 July 2003: 534.

its regulatory regime.[40] As a regulatory instrument, the precautionary principle goes further in food safety than the traditional principle of prevention by allowing products to be refused entry to or to be withdrawn from the market without scientific certainty that a risk exists.[41] Thus meaning, when uncertainty exists as to the risks posed to human health, stringent protective measures may be taken. Although precautionary regulation appeared in the 1970s, it was not until the late 1990s that a precautionary stance was seen as needed for governing all risk regulation.[42]

The precautionary principle had been firmly rooted in environmental policy, before it became established as a new general principle of community law.[43] Though explicitly noted in EU law in the Treaty on European Union (TEU) under the title of environmental protection, the precautionary principle is not defined anywhere in the TEU or in other Community instruments.[44] However, despite the lack of a clear link to policy domains other than the environment, "in practice the scope of this principle is far wider and also covers consumer policy and human, animal and plant health."[45] In order to create a basis for this wider application, the European Commission published a Communication in 2000 that established common guidelines on how the principle should be applied.[46] The Communication also outlines the factors triggering

[40] Christine Noiville, "Compatibility or Clash? EU Food Safety and the WTO," in *What's the Beef? The Contested Governance of European Food Safety*, Ansell and Vogel, eds. (Cambridge, MA: The MIT Press, 2006): 307.
[41] Noiville 307.
[42] Jonathan Wiener and Michael Rogers, "Comparing precaution in the United States and Europe," *Journal of Risk Research* 5.4 2002: 318.
[43] Nicolas de Sadeleer, "The Precautionary Principle in EC Health and Environmental Law," *European Law Journal* 12.2 March 2006: 139.
[44] EU, "The Precautionary Principle," *Summaries of Legislation*, http://europa.eu/legislation_summaries/consumers/consumer_safety/l32042_en.htm.
[45] EU, http://europa.eu/legislation_summaries/consumers/consumer_safety/l32042_en.htm.
[46] EU, http://europa.eu/legislation_summaries/consumers/consumer_safety/l32042_en.htm; de Sadeleer 141.

the use of the precautionary principle, as well as the appropriate measures that may result from its use.[47]

Furthermore, the Communication states that the precautionary principle is an important part of risk management within the risk analysis framework. It makes clear that use of the precautionary principle should be informed by three specific principles:

1. implementation of the principle should be based on the fullest possible scientific evaluation…;
2. any decision to act or not to act pursuant to the precautionary principle must be preceded by a risk evaluation and an evaluation of the potential consequences of inaction;
3. once the results of the scientific evaluation and/or the risk evaluation are available, all the interested parties must be given the opportunity to study of the various options available, while ensuring the greatest possible transparency.[48]

The Communication highlights the importance of scientific assessment, yet it also makes note of the role of a political response: "As regards the measures resulting from use of the precautionary principle, they may take the form of a decision to act or not to act. The response depends on a political decision and is a function of the level of risk considered 'acceptable' by the society on which the risk is imposed."[49] Consequently, while the implementation of the precautionary principle is supposed to rest on a scientific foundation, the Communication plainly provides for other intangible factors. However, the Commission makes clear as well that these intangibles, like social acceptance, should "never justify arbitrary decisions" at the moment of invocation or during the selection of implementation measures.[50] Finally, the Commission stressed that whenever regulatory measures were taken in accordance with the principle that they should be

[47] EU, http://europa.eu/legislation_summaries/consumers/consumer_safety/l32042_en.htm.
[48] EU, http://europa.eu/legislation_summaries/consumers/consumer_safety/l32042_en.htm.
[49] EU, http://europa.eu/legislation_summaries/consumers/consumer_safety/l32042_en.htm.
[50] EU, http://europa.eu/legislation_summaries/consumers/consumer_safety/l32042_en.htm.

"proportionate, non-discriminatory, consistent, based on cost-benefit analyses where feasible, and subject to review and ongoing risk assessment."[51]

Within the context of food safety, the precautionary principle is often thought of as a regulatory instrument of Europe, with the United States in opposition.[52] Though the precautionary principle is not unique to the EU, the US differs in that it has not officially adopted it as a basis for all risk regulation. Yet, in a comparison between the implementation of the precautionary principle in the US versus the EU, Jonathan Wiener and Michael Rogers conclude that we cannot categorically claim that the EU system is more precautionary than that of the US.[53] Rather, they argue that both states implement the precautionary principle in varying and inconsistent ways based on the context of the issue.[54] Part of the reason for differences in implementation stems from differences in variables, such as culture, the system of government, and access to policymaking for advocacy groups. In addition, differences may come from different perceptions of risk, which in turn are themselves influenced by cultural, governmental, and interest group variables. These inconsistencies are evident in EU and US food safety policies. Wiener and Rogers find that while the EU has been highly precautionary when dealing with hormone-treated beef, for example, it has been less strict than the US in terms of regulating blood safety after possible contamination with BSE.[55] This example highlights Wiener and Rogers' conclusion that specific cases must be analyzed, and to do so, an examination of a number of variables is required. The regulation of GMOs gives us an opportunity not only to

[51] Pollack and Shaffer 342.
[52] Wiener and Rogers 317.
[53] Wiener and Rogers 342-343.
[54] Wiener and Rogers 342.
[55] This is not meant to imply, however, that the EU was completely lax in protecting European citizens from potential contamination in the blood supply. The authors make clear that the EU had different constraints in its risk assessment as compared to the options of the US. See Wiener and Rogers for a more detailed discussion.

explore these variables, but also to examine the role of domestic French institutions in the process of risk regulation.

Analytical Foundations

Studies of EU policies largely focus on the policymaking process at the supranational level in the context of European integration. Member states' policies and their institutions are also examined, but usually in the context of how national policymaking influences the supranational process and how national institutions are becoming "Europeanized" to deal with EU directives and regulations. From the 1950s until the early 1980s, EU scholars developed several theories to explain the development of the European Union. Yet these main theories, namely neo-functionalism, intergovernmentalism, and liberal intergovernmentalism, concentrated on European integration rather than more specifically on policymaking processes.[56] Institutionalist analyses of the EU became more prevalent, as the emphasis on institutions increased in other areas of studies as well, with the rise of the three strands of the "new institutionalism."

Institutionalist emphasis on European integration

Rational choice institutionalist studies of the European Union principally examine the role of EU institutional rules in decision-making procedures, such as cooperation and co-decision, while sociological institutionalism focuses on the informal norms, conventions, and rules of the EU, usually in an international relations context.[57] Historical institutionalism, Mark A. Pollack asserts, takes its position between rational choice and sociological institutionalism, "focusing on the effects of institutions *over time*, in particular on the ways in which a given set of institutions, once established, can influence or constrain the behaviour of the actors who

[56] Mark A. Pollack, "Theorizing EU Policy-Making," in *Policy-Making in the European Union*, H. Wallace, W. Wallace, M. Pollack, eds. (Oxford: Oxford University Press, 2005): 15.
[57] Pollack 20.

established them."[58] Under the historical institutionalist framework, scholars have studied various phenomena, for example: path-dependence in the EU, the temporal dimension of European integration, and policymaking in the EU committees. But as Mark D. Aspinwall and Gerald Schneider point out, although institutionalist analyses of the EU have proliferated within all three strands, these studies concentrate solely on EU institutions or the role of national institutions in EU policymaking.[59] Institutionalist scholars rarely look at EU policies once they have entered the national forum for implementation.

Thus, the institutional literature on European Union policymaking has persistently focused on questions of European integration, such as: How do EU institutions impede or facilitate further integration into the EU? What role do national institutions play in EU policymaking? How are national and supranational preferences and policy choices shaped by institutions? Moreover, when implementation is addressed, the studies often concentrate on the process of transposition – which refers to the process of writing and passing EU directives into national legislation – without delving further into the implementation process. Often, "implementation" in euro-jargon refers only to transposition, and not to any subsequent actions taken by the member state to meet policy goals. As a result, the existing institutionalist approach to European integration does not provide a complete theoretical structure with which to study implementation – the moment when the control of these supranational actors retreats – in member states.

Expanding the institutionalist focus

This research project fills that gap, by providing an institutionalist study of the implementation of agricultural biotechnology policies in the case of France. Although the

[58] Pollack 20.
[59] Mark D. Aspinwall and Gerald Schneider, "Same Menu, Separate Tables: The Institutionalist Turn in Political Science and the Study of European Integration," *European Journal of Political Research* 38 (2000): 1-36.

institutional literature largely focuses on European integration, a few studies exist that provide theoretical models for this project. Paul Pierson is one such scholar who approaches the process of integration into and within the European Community with a historical institutional framework.[60] While his study focuses on European institutions rather than domestic ones, Pierson's work offers an excellent example of how the historical institutionalist approach can be applied to policymaking within an EU context.

Pierson's conceptualization of path dependence is particularly important for understanding the development of the EU and the French regulatory frameworks for GMOs. He defines path dependence as "referring to social processes that exhibit positive feedback and thus generate branching patterns of historical development."[61] His definition focuses the concept of path dependence on processes that are self-reinforcing. These types of processes can "produce more than one outcome," but they can also be highly susceptible to "relatively modest perturbations at earlier stages."[62] But, once a path is established, the self-reinforcing nature of the process makes reversals very difficult.[63] Although the initial perturbations may cause abrupt change in the institutional structures, Pierson also notes that scholars must pay attention to the slow-moving processes that lead to institutional development. A wide range of processes cannot be understood "unless analysts remain attentive to the unfolding of both causal processes and important political outcomes over extended periods of time."[64]

In the case of GMO regulation in Europe, I find that the perturbations of the public health and food safety scandals in the 1990s set the development of the French regulatory framework

[60] Paul Pierson, "The Path to European Integration: A Historical Institutionalist Analysis," *Comparative Political Studies* 29.2 (1996): 123-163.
[61] Paul Pierson. 2004. *Politics in Time. History, Institutions, and Social Analysis*. Princeton, NJ: Princeton University Press. 21.
[62] Pierson. *Politics in Time.* 10.
[63] Pierson. *Politics in Time.* 10.
[64] Pierson. *Politics in Time.* 13.

on a particular path, which is now so entrenched that a reversal in institutional structure seems impossible. Pierson argues that, "Exploring the sources and consequences of path dependence helps us to understand the powerful inertia or 'stickiness' that characterizes many aspects of political development – for instance, the enduring consequences that often stem from the emergence of particular institutional arrangements."[65] By examining the phases of the French framework's evolution (the "sources and consequences"), I demonstrate how path dependence helps us understand the persistence of French anti-GMO sentiment and the effects that it has had on the implementation of EU biotechnology legislation in France. In order to understand why the French do no implement EU agricultural biotechnology policies now, we must examine the slow-moving processes of the last two decades.

A key part of analyzing the development of the regulatory framework, then, is the sequencing of events. The timing and order of events matter, as "dynamics triggered by an event or process at one point in time reproduce themselves, even in the absence of the recurrence of the original event or process."[66] In the case of French GMO regulation, if the HIV-tainted blood scandal had not first crystallized the notion of "public health" into a salient policy domain, then the subsequent food safety crises of the 1990s may not have motivated the same reforms to public health regulatory institutions. The rapid onset of even more major public health issues (e.g. mad cow disease, dioxin contamination, asbestos) in 1996 became a critical juncture in institutional formation. Because of the failure of scientific experts to predict the consequences of potential risks, the French government institutionalized non-scientific opinions in its risk assessment process. In doing so, the government legitimized anti-GMO opposition, which at the domestic level has resulted in continued debate over whether GMOs should be accepted. The

[65] Pierson. *Politics in Time.* 11.
[66] Pierson. *Politics in Time.* 11.

choices to include conflicting opinions in the framework were reinforced over time, meaning that alternatives to this type of assessment have become less and less likely.

Francesco Duina provides another model for this study with his institutionalist approach to the implementation of gender policy within the member states.[67] Duina uses an institutional explanation to illustrate how directives are (or are not, as the case may be) implemented. This explanation, through the study of domestic institutions, posits that EU directives challenge deeply rooted social entities, which accordingly affects the directives' transposition into national law and the level of enforcement. His case study is the Equal Pay Directive of 1975 and its implementation in Great Britain and France. Like with many Directives, member states had flexibility in choosing this measure's application structure, but application was to take place within one year. Duina finds that results in France and in Great Britain varied on the transposition and applicative fronts, concluding that France achieved only partial implementation of the Equal Pay Directive, while Great Britain resisted any implementation of it. Such variation on policy implementation is not unusual, as pre-existing national legislation, domestic institutions, and adopted application measures differ between member states. But it is only through his institutional analysis that Duina discovers how domestic institutions in France and Great Britain, such as parliaments and well-established interest groups, play an important role in implementing this particular EU policy.

Duina's work provides an excellent theoretical template because it uses institutionalism as a lens to evaluate the role of national institutions in the implementation of EU legislation within member states. In addition, it reveals that variation in implementation occurs not only at a national level (when comparing member states to one another), but also within member states.

[67] Francesco G. Duina, *Harmonizing Europe: Nation-States within the Common Market* (Albany: State University of New York Press, 1999).

France, for example, implemented only parts of the Equal Pay Directive. In the context of biotechnology, this case rings true as well; France seemingly implements EU policies in some areas of biotechnology, such as in medicine, healthcare, and industrial processes, but resists implementation of policies in primary production and agro-food.

Biotechnology policymaking in the EU: a multi-level system

Studying the implementation of EU policies is further complicated by issues of authority over a policy domain. The EU follows the principle of subsidiarity, by which decisions should be made as close as possible to the citizen. This means that the EU does not take action on an issue, unless its action is in its exclusive areas of competence, or unless EU action would be more effective than that of the national, regional, or local government. In highly integrated policy areas, the EU has complete authority, meaning that EU institutions may be responsible for making and implementing EU directives, regulations, and recommendations. In other policy areas, policymaking may be shared between the EU and its member states, leading to conflict.[68]

The issue area of biotechnology is shared; policymaking occurs at both the supranational and the national levels. In addition, biotechnology is perceived as falling under several policy domains, including but not limited to: trade, agriculture, environment, and health. At the same time, the EU has begun to try to consolidate its authority over the issue of biotechnology. In a Communication to the European Parliament, the Council, the Economic and Social Committee, and the Committee of the Regions, the Commission notes that development in the field of biotechnology has presented Europe with a major policy choice: "[Europe must] either accept a passive and reactive role, and bear the implications of the development of these technologies

[68] See David Allen, "Cohesion and Structural Funds. Competing Pressures for Reform?" in *Policy-Making in the European Union*, H. Wallace, W. Wallace, M. Pollack, eds. (Oxford: Oxford University Press, 2005): 213-241. In this chapter, Allen outlines the conflicts that have arisen from the EU has establishing a "partnership in management of structural funds", which included regional and local institutions with the Commission and national authorities in policy planning, decisionmaking, and implementation (230).

elsewhere, or develop proactive policies to exploit them in a responsible manner, consistent with European values and standards," warning that "the longer Europe hesitates, the less realistic this second option will be."[69] The Communication goes on to outline how the EU should be involved in developing legislation in this policy area, in addition to detailing the responsibilities of the European community in responding to biotechnological developments.

In order to continue to expand the institutionalist literature and address the varying levels of authority within this policy domain, this work also locates its analysis within the framework of the multi-level governance literature. As Christos Paraskevopoulos, Panagiotis Getimis, and Nicholas Rees have noted, "the process of domestic policy and institutional change and adaptation… reflects the complexity of the EU multi-level governance structures and systems of interactions, especially in the areas of policy planning and implementation."[70] Their work on Cohesion and Central and Eastern European countries addresses the importance of looking at national institutions and domestic policymaking structures in order to understand better the implementation of regional and environmental policies.[71] This research project widens that understanding of the role of domestic institutions and pre-existing policymaking structures in the implementation of EU policies in France.

The multi-level governance literature also provides a framework which can be used to address the regulatory process that has become integral to EU integration. As Wolfgang Streeck highlights in his overview of the institutional framework of the EU, regulatory action has become a fundamental condition to European economic governance.[72] Regulatory action in

[69] European Commission, "Life Sciences and Biotechnology: A Strategy for Europe" L-2985 (Luxembourg: Office for Official Publications of the European Communities, 2002): 9.
[70] See Christos Paraskevopoulos, Panagiotis Getimis, and Nicholas Rees, eds. 2006. Adapting to EU Multi-Level Governance: Regional and Environmental Policies in Cohesion and CEE Countries. Aldershot: Ashgate: xvii.
[71] Paraskevopoulos, Getimis, & Rees, eds. 2006: xvii.
[72] See pages 65-67 in Wolfgang Streeck, "Neo-Voluntarism: A New European Social Policy Regime?" in *Governance in the European Union*, Marks *et al*. eds. (London: Sage Publications, 1996): 64-94.

Europe accelerated in the 1970s and 1980s,[73] and now regulations are an important tool for EU policymakers. Yet, the EU suffers from "an implementation deficit" for regulations and Directives, which leads to "inefficiency of Community action."[74]

Public policy studies

The implementation literature also supports an institutionalist approach to this study. As Michael Hill and Peter L. Hupe assert, within this school of thought an examination of implementation processes "needs to be seen as occurring in organized contexts where there are established norms, values, relationships, power structures and 'standard operating procedures.'"[75] In this case, policymaking and implementation in the EU are reiterative processes between the European level and the French level of government. Each level, which represents institutions involved in the policymaking process, has its own norms, values, relationships, power structures, and standard operating procedures. In addition, interactions between the EU and France as a member state have established a shared, organized context for policymaking and implementation processes.[76]

Besides supporting an institutionalist theoretical approach, implementation studies also allow me to examine the policy environment of the formation and implementation of agricultural biotechnology regulation. An analysis of the policy environment is crucial to this case study, as it draws attention to whether "policies can effectively address issues that may be influenced by phenomena over which governments can have little or no influence."[77] These phenomena might

[73] Giandomenico Majone, "The rise of the regulatory state in Europe", *Western European Politics*, 17.3 (1994): 84.
[74] Phillipe Schmitter, "Imagining the Future of the Euro-Polity with the Help of New Concepts," in *Governance in the European Union*, Marks *et al*. eds. (London: Sage Publications, 1996): 139.
[75] Michael Hill and Peter L. Hupe, *Implementing Public Policy* London: Sage Publications, 2002): 35.
[76] In order to establish how implementation structures were formed, and the extent to which those new and pre-existing institutions imposed constraints on the implementation process as well, I provide a thorough review of EU legislation, the political environment and public opinion in France during key periods of policymaking, and the national institutions responsible for implementation in Chapter 3 and Chapter 4.
[77] Hill and Hupe 136.

include: "changes in the moral climate of a nation, demographic change, or global economic forces."[78] In the case of agricultural biotechnology regulation, an analysis of the policy environment requires a review of the timing of public health and food safety scandals across Europe and in France, as well as an examination of public opinion.

This research not only focuses on the role of institutional constraints on implementation; it also draws on implementation studies of vertical public administration. Vertical public administration studies address the "impact of vertical links in the chain from policy formation to the street level."[79] Methodologically, these studies are complex, as they must address what Hill and Hupe refer to as the "layers" (the institutions) and the "levels" (the phases) of the policymaking and implementation processes. And, as Hill and Hupe note:

> A major factor contributing to [this methodological] complexity is the fact that often intervening levels, as layers in the political-administrative system, have a legitimate claim to engage in policy formulation and decision making: Where does 'policy formation' end and 'implementation' begin?[80]

Using vertical public administration studies, EU scholars have analyzed both the consequences of initial policy formation occurring outside the nation state and the process of "reformulation" of those policies that occurs within the phase of transposition.[81] Thus, these studies trace the process of policymaking through the EU institutions up through the process of transposition, which is labeled as implementation. Yet, Michael Hill and Peter L. Hupe rightly argue that "what is called 'implementation' in those studies in fact could be seen as 'policy formation.'"[82] Instead of examining the domestic implementation of EU regulations and policies within member states after transposition, these studies conclude once the process of transposition has been completed.

[78] Hill and Hupe 136.
[79] Hill and Hupe 126.
[80] Hill and Hupe 126.
[81] Hill and Hupe 127.
[82] Hill and Hupe 127.

In the case of agricultural biotechnology in the EU, I look specifically at implementation and not just policy formation and transposition. As such, I examine the institutional "layers," such as the European Commission, the European Food Safety Authority (EFSA), and French regulatory institutions, as well as the "levels" at which the policy process occurs – policy formation, transposition, or implementation, for example. In addition, the vertical public administration approach to implementation studies, with its recognition of the different institutional layers of policymaking and implementation, connects with a multi-level governance approach. This study thus recognizes the importance of the EU and what occurs within European institutions in the issue area of biotechnology as an important background variable to understanding French implementation.

However, there are differences in how each approach defines the concept of "level."[83] In the case of multi-level governance, the "levels" are the institutions involved in the policy process. In vertical public administration studies, "layers" represent those same institutions, while "levels" represent phases of policy formation and implementation processes. Though Hill and Hupe suggest they could conceptually introduce their approach as "multi-layer policy formation,"[84] I wish to maintain the conceptual language of the multi-level governance approach. As such, my use of "level" refers to the institutions involved in the policy process, at the European level or the domestic level for example. When referring to the different phases of policymaking and implementation, I use terms such as "formation," "implementation," or "transposition."

Finally, I also employ the concept of "triggering events" from the agenda-setting literature of public policy. Triggering events are "the catalysts for pressure that, in turn, lead to

[83] Hill and Hupe 128-129.
[84] Hill and Hupe 128.

demands for new or changed public policies."[85] The timing, scope, and intensity of the events affect the impact that they have on the public's values.[86] For the development of the GMO regulatory framework in the EU and in France, the scandals in the 1990s acted as triggering events by pushing public health and food safety onto the agenda. At the same time, the mishandling of these events by public authorities severely diminished the trust that European citizens had in the EU authorities and their national governments to effectively regulate those policy domains. Triggering events also act as the "starting point for public policy questions."[87] In this case, the public health and food safety crises raised questions about: the government's ability to protect public health, the prioritization of producer vs. consumer interests, and the role of scientific expertise in risk assessment.

French Resistance to GMOs

Despite the characterization that the European regulatory framework for food safety is more stringent than the US, France currently resists the EU's promotion of agricultural biotechnology through regulatory action. Why does France resist implementing these policies that, at an EU-level, are deemed to be essential to progress in the areas of economic growth, the environment, and public health? How do the pre-existing policymaking structures within France and its domestic institutions play a role in policy implementation and resistance to implementation? This research project answers these questions by examining the levels of governance in policymaking and implementation for France as a member state of the European Union. By using a historical institutionalist analysis, this research project shows how the timing

[85] Larry N. Gerston. 2004. *Public Policy Making: Process and Principles.* Third Edition. Armonk, NY: M.E. Sharpe. 45.
[86] Gerston. *Public Policy Making*. 45.
[87] Gerston. *Public Policy Making*. 45.

of institutional creation, both at a national and supranational level, has shaped the implementation process in France.

The European and French responses to GMOs were initially ones of risk assessment, management, and regulation. Both the EU and France created food safety authorities (EFSA and *l'Agence française de sécurité sanitaire des aliments* – AFSSA, respectively) and regulatory institutions in response to the public health and food safety crises of the early 1990s. These agencies embody the responsibilities of assessing risk and advising government.

But even before the creation of AFSSA, and eventually the *Haut Conseil des Biotechnlogies* (HCB), the public perception of GMOs had begun to shift in France to include concerns about GMOs beyond questions of public health and environmental impact. French anti-GMO interest groups had successfully introduced socio-economic issues, such as farmers' labor rights and fears of globalization, into the domestic GMO debate. These concerns were diluted at the EU-level during the creation of EFSA due to the interest in promoting biotechnology to bolster the EU's competitiveness on the world stage. Thus, on one side, the French government created its regulatory framework within a more precautionary context of public health, food safety, environmental protections, consumer rights, and labor rights, which left open the question of whether GMOs should be produced. On the other side, the EU also created its regulatory framework in a precautionary context, but it was rooted in the scientific assessment of public health and environmental risks. The initial differences in the development of these separate frameworks have become further entrenched in the decade since their creation, in the slow-moving processes that Pierson describes. And the *dialogue des sourds* followed.

Research Design and Data Collection

Implementation of EU policies is a series of interrelated actions that are taken at different organizational and governance levels and are linked to objectives set out within those policies. These actions may be promoted and/or obstructed by interest groups and public opinion, often through institutional channels. This study approaches implementation with an emphasis on the processes of coordination, as well as the factors facilitating or impeding implementation.[88] In addition, this implementation study highlights the different phases of the development of the biotechnology regulatory framework, as well as the levels of the separate entities with legitimate authority over this issue area.

In order to operationalize the process of implementation in this case, I examine policies on GMOs and GM products, which include EU directives, legislations, regulations, and related documents, as well as domestic legislation and practices. I also look at the interactions between the actors involved in the implementation process on different organizational levels, the organizations themselves (i.e. the regulatory institutions, Ministers, etc.) and organizational changes. In addition, this study establishes how the series of actions that constitute the implementation process are interconnected over time. In revealing this interconnectedness, emphasis is placed on the specific timing of policy changes. Both a document analysis and public opinion data are used to empirically reconstruct the macropolitical and implementation context and process. I recognize that a document analysis including public statements, formal policy discussions, and news reports may not fully reveal backroom bargains and discussions made during policymaking and implementation phases. In addition, as Alexander George and Andrew Bennett rightfully highlight, the written record may be purposefully self-serving for those who

[88] Hill and Hupe 60.

have created it.[89] However, these texts certainly provide the decisions that have been made and the context in which they were created, as they are the only empirical sources available, and that is important for understanding the process of implementation.

Moreover, public opinion surveys help to expand upon the data collected from the document analysis. The Eurobarometer surveys on biotechnology provide a systematic resource for monitoring patterns and trends in public perceptions, and the data from the surveys have informed official reports and been widely quoted in the media.[90] Although the authors of the Eurobarometer reports acknowledge there are limits to survey research, they note that the data are "useful as general indicators of the contours of public opinion, particularly when comparative and time series data are available."[91] For that reason, I use an analysis of the survey data as a complement to the more detailed review of my document analysis.

Conclusion

This chapter outlined the basic concepts utilized in this research, such as genetic engineering, agricultural biotechnology, risk, and the precautionary principle. In addition, it demonstrated that, although the EU has identified biotechnology as a key technology for its sustainable development and economic growth, several member states refuse to accept GMOs and GM crops. In part, this is due to the reluctance by some member states to transition to the new legal framework that regulates GMOs. Chapter 1 also ascertained that the timing of the arrival of GMO approvals onto the public policy agenda, coming amidst major public health and food safety crises, has negatively affected member state support for and public perception of agricultural biotechnology. Decisions made at critical junctures during the regulatory

[89] Alexander George and Andrew Bennett, *Case Studies and Theory Development in the Social Sciences* (Cambridge, MA: The MIT Press, 2005): 101.
[90] George Gaskell et al. 2006. "Europeans and Biotechnology in 2005: Patterns and Trends." *Final Report on Eurobarometer 64.3*. Brussels, Belgium: European Commission. 8.
[91] George Gaskell et al. "Europeans and Biotechnology in 2005." 9.

framework's development in France put the French system on a different path than that of the EU. The divergence to the two levels of biotechnology regulation has led to non-compliance in this domain on the part of France. Finally, this chapter reviewed the current literature on historical institutionalism, multi-level governance, and implementation studies to establish the analytical foundations and methodology for the following chapters.

Chapter 2. The Scandals that Rocked Europe: Tainted Blood, Mad Cow, and Dioxin Contamination

Several scholars have shown how the food safety and public health scandals of the *annus horriblis* (1996) linked issues of food safety and public health to genetic engineering and genetically modified products in the minds of the European public. This chapter summarizes those assertions and explores how that policy linkage evolved. The chapter delves first into the three cases reviewed here: the tainted blood scandal in France, the mad cow crisis, and the dioxin contamination episodes. A review of the tainted blood case, which came to light in 1991, helps to establish the historical context into which the issue of GMO approvals was introduced. It also shows how the tainted blood scandal shaped risk-averse policymaking strategies for subsequent public health crises, such as mad cow disease. The mad cow crisis, which developed into a full-fledged public health disaster in 1996, revealed itself to be the defining moment of the *annus horriblis*; it in turn shaped the regulatory responses to the dioxin contamination episode that followed in 1999. In addition, it further cemented the link between the concepts of public health and food safety in the minds of the public and of policymakers. Acting as triggering events, these cases motivated reforms to existing regulatory institutions, and eventually led to the creation of new regulatory institutions, to address public health and food safety issues. Together, these three cases shaped the policymaking environment in which the French regulatory responses to GMOs have been constructed.

L'Affaire du Sang Contaminé [1]

In 1991, France was rocked by revelations that, after being warned about potential contamination by the human immunodeficiency virus (HIV), "officials at the country's National Blood Transfusion Centre had decided that distribution of non-heat-treated blood products to hemophiliacs would continue until all the stocks were depleted or until the law forbade it."[2] While other governments, such as in the US and Japan, were also blamed for mishandling the HIV crisis and the safety of the blood supply, *l'affaire du sang contaminé* was especially damaging to the French government due to the assertions that French public officials were to blame and to the punishments that were meted out. The French media played an important role in drawing the public's attention to this issue, starting with the initial journalistic exposé. In the ensuing media frenzy, it became clear that officials had known that the factor concentrate (a clotting product given to hemophiliacs) was contaminated with HIV, but had chosen to withhold that information from France's hemophilia association and the Ministry of Health,[3] even though methods to detect and eliminate the virus were available at the time.[4] Those decisions directly led to the high rates of transfusion-related HIV-infection among French hemophiliacs and fueled public outrage toward the government.

The roots of the case began in the 1980s. Early in that decade, the medical establishment was working on identifying a newly documented disease that would eventually be known as

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[1] *L'Affaire du sang contaminé* is the French phrase used to denote the HIV-tainted blood scandal. Though the contamination and cover up took place in the 1980s, it was not until the early 1990s that the French public became aware of what had happened. *L'Affaire du sang contaminé* usually refers to the time period from when the first policy decisions that would impact the regulation of tainted blood were made (1983) until the last judicial rulings in the resulting courts cases were entered (2002).

[2] Michael Orsini, "Reframing Medical Injury? Viewing People With Hemophilia as Victims of Cultural Injustice." *Social & Legal Studies* 16.2 (2007): 245.

[3] Orsini 245.

[4] Marlise Simons, "France Convicts 3 in Case of H.I.V.-Tainted Blood," *The New York Times* (October 24, 1992) http://www.nytimes.com/1992/10/24/world/france-convicts-3-in-case-of-hiv-tainted-blood.html?src=pm (accessed August 2011).

acquired immunodeficiency syndrome (AIDS) and its cause, HIV. Between 1981 and 1985, researchers discovered cases of the disease, developed a test to detect HIV in blood, and devised a method for heat-treating blood to inactivate HIV in plasma.[5] However, by the time the heat-treating process was developed, contaminated blood products had already entered the blood supply. Hemophiliacs were particularly affected by this contamination. For example, by the late 1980s, 90% of severe hemophiliacs in the US were infected and close to half of all hemophiliacs (approximately 10,000 Americans) were HIV-positive.[6] In France, 1,200 out of 3,000 severe hemophiliacs had contracted HIV, and there were 4,000-6,000 transfusion-related cases of HIV infection.[7] Research from the mid-1990s shows that France had the highest rates of infection in transfusion-related AIDS cases as a percentage of its total AIDS cases when compared to the US, UK, Germany, Australia, Switzerland, and Canada.[8]

French historian Sophie Chauveau has written extensively on the HIV-tainted blood scandal.[9] She argues that the HIV-tainted blood scandal transformed the French conceptualization of and their approach to public health as a policy domain. *L'affaire du sang contaminé* was the first case that was truly a public health crisis (*crise sanitaire*) for the French, and it led directly to the creation of governmental agencies responsible for promoting and regulating public health issues.[10] Chauveau notes that the tainted blood scandal is often characterized as the catalyst for regulatory reform because it exposed how unprepared the government was to face new risks.[11] Rattled by the revelations of the scandal, the French public

[5] Eric A. Feldman, "Blood Justice: Courts, Conflict, and Compensation in Japan, France, and the United States," *Law and Society Review* 24.3 (2000): 660.
[6] Feldman 669.
[7] Feldman 669.
[8] Michael Trebilcock, Robert Howse, Ron Daniels. "Do Institutions Matter? A Comparative Pathology of the HIV-Infected Blood Tragedy." *Virginia Law Review* 82.8 (Nov 1996): 1418.
[9] Sophie Chauveau. 2011. *L'Affaire du sang contaminé (1983-2003).* Paris: Les Belles Lettres.
[10] Chauveau. *L'Affaire du sang contaminé.* 19.
[11] Chauveau. *L'Affaire du sang contaminé.* 16.

blamed the government for failing to protect public health; the government's response was to create new agencies to satisfy the public's demand for more public health protection.[12]

As a result of the scandal being brought to light, four public officials were charged with crimes: Michel Garretta, Jean-Pierre Allain (respectively, director and assistant director of the National Blood Transfusion Centre at the time), Jacques Roux (former Director General of Health), and Robert Netter (former head of the Public Health Laboratory). Garretta and Allain were charged with misrepresenting the quality of commercial products, while Roux and Netter were accused of failing to help "persons in danger."[13] Garretta and Allain were convicted and sentenced to four years in prison, though each had two years suspended, in addition to being ordered to pay the equivalent of $1.8 million in compensation to those with AIDS and their families.[14] Roux received a four-year suspended sentence for his charges, and Netter was acquitted.[15]

While the basis of the case was in and of itself abhorrent, public outrage intensified when the trial revealed that officials delayed implementing the heat-treating process and HIV tests for "commercial" reasons. By early 1985, American officials had warned that hemophiliacs were at risk of infection from non-heat treated blood products, and they had taken measures to cleanse the virus from the American supply.[16] American manufacturers of HIV tests tried to sell their products in France in February 1985 for availability in March, but they were turned down.[17]

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[12] Chauveau. *L'Affaire du sang contaminé*. 16.
[13] Alan Riding, "Ex-French Officials Go on Trial in AIDS Case," *The New York Times* (June 25, 1992) http://www.nytimes.com/1992/06/25/world/ex-french-officials-go-on-trial-in-aids-case.html?src=pm (accessed August 2011).
[14] Simons.
[15] Simons.
[16] Simons.
[17] Simons.

Instead, French officials did not take any action until the French Pasteur Diagnostics[18] kit was approved in June 1985. It has been reported that the minutes of an interministerial cabinet meeting indicate that "approval of the American blood testing kits was deferred because the French government wanted to secure 35% of the national market for Pasteur."[19] Thus, the delay was a result of pressure from the Health Ministry on the National Blood Transfusion Centre "to become profitable and to compete better with France's neighboring countries."[20]

In this case, the judicial system took a "blamist" approach to handling the scandal, targeting liability precisely on specific decisionmakers,[21] namely the leadership at the National Blood Transfusion Centre. Even though efforts at that time to try three former Cabinet ministers for their political responsibility in the episode failed, the ministers were publicly identified as complicit.[22] In 1999, however, Laurent Fabius (former Prime Minister), Edmond Hervé (former Health Minister), and Georgina Dufoix (former Social Affairs Minister) were charged with manslaughter and tried by a special tribunal for their role in the scandal. Fabius and Dufoix were acquitted; Hervé was convicted, though he did not receive a sentence with the judge finding that "due to the length of the scandal, the former health minister had not benefited from the 'presumption of innocence to which he is entitled'" and would therefore go officially unpunished.[23]

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[18] Pasteur Diagnostics was a subsidiary of the French pharmaceutical company Sanofi. Sanofi was known as Sanofi-Aventis, after its 2004 takeover of Aventis, until May 2011 when it dropped Aventis from its name.
[19] Trebilcock *et al*. 1452; see also Feldman, note 10, 663.
[20] Simons.
[21] Christopher Hood and David K.C. Jones, "Liability and blame: pointing the finger or nobody's fault," in *Accident and Design: Contemporary debates in risk management*, Hood and Jones, eds. (London: Routledge, 1996/2002): 46.
[22] Simons. Simons also reported that activists and victims were outraged by the admission of Edmond Hervé (Deputy Health Minister in 1985) in open court that he and other government officials knew the blood-clotting factor was contaminated more than four months before it was ordered withdrawn and by the parliamentary commission's decision not to proceed with the case at that time.
[23] N.A., "Blood scandal ministers walk free," *BBC News*, Section: World: Europe (March 9, 1999) http://news.bbc.co.uk/2/hi/europe/293367.stm (accessed August 2011).

The role of the media and public opinion

In addition to first breaking the news of the scandal, the French media played an essential role throughout *l'affaire du sang contaminé*. Chauveau contributes the widespread interest of and coverage by the media to several factors. For one, the scandal provided a sensational story, especially because the victims' stories provoked deep emotions.[24] The press focused on stories of young hemophiliacs who, through no fault of their own, had contracted this devastating disease.[25] Secondly, journalists for print media had played a significant role in bringing the scandal to light,[26] and it provided an opening for younger journalists to establish themselves. The press "grasped at this opportunity to modify [their] relations with politicians, the medical profession, and the legal world – three areas of society in which the French press had relatively little autonomy [before the scandal]."[27] As a consequence, the HIV-tainted blood scandal also encouraged more investigative journalism, a field that had been fairly undeveloped in France.[28] Thirdly, although the victims of the contaminated blood were at first reluctant to go public with their stories, eventually they used the press to their political advantage to draw attention to their plight and to get the government to respond.[29] Chauveau concludes that the media coverage of the scandal operated at two levels: efforts to provide information about the scandal and the disease in the press; and the use or exploitation of the scandal to denounce public authorities for their failures and to motivate them to act.[30]

[24] Chauveau. *L'Affaire du sang contaminé*. 17.
[25] Chauveau. *L'Affaire du sang contaminé*. 17.
[26] Chauveau. *L'Affaire du sang contaminé*. 17.
[27] Monika Steffan. 1999. "The Nation's Blood. Medicine, Justice, and the State in France." In *Blood Feuds. AIDS, Blood, and the Politics of Medical Disaster*. Eric A. Feldman and Ronald Bayer, eds. New York: Oxford University Press. 95-126. Here 112.
[28] Steffan. "The Nation's Blood." 112.
[29] Chauveau. *L'Affaire du sang contaminé*. 17.
[30] Chauveau. *L'Affaire du sang contaminé*. 17.

Policy implications

While much has been made of the mad cow crisis as the impetus for changes in the EU's and individual member states' food safety regulatory regimes,[31] it is also important to note the impact that the HIV-tainted blood scandal of the late 1980s and early 1990s had in France. The timing of the mad cow crisis was certainly a factor in eroding trust in governmental institutions and their ability to protect the food supply, especially when combined with other issues of hormone treated beef, a listeria outbreak, and the dioxin scare. However, the HIV-tainted blood scandal, which occurred just a few years before, left deep scars in the public's trust of the French government's ability to protect public health. It also raised concerns that the government was more worried about protecting industry's profits than protecting public health.

Following the disclosure of how HIV-tainted blood products were handled, the French government promised that it would protect its public from future public health crises.[32] To do so, the government enacted several reforms for the regulation of the national blood supply. The French government abolished the previous institutions and decisionmaking structures for blood regulation and disseminated their responsibilities among newly created regulatory agencies with "independent expert authority."[33] Perhaps most importantly, the mishandling of the HIV-tainted blood supply established that the government needed "to act in the face of potential risk."[34] Yet, just a few years later, the government was left reeling from the impact of the mad cow crisis, and the French public was left wondering why. If regulatory responsibility and oversight of public

[31] For examples, see: Ansell and Vogel, eds., *What's the Beef? The Contested Governance of European Food Safety* (Cambridge, MA: The MIT Press, 2006); Debra Holland and Helen Pope, *EU Food Law and Policy* (The Hague: Kluwer International Law, 2004); Damian Chalmers, "'Food for Thought': Reconciling European Risks and Traditional Ways of Life" *The Modern Law Review* 66.4 (July 2003).
[32] Sophie Chauveau, from interview with the author (January 30, 2012).
[33] Steffan. "The Nation's Blood." 121.
[34] Steffan. "The Nation's Blood." 123.

health issues were supposed to have been improved in light of the HIV-tainted blood scandal, why were they not working?[35]

The Mad Cow Crisis

While *l'affaire du sang contaminé* was the first public health scandal in Europe to significantly undermine the public's trust in government regulation of food and safety issues, it was the mad cow crisis that led to widespread public awareness of the potential dangers of GMOs. Like the HIV-tainted blood scandal, the roots of mad cow can be found years before the scope of the crisis came to light. In the late 1970s, changes were made in the UK to the procedures required to treat animal byproducts that were to be added to livestock feed to fortify it with protein. Due to environmental and cost concerns, these byproducts were no longer required to be treated with hexane gas as a way to rid them of pathogenic agents.[36] In addition, the temperature of the heat-treating process to which they were subjected – also to destroy pathogenic agents in the tissues – was lowered.[37] In hindsight, as Pierre-Marie Lledo notes, the lower temperature was too low; pathogenic agents were not completely eradicated at that temperature.[38] Between April and September of 1985, veterinarians in the UK began to observe a disease afflicting British cattle. Though similar to scrapie, a neurodegenerative disease observed in sheep, the illness had never before been identified in cows. After further studies, the disease was identified as bovine spongiform encephalopathy (BSE) in 1986. At the time, however, UK veterinarians found the illness to be more of a medical curiosity than a cause for alarm.[39]

But by 1988 the outlook on this new disease had changed. Significant increases in the number of sick animals raised the profile of BSE from medical curiosity to that of a major

[35] Sophie Chauveau, from interview with the author (January 30, 2012).
[36] Pierre-Marie Lledo. 2001. *Histoire de la vache folle*. Paris: Presses Universitaires de France: 37.
[37] Lledo. 2001. *Histoire de la vache folle*, 37.
[38] Lledo. 2001. *Histoire de la vache folle*, 37.
[39] Lledo. 2001. *Histoire de la vache folle*, 36.

animal health issue. By March of that year, UK scientists had determined that sick animals had consumed animal-protein fortified feed, and in July, Margaret Thatcher's government banned the use of animal byproducts in animal feed destined for ruminants.[40] Yet, despite recognition of the potential harm from using animal-protein fortified feed, the UK agricultural lobby successfully pressured the government to grant a five-week reprieve on the ban in order to allow cattle owners to exhaust their existing stocks of feed.[41] The UK took measures to control the spread of the disease a step further when in August 1988 it required that all animals suspected of infection were to be slaughtered and destroyed by incineration. Then, in November 1988, the UK instituted another ban, this time on the sale of milk from infected cattle for human or animal (with the exception of calf) consumption.

The UK government created two committees to analyze what exactly was happening and to provide suggestions on how the disease should be handled. An Oxford zoology professor, Sir Richard Southwood, was selected as director of a Working Party on BSE, whose objectives were to conduct an expert risk assessment, identify any threats to human beings, and provide overall guidance to the government for BSE-related issues.[42] In February 1989, the Working Party on BSE published the Southwood Report. It was a "contradictory report," in that it ruled out the possibility of BSE crossing the species barrier into humans at the same time that it called for the exclusion of high-risk material from products like baby food.[43] Dr. David Tyrrell, a microbiologist, led a second consultative committee in 1989 and, later, its reformed incarnation as the Spongiform Encephalopathy Advisory Committee in 1990. The Tyrrell Committee was

[40] The distinction of ruminants refers to mammals that digest food by ruminating (a process of chewing and regurgitation), such as cows, sheep, goats, deer, and camels.
[41] Lledo. 2001. *Histoire de la vache folle*, 37. Lledo also states that even after the five weeks passed, there is evidence that some cattle farmers continued to use the banned feed.
[42] Matthias Beck, Darinka Asenova, and Gordon Dickson. "Public Administration, Science, and Risk Assessment: A Case Study of the U.K. Bovine Spongiform Encephalopathy Crisis." *Public Administration Review* July/August 2005, Vol. 65, No. 4: 396-408. (here p.400)
[43] Beck, Asenova, and Dickson. "Public Administration, Science, and Risk Assessment." 401.

responsible for analyzing leading research and identifying what future research might be required.[44] The Tyrrell Committee report, published just a few months after the Committee's formation, "emphasized the need to develop scientific knowledge in a number of areas and cautiously noted that no reliable conclusions could be drawn about the spread of BSE to humans."[45] It did recommend, however, that additional research was needed, although there was no immediate follow up by the government on the recommendations.[46] In the mid-1990s, Dr. Tyrrell even went so far as to state publicly that "British beef can be eaten by everyone."[47] Thus, the UK government continued to maintain that beef was safe to eat, claiming that scientific and medical studies supported this assertion.[48]

Nonetheless, public anxiety and confusion in the UK over mad cow were beginning to build and were further inflamed when scientific experiments showed that other animals could become infected from ingesting meat from infected cows. Sophie Reibel captured the feeling of that time:

> After assessing the available information, the public's reasoning was as such: if the disease could be transmitted to cats, mice, pigs, marmosets, sheep, goats, and mink, and if cattle had become infected after eating sheep byproducts, then couldn't there also exist a risk for humans if they ate contaminated beef?[49]

Reibel argues that the public's confusion over what to believe about mad cow disease was justified. Writing in 1994, before it was officially recognized that BSE could, in fact, cross the

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[44] Beck, Asenova, and Dickson. "Public Administration, Science, and Risk Assessment." 401.
[45] Beck, Asenova, and Dickson. "Public Administration, Science, and Risk Assessment." 401.
[46] Beck, Asenova, and Dickson. "Public Administration, Science, and Risk Assessment." 401.
[47] Beck, Asenova, and Dickson. "Public Administration, Science, and Risk Assessment." 401.
[48] "On this day: May 16, 1990: Gummer enlists daughter in BSE fight." *BBC News*. May 16, 1990. http://news.bbc.co.uk/onthisday/hi/dates/stories/may/16/newsid_2913000/2913807.stm (accessed February 21, 2012).
[49] Original text: "Interprétant les informations à sa disposition, le raisonnement du public est suivant: si la maladie se transmet au chat, à la souris, au porc, au ouistiti, au mouton, à la chèvre et au vison, et si les vaches s'infectent suite à la consommation d'abats ovins, existe-t-il un risque que l'homme puisse être contaminé après ingestion de produits bovins?" (my translation). Sophie Reibel. *Encéphalopathie Spongiforme Bovine. Épidémiologies et Implications*. Paris: Polytechnica, 1994: 130.

species barrier between cows and humans, she noted that the public was overwhelmed with scientific "opinions" that alternated between declarations that beef was safe to eat and catastrophic predictions that a whole generation of Britons would be lost to mad cow disease.[50]

The British government certainly did not help to dispel the confusion; at the same time that it was implementing bans on milk consumption and on animal-based proteins in feed, it was also spending one million pounds on a public relations campaign in May 1990 centered on the slogan, "Beef is safe."[51] One of the most infamous parts of this campaign included the efforts made by the then-Minister of Agriculture John Gummer to get his four-year-old daughter to eat a hamburger for publicity just six days after it was revealed that BSE could pass from cows to cats through tainted meat.[52] Though she refused, he took a large bite of the burger for the cameras, declaring it to be "absolutely delicious."[53] Mr. Gummer was later made to explain during an official inquiry into the handling of the crisis why he delayed a ban on beef offal in 1989. His response was that he "did not believe it was 'essential for public health' because the Southwood report on the issue had only suggested a ban,"[54] rather than making it a requirement.

At the European-level, "the European Commission accepted assurances from the British Ministry of Agriculture that it posed no danger to humans" when BSE was first detected in the mid-1980s in UK herds.[55] But, as more studies showed the transmission of BSE to other mammals, Britain was forced to notify other EU member states of a potential food safety

[50] Reibel, *Encéphalopathie Spongiforme Bovine*. 130-131.
[51] Reibel, *Encéphalopathie Spongiforme Bovine*. 131.
[52] "John Gummer: Beef Eater." *BBC News*. October 11, 2000. http://news.bbc.co.uk/2/hi/uk_news/369625.stm (accessed February 21, 2012).
[53] "On this day: May 16, 1990: Gummer enlists daughter in BSE fight." *BBC News*. May 16, 1990. http://news.bbc.co.uk/onthisday/hi/dates/stories/may/16/newsid_2913000/2913807.stm (accessed February 21, 2012).
[54] "John Gummer: Beef Eater." *BBC News*. October 11, 2000. http://news.bbc.co.uk/2/hi/uk_news/369625.stm (accessed February 21, 2012).
[55] David Vogel, "The Hare and the Tortoise Revisited: The New Politics of Consumer and Environmental Regulation in Europe." *British Journal of Political Science*, Vol. 33, No. 4 (Oct., 2003), pp. 557-580. (here: 569)

problem.[56] In 1989, the EU placed restrictions on the importation of live cattle from the UK. European states began to take individual protective measures as well. In 1990, France instituted its own ban on animal-based animal feed for cows, which was shortly followed by an EU ban in 1991 on animal-based feed for all ruminants. By 1994, France had completed the extension of its ban to all ruminants to meet EU standards. In an effort to diminish the damage that BSE fears were having on the UK's agricultural sector, the Minister of Health at that time, Stephen Dorrell, assured the public that there was "no conceivable risk" to public health from eating British beef in 1995.[57]

Public panic: the first wave

Yet, just a few months later, the first major wave of the BSE crisis broke, forcing the UK government to reverse its position. In March 1996, the British government announced that the transmission of BSE from cows to humans was possible[58] and that the variant Creutzfeldt-Jakob disease (vCJD) – a new form of a fatal neurodegenerative illness affecting humans – was related to eating contaminated beef. As Matthias Beck, Darinka Asenova, and Gordon Dickson note, "with about 30,000 suspected cases of infected cattle and 10 reported vCJD cases in young people, the government's view [that British beef was safe to eat] had become impossible to sustain."[59] In the UK, "the news that humans had likely been infected with BSE hit the United Kingdom, like a bombshell."[60] The British cattle industry was nearly bankrupted and the revelations played a key role in the defeat of the Conservative government, which had been

[56] David Vogel, "The Hare and the Tortoise Revisited." 569.
[57] Michael White, "Dorrell says he regrets giving 'no risk' advice." *The Guardian*. October 28, 2000. http://www.guardian.co.uk/uk/2000/oct/28/bse.michaelwhite (accessed February 21, 2012).
[58] Jocelyn Raude. *Sociologie d'une crise alimentaire. Les consommateurs à l'épreuve de la maladie de la vache folle*. Paris: Lavoisier, 2008: 7.
[59] Beck, Asenova, and Dickson. "Public Administration, Science, and Risk Assessment." 402.
[60] Michael Balter. "Tracking the Human Fallout from 'Mad Cow Disease.'" *Science*, Vol. 289, No. 5484 (Sep. 1, 2000), pp. 1452-1454 (here 1453).

downplaying the danger from BSE, in the 1997 parliamentary election.[61] With increased anxiety among consumers – expressed through public protests and plummeting beef sales – a complete ban on cattle of more than thirty months was introduced, resulting in 3.3 million cattle being destroyed between 1996 and 1999.[62] In addition, the EU passed legislation prohibiting all British cattle and beef exports.

Consumer reactions in the European marketplace were swift and severe. For example, in France, the number of households purchasing beef fell by 30% in the weeks following the announcement.[63] However, with the French government implementing measures such as a ban on the importation of British beef and a recall of specified risk materials (SRM),[64] sales were able to recover some ground.[65] Statistics from the French Ministry of Agriculture show that by the end of 1996, sales of beef overall were only 9% less than sales figures from 1995.[66] In addition to decreased sales, from 1996 onward, EU officials implemented eradication programs within individual member states whenever they diagnosed BSE in cattle.[67] By 1997, the total number of recorded BSE cases identified in cattle reached 179,087 in the EU, of which 99.5% were located in the UK.[68]

Public panic: the second wave

After a brief period of calm, the second wave of the crisis hit Europe in October 2000, and this time it was clear that the phase would be more serious and would last longer than the

[61] Michael Balter. "Tracking the Human Fallout from 'Mad Cow Disease.'" 2000: 1453
[62] Beck, Asenova, and Dickson. "Public Administration, Science, and Risk Assessment." 402.
[63] Jocelyn Raude. *Sociologie d'une crise alimentaire.* 2008: 7.
[64] Known in French as *matériaux risque spécifiés* (MRS), in the context of the BSE crisis, specified risk materials are tissues such as the brains, eyes, spine, and marrow of infected animals that were identified as posing a higher risk of infection.
[65] Jocelyn Raude. *Sociologie d'une crise alimentaire.* 2008: 7.
[66] Jocelyn Raude. *Sociologie d'une crise alimentaire.* 2008: 7.
[67] Heather Berit Freeman, "Trade Epidemic: The Impact of the Mad Cow Crisis on EU-U.S Relations," B.C. Int'l & Comp. L. Rev. 343, 25 (2002), http://lawdigitalcommons.bc.edu/iclr/vol25/iss2/9 (accessed February 21, 2012).
[68] Beck, Asenova, and Dickson. "Public Administration, Science, and Risk Assessment." (Table 1): 399.

first.[69] Scientific experts and public policymakers had expected to see a decline in the number of cases of BSE in cattle, due to the series of measures implemented dating back to the 1980s, including the ban on animal protein-fortified feed.[70] But instead of declining, the number of post-ban cases kept climbing, numbering 30,000 by 1997 and indicating that there was "either a higher cattle-to-calf rate of transmission than had previously been understood, or that the consumption of infected feed had continued."[71] Whatever the cause of the increasing number of cases, officials concluded that a large number of infected animals that had not exhibited symptoms had entered the human food chain.[72]

By November 2000, 185,000 British cows were found to be infected with BSE. Between the first noted observance of the disease in 1985 and September 2000, 4.3 millions cows had been slaughtered in the UK.[73] And the epidemic was spreading. Cases of BSE were found in twelve European countries and in the Falkland Islands, Canada, and Oman by 2001.[74] This second wave caused even more damage to the UK's agricultural sector. A poll from January 2001 showed that 45% of French citizens surveyed had reduced or stopped their consumption of beef.[75] Another survey gave more precise numbers: in the last four months of 2000, sales of beef in France had fallen nearly 35% in volume, and one household in four had reduced its purchases of beef while one household in ten no longer ate beef at all.[76] Consumers in other European countries exhibited similar behavior: Italy saw a 45% decrease in beef sales and Germany saw a

[69] Jocelyn Raude. *Sociologie d'une crise alimentaire.* 2008: 7; Lledo. 2001. *Histoire de la vache folle*, 39.
[70] Beck, Asenova, and Dickson. "Public Administration, Science, and Risk Assessment." 401.
[71] Beck, Asenova, and Dickson. "Public Administration, Science, and Risk Assessment." 401.
[72] Beck, Asenova, and Dickson. "Public Administration, Science, and Risk Assessment." 401.
[73] Lledo. 2001. *Histoire de la vache folle*, 39.
[74] Lledo. 2001. *Histoire de la vache folle*, 40.
[75] Jocelyn Raude. *Sociologie d'une crise alimentaire.* 2008: 7.
[76] Jocelyn Raude. *Sociologie d'une crise alimentaire.* 2008: 7.

60% decrease.[77] The European Commission estimated that the costs of dealing with the BSE crisis across Europe totaled 100 billion euro.[78]

The role of the media and public opinion

Besides the growing severity of the BSE crisis as an animal health issue, the public anxiety over human health reached hysterical proportions, and with good reason. Some early reports in the UK estimated the maximum possible number of human cases at around 500,000, though by the year 2000 that estimate had been scaled down to 136,000.[79] Raude maintains that the BSE crisis was, more than any other public health issue, presented in the media with overwhelming fear and as a collective psychosis.[80] An article from the *New York Times* in December 2000 provides an example of this type of portrayal of BSE as an unfathomable and terrifying disease:

> The human toll might seem small when compared with diseases like malaria, which kills millions of people every year. But the prospect of turning loose a stealthy, deadly and largely unknown pathogen is what most concerns scientists across Europe. The mad cow scare has touched off a panicky reaction against eating beef, but the worrisome fact is that many people already may be infected, perhaps because proteins known as prions that had somehow become aberrant were lurking in their baby food or hamburger many years ago. The danger to

[77] Jocelyn Raude. *Sociologie d'une crise alimentaire.* 2008: 7.
[78] Jocelyn Raude. *Sociologie d'une crise alimentaire.* 2008: 7.
[79] Michael Balter. "Tracking the Human Fallout from 'Mad Cow Disease.'" 2000: 1452. In actuality, as of November 2011, The National Creutzfeldt-Jakob Disease Research & Surveillance Unit (NCJDRSU) – an organization created by the UK government to track the prevalence of vCJD – had confirmed 226 cases worldwide. The overwhelming amount (176 cases or approximately 78% of the total) were in the UK. France had the second highest rate with 25 confirmed cases or approximately 11% of the total. The remaining 25 cases are spread out over ten countries. NCJDRSU. 2011. "Variant Creutzfeldt-Jakob Disease Current Data (November 2011)." *NCJDRSU Site*. http://www.cjd.ed.ac.uk/vcjdworld.htm (accessed February 28, 2012).
[80] Jocelyn Raude. *Sociologie d'une crise alimentaire.* 2008: 7-8 (my translation). In the original text, Raude writes that the media portrayed the crisis as: *un phénomène hystérique, une peur panique ou une psychose collective*. She illustrates this by citing a few headlines from that time, including: "*La grande peur de la vache folle*" ("The Great Fear of Mad Cow") from the November 8, 2000 issue of *Le Monde*; "*Un climat de psychose*" ("A Psychotic Atmosphere") from the November 10, 2000 issue of *Le Parisien*); and "*Panique sur le bœuf*" ("Panic over Beef") from the November 17, 2000 issue of *France Soir*.

> humanity, scientists say, is that the general level of potential infection will rise, making it easier for the disease to emerge in future generations.[81]

The human symptoms of the disease fueled this panicked depiction of vCJD as "mad cow disease." Patients with vCJD exhibit "a progression of psychiatric and neurological symptoms that culminate in death, usually a year or two after the onset of the first indications of illness."[82] Unlike the known sporadic CJD strain that had been observed previously in humans and typically affects the 50-to-70-year-old age group, the great majority of vCJD cases have been found in people under the age of 30.[83] Furthermore, between the first and second waves the public had seen the misery of those suffering from vCJD paraded across their television screens,[84] just like the stories of the young hemophiliacs with AIDS who had come before them. Fears of the disease were compounded by the fact that, because of the large number of bovine-derived products, "consumption of meat and dairy products and exposure to products containing either tallow or gelatin (or their derivatives) is nearly universal," meaning that almost all consumers were potentially at risk.

Policy implications

In France, politicians – still reeling from the fallout due to the earlier blood scandal and conscious of the consequences of blame in light of the prosecutions of officials in charge – adopted a risk-averse policy position in response to the mad cow crisis. As mentioned, early measures by France in response to the BSE crisis included adherence to EU restrictions on the importation of live cattle from the UK and the ban on animal-based animal feed for cows, which

[81] Barry James. "Europe's Spreading Food Scare : Untangling the Deadly 'Mad Cow' Mystery." *New York Times*. December 7, 2000. http://www.nytimes.com/2000/12/07/news/07iht-bse.2.t.html?pagewanted=all (accessed February 28, 2012).
[82] Paul Brown. "Mad-Cow Disease in Cattle and Human Beings: Bovine spongiform encephalopathy provides a case study in how to manage risks while still learning the facts." *American Scientist*, Vol. 92, No. 4 (July-August 2004), pp. 334-341 (here 334).
[83] Michael Balter. "Tracking the Human Fallout from 'Mad Cow Disease.'" 2000: 1453; Paul Brown. "Mad-Cow Disease in Cattle and Human Beings." 2004. 339.
[84] Lledo. 2001. *Histoire de la vache folle*, 15.

later was extended to all ruminants. By 1999, the EU required the removal of all SRM from both the animal and human food chains; systematic screening of animals, healthy or at risk; a ban on *le jonchage* (a method used to immobilize cattle before they are slaughtered);[85] and a ban on any feed that contained meat- or bone-meal additives.[86] France had also taken the additional action of eliminating certain animal fats from animal feed.[87]

France initially followed the EU's lead on embargoes on beef imports from the UK and from Portugal, which had commenced in 1996 and 1998, respectively. But the French government's reaction to the BSE crisis was much more severe than other member states', resulting in serious friction between the UK and France. In 1999, for example, while the EU decided to lift the embargo on all British beef and live cattle, the French government, under the advisement of the newly formed French food safety authority (*l'Agence française de sécurité sanitaire des aliments* – AFSSA) decided to maintain it.[88] Even with these measures in place, by October 2000 France had found 175 cases among its cattle herds.[89]

In France, it was not the rising number of BSE cases in cattle after 1996 or any new, significant scientific findings that triggered the "emotion" of the second crisis in 2000. Rather, it was the diagnosis of BSE in a French cow just as it was to enter the slaughterhouse that

[85] The method of *jonchage* entails paralyzing the cow by thrusting a metal rod into its brain to destroy its nervous system. The French government identified this process as a possible means of BSE contamination. Catherine Coroller. "Saines mises à mort dans les abattoirs. L'abattage par jonchage, facteur possible de contamination de l'ESB, sera interdit." *La Libération*. March 15, 2000. http://www.liberation.fr/societe/0101327587-saines-mises-a-mort-dans-les-abattoirs-l-abattage-par-jonchage-facteur-possible-de-contamination-de-l-esb-sera-interdit (accessed February 22, 2012).

[86] AFSSA. Nutrition et risques alimentaires. Vos questions sur… oméga 3, iode, allergies, sucre, vache folle, soja, promesses santé, eau… les scientifiques répondent. Series: Les Cahiers de l'AFSSA, vol.1. Évreux: Les Presses de Kapp, 2005: 56.

[87] AFSSA. Nutrition et risques alimentaires. 2005: 56.

[88] AFSSA. Nutrition et risques alimentaires. 2005: 57-58. France did not lift its ban on British beef until October 2002. The EU attempted to lift the ban on Portuguese beef in 2001, but it was reinstated in 2003 after France complained the EU had not performed rigorous enough health checks.

[89] Lledo. 2001. *Histoire de la vache folle*, 40.

unleashed the panic of the second wave.[90] France had previously established eradication rules that required animals from the same herd to be culled and destroyed, but in this case, several cows from the affected herd had already been slaughtered and had entered the food chain before they could be identified.[91] This revelation led French supermarket chains to recall significant quantities of meat and to considerable media attention and public emotion.[92] Individual municipalities responded with immediate bans on beef in school cafeterias, and the government, under pressure from the media and the political turmoil, extended the ban of meat- and bone-meal for ruminants to all animals.[93]

Even though the number of BSE cases remained low in France (at approximately ten cases per million head of cattle per year), particularly in comparison to rates in the UK, Ireland, and Portugal,[94] France has maintained a risk-averse position in its policymaking. David Vogel links this risk-averse position in France to the consequences of the HIV-tainted blood scandal:

> [The HIV-tainted blood scandal] shocked French public opinion, calling into question the public's historic high regard for the competence of the public sector in a highly paternalistic state. It also continues to haunt French politicians, making them highly risk-averse, particularly with respect to potential threats to public health.[95]

In short, French politicians became more concerned with the consequences of blame in light of not only the hundreds of deaths traced to tainted blood products, but also the criminal prosecution of the officials in charge. Furthermore, Vogel attributes the high rate of acceptance

[90] Michel Setbon, Claude Fischler, Esther Lukasiewicz, Jocelyn Raude, and Antoine Flahault. "Could measuring of perceived risk among general practitioners have helped anticipate the French BSE crisis?" *European Journal of Epidemiology* 19: 377-381, 2004. (here 377).
[91] Setbon et al. "Could measuring of perceived risk among general practitioners have helped anticipate the French BSE crisis?" 2004: 377.
[92] Setbon et al. "Could measuring of perceived risk among general practitioners have helped anticipate the French BSE crisis?" 2004: 377.
[93] Setbon et al. "Could measuring of perceived risk among general practitioners have helped anticipate the French BSE crisis?" 2004: 377.
[94] Lledo. 2001. *Histoire de la vache folle*, 52.
[95] David Vogel, "The Hare and the Tortoise Revisited." 571.

of AFSSA's recommendations by French ministers to the officials' fear of being blamed for endangering public health.[96] This near-blanket acceptance of AFSSA's recommendations created tension between the EU and France during the second wave of the mad cow crisis, when France maintained its ban on imports of British beef at AFSSA's recommendation rather than following the EU's decision to lift the embargo.[97]

Although the mad cow crisis was not the first major regulatory failure in Europe, "the EU's belated failure to recognize [the] health hazards [of BSE] severely undermined public trust in EU food safety regulations and the scientific expertise on which they were based."[98] In France, the conceptualization of the idea of *les crises sanitaires* (public health crises), which had begun during the HIV-tainted blood scandal, became further cemented in the public consciousness.[99] It also showed that authority over food safety had to be elevated to the EU-level; the crisis had started in the UK and then spread throughout the common market. Even beyond the borders of the EU, the spread of mad cow disease was different from preceding public health crises because it "represented a global risk by the measure of the number of populations (European, African, and Asian) that were exposed – in varying degrees – to the potentially dangerous products" due to the worldwide export of British beef between 1986 and 1996.[100] Because of its extent, the BSE crisis can thus be considered as the first real global crisis in food safety.[101]

[96] David Vogel, "The Hare and the Tortoise Revisited." 571.
[97] David Vogel, "The Hare and the Tortoise Revisited." 571.
[98] David Vogel, "The Hare and the Tortoise Revisited." 569.
[99] Didier Fassin and Boris Hauray (eds). *Santé publique: L'état des savoirs.* Paris: La Découverte, 2010; Boris Hauray, from interview with the author (February 9, 2012).
[100] Raude. *Sociologie d'une crise alimentaire.* 2008: 6.
[101] C. Fischler. "La maladie de la vache folle." In: Apfelbaum M. (dir.), *Risques et peurs alimentaires.* Paris: Odile Jacob, 1998: 118-126 – as cited by Raude. *Sociologie d'une crise alimentaire.* 2008: 6.

In addition to the broad scope of the BSE crisis, the policy impact of the many regulatory failures during the 1980s and the 1990s has been deeper than in previous time periods.[102] The "cumulative impact" of these crises "has been to increase the public's sense of vulnerability to and anxiety about the risks associated with modern society and this in turn has affected the political context in which regulatory policies have been made."[103] In response to these concerns, individual member states, such as the UK, France, and Germany, created food safety authorities or new ministries to handle these types of issues.[104] The formation of the European Food Safety Authority (EFSA) was also a result of the BSE crisis.

The creation of these agencies, which are responsible for risk assessment though not risk management, was in part an effort to help rebuild the trust of the European people in their governments' ability to regulate food safety effectively. The new, more "independent" agencies were also supposed to be less vulnerable to regulatory capture than the comitology system that had been in place during the BSE crisis.[105] These regulatory agencies were supposed to remove the overwhelming power of the industry from the policymaking process and give some semblance of responsibility and control to politicians. Furthermore, as Mark Thatcher and Alec Stone Sweet assert, the creation of new regulatory agencies also provided elected officials with potential "scapegoats for hard choices for which they might not otherwise be blamed."[106]

Dioxin Contamination

A little over a year before the second wave of the mad cow crisis hit Europe, the Belgian government announced the widespread contamination of animal feed with dioxins on May 27,

[102] David Vogel, "The Hare and the Tortoise Revisited." 571.
[103] David Vogel, "The Hare and the Tortoise Revisited." 571.
[104] David Vogel, "The Hare and the Tortoise Revisited." 570.
[105] David Vogel, "The Hare and the Tortoise Revisited." 570.
[106] Mark Thatcher and Alec Stone Sweet. "Theory and Practice of Delegation to Non-Majoritarian Institutions." In: *The Politics of Delegation*, Thatcher and Stone Sweet (eds.). London: Frank Cass and Company Ltd., 2003. p. 1-22. here p. 9.

1999.[107] This newest public health scandal "erupted when European consumer confidence in food was particularly low," coming not only on the heels of the first wave of BSE, but also after a listeria outbreak (1995) and during the ongoing dispute between the EU and the US over the European refusal to accept American imports of hormone-treated beef.[108] Contamination most likely occurred in mid-January 1999, when animal fat at a Belgian fat and oil processing plant and animal feed manufacturer were mixed with dioxin-contaminated industrial oils.[109] In February, animal producers began to notice an increase in egg-laying impairments and neural disorders in chickens.[110] These problems were then traced to the contaminated fat in the hens' feed.[111] The Belgian Ministry of Agriculture received a report on the situation on April 21, 1996, with a laboratory analysis confirming that "dioxin was present at high levels in the hens' feed and body fat" coming five days later.[112]

Despite having information in April 1999 that public health could be endangered, the Belgian government withheld this information from the public for another month. Ostensibly, the delay was due to the compilation of a list of farms that might have received contaminated feed and the completion of additional tests to determine whether dioxin had definitely reached the human food supply.[113] This delay, however, would be the eventual undoing of the ruling administration. By the time the government went public, over 1,000 Belgian farms had been

[107] Dioxins are "a group of chemical compounds released by processes such as waste incineration and the burning of household fuel, have been linked to health effects ranging from skin disease to cancer." David A. Taylor. "Animal Feed to People Food: The Belgian Dioxin Incident." *Environmental Health Perspectives*, Vol. 109, No. 3 (Mar., 2001), p. A133.
[108] A. J. McMichael. "Dioxins in Belgian Feed and Food: Chickens and Eggs." *Journal of Epidemiology and Community Health*, Vol. 53, No. 12 (Dec., 1999), pp. 742-743. here 743.
[109] Casey J. Jacob, Corie Lok, Katija Morley, and Douglas A. Powell. 2011. Government management of two media-facilitated crises involving dioxin contamination of food. *Public Understanding of Science*. 20(2): 261-269. here 263; McMichael. "Dioxins in Belgian Feed and Food: Chickens and Eggs." 743.
[110] McMichael. "Dioxins in Belgian Feed and Food: Chickens and Eggs." 743.
[111] Jacob et al. Government management of two media-facilitated crises involving dioxin contamination of food. 264.
[112] Jacob et al. Government management of two media-facilitated crises. 264.
[113] Jacob et al. Government management of two media-facilitated crises. 264.

endangered by contaminated animal feed, and farms in the Netherlands, France, and Germany were at risk.[114]

The role of the media and public opinion

After the announcement of the contamination, the public backlash, fueled by media scrutiny of the government's actions, was immediate and it escalated the situation into a crisis.[115] Because of the government's prior knowledge and the month-long delay leading up to public acknowledgement of the contamination, the media accused the government of a cover-up.[116] The Belgian Ministry of Agriculture was seen to have prioritized the potential effects of notification on the food trade over concerns about consumer safety.[117] Not only did the scandal break during a period in which consumer confidence in food safety was especially low due to the mad cow crisis, but also, as A.J. McMichael argues, "[t]his narrative mirrored the primacy given to producer interests in Britain's mad cow episode, at the expense of consumer interests."[118] Accusations were also framed around the impending general elections, with the implication that the government delay was "serving the economic interests of farmers' unions and the meat industry, and trying to protect itself in preparation for the upcoming general elections, rather than protecting public health."[119] Finally, the delay was painted as "an irresponsible move by the Belgian government," which resulted in the public focusing "its blame on the government rather than those actually responsible for the contamination."[120]

Adding to consumers' anxiety was the fact that, unlike with vCJD, human health effects from dioxin contamination are not physically obvious or easily assessable through medical

[114] McMichael. Dioxins in Belgian Feed and Food: Chickens and Eggs. 743.
[115] Jacob et al. Government management of two media-facilitated crises. 264.
[116] Jacob et al. Government management of two media-facilitated crises. 264.
[117] McMichael. Dioxins in Belgian Feed and Food: Chickens and Eggs. 743.
[118] McMichael. Dioxins in Belgian Feed and Food: Chickens and Eggs. 743.
[119] Ammerlaan, N. (1999) "Chicken Scare Flavour of the Day in Belgian Campaign," Reuters 31 May, as cited by Jacob et al. Government management of two media-facilitated crises. 264.
[120] Jacob et al. Government management of two media-facilitated crises. 264.

tests.[121] Even after several years, "Not one person [had] been detected with any observable consequence of dioxin poisoning"[122] and no acute clinical health effects had been reported.[123] But that did not mean that Belgians were without risk of future consequences from dioxin contamination. A scientific analysis of potential exposure found that, while Belgians had been exposed to much smaller amounts of dioxins compared to populations in other known contamination incidents, a much larger percentage of the population was affected.[124] Furthermore, "the analysis suggests that in terms of added cancer risk, the incident could result in between 32 and 1,540 additional cancer deaths over the projected lifetime of the total Belgian population of 10 million,"[125] though it would be difficult to trace those deaths to this episode. Thus, media coverage of the dioxin contamination scandal differed from that of the mad cow crisis because it did not include the horrific images and stories that chronicled the debilitating effects of a disease on the human body. Yet, it was similar in that it played upon the fears of the unknowable, future impacts on human health.

Despite the differences between the potential human health consequences of vCJD and dioxin contamination, the media made comparisons between the two scandals. As Luc Bonneux and Wim Van Damme note, "In a global world with global media coverage and competition for sensational news, any hypothetical doomsday scenario that could capture the public imagination

[121] McMichael. Dioxins in Belgian Feed and Food: Chickens and Eggs. 742.
[122] Luc Bonneux and Wim Van Damme. An Iatrogenic Pandemic of Panic. *BMJ: British Medical Journal*, Vol. 332, No. 7544 (Apr. 1, 2006), pp. 786-788. here 786.
[123] Nik van Larebeke, Luc Hens, Paul Schepens, Adrian Covaci, Jan Baeyens, Kim Everaert, Jan L. Bernheim, Robert Vlietinck, and Geert De Poorter. The Belgian PCB and Dioxin Incident of January-June 1999: Exposure Data and Potential Impact on Health. *Environmental Health Perspectives*, Vol. 109, No. 3 (Mar., 2001), pp. 265-273. here 272.
[124] Taylor. "Animal Feed to People Food." A133.
[125] Taylor. "Animal Feed to People Food." A133.

risks unleashing a media storm… The perception of risk is then easily distorted from the actual risk."[126] An article from *Le Monde* provides an illustrative example:

> In less than a week, the dioxin-contaminated chicken scandal has taken on an international dimension. Described initially as a simple accident in a Belgian factory that provides fat for chicken feed production, it has become "Chickengate" and, in doing so, replicates and reinforces all the same elements that were observed three years ago at the beginning of the "mad cow" crisis: a real health risk, which the experts swear they cannot evaluate with precision, unfolding from an original, and more-or-less mysterious, case of contamination; a peek into the unsavory back rooms of the food-processing and agricultural industries; and a reminder that it is impossible to trace exactly how the majority of the products that we consume are produced.[127]

Such media comparisons to mad cow disease exaggerated the public's perception of the risks related to dioxin contamination. The amplification of risk was also aided by the public's outrage at "the toxic notoriety of dioxins, the invisibility of the hazard, and the sense that officialdom had conspired against consumer interests," because "as risk experts remind us, the perceived risk reflects both the assumed actual hazard and the attendant level of outrage."[128]

The heightened level of anxiety during the dioxin contamination episode certainly contributed to exaggerated fears over the alleged contamination of Coca-Cola, which unfolded that same summer. At the beginning of June 1999, approximately thirty children from the same elementary school in Northern Belgium experienced gastro-intestinal problems after drinking Coca-Cola.[129] By June 17, 1999, two hundred Belgians and two Frenchmen had reported feeling

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[126] Bonneux and Van Damme. An Iatrogenic Pandemic of Panic. 787.

[127] Original text: En moins d'une semaine, l'affaire des poulets à la dioxine vient de prendre une dimension internationale. Décrite initialement comme un simple accident dans une usine belge fournissant des graisses à des fabricants d'aliments pour volailles, elle est devenue un "chickengate" qui reproduit en les amplifiant tous les mécanismes observés il y a trois ans lors de la crise de la "vache folle": un risque sanitaire réel, mais que les experts avouent ne pas savoir évaluer avec précision, découlant d'une contamination d'origine plus ou moins mystérieuse; un regard jeté vers les coulisses bien peu ragoûtantes de l'agroalimentaire et d'une agriculture industrielle; l'impossibilité de retrouver la trace exacte des circuits empruntés par la plupart des aliments que nous consommons. (my translation). Nau, J.Y. Le temps des angoisses alimentaires (A propos du poulet à la dioxine). *Le Monde*. June 8, 1999.

[128] McMichael. Dioxins in Belgian Feed and Food: Chickens and Eggs. 742.

[129] J.Y. Nau. Un mystère médico-toxicologique sur fond de surenchères sanitaires. L'Affaire Coca-Cola. *Le Monde*. June 26, 1999.

ill after drinking Coke, amidst other complaints that some Coca-Cola products had a "funny" taste (products traced to a factory in Belgium) or a "strange" odor (products traced to a factory in France).[130] Despite not having any scientific evidence linking consumption of Coca-Cola to the reported illnesses, the Belgium government ordered a recall – unprecedented in scope – of over 15 million cans and bottles of Coca-Cola products.[131] It also prohibited the sale of all Coca-Cola products, including Coca-Cola, Diet Coca-Cola, Cherry Coke, other sodas (such as Fanta or Sprite), Minute Maid juices, Nestea, and the brand's bottled water.[132] The French government responded to the alleged contamination within its borders by halting the manufacture of four of the five product lines at the French Coca-Cola factory associated with the "tainted" products, and it advised the French public not to drink Coca-Cola beverages until more information could be gathered.[133]

Eventually, scientific tests performed by poison control centers in Belgium showed no link between Coca-Cola products and the afflictions of the "victims." Press reports at the time even suggested that ailments were the result of a "collective psychosis" resulting from the anxiety of the dioxin-contaminated chicken crisis, not from tainted beverages.[134] Observers noted that "the poisoning cases seemed to concern, for the most part, children and adolescents living in the regions that had been the most affected by the dioxin-contaminated chicken crisis."[135] Thus,

[130] Nau. Un mystère médico-toxicologique. June 26, 1999; J.Y. Nau. Le gouvernement suspend la commercialisation des boissons Coca-Cola. *Le Monde*. June 17, 1999.
[131] L. Belot. Les produits Coca-Cola ont été retirés de la vente en Belgique à la suite de cas d'intoxication. *Le Monde*. June 16, 1999.
[132] Belot. Les produits Coca-Cola ont été retirés de la vente en Belgique. June 16, 1999.
[133] Nau. Le gouvernement suspend la commercialisation des boissons Coca-Cola. June 17, 1999.
[134] Nau. Le gouvernement suspend la commercialisation des boissons Coca-Cola. June 17, 1999; Nau. Un mystère médico-toxicologique. June 26, 1999.
[135] Original text: …certains observateurs avaient noté que les cas d'intoxications semblaient concerner, pour l'essentiel, des enfants et des adolescents vivant en collectivité dans les régions belges les plus touchées par la crise du "poulet à la dioxine". (my translation) Nau. Le gouvernement suspend la commercialisation des boissons Coca-Cola. June 17, 1999.

the major public health scare of the dioxin-contaminated chicken episode directly contributed to how the Belgian and French governments handled the alleged Coca-Cola contamination.[136]

Policy implications

The ramifications of the media coverage and the public outrage over the government's (mis)handling of the dioxin contamination extended beyond the severe responses to the allegations of tainted Coca-Cola. The policy responses of the Belgian and French governments and of the EU were also, in hindsight, excessive in light of the actual risk to consumers.[137] After the Belgian government publicly acknowledged the dioxin contamination at the end of May 1999, it began to take steps to limit the public's exposure to contaminated products. On June 1, 1999, the Belgian government announced its ban on the sale of all Belgian chicken and eggs. In addition, the Ministry of Public Health ordered recalls for poultry, poultry-derived products (meat, eggs, mayonnaise, cakes, etc.), and all meat products with a fat content greater than 25%.[138] The Public Health Ministry also began a program for widespread product sampling and analysis, ordering any products determined to have excessive dioxin levels to be destroyed.[139]

On June 4, 1999, the European Commission announced the prohibition of any Belgian animal or animal product that was suspected of contamination from entering the Common Market. On the same day, France announced that it would implement a more extensive ban than the EU's measure, by prohibiting the importation of all live animals and animal products from Belgium. This measure also included a ban on the exportation of any French animal or animal products suspected of contamination due to the importation of dioxin-tainted feed to French

[136] David Vogel, "The Hare and the Tortoise Revisited." 569-570.
[137] McMichael. Dioxins in Belgian Feed and Food: Chickens and Eggs. 742.
[138] Nik van Larebeke, Luc Hens, Paul Schepens, Adrian Covaci, Jan Baeyens, Kim Everaert, Jan L. Bernheim, Robert Vlietinck, and Geert De Poorte. The Belgian PCB and Dioxin Incident of January-June 1999: Exposure Data and Potential Impact on Health. *Environmental Health Perspectives*, Vol. 109, No. 3 (Mar. 2001), pp. 265-273. here 265.
[139] Van Larebeke et al. The Belgian PCB and Dioxin Incident of January-June 1999. Mar. 2001. 265.

farms. The Netherlands, Spain, Austria, and Hungary announced that they would implement the stricter embargo as well.[140] Internationally, the US took this opportunity to institute a ban on all meat and dairy products from Europe.[141] Other countries outside of Europe, such as Canada, South Korea, Russia, South Africa, and some Middle Eastern countries, employed partial bans.[142] Together, these measures resulted in the slaughter and destruction of seven million chickens and 60,000 pigs,[143] and they brought Belgian trade to a "virtual standstill."[144]

Like its more extensive ban on British beef during the mad cow crisis, France's blanket-ban on Belgian animals and animal products created friction between France and Belgium; the Belgium government insisted that only certain products were at risk and that a complete ban on all Belgian animal products was excessive. An article in Belgium's main French-language newspaper described the ban as such:

> Is this "contaminated blood syndrome"? In any case, after the trial this past winter of three former Socialist ministers accused of letting AIDS-infected blood products into the blood supply in the mid-1980s, France no longer fools around with public health. Even though it judges the risks to be minimal, France has brought out the heavy artillery in response to "Chickengate." In its latest decree, it is no longer just chicken, beef, and pork from Belgium that are undesirable; all animals raised in Belgium between January 15 and June 1, 1999 (and their derivative products) are banned from importation into France.[145]

Furthermore, France's decision to go beyond the EU measure inflamed the public spat that was developing between the European Union's then-Agriculture Commissioner (Franz Fischler) and France's then-Minister of Agriculture (Jean Glavany) over the timing of the French response. EU Commissioner Fischler accused the French government of not responding appropriately when

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[140] J.Y. Nau. Dioxine : la France décrète un embargo sur tous les produits animaux. *Le Monde*. June 7, 1999.
[141] McMichael. Dioxins in Belgian Feed and Food: Chickens and Eggs. 743.
[142] McMichael. Dioxins in Belgian Feed and Food: Chickens and Eggs. 743; Jacob et al. Government management of two media-facilitated crises. 265.
[143] Bonneux and Van Damme. An Iatrogenic Pandemic of Panic. 786.
[144] Jacob et al. Government management of two media-facilitated crises. 265.
[145] Joelle Meskens. Paris a déclenché l'artillerie lourde pour rassurer. *Le Soir*. June 7, 1999. http://archives.lesoir.be/paris-a-declenche-l-artillerie-lourde-pour-rassurer-les_t-19990607-Z0GVRY.html (accessed March 6, 2012).

French authorities had been aware as early as May 3, 1999 of the exportation of possibly contaminated animal feed to a French feed distributer.[146] French Minister Glavany countered that the information, which had been faxed to the *Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes*,[147] had been "banal" and that the Belgian government had not indicated the severity of the situation until May 28, 1999, when it formally notified the European community at-large.[148] Moreover, French officials claimed that it was the responsibility of the Belgian authorities to forward that information on to French institutions designated as better equipped to assess the risk (AFSSA and the *Institute de veille sanitaire* – IVS).[149] The dispute devolved into Fischler denouncing the French government for failing to protect European public health, and Glavany accusing Fischler of being "anti-French" and "anti-democracy."[150]

In response to the mud-slinging, the European Commission ordered the French government to present a report of the measures it had taken to deal with the dioxin-contamination crisis. On June 7, 1999, Glavany and Dominique Strauss-Kahn (then-Minister of Economy, Finance, and Industry) presented the Commission with an open letter detailing the policies the French had adopted in the face of possible dioxin-contamination.[151] French officials took the report as an opportunity to point out that not only had France responded immediately when the risk had become evident, but that it also took measures beyond what the EU had recommended. In addition, the report highlighted that it was the Belgian officials who had

[146] J.Y. Nau. Polémique entre Jean Glavany et Franz Fischler. *Le Monde*. June 7, 1999.
[147] The *Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes* (General Directorate of Competition, Consumption & Repression of Frauds) is an agency under the purview of the French Ministry of Economy, Finance, and Industry.
[148] Nau. Polémique entre Jean Glavany et Franz Fischler. June 7, 1999.
[149] The *Institut de veille sanitaire* (Sanitary Surveillance Institute) is a French public health agency responsible for monitoring the health of the French population. It is part of the Health Ministry. J.Y. Nau. Critiquée par la Commission européenne, la France cherche à se justifier. *Le Monde*. June 8, 1999.
[150] Nau. Critiquée par la Commission européenne, la France cherche à se justifier. June 8, 1999.
[151] Nau. Critiquée par la Commission européenne, la France cherche à se justifier. June 8, 1999.

delayed in alerting the EU member states, and that the EU had failed in following proper notification procedures.[152]

In the wake of public criticism of their poor crisis management, both at home and abroad, the Belgian Agriculture and Public Health Ministers resigned. Although the ministers insisted that they had handled the situation properly, they claimed that their resignations were an effort to help restore calm and public trust.[153] The incumbent Belgian government, though, could not staunch the damage with resignations. On June 14, 1999, the ruling coalition was defeated, in part due to having lost credibility during the crisis.[154] The dioxin-contaminated chicken crisis also helped the Belgian "green" party, Ecolo, to climb in political standing, with the press declaring that Ecolo was the real "winner" of the general elections.[155]

GMOs on the Agenda

These cases helped shape the social, political, and institutional contexts into which GMOs were introduced in Europe. In the social sphere, public anxieties over risks to the food supply and over the government's ability to regulate it were growing. Citizens were no longer confident of their government's commitment to protecting public health. In all three cases, public officials appeared to be more concerned with commercial interests than with public health consequences.

For European politicians, the lessons from the cases were clear. Missteps could lead to being voted out of office or, worse, to criminal charges. Amidst fears of being blamed for policy decisions gone wrong, French political responses to public health threats evolved from ones of

[152] Nau. Critiquée par la Commission européenne, la France cherche à se justifier. June 8, 1999.
[153] Reuters. "Belgian Farm, Health Ministers Offer to Quit Government," June 1, 1999, as cited by Jacob et al. Government management of two media-facilitated crises. 264.
[154] Jacob et al. Government management of two media-facilitated crises.
[155] Pierre Bouillon. PS et PSC chutent, le PRL stagne, Ecolo grimpe. *Le Soir*. June 14, 1999. http://archives.lesoir.be/ps-et-psc-chutent-le-prl-stagne-ecolo-grimpe_t-19990614-Z0GWPW.html (accessed March 6, 2012).

delay to almost immediate zero-tolerance by the end of the decade. The series of public health and food safety crises of the 1990s thus contributed to the development of risk-averse policymaking strategies to avoid blame. The government needed to act in response to potential risks to avoid future crises. Politicians began to delegate more political responsibility to regulatory agencies. The creation of these new regulatory institutions occurred at both the EU-level with EFSA and the state-level, with AFSSA in the case of France. Their formation will be discussed in more detail in Chapters 3 and 4, respectively, but it is important to note here that decisions on institutional structure and function were influenced by the scandals of the 1990s.

The links between GMOs and l'affaire du sang contaminé

The repercussions of the HIV-tainted blood scandal clearly demonstrate the interest of the French population in blaming public officeholders for public health scandals, as the pursuit of criminal charges in this case lasted for almost a decade. The timing of this case affected the social context into which GMO approval was introduced, since as Hood has noted, approaches to blame risk are shaped by institutional and social contexts. The first criminal trial coincided with the beginning of debates on market approval for GMOs. Actual market approval and the mad cow crisis occurred just four years later. The second trial coincided with the creation of the French food safety authority. While mad cow has been more clearly linked to questions about GMOs within the context of food safety in the literature, the blood scandal drew attention to larger questions about the government's ability to make the right decisions to protect public health. And, the length of this case kept these questions at the forefront of the French public's minds.

For the case of GMOs, *l'affaire du sang contaminé* established the social and institutional contexts that blame would be targeted at individual decisionmakers, who in turn could be

punished with criminal charges. In addition, the case demonstrated both perceived avoidable harm or loss (PAH) and perceived responsibility or agency (PR) elements of blame. Public health officials could have handled the matter differently by destroying the contaminated blood supply or by approving American HIV tests for use. They were also responsible for not passing on information to the hemophiliac community or a wider circle of Ministry of Health officials. Blame in this case also meets another element of PR: harm could have been avoided, but instead public officials pursued commercial greed ahead of protecting public health.

As such, following this case and the subsequent reinforcement by the BSE crisis and the dioxin contamination of chicken and eggs, public officeholders recognized the issue of agricultural biotechnology as one of high blame risk. Hood notes that policy strategies often change following a blame episode.[156] Consequently, public officials became aware that they were responsible for responding not only to existing risks, but also to *potential* risks. For questions about GMO regulation following these crises, that meant that public policymakers shifted to a strategy of abstinence. Abstinence in this case entails not approving GM crops for cultivation, which in turn allows public officials to avoid responsibility for regulating those crops and the products for which they were destined.

In managing the risks of new technology, Collingridge argues that: "Decisionmakers can never relax in the assurance that they have identified the very best option; any choice may be shown to be mistaken by future events that surprise decisionmakers."[157] Although the overwhelming number of scientific studies shows GMO crops and GM products to be of low risk to human health, anti-GM groups argue that risk assessments do not take the unpredictability of

[156] Christopher Hood, *The Blame Game: Spin, Bureaucracy, and Self-Preservation in Government* 150.
[157] David Collingridge, "Resilience, Flexibility, and Diversity in Managing Risks of Technologies," in *Accident and Design: Contemporary debates in risk management*, Hood and Jones, eds. (London: Routledge, 1996/2002): 45.

genetic transfer or possible long-term consequences into sufficient consideration.[158] Thus, while no new scientific information has demonstrated a direct link between GMO consumption and risks to human health, perceived uncertainty about the long-term effects of GMOs allow the policy strategy of abstinence to remain entrenched. This entrenchment, even when faced with high costs of maintaining abstinence, continues because public policy makers see changes to strategy as costly,[159] in addition to their concerns about the high level of blame risk they will face if wrong. Furthermore, anti-GM interest groups have been able to exploit blame risk successfully in order to paralyze the GMO approval process.

The links between GMOs and the mad cow crisis

The mad cow crisis broke at a moment when French consumers were particularly vulnerable to threats to public health. Following the revelations of the HIV-contaminated blood supply, the first wave of the BSE crisis occurred between the two rounds of trials related to the blood case. At that moment in time, the French public was engaged in questioning whether its government has the best interests of the public – and not business – in mind. The BSE crisis also raised important questions about the process of food production. European consumers began to more actively contemplate where their food was coming from and how it was produced.

Furthermore, the media coverage of the BSE crisis influenced the European public's perception of governmental ability to effectively protect public health. This loss of confidence spilled over into the debate on GMO approvals and regulation. Dominique Brossard and James Shanahan argue that in Europe "previous news coverage of issues such as mad cow disease had resulted in damage to public trust" and that this damage shaped the environment into which the

[158] Simon Shohet, "Risk and Emerging Technology: The Case of Process-based Regulation of Biotechnology in Europe," in *Accident and Design: Contemporary debates in risk management*, Hood and Jones, eds. (London: Routledge, 1996/2002): 195-201.
[159] Christopher Hood, *The Blame Game: Spin, Bureaucracy, and Self-Preservation in Government* 150.

topic of GMOs was introduced.[160] They further claim that "the new cycles of public interest in agricultural biotechnology were tilted from the start toward a negative outcome" due to this pre-existing damage.[161]

Their argument is borne out by the results of the Eurobarometer survey from 1999, "The Europeans and Biotechnology."[162] The survey looked at "Europeans' attitudes to various problems connected with biotechnology," and it included questions to help determine, among other things: the attitudes of Europeans to the development of biotechnology; Europeans' knowledge of genetics; and an idea of which groups Europeans trust in this field.[163] Compared to the results of a similar survey in 1996, the report shows a drop in the percentage of all European respondents who believe that their way of life would improve as a result of genetic engineering (from 43% in 1996 to 37% in 1999).[164] Other data from the survey show that Europeans had, in general, negative feelings toward GM food, although they were more neutral on the idea of GM crops.[165] George Gaskell attributes this discrepancy to "different perceptions of use, risk, and moral acceptability" in regard to GM food versus GM crops.[166] Moreover, he finds that the negative European perceptions of GM foods as not "useful" or "acceptable" and as "risky" can be traced to the BSE crisis and other food scares. As a result, Europeans' increased sensitivity to food safety concerns after mad cow means: "People simply do not want to take the risk of eating

[160] Dominique Brossard and James Shanahan. "Perspectives on Communication about Agricultural Biotechnology." In: *The Media, the Public, and Agricultural Biotechnology.* Brossard, Shanahan, and Nesbitt (eds.). 2007. Oxon, UK: CAB International. p.3-20. here p.10.
[161] Brossard and Shanahan. "Perspectives on Communication about Agricultural Biotechnology." 10.
[162] INRA (Europe) - ECOSA. "The Europeans and Biotechnology." *Eurobarometer* 52.1, March 2000.
[163] INRA. "The Europeans and Biotechnology." a.
[164] INRA. "The Europeans and Biotechnology." 8.
[165] INRA. "The Europeans and Biotechnology." 34. For a more detailed review of public opinion data on this topic, see Chapter 5.
[166] George Gaskell. "Agricultural Biotechnology and Public Attitudes in the European Union." *AgBioForum.* Volume 3, Number 2&3, 2000. p.87-96. here 89.

GM foods and the absence of labeling and consequent denial of choice in the matter is the crucial concern."[167]

When the survey data is separated by member state, French respondents show clearly negative attitudes to GM food. For example, French respondents were more likely to agree with the statement that "GM food threatens the natural order of things," when compared to other Europeans. They were also more likely to disagree with the statement that "If a majority of people were in favour of GM food, it should be permitted."[168] The French also showed lower levels of trust in the actors involved in GMO production and regulation than their European counterparts. The majority of French respondents did not believe that the industry developing new products through the use of biotechnology "does good work for society."[169] When compared to other member states, the French scored low on their level of trust in the ethical committees responsible for addressing the moral aspects of biotechnology. Additionally, they were more likely to respond that the French government and the companies responsible for food safety do "not do good work" in regulating biotechnology.[170] Despite their comparatively negative attitudes toward the actors involved in biotechnology production and regulation, the French exhibited a higher level of trust in the environmental protection organizations that were campaigning against biotechnology.[171]

Sylvie Bonny also places the introduction of GMOs onto the agenda within the context of the mad cow crisis and the contaminated blood scandal, arguing that public opinion had been "strongly marked" by these affairs when transgenic seeds began to arrive in Europe in late

[167] Gaskell, "Agricultural Biotechnology and Public Attitudes," 88-89.
[168] INRA. "The Europeans and Biotechnology." 52.
[169] INRA. "The Europeans and Biotechnology." 67-68.
[170] INRA. "The Europeans and Biotechnology." 69, 70.
[171] INRA. "The Europeans and Biotechnology." 69. See Chapter 5 for a more detailed discussion of anti-GM interest groups in France.

1996.[172] She asserts that the "debate on GMOs (authorization, importation, labelling, impact, etc.) was situated in a context strongly influenced by food safety issues (BSE, listeriosis, etc.) that had been widely publicized."[173] Public attention to GMOs was increasing just as confidence in institutions and in certain technological advances decreased, resulting in extensive media coverage of the burgeoning anti-GM movement and, in turn, a "fairly critical" view of GMOs within the media and general social debate.[174] As one GMO opponent notes, "Old Europe was truly not ready. Already worried about public health because of potentially contaminated meat, Europe was not prepared to welcome the first arrivals of GM soy and maize peacefully."[175]

Anxiety over GMOs was apparent in news reports at that time. An illustrative example can be found in the November 1, 1996 edition of the French newspaper *Libération*.[176] Though the photo of a small pile of soybeans was fairly innocuous, the headline of the cover story that day was more threatening: *Alerte au Soja Fou* (see Image 2.1). Loosely translated as "Warning: Mad Soy," the front page warned of the impending arrival from the United States of several thousand tons of genetically modified soybeans. It also noted that the "arrival of this mutant legume, destined for a number of food products, was inciting protest campaigns by

[172] "Transgenic" is a term used to more specifically reference modifications that are the result of the insertion of foreign genetic material into a species. Sylvie Bonny. "Why are most Europeans opposed to GMOs? Factors explaining rejection in France and Europe." *Electronic Journal of Biotechnology*. Vol.6 No.1, 2003. p.50-71. here 53. In this case, American GM soy arriving in Europe had been modified with the insertion of genes from three bacterial strains and from the petunia flower to make the soy resistant to the herbicide Roundup.
[173] Bonny. "Why are most Europeans opposed to GMOs?" 53.
[174] Bonny. "Why are most Europeans opposed to GMOs?" 53.
[175] Original text: "La vieille Europe n'était vraiment pas prête. Déjà inquiète pour sa sécurité alimentaire à cause de viandes possiblement contaminantes, elle n'était pas mûre pour accueillir sereinement les premiers arrivages de soja et de maïs transgéniques." (my translation). Dorothée Benoît Browaeys. *Des Inconnus dans… nos assiettes. Après la vache folle, les aliments transgéniques!* Paris: Raymond Castells Éditions, 1998. 19.
[176] In addition to being referenced in the literature on GMOs (for example in Browaeys, 19), this cover story was mentioned by three interviewees (Chauveau, Hauray, Borraz) as a crystallizing moment in the GMO debate.

environmental organizations."[177] The final sentence in the cover story preview informed readers that these "genetically transformed organisms" still raised many questions among scientists.

Image 2.1. Cover of *Libération* (November 1, 1996)

Image 2.2. Cover of *Libération* (November 1, 1996)

Also printed on the front page was a preview of the stories inside the paper. An article on the seizure of 300 kilograms of British beef by French authorities from the Paris Hard Rock Café, "*Vache folle. Du bœuf britannique au Hard Rock Café,*" appears in the middle of the list (see Image 2). A link between the issues of GMOs and mad cow, though, is not limited to their proximity on the newspaper's front page; the articles inside explicitly connect fears about the risks of GMOs to the mad cow crisis. The cover story article notes that: "Manufacturers and importers pledge that this mutant presents no danger, but the mad cow scandal has taught

[177] Original text: "L'arrivée de ce légume mutant, qui entre dans la composition de nombreux produits alimentaires, suscite une campagne de protestation au sein des organisations écologistes." (my translation).

European consumers to be wary of such reassurances."[178] In addition, an editorial included as part of the GM soy coverage makes a connection between genetically modified crops, mad cow, and the AIDS epidemic. Other articles on the topic place the GMO debate in the context of mad cow as well, with one entitled, "Brussels has not learned its lessons from mad cow. European directives are opposed to specific labeling."[179] The paper also has an article appearing on page 13, "*Vache folle. Creutzfeldt-Jakob: un 'cas limite,'*" which reports on a probable case of the human form of mad cow disease in France from 1995. Alexis Roy asserts that, while it is difficult to point to any one incident as the defining start of the GMO debate in France, this edition of *Libération* captures the connections being established in the French public consciousness and media between the mad cow crisis and genetically modified crops.[180]

Bonny traces the generally negative attitude toward GMOs presented in the media to several factors. For one, the media focused more on the potential risks of GMOs and the arguments of the anti-GM movement than on the possible benefits.[181] She also maintains that journalists charged with covering the GMO debate usually had past experience reporting on the BSE crisis and HIV-tainted blood scandal, leading them to draw parallels between GMOs and those scandals in their writing.[182] Finally, she draws attention to the strong competition among media outlets, and the resulting desire to attract a wider audience through shocking headlines and dramatic reporting.[183]

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[178] Original text: "Fabricants et importateurs assurent que ce mutant ne présente aucun danger (lire interview), mais l'affaire de la vache folle a appris aux consommateurs européens à se méfier des discours rassurants." (my translation).
[179] Jean Quatremer. "Bruxelles n'a pas tiré les leçons de la vache folle. Les directives européennes s'opposent à un étiquetage spécifique." *Libération*. November 1, 1996. p.3.
[180] Alexis Roy. *Les Experts face au risque: le cas des plantes trangéniques*. Paris: Presses Universitaires de France, 2001: 13-14.
[181] Bonny. "Why are most Europeans opposed to GMOs?" 54.
[182] Bonny. "Why are most Europeans opposed to GMOs?" 54.
[183] Bonny. "Why are most Europeans opposed to GMOs?" 54.

At the same moment that GM soy was arriving in Europe and GM maize was under consideration for market approval, the mad cow crisis was raising important questions about the process of food production, the safety of the food supply, and also the "naturalness" of the process. Roy notes that after the announcement by the British government of the probable link between BSE and vCJD in March 1996, the French were exposed regularly to news reports on television, on radio, and in the printed press that "informed them that the contents of their plates hid an invisible danger."[184] And, it was within this context that French consumers discovered another incarnation of this "agriculture gone mad": GMOs.[185] Thus, GMOs became symptomatic of an industrialized agricultural system that privileged quantity and profit to the detriment of quality, public health, and the environment.[186] Even though regulatory bodies claimed that the GM soybeans presented no health hazards, "tampering with the food chain without public consultation touch[ed] an extremely raw nerve..."[187] The mad cow crisis instigated a growing interest among European consumers in traceability and labeling requirements for food products. The arrival of the American GM soy, which was mixed with unmodified soy and was thus set to enter the food chain unlabeled, in turn generated a more urgent interest in setting stringent traceability and labeling standards.

The mad cow crisis also illustrated the necessity of setting standards at the EU-level. Because of the European common market practices of the free movement of goods and people, the consequences of BSE rippled out from the UK across Europe. And, with food chains becoming ever-more globalized, these ripples even moved beyond European borders to far

[184] Original text: "… le contenu de nos assiettes recèle un danger invisible…" (my translation). Roy. *Les Experts face au risque*. 11.
[185] Roy. *Les Experts face au risque*. 11.
[186] Roy. *Les Experts face au risque*. 11.
[187] Nigel Williams. Agricultural Biotech Faces Backlash in Europe. *Science*, Vol. 281, No. 5378 (Aug. 7, 1998), pp. 768-771. here 769.

corners of the globe. Calls for a European food authority were mounting. The need for what would become known as EFSA only became clearer with the dioxin contamination episode.

The links between GMOs and dioxin contamination

The dioxin contamination of Belgian chicken and eggs reinforced the fears and concerns that the first major wave of the mad cow crisis had stirred up. For one, the timing of the dioxin episode meant that public interest in food safety was high and it would continue to remain high into the next wave of the mad cow crisis. The reaction of the French to the dioxin contamination also showed their developing risk-averse position to food safety issues. Finally, this episode became a moment for French officials to question the EU's competency in its control over food safety. As with the mad cow crisis, dioxins became linked to the debate over GMOs within the larger context of food safety regulation.

France used the dioxin episode to push not only for the creation of a European food safety authority, but also to promote a ban on animal feed derived from bone-meal or other animal proteins. For example, on June 8, 1999, in a meeting of the European Commissioners for Health to discuss the dioxin contamination, Bernard Kouchner, France's then-Minister of Health, called for the creation of a European agency for food safety.[188] In an interview with *Le Monde* following the meeting, Kouchner highlighted the importance of public health concerns on the EU policy agenda. He framed the need to organize such a system to respond to those concerns at the EU-level: "In effect, the dioxin crisis is, before anything else, a European crisis, like mad cow was [before it] and like how the health consequences using genetically modified organisms might be tomorrow."[189] Member states needed to stop the "nationalism of [their] forks."[190]

[188] J.Y. Nau. "'Il nous faut interdire au plus vite les farines animales en Europe,' Bernard Kouchner, secrétaire d'Etat français à la santé et à l'action sociale." *Le Monde*. June 10, 1999.

[189] Original text: En effet la crise de la dioxine est, avant toute chose, une crise européenne, tout comme l'a été celle de la "vache folle" et comme le seront peut-être demain les conséquences sanitaires de l'utilisation des organismes

Kouchner continued by stating that the EU needed to ban immediately the use of animal products in animal feed.[191]

Conclusion

Despite these calls for an EU regulatory agency and a more cohesive approach to food safety at the European-level, France did not follow suit with the EU's decisions in the following months regarding the decision to lift the embargo on British beef. A front page article from *Le Monde* from August 5, 1999, sums up French sentiment regarding the decision:

> Just a few days after being threatened by the wrath of the Belgian government, which is guilty of not having warned of or managed the dioxin contamination scandal affecting various animals and food products, the European Commission demonstrates the paradoxical limitations of its competence in the area of food safety [by lifting the ban on British beef]…[192]

Better and more comprehensive EU regulation of food safety and public health concerns was recognized at both the EU-level and the member state-level as essential, but the French government did not perceive the recommendations being made by the EU on British beef as reaching the more precautionary standards that France would go on to set for itself. The timing of the disagreement over removing the embargo on British beef, which was happening while the dioxin scandal was still playing out, in addition to the growing mad cow crisis, increased French calls for the reform of EU food safety policies.

Besides the increased calls for the creation of food safety agencies, these crises also demonstrated the need to develop regulatory responses at the European-level. While the HIV-tainted blood scandal was distinctly French with significant domestic repercussions, the wave of

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génétiquement modifiés." (my translation). Nau. "'Il nous faut interdire au plus vite les farines animales en Europe.'" June 10, 1999.

[190] Nau. "'Il nous faut interdire au plus vite les farines animales en Europe.'" June 10, 1999.

[191] Nau. "'Il nous faut interdire au plus vite les farines animales en Europe.'" June 10, 1999.

[192] Original text: Quelques jours seulement après avoir menacé de ses foudres le gouvernement belge, coupable de ne pas avoir su prévenir et gérer l'affaire… des diverses intoxications animales et alimentaires par les dioxines, la Commission européenne montre paradoxalement les limites de son action dans le champ de la prévention sanitaire… (my translation). J.Y. Nau. "'Vache folle': incohérences bruxelloises." *Le Monde*. August 5, 1999.

"European" crises hit close to home as well because of the EU common market and the free circulation of goods and people. Infected beef and contaminated eggs and chicken moved easily between European countries until the embargoes were put in place. It became clear that the regulatory provisions in place during the 1990s were not sufficient to deal with increased integration in the common market. As Bonny notes, these concerns translated into the debates on how to regulate GMOs:

> The regulatory regime of the 1990s eventually collapsed in the wake of a series of health scandals and scares in Europe. These were not directly related to the [genetically engineered organisms] issue but dramatically affected public trust in policymakers, legislative frameworks, and regulatory institutions on both national and EU levels, and highlighted persisting problems in dealing with scientific evidence and uncertainty in risk assessment.[193]

The result of weakened public trust in policymakers, legislative frameworks, and regulatory institutions meant the current regulatory regime was created with "more emphasis on precaution, transparency, labeling, and stakeholder participation as well as on clear-cut separation of science and policy in risk-assessment procedures."[194]

Within France, the media played a significant role in the linkage of the issue of GMOs to the food safety failures. Bonny finds that the timing of the arrival of GMOs on the public policy agenda was also important for how the issue was perceived by the French public and how it led to the promotion of the precautionary principle when dealing with perceived risks:

> …GMOs surfaced in force at about the same time as the public's confidence in institutions and certain technological advances had been shaken by several safety affairs, in particular the issues of contaminated blood, mad cow disease, asbestos, etc… These events led to definite distrust of firms and public authorities and

[193] Armin Spök. "Biotechnology Policy in the European Union." In: *Genetically Engineered Crops. Interim Policies, Uncertain Legislation.* Iain E.P. Taylor (ed.). New York: Haworth Food and Agricultural Products Press, 2007. p. 229-263. here p.231.

[194] Armin Spök. "Biotechnology Policy in the European Union." In: *Genetically Engineered Crops. Interim Policies, Uncertain Legislation.* Iain E.P. Taylor (ed.). New York: Haworth Food and Agricultural Products Press, 2007. p. 229-263. here p.231. The development of the EU regulatory regime will be discussed in more detail in the following chapter.

> increased the public's attention to critical voices, and so the principle of precaution become an omnipresent reference.[195]

The cumulative effects of the crises laid the foundation for the GMO debate between the EU institutions and the member states to become a *dialogue des sourds*.

As a result of the crises, the European public did not trust either the EU authorities or their national governments to regulate GMOs appropriately. In response to declining public trust in the national government and to pressure for better health and food safety protections, the French government began to pursue strategies of abstinence (moratoriums for GMO approvals, refusing positive scientific assessments of GMOs, etc.) in order to avoid potential risks and potential blame. Domestically, that meant the institutionalization of public opinion and anti-GMO sentiment in the policymaking process. The evolution of the French regulatory framework left open the question of whether GMOs should even be produced. At the EU-level, however, public authorities began to develop a regulatory framework that implicitly accepted GMOs as inevitable. Accordingly, the EU's efforts have centered on assessing and managing GMO risks by setting stringent standards and monitoring procedures for all levels of the GMO production process. Thus, although both levels of governance are attempting to assess and manage the risks of GMOs, they are wrestling with different core concerns. The French are trying to determine if they should approve GMOs; the EU is trying to determine how they should approve GMOs.

[195] Sylvie Bonny. "Opposition to GMOs in France and Europe." In: Consumer Acceptance of Genetically Modified Foods, R.E. Evenson and V. Santaniello (eds.). Oxon, UK: CAB International Publishing, 2004. p.169-187. here p.174.

Chapter 3. European Union Food Safety Regulation

The public health and food safety scandals of the 1990s acted as critical catalysts in the regulation of food safety in the EU. As a consequence of growing public concerns about food safety, the EU quickly asserted more authority over regulating primary production and agro-food biotechnology. Not only did these crises push the EU to procure more authority in this policy domain, but the EU's responses to them also helped shift the perception of the EU from being that of a laggard to a leader of regulatory standards when compared to the US. At the same time as the EU regulatory framework for GMOs was evolving, national regulatory frameworks were also developing in each member state. And, although the EU's legislation in this policy area was meant to shape member state policies, the EU risk assessment process developed quite differently than that of France. The EU's risk assessment process remained rooted in scientific evaluation of potential public health, food safety, and environmental risks, while the French process was reformed to include social and economic factors as well. Thus, despite the EU's apparent authority over agricultural biotechnology regulation, the differences in the regulatory systems between the two levels and the subsequent refusals by several member states, including France, to accept GMO approvals made at the EU-level has led the European Commission to openly reconsider relinquishing competence in this issue area back to the individual member states.

In order to understand how the Commission has reached this point, it is necessary to understand the EU's policymaking processes and regulatory framework for agricultural biotechnology. Chapter 3 first provides an overview of the EU actors and policy types relevant to the issue area. Furthermore, EU policy does not develop in a vacuum; international agreements and trade relationships shape EU policy development. Thus, this chapter also examines the

development of the current European regulatory framework in contrast to the regulatory framework that has developed in the US, with particular attention paid to the role of EU actors in agricultural biotechnology regulation. Chapter 3 also examines the EU legislation that deals with agricultural biotechnology regulation. Finally, this chapter turns to the international agreements that act upon the EU as well. The analysis of the EU's policymaking processes, and of the external influences that shape them, helps to establish the inherent differences between the European and French regulatory frameworks for GMOs and to explain the deadlock that has resulted from those differences.

The European Policy Process

The policymaking process in the EU is extremely complex. The structures of the different institutions, their influence in policymaking, and the very rules of decisionmaking have been repeatedly modified in the decades since the founding treaties were signed. In addition, the policymaking process and the role of institutions vary across issue domains; the constellation of institutions involved in making monetary policy, for example, differs significantly from the institutions responsible for biotechnology policies. An exhaustive review of each EU institution, the policymaking processes, and the decisionmaking rules are beyond the scope of this work.[1] However, this section provides a brief overview of the EU's legal framework, which underlies the policy process for agricultural biotechnology. In addition, it reviews the central EU institutions and their role in decisionmaking.

[1] For a more detailed look at the EU's institutions, policymaking processes, and decisionmaking rules, please see: John Peterson and Elizabeth Bomberg. 1999. *Decision-making in the European Union.* New York: St. Martin's Press; John Peterson and Michael Shackleton, eds. 2002. *The Institutions of the European Union*. Oxford: Oxford University Press; Elizabeth Bomberg and Alexander Stubb, eds. 2004. *The European Union: How Does It Work?* Oxford: Oxford University Press; and Helen Wallace, Mark Pollack, and Alisdair Young, eds. 2010. *Policy-Making in the European Union*. Sixth edition. Oxford: Oxford University Press.

The legal framework

The roots of the European Union were planted in the early 1950s with the creation of the European Coal and Steel Community (ECSC) by Belgium, France, Germany, Italy, Luxembourg, and the Netherlands. Further cooperation between the founding states was codified in treaties in the late 1950s and the 1960s, such as the Treaties of Rome, which created the European Economic Community (EEC) and the European Atomic Energy Community (Euratom), and the Merger Treaty, which streamlined the Community's institutions. The European Union has continued to develop, amend, and/or replace its treaties, in order to "make the EU more efficient and transparent, to prepare for new member countries and to introduce new areas of cooperation – such as the single currency."[2] Treaties are the basis for the rule of law in the EU, as they are binding agreements between the member states. The treaties "set out EU objectives, rules for EU institutions, how decisions are made and the relationship between the EU and its member countries."[3] Thus, "every action taken by the EU is founded on treaties that have been approved voluntarily and democratically by all EU member countries."[4]

The Single European Act (SEA) came into force in 1987, and it was the first major revision to the Rome Treaties. Its main purpose was "to reform the [EU] institutions in preparation for Portugal and Spain's membership" and to "speed up decision-making in preparation for the [creation of the] single market."[5] The SEA had a significant impact on voting procedures in EU decisionmaking, as it expanded the use of qualified majority voting (QMV) in the Council of the European Union (known as the Council) to cover more policy domains, which

[2] European Union. "EU Treaties." *Decision-making in the European Union*. http://europa.eu/about-eu/basic-information/decision-making/treaties/index_en.htm (accessed April 2012).
[3] European Union. "EU Treaties." (accessed April 2012).
[4] European Union. "EU Treaties." (accessed April 2012).
[5] European Union. "EU Treaties." (accessed April 2012).

made it "harder for a single country to veto proposed legislation."[6] The SEA also created cooperation and assent procedures, which gave the European Parliament more influence. It was under this legal framework that the EU passed its first directive regarding GMOs, Directive 90/220/EEC (discussed in more detail below).

During the time period addressed by this study – 1990 to 2010 – the European Union ratified four treaties: the Treaty on the European Union, the Treaty of Amsterdam, the Treaty of Nice, and the Treaty of Lisbon (see Table 3.1 for an overview of these treaties). The Treaty on the European Union (TEU), also known as the Maastricht Treaty, came into force in November 1993. The TEU is primarily known for creating the European Monetary Union (EMU) and the common currency unit that would become known as the euro. Moreover, it introduced elements for a more politically-integrated union, including efforts to coordinate European citizenship and foreign affairs. The TEU made several major changes to the decisionmaking process, namely by introducing the co-decision procedure, which gave the European Parliament more of a voice in decisionmaking, and by creating new areas of cooperation among member state governments, such as in defense and justice and home affairs.[7] The co-decision procedure established that "the directly elected European Parliament has to approve EU legislation together with the Council (the governments of the [now] 27 EU countries),"[8] while the European Commission is responsible for drafting and implementing legislation.

[6] European Union. "EU Treaties." (accessed April 2012). Qualified majority voting, or QMV, replaced required unanimity in many policy domains. QMV is "the number of votes required in the Council for a decision to be adopted. More specifically, QMV is now the method required "when issues are being debated on the basis of Article 16 of the Treaty on European Union and Article 238 of the Treaty on the Functioning of the European Union." Since the SEA, "the scope of the voting procedure for unanimity has become more and more restricted." European Union. "Qualified Majority." *Glossary*. http://europa.eu/legislation_summaries/glossary/qualified_majority_en.htm (accessed May 2012).

[7] European Union. "EU Treaties." (accessed April 2012).

[8] European Union. "Decision-making in the European Union." *Basic Information*. http://europa.eu/about-eu/basic-information/decision-making/index_en.htm (accessed April 2012).

The co-decision procedure was extended and made more effective by the Treaty of Amsterdam in 1999, and was eventually renamed the "ordinary legislative procedure" when it became the main legislative procedure of the EU's decisionmaking system with the Treaty of Lisbon in 2009. The adoption of the co-decision procedure gave the European Parliament, representing the EU's citizens, "the power to adopt instruments jointly with the Council of the European Union."[9] This change meant that the Parliament became "a co-legislator, on an equal footing with the Council, except in the cases provided for in the Treaties where the procedures regarding consultation and approval apply."[10] In addition, the purpose of the Treaty of Amsterdam was to reform the EU institutions, again in preparation for the entry of new member states into the EU. This included efforts to make decisionmaking more transparent, in part by increasing the use of the co-decision voting procedure.

Similar efforts – reforms to pave the way for new member states and changes to the co-decision procedure – were the main purpose behind the Treaty of Nice, which was signed in 2001 and entered into force in 2003. This treaty introduced a new qualified majority system that redefined the voting system in the Council, and it included a "demographic verification" clause. These changes meant that the "number of votes allocated to each Member State was re-weighted, in particular for those States with larger populations, so that the legitimacy of the Council's decisions can be safeguarded in terms of their demographic representativeness."[11] The Treaty of Nice also included new methods for changing the composition of the Commission.

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[9] European Union. "Codecision procedure." *Glossary*. http://europa.eu/legislation_summaries/glossary/codecision_procedure_en.htm (accessed May 2012).

[10] European Union. "Codecision procedure." (accessed May 2012).

[11] European Union. "Qualified Majority." (accessed May 2012). These safeguards include an increase in the qualified majority threshold to 255 votes out of a total of 345, following the 2007 enlargement, in order to represent a majority of the member states. In addition, "a Member State may request verification that the QM represents at least 62% of the total population of the Union. If this is not the case, the decision is not adopted."

In addition to adopting the co-decision procedure as the "ordinary legislative procedure" when it entered into force in 2009, the Treaty of Lisbon was intended "to make the EU more democratic, more efficient and better able to address global problems, such as climate change, with one voice."[12] To do so, the Treaty gave more power to the European Parliament and changed the voting procedures in the Council. It also created a citizens' initiative, a permanent president of the European Council, a new High Representative for Foreign Affairs, and a new EU diplomatic service.[13]

Furthermore, the Lisbon Treaty clarified the principle of subsidiarity by outlining which powers belong to the EU, which ones belong to EU member countries, and which ones are shared. Subsidiarity, originally defined in the TEU,

> ensures that decisions are taken as closely as possible to the citizen and that constant checks are made to verify that action at Union level is justified in light of the possibilities available at national, regional or local level. Specifically, it is the principle whereby the Union does not take action (except in the areas that fall within its exclusive competence), unless it is more effective than action taken at national, regional or local level. It is closely bound up with the principle of proportionality, which requires that any action by the Union should not go beyond what is necessary to achieve the objectives of the Treaties.[14]

The Treaty of Lisbon requires that the principle of subsidiarity be respected in all draft legislative acts, and it "allows national parliaments to object to a proposal on the grounds that it breaches the principle, as a result of which the proposal may be maintained, amended or withdrawn by the Commission, or blocked by the European Parliament or the Council."[15] These changes place more power in the hands of the European Parliament, as well as provide a method through which member states can challenge the EU's authority in certain policy domains.

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[12] European Union. "EU Treaties." (accessed April 2012).
[13] European Union. "EU Treaties." (accessed April 2012).
[14] European Union. "Subsidiarity." *Glossary*. http://europa.eu/legislation_summaries/glossary/subsidiarity_en.htm (accessed May 2012).
[15] European Union. "Subsidiarity." (accessed May 2012).

TABLE 3.1

Overview of EU Treaties (1990-2010)		
Treaty, Ratification Year	**Main Objectives**	**Impact on Institutional Functions**
Single European Act (SEA) Signed: 1986 Entered into force: 1987	• reform EU institutions in preparation for new members • reform EU institutions to speed up decisionmaking in preparation of the creation of the single market	• expanded the use of QMV in the Council to cover more policy domains • made it harder for an individual member state to veto proposed legislation • created new cooperation and assent procedures
Treaty on the European Union (TEU) Signed: 1992 Entered into force: 1993	• creation of the three pillar structure • creation of the European Monetary Union (EMU) and a common currency unit (euro) • coordination of European citizenship and foreign affairs	• introduced co-decision procedure for the EP and Council • expanded use of QMV in Council • formalized the European Council as an EU institution • defines subsidiarity
Treaty of Amsterdam (ToA) Signed: 1997 Entered into force: 1999	• reform EU institutions in preparation for new members • make EU decisionmaking more transparent	• extended co-decision procedure and made it more effective • EP becomes co-legislator with the Council
Treaty of Nice (ToN) Signed: 2001 Entered into force: 2003	• reform EU institutions in preparation for new members	• new methods for changing the composition of the Commission • new QMV system in Council • addition of demographic clause
Treaty of Lisbon (ToL) Signed: 2007 Entered into force: 2009	• make the EU more democratic, more efficient, and better able to address global problems • reorganization of treaties	• renamed co-decision procedure “ordinary legislative procedure” • gave more power to EP • changed the voting procedures in the Council • other institutional changes

EU institutions

The clarification of the subsidiarity principle is part of the EU's efforts to address critics who allege that there is a "democratic deficit" in EU governance.[16] The changes to voting procedures and the regular increases in power for the European Parliament have been a part of those efforts as well. The purpose of the ratification of new treaties and the amendments to older ones – from the SEA to the Lisbon Treaty – is ostensibly to ensure a more democratic, efficient, and effective Union. These changes to the legal framework also mean that the role and influence of the EU institutions have shifted during the time period being studied. Thus, in order to study the EU policymaking process, it is necessary to trace the shifts within these institutions (see Table 3.2 for a summary of the institutions).

The European Council is the institution that sets the agenda within the EU. The European Council began in 1974 as an informal forum for the heads of state or government of the EU member states.[17] Over time, it acquired a full-time president. It achieved formal institutional status in 1992, and under the Lisbon Treaty, the European Council became one of the EU's seven official institutions in 2009. Summit meetings occur at least twice a year, though on average the European Council meets four times annually. In addition to the European Council members and president, the Commission's president and the EU's High Representative for Foreign Affairs and Security Policy also attend meetings. In general, the European Council convenes to decide on "broad political priorities and major initiatives."[18]

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[16] The EU defines the democratic deficit as "the argument that the European Union and its various bodies suffer from a lack of democracy and seem inaccessible to the ordinary citizen because their method of operating is so complex." European Union. "Democratic deficit." *Glossary*. http://europa.eu/legislation_summaries/glossary/democratic_deficit_en.htm (accessed May 2012).

[17] European Union. "European Council." *EU institutions and bodies.* http://europa.eu/about-eu/institutions-bodies/european-council/index_en.htm (accessed May 2012).

[18] European Union. "European Council." (accessed May 2012).

The objectives of the European Council are twofold; it sets the EU's general political direction and priorities, and it deals with "complex or sensitive issues that cannot be resolved at a lower level of intergovernmental cooperation."[19] Although it is influential in that it sets the EU's political agenda, the European Council has no power to pass laws.[20] It is seen, however, as the arena for collective action in which the "big and more strategic questions" about the core tasks of the EU are debated, as well as the issues that "define" the EU's identity.[21] Despite its broad influence, the European Council has not played a significant role in the domain of agricultural biotechnology.

The main institutions responsible for EU legislation are the European Parliament (EP), the Council of the European Union (the Council),[22] and the European Commission. Through the ordinary legislative procedure, these institutions produce the policies and procedures of the EU.[23] In principle, the legislative powers are separated as such: "the Commission proposes new laws, and the Parliament and Council adopt them. The Commission and the member countries then implement them, and the Commission ensures that the laws are properly applied and implemented."[24] In this way, the Commission works as a type of collective executive, while the Parliament and the Council act, respectively, as the parliamentary chamber and a collective forum for member state representatives.[25]

Members of the European Parliament (MEPs) were elected directly for the first time in 1979, after years of being appointed from national parliaments. MEPs serve five year terms, and

[19] European Union. "European Council." (accessed May 2012).
[20] European Union. "European Council." (accessed May 2012).
[21] Helen Wallace. 2010. "An Institutional Anatomy and Five Policy Modes." in Wallace, Pollack, and Young, eds. 2010. *Policy-Making in the European Union*. Sixth edition. Oxford: Oxford University Press: 69-104. Here p.82.
[22] The Council of the European Union is not to be confused with the European Council. They are different bodies with distinct and separate members and objectives.
[23] European Union. "EU institutions and bodies." *How the EU works.* http://europa.eu/about-eu/institutions-bodies/index_en.htm (accessed May 2012).
[24] European Union. "EU institutions and bodies." (accessed May 2012).
[25] Wallace. 2010. "An Institutional Anatomy and Five Policy Modes." p.70.

the Treaty of Lisbon sets their number at 754 members. Representation for each member state is proportionally based on state population. Rather than being grouped by member state, MEPs organize themselves by party affiliation. Among these party groupings, the European People's Party, a center-right grouping, and the European Socialists, a center-left grouping, are "by far the largest and most important."[26] Other groupings include "coalitions of liberal, Green, far-right, far-left, and 'Euro-sceptical' or nationalist MEPs."[27] Party affiliation has become more important over time, as MEPs are more likely now to vote along party lines rather than by national ties.[28]

As mentioned, the European Parliament has gained more power and influence in the policymaking process through treaties and treaty revisions. Furthermore, "[t]he net result of [the successive treaty reforms] is that the EP is a force to be reckoned with across a wide range of policy domains."[29] This power is evident in the domain of agricultural biotechnology, and it results in the Parliament becoming a target of outside institutions that seek to influence legislation.[30] The European Parliament has played a significant role in agricultural biotechnology regulation, in particular vis-à-vis the role of the Commission.

The European Parliament is responsible for scrutinizing EU institutions, especially the Commission, to make sure they are working democratically. In addition, the EP works closely with the Council in its other main roles: debating and passing European laws and debating and adopting the EU's budget.[31] The Council is comprised of representatives from the governments of each member state. As Wallace notes, "[i]n principle and in law there is only one Council,

[26] Wallace. 2010. "An Institutional Anatomy and Five Policy Modes." p.82.
[27] Wallace. 2010. "An Institutional Anatomy and Five Policy Modes." p.82.
[28] Wallace. 2010. "An Institutional Anatomy and Five Policy Modes." p.82.
[29] Wallace. 2010. "An Institutional Anatomy and Five Policy Modes." p.84.
[30] Wallace. 2010. "An Institutional Anatomy and Five Policy Modes." p.84.
[31] European Union. "European Parliament." *EU institutions and bodies.* http://europa.eu/about-eu/institutions-bodies/european-parliament/index_en.htm (accessed May 2012).

empowered to take decisions on any topic, though its structures are more complex."[32] In reality, the Council is quite complex; it is made up of ministers from member state governments, but "which ministers attend meetings depends on the subjects being discussed."[33] As a result, the Council has developed specific formations around ministerial portfolios, such as on economic and financial affairs, transportation, environment, or agriculture. Altogether, the permanent representations contain approximately 1,500 national officials and an estimated 250 working groups.[34]

The Council is charged with several responsibilities. It must: pass EU laws; coordinate the broad economic policies of EU member countries; sign agreements between the EU and other countries; approve the annual EU budget; develop the EU's foreign and defense policies; and coordinate cooperation between courts and police forces of member states.[35] The Council mostly negotiates detailed proposals for EU action, and the majority of Council texts – about 70% – are agreed upon within its working groups.[36] The Council has played less of a role in policymaking in the area of agricultural biotechnology when compared to the Parliament and the Commission. However, its failure to attain qualified majority decisions for or against GMO approvals, in its Agriculture or Environmental formations, has had a significant impact on decisions made by the Commission.[37]

[32] Wallace. 2010. "An Institutional Anatomy and Five Policy Modes." p.75.
[33] Wallace. 2010. "An Institutional Anatomy and Five Policy Modes." p.75.
[34] Wallace. 2010. "An Institutional Anatomy and Five Policy Modes." p.77.
[35] European Union. "European Parliament." (accessed May 2012).
[36] Wallace. 2010. "An Institutional Anatomy and Five Policy Modes." p.78, 77.
[37] Mark A. Pollack and Gregory C. Shaffer. 2010. "Biotechnology Policy." In Wallace, Pollack, and Young, eds. *Policy-Making in the European Union*. Sixth edition. Oxford: Oxford University Press: 331-355. Here: 349. The Council's failure to take definitive action is discussed in more detail below, in the EU Regulation of Agricultural Biotechnology section.

The European Commission[38] is currently made up of twenty-seven Commissioners, one from each EU member state. The Commissioners serve five-year terms that coincide with the Parliament, and they act as the Commission's political leadership.[39] The President of the Commission assigns specific policy portfolios (Foreign Affairs, Transport, Industry, Environment, etc.) to each Commissioner. The European Council nominates the President of the Commission, and the nomination is subject to the approval of the European Parliament. The European Council also appoints the other Commissioners, in agreement with the nominated President and the member state governments. Although the Commissioners are chosen from the upper echelons of politicians and officials from the member states, they swear an oath of independence when they take office.[40] Once in office, the Commissioners and the President "remain accountable to Parliament, which has sole power to dismiss the Commission."[41] With this independence from the member states, the Commission represents the interests of the EU as a whole.

The Commission has specific responsibilities for overseeing and implementing EU policies: "proposing new laws to Parliament and the Council; managing the EU's budget and allocating funding; enforcing EU law (together with the Court of Justice); representing the EU internationally, for example, by negotiating agreements between the EU and other countries."[42] The Commission's staff, which is organized into Directorates-General (DGs), manages the day-

[38] The term "Commission" can be used to refer to the 27 individual Commissioners, the permanent staff or the institution as a whole.
[39] European Union. "European Commission." *EU institutions and bodies.* http://europa.eu/about-eu/institutions-bodies/european-commission/index_en.htm (accessed May 2012).
[40] Helen Wallace. "An Institutional Anatomy and Five Policy Modes." 71.
[41] European Union. "European Commission." (accessed May 2012). For example, the Parliament famously forced the resignation of the "Santer Commission" in 1999 under charges of financial mismanagement. Brigid Laffan and Johannes Lindner. 2010. "The Budget." In Wallace, Pollack, and Young, eds. *Policy-Making in the European Union*. Sixth edition. Oxford: Oxford University Press: 207-228. Here: 224-226.
[42] European Union. "European Commission." (accessed May 2012).

to-day operation of the Commission.[43] The DGs form the civil service of the EU and their staffs are recruited from the member states.[44] The Commission's powers vary across policy domains, and although each policy topic is assigned one DG as a *chef de file*, many policy areas require coordination among several DGs.[45] In the agricultural biotechnology policy domain, the DGs for the Environment (DG ENV), Health and Consumers (DG SANCO), Trade (DG Trade), Research and Innovation (DG Research), and Enterprise and Industry (DG Industry) have played a part in policymaking.

The Court of Justice of the European Union, also known as the European Court of Justice (ECJ), has played an important role in the enforcement process of agricultural biotechnology regulation through its rulings (discussed in more detail below). The ECJ is charged with interpreting "EU law to make sure it is applied in the same way in all EU countries."[46] In addition, it "settles legal disputes between EU governments and EU institutions," and individuals, companies, or organizations can bring cases before the ECJ if an EU institution has violated their rights. [47]

The ECJ includes one justice from each member state, and they, in turn, are helped by eight advocate-generals who present impartial opinions on the cases brought before the Court. The ECJ rules on different types of cases, though five types make up the majority of cases heard:

> 1. requests for a preliminary ruling (when national courts ask the ECJ to interpret a point of EU law);
> 2. actions for failure to fulfill an obligation (brought against EU governments for not applying EU law);
> 3. actions for annulment (against EU laws thought to violate the EU treaties or fundamental rights);

[43] European Union. "European Commission." (accessed May 2012).
[44] Helen Wallace. "An Institutional Anatomy and Five Policy Modes." 71.
[45] Helen Wallace. "An Institutional Anatomy and Five Policy Modes." 71.
[46] European Union. "Court of Justice of the European Union." *EU institutions and bodies.* http://europa.eu/about-eu/institutions-bodies/court-justice/index_en.htm (accessed May 2012).
[47] European Union. "Court of Justice of the European Union." (accessed May 2012).

4. actions for failure to act (against EU institutions for failing to make decisions required of them);
5. direct actions (brought by individuals, companies or organizations against EU decisions or actions).[48]

For example, the ECJ has taken actions against France for France's failure to fulfill obligations to agricultural biotechnology regulation. In these types of cases, the Commission or another member state can begin proceedings if "it believes that a member country is failing to fulfill its obligations under EU law."[49] The ECJ then investigates the allegations and passes judgment. Once the ECJ has ruled, and if the member state is found to be at fault, the member state is responsible for immediately rectifying its failure. If the ECJ later finds that the offending member state has not followed the ruling, the Court can issue a fine.[50]

The ECJ has established a number of important principles of European law in key cases, namely: "the supremacy of EC law over the law of the member states; the direct effect of EC law in national legal orders; a doctrine of proportionality, and another of non-discrimination on the basis of nationality among nationals of EU member states."[51] In this way, the ECJ not only plays an important role in EU policymaking, it has also had a significant role in the EU's efforts to force France to comply with EU biotechnology regulation.

[48] European Union. "Court of Justice of the European Union." (accessed May 2012).
[49] European Union. "Court of Justice of the European Union." (accessed May 2012).
[50] European Union. "Court of Justice of the European Union." (accessed May 2012).
[51] Helen Wallace. "An Institutional Anatomy and Five Policy Modes." 85.

TABLE 3.2

Summary of EU Institutions*		
Institution	**Main Purpose**	**Role in Biotech Policy**
European Council	• sets the EU's general political direction and priorities • deals with complex or sensitive issues that cannot be resolved at a lower level of intergovernmental cooperation.	Has not played a significant role.
European Parliament (EP)	• acts as parliamentary chamber • reviews democratic functions of other EU institutions • debates and adopts European laws and the EU's budget with the Council	Has played a significant role.
Council of the European Union (the Council)	• acts as a collective forum for member state representatives • coordinates broad economic policies of member states • signs agreements between the EU and other countries • develops the EU's foreign and defense policies • coordinates cooperation between courts and police forces of member states • debates and adopts European laws and the EU's budget with EP	Has played a role, in particular through its failure to attain qualified majority decisions for or against GMO approvals.
European Commission	• works as a type of collective executive • oversees and implements EU policies • proposes new laws to the EP and the Council • manages the EU's budget and allocates funding • enforces EU law together with the Court of Justice • represents the EU internationally	Has played a significant role, in particular through DG ENV, DG SANCO, DG Trade, DG Research, DG Industry.
Court of Justice of the European Union/European Court of Justice (ECJ)	• interprets EU law to make sure it is applied in the same way in all member states • settles legal disputes between EU governments and EU institutions • can hear cases brought by individuals, companies, or organizations	Has played a significant role.

* Not all EU institutions are summarized in this chart; only the ones reviewed in the text are included.

Legislative forms

With the treaties as their legal foundation, EU institutions can adopt legislation, which the member countries are then responsible for implementing.[52] EU laws, in the form of decisions, directives, and regulations, "take precedence over [the member states'] national law and are binding on national authorities."[53] This means that member states have ceded part of their sovereignty to the EU institutions that adopt laws. In addition to binding legislation, the EU also issues non-binding instruments, such as recommendations, opinions, and rules governing how EU institutions work.[54]

Decisions, directives, and regulations differ in the actions that must be taken by the governments of the member states and in their potential scope. As mentioned, the ECJ has played a role in the implementation process within member states in the issue area of agricultural biotechnology. The ECJ's judicial rulings are binding on the specific parties to the case. Decisions made by the Council or Commission are similarly binding. The European Commission defines such decisions as:

> EU laws relating to specific cases. They can come from [the Council] (sometimes jointly with the European Parliament) or the Commission. They can require authorities and individuals in Member States either do something or stop doing something, and can also confer rights on them. EU decisions are: addressed to specific parties (unlike regulations), fully binding. [55]

Directives may also be directed at specific member states. However, directives can be blanket legislative acts that all member states must adopt domestically. The European Commission defines directives in the following manner:

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[52] European Union. "EU Treaties." (accessed April 2012).
[53] European Commission. "What is EU Law?" *Application of EU Law*. http://ec.europa.eu/eu_law/introduction/treaty_en.htm (accessed April 2012).
[54] European Commission. "What is EU Law?" (accessed April 2012).
[55] European Commission. "What are EU decisions? *Application of EU law.* http://ec.europa.eu/eu_law/introduction/what_decision_en.htm (accessed April 2012).

> EU directives lay down certain end results that must be achieved in every Member State. National authorities have to adapt their laws to meet these goals, but are free to decide how to do so… Directives are used to bring different national laws into line with each other, and are particularly common in matters affecting the operation of the single market (e.g. product safety standards).[56]

As such, the EU provides a specific date by which member states are required to have transposed the "certain end results." This delineated time period gives "national authorities the room for manoeuvre," and it accounts for the differing systems and structures in each member state.[57]

Regulations differ from decisions and directives because they are immediately binding on all member states. This characteristic makes regulations the "most direct form of EU law."[58] In addition, the member state governments do not need to take specific actions to respond to regulations. Regulations can be passed either jointly by the Council and the Parliament, or by the Commission alone.[59] The regulatory mode became a more frequent mode of policymaking in the EU as the single European market developed and the EU pushed to remove barriers between its member states' economies.[60] Helen Wallace argues that the "strength of the European legal process, the machinery for promoting technical cooperation, and the distance from parliamentary interference were all factors that encouraged [the development of a regulatory mode of policymaking] further, namely by removing national barriers to the creation of the single market."[61] The regulatory mode has been the predominant policymaking method at the EU-level in the domain of agricultural biotechnology.

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[56] European Commission. "What are EU directives?" *Application of EU law.* http://ec.europa.eu/eu_law/introduction/what_directive_en.htm (accessed April 2012).
[57] European Commission. "What are EU directives?" (accessed April 2012).
[58] European Commission. "What are EU regulations?" *Application of EU law.* http://ec.europa.eu/eu_law/introduction/what_regulation_en.htm (accessed April 2012).
[59] European Commission. "What are EU regulations?" (accessed April 2012).
[60] Helen Wallace. "An Institutional Anatomy and Five Policy Modes." 95.
[61] Helen Wallace. "An Institutional Anatomy and Five Policy Modes." 95.

The Evolution of European and American Risk Management of Genetic Engineering

Although differences exist across the globe among the regulatory regimes that now handle the specific issue area of agricultural biotechnology,[62] there are a few broad features that can be used to characterize contemporary biotechnology regulation. For one, agricultural biotechnology regulation has been relatively permissive in comparison to other risk systems like that of medicine and healthcare.[63] In addition, regulatory systems, until recently, had been predicated on the assumption that biotechnological products should be individually assessed before being approved.[64] Beyond questions of safety and health, issues of biotechnology and its regulation frequently raise moral concerns. Finally, the development of each state's regulatory system continues to be shaped by what is occurring in the systems of other countries. External influences in system development also include obligations to the World Trade Organization (WTO), the Biosafety Protocol, and the United Nation's Codex Alimentarius.

American differences

Despite these broad similarities, the American biotechnology regulatory system is clearly different than that of its European counterparts. Darrell West attributes the *laissez-faire* regulatory approach that Americans have toward GMOs in the food supply to the strength of the agribusiness lobby and the American desire to export food to other countries.[65] In fact, in the US there is little regulation by the government of GM plants that enter food sources intended for human consumption, although the US does more closely regulate animal products.

Authority over the regulation of genetic engineering has shifted since the 1970s. The US Food and Drug Administration (FDA), which oversees food safety, adopted its first policy on

[62] Agricultural biotechnology is the direct descendant of the original recombinant DNA activities of the 1970s.
[63] Steven McGiffen, *Biotechnology: Corporate Power versus Public Interest* (London: Pluto Press, 2005): 1.
[64] McGiffen 1.
[65] Darrell West, *Biotechnology Policy Across National Boundaries: The Science-Industrial Complex* (New York: Palgrave Macmillan, 2007): 49.

biotechnology in 1986. Called the Coordinated Framework for Regulation of Biotechnology, it gave the FDA the authority over the regulation of recombinant DNA and bioengineered food products.[66] Under this framework, the FDA was granted powers to secure the food supply, which included the ability to remove products from the market if need be. It also established that bioengineered agriculture products would be held to the same safety standards as other food products.[67]

The FDA's power was further extended in 1992, when it broadened its authority to include regulation of "pre-market" products.[68] Moreover, during the approval process of the first few products, after its power had been expanded, the FDA developed its doctrine of "substantial equivalence" for GM food. This standard meant that if a modified product was genetically similar to a current "natural" crop, then the FDA would consider it a natural product; it could be "sold, marketed, and consumed without fear of negative impact on health or safety."[69] The FDA also did not require labeling of products to alert consumers to GM content.

These practices – the standard of "substantial equivalence" and a lack of labeling – contribute to the Americans' *laissez-faire* approach to agricultural biotechnology regulation. Additionally, West notes that the American public has shown very little awareness of GM food.[70] The Pew Initiative on Food and Biotechnology (PIFB) has carried out several major national opinion polls to determine American consumers' views on agricultural biotechnology, which show that the majority of Americans report having heard relatively little about GM foods.[71] Not

[66] West 52.
[67] West 52.
[68] The "pre-market" stage of food production refers to whole foods before they are processed and mixed with other components.
[69] West 53.
[70] West 55.
[71] W. Fink and M. Rodemeyer, "Genetically Modified Foods: US Public Opinion Research Polls," in *The Public, the Media, and Agricultural Biotechnology*, D. Brossard, J. Shanahan, and T.C. Nesbitt, eds. (Oxon, UK: CAB International, 2007): 126, 130.

only do surveys of Americans show that there is a general ignorance among them about GMOs in food sources, they also reveal that most Americans are highly unaware that they have almost definitely consumed such products.[72] In general, PIFB has concluded that the issue of GMOs in food is not a "top of mind" issue for most American consumers.[73]

Regulatory shifts

As Vogel points out, American environmental protection standards were viewed as more stringent than their European counterparts from the late 1960s through the mid-1980s. American regulatory responses to suspected human carcinogens, pesticides, Red Dye No. 2, and DDT were more stringent than those across the Atlantic. The US was also more restrictive on the regulation of chemicals, of vehicle emissions, and of chloro-fluorocarbons.[74] According to Vogel, the US did, in fact, embrace the precautionary principle in the 1960s and 1970s with stricter environmental impact assessments and a stricter approval process for prescription drugs.[75] Yet despite this strong record of stringent regulatory responses and high standards when compared to European states, the US did not maintain the same reputation, starting in the mid-1980s through the 1990s, in environmental regulation or in the areas of public health and food safety. A review of the changes in American and European regulatory approaches, which are often characterized as a trading of places, helps us to understand the different administrative bodies that are charged with regulating GMOs.[76]

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[72] West cites a survey by the Food Policy Institute at Rutgers University, from 2001, that shows that 58% of Americans thought they had never eaten a genetically modified product, while half were unaware genetically modified products were even sold in the US. He goes on further to state that experts estimate that 60% to 70% of American processed food includes genetically modified ingredients, making it extremely likely that most American have ingested GM products (56). This lack of awareness was further supported by a survey done by PIFB that showed that only 25% of respondents thought they had ingested GM foods (Fink and Rodemeyer, 136).

[73] Fink and Rodemeyer, 130.

[74] Vogel 558-560.

[75] Vogel 560-561. He also points out that the stricter approval process for prescription drugs was in part brought about as a reaction to the near-approval of thalidomide.

[76] Vogel 558.

Cracks in the American reputation for stringency appeared because the US did not maintain its pace in creating a high number of new regulations;[77] meanwhile, European regulators were churning out more stringent standards, particularly in the area of food safety. This was due, in part, to the European public health and food safety scares of the 1990s. This burst of European regulatory action contributed to the perception that the US was lagging, while the EU was becoming the leader. Vogel points out that the roots of this European shift toward stringency can be found in the mid-1980s. In 1985, the EU banned growth hormones for beef, and a moratorium on the use of hormones in milk production soon followed.[78] Regulatory responses to mad cow disease also illustrate the changing positions of the US and the EU, with the US lagging in response time to addressing the crisis, as compared to the UK and to Europe as a whole. Thus, this time period marks a definitive transition to a more stringent approach for the EU. Yet, Vogel also notes that Europe's new regulatory stringency focused on new food technologies, rather than on the risks of traditional foods (like raw milk cheeses), which Europeans have embraced.[79] This example highlights the difference in American and European perceptions of the risks of new food technologies.

Hommel and Valceschini delve further into understanding these differences in perception.[80] They argue that tension will exist between the US and the EU in the issue area of agricultural biotechnology as long as the EU continues to characterize GMOs as "novel foods" (new foods that could affect public health and have an impact on the environment). Americans

[77] It is important to note that, as Vogel states, the US did not repeal any of the stringent regulations it had in place, nor did it suffer the same major regulatory failures that struck in Europe in the 1990s (577-578). From Vogel's point of view, however, the regulatory failures in Europe of the 1980s and 1990s had been "broader and deeper," leading to an "increase in the public's sense of vulnerability to and anxiety about the risks associated with modern society and this in turn has affected the political context in which regulatory policies have been made" (571).
[78] Vogel 562.
[79] Vogel 562.
[80] Thierry Hommel and Egizio Valceschini, "La Construction incomplète du marché européen des OGM. Une comparaison des cadres institutionnels européen et américain à partir de la théorie des droits de propriété," *Oléagineux, Corps Gras, Lipides* (14.2 Mars-Avril 2007): 77.

regard GMOs as "products" that already fit into their existing regulatory frameworks; by contrast, "novel foods" would require new regulations and standards.[81] This primary difference in perception leads to different risk assessment processes on each side of the Atlantic. In the US, GMOs are assessed based on their genetic properties as compared to existing plants and the concept of substantial equivalence. If the chemical makeup of a tomato and the genetic material being added to it, for example, were not separately deemed risky, then an American regulator will determine the modified tomato to be safe without additional testing.[82] European regulators do not consider this comparative, chemical analysis to an existing plant to be sufficiently complete, though they may include such an assessment in a broader range of testing.

In the EU, the regulatory approach to GMOs is two-pronged, through what is deemed "horizontal" and "vertical" legislation, and it includes policies in the form of both directives and regulations. "Horizontal" legislation is composed of EU directives that treat all biotechnology as a domain in which environmental protections and public health and safety need to be considered[83] (see Diagram 3.1). "Horizontal" legislation regulates GMOs in general, and is not limited to specific product categories (like pharmaceuticals, agriculture, industrial, etc.).[84] "Vertical" legislation, by comparison, is made up of directives and regulations that target the specific categories of GMOs and GM products[85] (see Diagram 3.2). Thus, GMOs and GM products covered by "vertical" legislation must meet the regulatory standards of their particular sectors, in both development and production.[86] In this way, GM crops and products were placed in different policy domains by the US and the EU, and this differential placement continues to

[81] Hommel and Valceschini 76-77.
[82] Hommel and Valceschini 76-77.
[83] Hommel and Valceschini 77.
[84] Sebastiaan Princen, *EU Regulation and Transatlantic Trade* (The Hague: Kluwer Law International, 2002): 211.
[85] Princen 211.
[86] Hommel and Valceschini 77.

shape the regulatory responses to them. Existing American regulatory bodies were charged with overseeing new versions of an old product, while in Europe, new institutions were developed to deal with these "novel" crops and foods.

DIAGRAM 3.1. Horizontal EU Agricultural Biotechnology Legislation

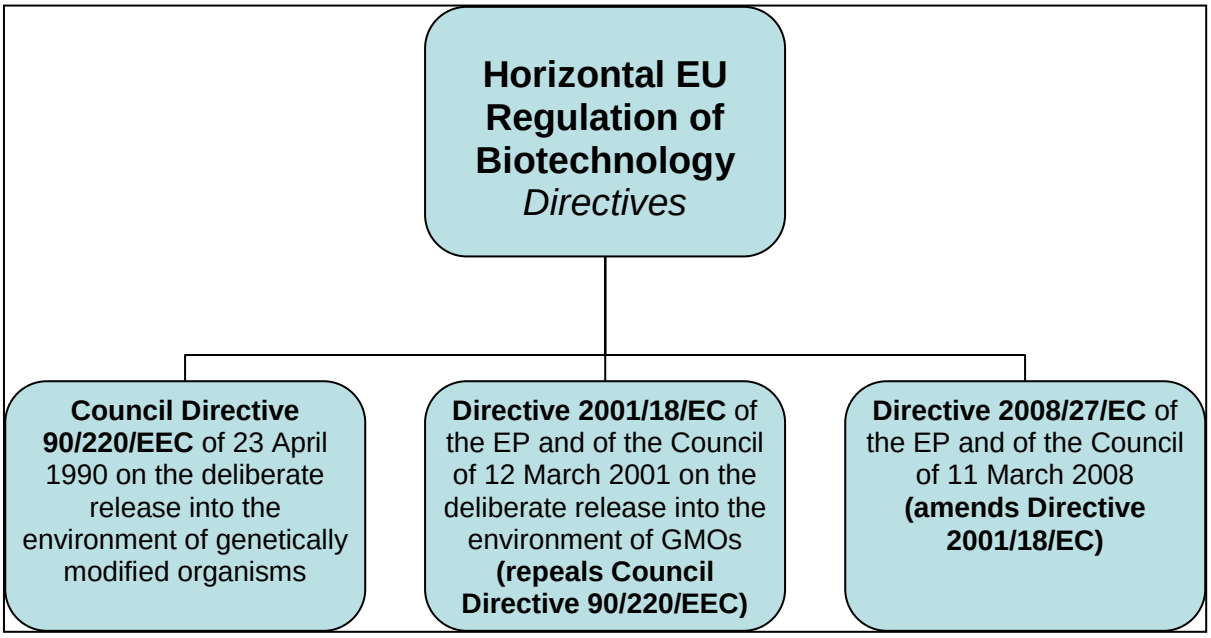
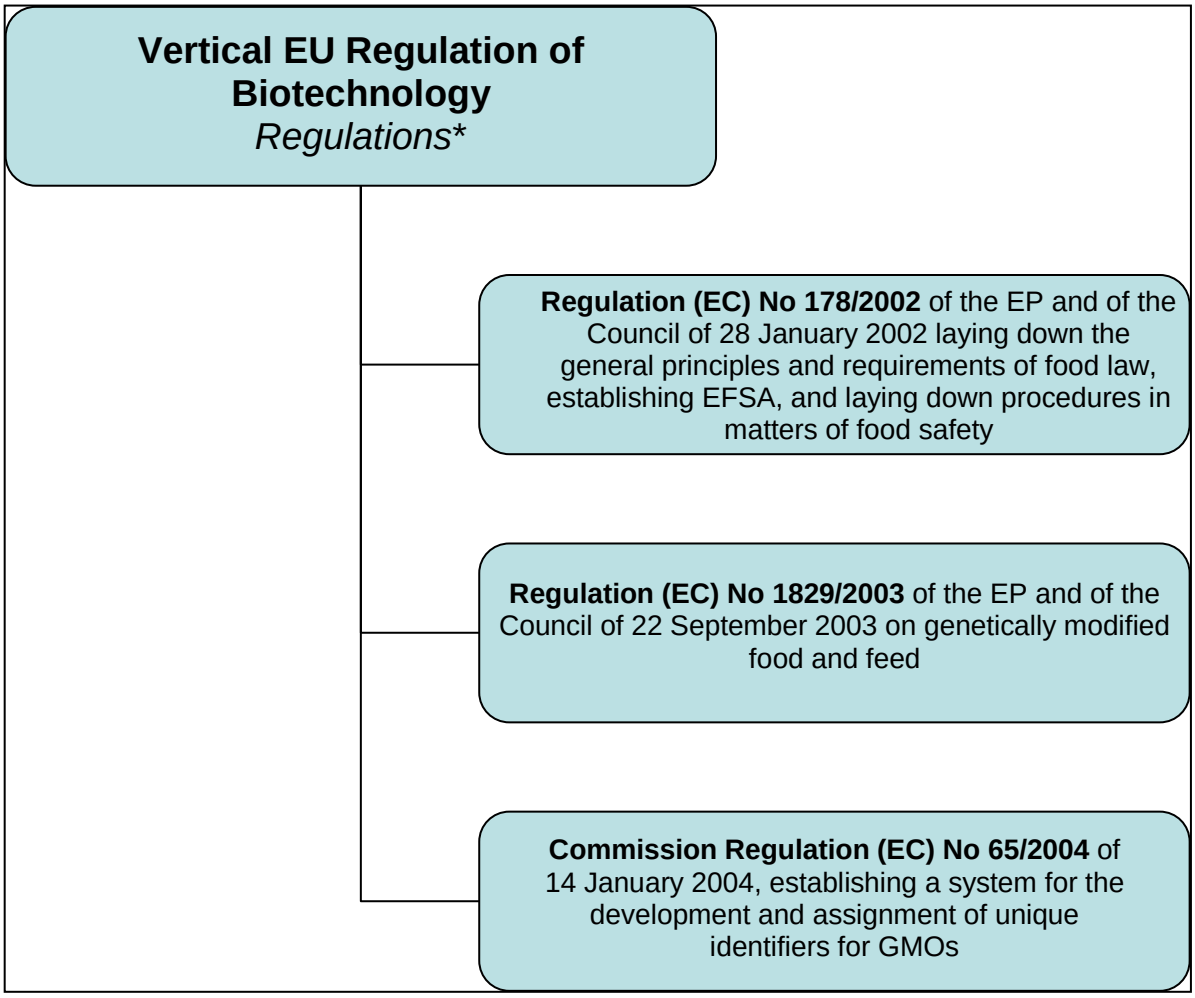


DIAGRAM 3.2. Vertical EU Agricultural Biotechnology Legislation



* Diagram 3.2 provides includes only three examples of EU regulations for agricultural biotechnology. For a complete list, see the Appendix of EU Legislation & Related Documents.

EU Regulation of Agricultural Biotechnology

As a whole, European states have been much more cautious in their risk assessment and management of genetically engineered agricultural products. The EU has come to rely on the precautionary principle to frame its approach to the regulation of genetic engineering. The precautionary principle can be plainly defined as "the assumption that experimentation should only proceed when there is a guarantee that the outcome will not be harmful."[87] This standard is also upheld in regards to allowing GM components into food products (see Table 3.3 for an overview of current EU legislation governing GMOs and GM products). The EU has addressed this issue more directly with its Regulation on Novel Foods and Novel Food Ingredients, issued in 1997. The EU Directive on Deliberate Release of Genetically Modified Organisms, replacing the original Council Directive from 1990 (90/220/EEC), was passed four years later. In addition, six European states within the EU have issued bans on GMOs by invoking the safeguard clause: Austria, France, Germany, Greece, Hungary, and Luxembourg.[88]

Besides the early regulatory responses to laboratory procedures, which had lasting effects on the current regulatory frameworks, external influences have played a significant part in the development of Europe's regulatory system. Because of more stringent European regulations, particularly in regards to the labeling requirements and a ban on the importation of GMOs from 1998 to 2004, American agricultural biotech products have been refused entry into the EU marketplace. As a consequence, American leaders filed a complaint with the WTO in 2003, accusing Europe of "illegally restricting imports."[89] The US was successful in its petition, and the

[87] Tony Gilland, "Trade War or Culture War? The GM Debate in Britain and the European Union," in *Let Them Eat Precaution*, Jon Entine, ed. (Washington, DC: The AEI Press, 2006): 57. See Chapter 1 for a more detailed review of the precautionary principle.
[88] DG Health and Consumers. "Rules on GMOs in the EU - Ban on GMOs cultivation." *Food and Feed Safety.* http://ec.europa.eu/food/food/biotechnology/gmo_ban_cultivation_en.htm (accessed August 2012).
[89] West 57.

WTO ordered the European Commission to allow GM food into the EU. Still, most European states and the EU continue to require rigid labeling criteria, although there is some confusion over how to define "GM-free" food,[90] although some states continue to refuse to implement EU legislation. In addition to a seemingly more cautious approach at the political level, the general public in Europe has a much higher level of awareness, and of fear, of GM food products.[91]

But not every scholar paints the EU as a reluctant actor in the debate over the risk management of GM food. Steven McGiffen argues that certain EU authorities do not have a particularly negative view of the agricultural biotechnology industry, and instead European leaders are pushing for the EU to catch up in terms of research and development and trade opportunities.[92] And, when one examines Europe as individual states, variation in public opinion and in the regulatory systems created to handle GM products becomes evident. In his analysis, McGiffen takes care to separate out national policy choices from EU regulations. He points to the Barcelona Declaration of 2002, in which the European Council pushed the biotechnology industry as an important part to Europe's economic future, as evidence that the leadership of Europe will allow development in this issue area.[93]

However, the European Commission, which seems to favor relaxing regulation of genetic engineering and GM products, does not have exclusive competence over the broad issue area of biotechnology. Rather, different institutions within the EU or its member states may hold policymaking authority over issues of biotechnology, depending on the industrial sector involved and on the principle of subsidiarity.[94] The overlapping and sometimes conflicting regulations in

[90] West 57-58.
[91] West 60.
[92] McGiffen 6.
[93] McGiffen 6-7.
[94] McGiffen 7.

this area of shared competence (where both the member states and the EU have policymaking powers) create challenges for both horizontal and vertical regulatory measures.

TABLE 3.3

Current EU legislation governing GMOs and GM products*	
Applicable EU legislation	**Step-by-step activities in the production process**
Contained Use Directive 90/219 Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms.	GMO research in laboratories
Directive 2001/18/EC Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.	GMO experimental releases (field trials)
Regulation 1829/2003 & Directive 98/95/EC Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed; Council Directive 98/95/EC of 14 December 1998 (amended earlier Directives on GM seeds).	GMO environmental releases for crops
Regulation 1829/2003 & Directive 98/95/EC	Authorization of marketing of GM seeds (for environmental releases of crops)
Regulation 1829/2003	Authorization of marketing of GM food and feed
Regulation 1829/2003	Labeling of GM seed, food, and feed
Regulation 1830/2003 Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.	Traceability and labeling of GM products

* This table has been adapted from: Mark A. Pollack and Gregory C. Shaffer. 2010. "Biotechnology Policy." In Wallace, Pollack, and Young, eds. *Policy-Making in the European Union*. Sixth edition. Oxford: Oxford University Press: 344. The table does not include all EU legislation on agricultural biotechnology. For a complete list of all EU legislation in this domain, see the Appendix of EU Legislation & Related Documents.

The EU regulatory framework for agricultural biotechnology

For GMO policy, the EU has become the "locus of legislative activity" for its member states, though some have adopted additional, national regulations.[95] Moreover this EU legislative activity is all regulatory for GMOs and GM products. In particular in this issue area, the EU has created the Directive 2001/18/EC on the Deliberate Release into the Environment of Genetically Modified Organisms (which replaced Directive 90/220/EEC, the original legal basis of EU regulation) and its related legislation: Directive 2008/27/EC (an amendment to Directive 2001/18/EC), Regulation (EC) No 1830/2003 (on labeling and traceability of GMOs), and Commission Regulations (EC) No 641/2004 and No 1981/2006 (rules for implementation). The main aim of Directive 2001/18/EC was:

> to make the procedure for granting consent for the deliberate release and placing on the market of genetically modified organisms (GMOs) more efficient and more transparent, to limit such consent to a period ten years (renewable) and to introduce compulsory monitoring after GMOs have been placed on the market.[96]

The subsequent regulations on GMOs, such as Regulation (EC) No 1830/2003, were intended to clarify the requirements laid out in Directive 2001/18/EC for the traceability and labeling of GMOs and products derived from GM crops. The EU added additional layers of detailed rules for implementation of oversight and authorization procedures and GMO traceability with Commission Regulations (EC) No 641/2004 and No 1981/2006. The objective of these later regulations was to harmonize the differing implementation measures that were being taken in the member states, by spelling out more specifically the standards and rules that the states were to follow.

[95] Prakesh and Kollman, "Biopolitics in the EU and the US," p.622.
[96] European Commission, "Summaries of Legislation: Deliberate Release of Genetically Modified Organisms (GMOs)," http://europa.eu/legislation_summaries/agriculture/food/l28130_en.htm (accessed Dec 2010).

Although the EU has become the locus of legislative activity in this policy domain, it also has provided a "safeguard clause" from which the individual member states retain some power. Originally included in Directive 90/220/EEC, and preserved in its replacement Directive (2001/18/EC), the safeguard clause allows member states to "provisionally restrict or prohibit the use and/or sale of that product on its territory" if they have "justifiable reasons to consider that a GMO, which has received written consent for placing on the market, constitutes a risk to human health or the environment."[97] The clause is seen by anti-GM proponents as a way to safeguard the sovereignty of the member states to make decisions regarding concerns about the environment, public health, and food safety. It is also the main instrument that a state can use to protect its right to regulate in those domains as the national government sees fit.

The safeguard clause has been invoked on nine separate occasions, including twice by France: in 1996 with Ms1xRf1 oilseed rape (a crop frequently used in the production canola oil), and in 2008 with MON 810 maize.[98] Moreover, six states total have invoked the clause (France, Austria, Germany, Greece, Luxembourg, and the UK), which has contributed to the gridlock in the GMO approval process. By 1998, six member states (including France) were pushing the EU to impose a moratorium on approvals of GM products. These states argued that a moratorium should be in place until a new and more stringent system of regulation was developed.[99] By voting to block all new GMO approvals in the Council, "these countries were able to prevent any new GM varieties from being authorized for sale between 1998 and 2004; the only exceptions

[97] Directorate General for Health and Consumers, "GMOs in a nutshell," *Food Safety – From the Farm to the Fork*, http://ec.europa.eu/food/food/biotechnology/qanda/d1_en.htm#d (accessed July 2011).
[98] Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to genetically modified crops (Bt176 maize, MON810 maize, T25 maize, Topas 19/2 oilseed rape and Ms1xRf1 oilseed rape) subject to safeguard clauses invoked according to Article 16 of Directive 90/220/EEC, *The EFSA Journal* 338 (2006), p.1-15; "Maize MON 810: France triggers safeguard clause," *GMO Compass* (13 Jan 2008), http://www.gmo-compass.org/eng/news/319.maize_mon_810_france_triggers_safeguard_clause.html (accessed August 2011).
[99] David Vogel. 2012. *The Politics of Precaution. Regulating Health, Safety, and Environmental Risks in Europe and the United States*. Princeton: Princeton University Press. p.78.

were foods judged 'substantially equivalent' to those produced by conventional seeds."[100] The moratorium remained in place until 2004, after the EU adopted new regulations on GMO marketability, traceability, labeling, and approval standards.

The policymaking process in agricultural biotechnology

Nonetheless, despite the safeguard clause, the Single European Act in 1987 more firmly established support for the EU as the main regulatory body in terms of institutional authority over agricultural biotechnology, due to changes in voting procedures.[101] The inclusion of the precautionary principle in the TEU and the later call upon the Council and the Parliament in the Treaty of Amsterdam to "achieve high levels of health, safety, environmental and consumer protection" further bolster the EU's claim to authority.[102] To initiate legislation, the Commission's Environment Directorate-General (DG ENV) had control over proposing environmental policies in the EU, a category under which issues of biotechnology frequently fall, until July 2010. However, DG ENV was perceived as not being particularly cooperative in efforts to unblock the approval process for GMO crops.[103] Thus, as part of his attempts to overcome the impasse between pro- and anti-GM member states, Commission President Barroso shifted control to DG SANCO. Anti-GM groups (such as Greenpeace) criticized this decision, arguing that this shift in control was only to circumvent ethical or socio-economic challenges to approvals.[104]

After an initial policy proposal from a DG, legislation must pass through the convoluted EU system with the adoption process involving "the Council, the European Parliament, and the

[100] Vogel. *The Politics of Precaution.* 78.
[101] Vogel, "Hare and the Tortoise Revisited," p.573. These changes included the introduction of the cooperation procedure, which gave the European Parliament more power to adopt legislation through qualified majority voting, in collaboration with the Council. The SEA Act also expanded the number of areas in which qualified majority voting could be used.
[102] Vogel, "Hare and the Tortoise Revisited," p.573.
[103] Prakesh and Kollman, "Biopolitics in the EU and the US," p.622.
[104] Cahill, "Cultivating."

Commission, and that varies according to the type of policy being debated."[105] Despite the centrality of the Commission in the policy adoption process, the Council has remained a powerful actor.[106] In addition, Prakesh, Kollman, and Vogel agree that earlier treaty changes to the co-decision procedure gave more power to the European Parliament, which in turn enabled it to pressure the Council to adopt more stringent measures for GMO regulation.[107] Yet while DG ENV was the key actor in proposing legislation through the Commission, it also had to contend with other interested DGs (such as the Trade, Agriculture, and Enterprise DGs) and it frequently fielded criticism from DG SANCO and the DG for Research and Innovation.[108] Thus, several DGs, in addition to the Parliament and Council, have had input into and influence over the creation of GM regulatory measures.

The GMO approval process

For approvals of specific GMOs, the process begins in the Commission, which acts as the chair of the Standing Committee on the Food Chain and Animal Health (see Diagram 3.3 for a flowchart of the approval process). The Commission drafts an "opinion" on an authorization proposal for a particular GMO and then presents that draft to a committee of member state representatives.[109] A QMV of the committee members in favor of the draft is needed in order to allow the Commission to adopt it and to require the member states to implement it.[110] If the committee chooses to reject the proposal, the Commission must then submit it to the Council,

[105] Prakesh and Kollman, "Biopolitics in the EU and the US," p.622.
[106] Prakesh and Kollman, "Biopolitics in the EU and the US," p.622.
[107] Prakesh and Kollman, "Biopolitics in the EU and the US," p.623; Vogel, "Hare and the Tortoise Revisited," p.574.
[108] Prakesh and Kollman, "Biopolitics in the EU and the US," p.623. One can expect that DG SANCO will also be subject to criticism from competing DGs in its new capacity.
[109] Grace Skogstad, "Contested Accountability Claims and GMO Regulation in the European Union," *Journal of Common Market Studies* vol. 49, no. 4 (2011), pp.904-905.
[110] Skogstad, "Contested Accountability Claims," p.905.

who may also stop the progress of the proposal with a QMV against it.[111] However, if the member state committee fails to decisively agree on the draft (either to adopt or reject it with a QMV) in the stipulated three-month period, the Commission, acting as the College of Commissioners, must approve it.[112] This outcome – a lack of decisive action resulting in compulsory approval – creates the basis for contestation over authority in the domain of agricultural biotechnology.

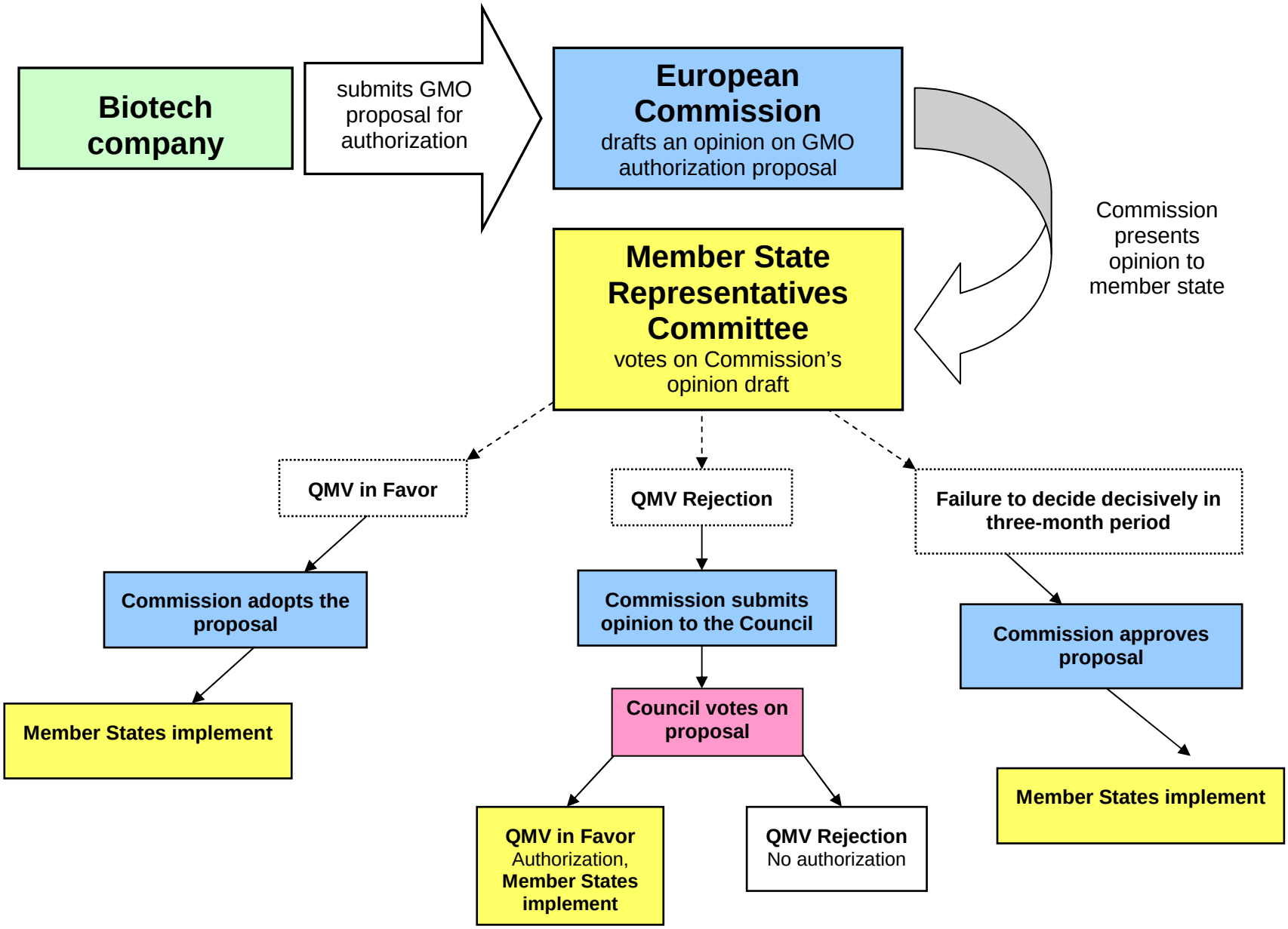
As Grace Skogstad notes: "Since 2004, although more than a dozen GMOs have been authorized for import into the EU for use as *animal feed and/or processing*, none was approved by a QMV of Member States."[113] Member states have been reluctant within the regulatory committee "to impose a decision to authorize the cultivation of a GM crop on recalcitrant fellow national governments and to require Member States to lift safeguard bans that prohibit EU-approved GMOs in their country."[114] A minority of member states has consistently blocked a favorable GMO approval at the committee level, and divisions within the Council have also resulted in an inability to gather the QMV to decisively reject or support the Commission's proposals.[115] Thus, all approvals have been the result of the College of Commissioners *de facto* adoption of the Commission's proposals.

This process has undermined the legitimacy of the EU's authority, as decisions are moving forward without a consensus among the member state representatives. Bentham asserts that "those who regulate and govern the behaviour of others do so conditional on the latter's acceptance of their right to do so."[116] Yet, because this process disregards that lack of consensus,

[111] Skogstad, "Contested Accountability Claims," p.905.
[112] Skogstad, "Contested Accountability Claims," p.905.
[113] Skogstad, "Contested Accountability Claims," p.905.Italics in original.
[114] Skogstad, "Contested Accountability Claims," p.906.
[115] Skogstad, "Contested Accountability Claims," p.905.
[116] D. Bentham, *The Legitimation of Power* (1991), as referenced in Skogstad, "Contested Accountability Claims," p.897.

there are few incentives for member states, especially those in which GMOs are a source of political contestation, to support EU regulation. Instead, there is plenty to attack in terms of the EU's legitimacy.[117] Consequently, EU member states are challenging the EU's right to regulate agricultural biotechnology by refusing to implement EU legislation, which rescinds their acceptance of the EU's right to competence in this domain.

[117] Skogstad, "Contested Accountability Claims," p.908.


Biotech company
submits GMO proposal for authorization
European Commission
drafts an opinion on GMO authorization proposal
Commission presents opinion to member state
Member State Representatives Committee
votes on Commission's opinion draft
QMV in Favor
QMV Rejection
Failure to decide decisively in three-month period
Commission adopts the proposal
Commission submits opinion to the Council
Commission approves proposal
Member States implement
Council votes on proposal
Member States implement
QMV in Favor
Authorization,
Member States implement
QMV Rejection
No authorization

The European Food Safety Authority

In August 2001, the EU member states agreed to create a European-wide authority to oversee food standards.[118] Through changes to its regulatory regime, the EU hoped to attain the highest standard of food safety while restoring consumer confidence,[119] and by the end of 2001 the European Parliament had voted for the European Food Safety Authority (EFSA) to be put into place.[120] However, EFSA is only responsible for food safety risk assessment, not for risk management. Other EU institutions carry out risk management responsibilities:

> As the risk assessor, EFSA produces scientific opinions and advice to provide a sound foundation for European policies and legislation and to support the European Commission, European Parliament and EU Member States in taking effective and timely risk management decisions.[121]

EFSA, though, is not completely dependent on these institutions for delegated tasks. Previously, the scientific community had to wait for Commission requests before responding with advice.[122] Now, EFSA may carry out its own assessments on the safety of the food supply, as well as respond to requests by the aforementioned institutions or national food authorities; though where consultation is mandatory, the Commission retains exclusive authority over requests for scientific information.[123]

However, despite its explicit mandate to carry out risk assessment, EFSA "lacks formal authority to reach binding resolutions on potentially contentious scientific issues."[124] This is illustrated, for example, in the invocation of the safeguard clause for MON 810 seeds. EFSA had

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[118] Wim Weber, "The Road ahead for the European Food Safety Authority," *The Lancet* vol. 358 (25 Aug 2001), p.650.
[119] Alberto Alemanno, "Food Safety and the Single European Market," in Ansell and Vogel (eds.), *What's the Beef? The Contested Governance of European Food Safety* (Cambridge, MA: The MIT Press, 2006), p.247.
[120] Arthur Rogers, "European food safety agency takes one more step closer to reality," *The Lancet* vol. 358 (15 Dec 2001), p.2060.
[121] European Food Safety Authority (EFSA), "About EFSA," *European Food Safety Authority* (2007), http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_AboutEfsa.htm (accessed December 2007).
[122] Alemanno, "Food Safety and the Single European Market," p.249.
[123] Alemanno, "Food Safety and the Single European Market," p.249.
[124] Alemanno, "Food Safety and the Single European Market," p.249.

concluded that there was "no new evidence that would justify overturning the EU's decision to authorize [its] cultivation."[125] However, in March 2009, the EU council of environment ministers voted 22 to 5 to allow Austria and Hungary to maintain their bans.[126] This decision meant that "member states that had exercised their 'safeguard' prerogatives would no longer be required to provide any scientific justification for their decisions."[127] Since EFSA's creation, eight member states have enacted temporary bans on eight different GMO varieties; EFSA has not found any of these bans to be scientifically justified.[128] But, with no direct regulatory powers, EFSA is left to offer opinions and to develop safety norms and standards.[129] Thus at the EU-level of policymaking, the Commission and EFSA are "consistently more favorable toward the introduction of GMOs into Europe," while the Council, the EP, and several member states have been resistant.[130]

Role of national institutions

Within the member states, the national food safety agencies have different responsibilities and levels of influence within their respective national decisionmaking procedures. At the EU-level, these agencies may advise their national governments on implementation of EU law and on European food safety and public health issues. Subsequently, public opinion can play an important role in decisionmaking, as national politicians must respond to risk-averse publics and the consequences of any potential scandals.[131] These national agencies are supposed to protect against regulatory capture by one institution or interest group, a particular concern after the

[125] Gunjan Sinha, "Up in Arms," *Nature Biotechnology* vol.27, no.7 (July 2009), p.593.
[126] Sinha, "Up in Arms," p.594.
[127] Vogel. *The Politics of Precaution.* 80.
[128] Vogel. *The Politics of Precaution.* 80.
[129] Damian Chalmers, "'Food for Thought': Reconciling European Risks and Traditional Ways of Life," *The Modern Law Review* 66.4 (July 2003), p.532.
[130] Vogel. *The Politics of Precaution.* 80.
[131] Vogel, "Hare and the Tortoise Revisited," p.571.

mishandling of the "mad cow" crisis.[132] They are also responsible for regulating field trials of GMOs and the coexistence of GM and non-GM crops within their borders.[133] Nevertheless, "only EFSA, not the competent national authority, is mandated [by the EU] to issue an opinion on whether a GM food or feed product will have adverse effects on human health, animal health or the environment and/or should be placed on the market."[134] Despite, the EU's approval of new GM varieties since the end of the moratorium in 2004, many member states (Austria, Italy, Luxembourg, Greece, Ireland, Hungary, and France) and regional governments continue to refuse to accept GMOs approved by the Commission.[135] The national agencies have played a role in supporting the anti-GM stance of certain member states.

After being hit hard domestically by a number of crises, the French established its *Agence française de sécurité sanitaire des aliments* (AFSSA) in 1998 to avoid future scandals and to regulate food safety efficiently.[136] Taking a cue from the efforts to reinforce the management capacities of the Ministry of Health with the creation of independent agencies, the French government launched AFSSA to provide scientific risk assessment to help set regulation, to improve the transparency of the decisionmaking process, and to implement the precautionary principle when necessary.[137] In contrast to EFSA, AFSSA was supposed to have competency in both risk assessment and risk management. Like EFSA, however, AFSSA was weak in that it had little or no means or legitimacy to introduce economic, political, or social considerations in

[132] Vogel, "Hare and the Tortoise Revisited," p.571.
[133] Skogstad, "Contested Accountability Claims," p.904.
[134] Skogstad, "Contested Accountability Claims," p.904.
[135] Vogel. *The Politics of Precaution.* 81.
[136] AFSSA merged with the *Agence française de sécurité sanitaire de l'environnement et du travail* in July 2010 to form the *Agence nationale chargée de la sécurité sanitaire de l'alimentation, de l'environnement et du travail* (the French Agency for Food, Environmental, and Occupational Health – ANSES). Because this research addresses the time period from 1990-2010, we will continue to use AFSSA to refer to the French agency responsible for food safety.
[137] Olivier Borraz, Julien Besançon, & Christophe Clergeau, "Is It Just about Trust?" in Ansell and Vogel (eds.), *What's the Beef? The Contested Governance of European Food Safety,* (Cambridge, MA: The MIT Press, 2006), p.128.

its risk assessment.[138] Additionally, the relevant national ministries wished to retain their control over risk management, at the expense of AFSSA's authority.[139]

AFSSA is a relevant institution for study, despite its lack of national power, for the legitimacy that it bestowed on the French government at an EU-level. During an attempt by the Commission to lift the moratorium on GM-crops in 1998, AFSSA opposed the risk assessment of Bt-11 maize by the EU's scientific committees, and later the assessments by EFSA; AFSSA claimed that there was not sufficient data to determine whether the maize posed a risk to human health.[140] As a result, France delayed implementation of the approval process for GMOs.[141] In this case, we thus see that France, as a member state, was asserting its right to assess and manage risk at the state-level. This situation left not only the relationship between national agencies and EFSA unclear, but it also foreshadowed the continuing conflict between France and the EU on the issue of GMOs.

Individual states have also influenced EU decisionmaking in other ways. Some states considered "leaders" within the EU, with their national policies more stringent than EU standards, promote their environmental policies on the EU stage.[142] These states have bolstered their influence by pushing domestic industry groups to demand broader European adherence to their national policies in order to maintain fair market competition.[143] Industry was involved as

[138] Borraz *et al.*, "Is It Just about Trust?" p.134.
[139] Borraz *et al.*, "Is It Just about Trust?" p.133.
[140] Borraz *et al.*, "Is It Just about Trust?" p.149.
[141] Borraz *et al.*, "Is It Just about Trust?" p.149.
[142] Prakesh and Kollman, "Biopolitics in the EU and the US," p.623. This "leader" group includes Germany, Denmark, the Netherlands, and Sweden.
[143] Prakesh and Kollman, "Biopolitics in the EU and the US," p.623.

well in the original push for approval of GMO crops in the 1990s, with biotechnology companies arguing that their products were safe and efficient.[144]

European judicial decisions

Interestingly, in 1996 France initially supported the biotech industry's efforts to gain approval for GM crops. As detailed in the Introduction, French authorities backed Novartis' application for approval from the EU for commercialization of three Bt maize varieties.[145] Moreover, the French plant registration office issued the license required for entry of Bt maize onto the market. It was not until Greenpeace challenged the French government's risk assessment that the French *Conseil d'État* suspended commercialization of the maize in 1998, based on the grounds that the proper constitutional process had not been followed.[146] Because this reversal placed France in violation of the EU's approval of the maize, the *Conseil d'État* turned to the ECJ for a resolution. The ECJ, in turn, ruled that France was bound by its original opinion in support of the GMO's approval.[147] In addition, the ECJ made it clear that France's failure to present new scientific information showing the GMO to be unsafe (a requirement at the time for invoking the safeguard clause) undermined France's attempt at reversing its position.

The shift from support of GMOs to opposition developed into a long-term position of French resistance to implementing EU regulation in this domain. This resistance is rooted in the belief that stringent regulations based on scientific evaluation will never be sufficient; rather, GMOs and GM products should not be approved at all. Because of persistent non-compliance

[144] Arnaud Apoteker, Gay Philippe, Riesel René, Marteau Didier, and Guillou Marion, "Les OGM: les points de vue en presence. Conférence de citoyens sur l'utilisation des organismes génétiquement modifiés," *Économie rurale* no.248 (1998), p.47-48.
[145] Sabine Louët, "EU Court overrules France's *Bt* maize ban," *Nature Biotechnology* vol. 18 (May 2000), p.487.
[146] Louët, "EU Court overrules ban," p.487.
[147] Press Release No. 18/00 on Case C-6/99 *Association Greenpeace France and Others v Ministère de l'Agriculture et de la Pêche and Others* [2000], http://curia.europa.eu/en/actu/communiques/cp00/aff/cp0018en.htm (accessed July 2011). Full text of the decision can be found at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:61999J0006:EN:PDF.

with EU legislation, the French position has led to two other key judicial decisions, with pressure to enforce implementation of GMO regulation coming from both the European Commission through the ECJ and from major GM crop exporters (the US, Canada, and Argentina) through the WTO.

The Commission has launched many cases against member states for non-compliance, usually as a pressure tactic for states to complete transposition of the legislation into their national systems. Traditionally, if the state completes transposition and becomes compliant before the legal proceedings are resolved, the Commission drops the case and the member state avoids a penalty payment. However, in the most recent case against France, a new precedent has been set by the ECJ. The Commission had previously initiated and won a proceeding against France in 2004, in which the ECJ ruled that France had "infringed Community law by failing to transpose Directive 2001/18/EC."[148] But France still failed to transpose the Directive following the ruling, and in 2007 the Commission initiated new proceedings. To avoid penalty payments that would be imposed again, France complied with the Directive and transposed the EU legislation late in the legal proceedings. Predictably, the Commission then dropped its request for those penalty payments accrued during the period of non-compliance.

However, despite the fact that France had finally been pushed to transpose the Directive, the Commission did not drop its request that France pay a lump sum penalty (different from the dropped penalty payments) for failure to comply with the 2004 judgment. This tested a new enforcement policy of the Commission – to impose both penalty and lump sum payments on states that were non-compliant.[149] The earlier enforcement policy, in which only penalty

[148] European Commission, "Summary: C-121/07 Commission v. France, judgment of 9 December 2008," *Summaries of Important Judgments*, http://ec.europa.eu/dgs/legal_service/arrets/07c121_en.pdf.
[149] Brian Jack, "Enforcing Member State Compliance with EU Environmental Law: A Critical Evaluation of the Use of Financial Penalties," *Journal of Environmental Law* (November 26, 2010).

payments were pursued, had been deemed ineffectual; member states would delay transposition as long as possible, then they would transpose the legislation at the last minute to avoid fines. The new policy would still allow states to avoid the penalty payments if they transposed the legislation before the end of proceedings, but they would not avoid the possible lump sum payments for long-term non-compliance, making long delays less attractive. The *Commission v. France* case was the first to be considered by the ECJ under this new enforcement policy. Citing a failure to comply with its judgment as a "particularly significant breach of Member States' obligations" and taking into account "France's conduct in persistently failing to implement EU directives on GMO issues as well as the length of time that France had taken to comply with its initial judgment," the ECJ ruled that France would pay a lump sum of 10 million euro.[150]

External pressures

In addition to institutional pressures from within the EU, external influences, such as the WTO ruling in 2003, have played a significant part in the development of Europe's regulatory system. The foundational differences between the US and the EU in their perception of the risks posed by GMOs and their resulting regulatory responses become clear in international forums, particularly in the context of EU-US trade disputes. Joseph Murphy and Les Levidow argue that because of their divergence in regulatory approaches in the 1990s, the actions of the EU and US in international forums can be interpreted as efforts to strengthen their respective positions for any future WTO disputes.[151] Thus, agricultural biotechnology governance at the global level is constructed through the WTO and the UN.

WTO disputes are legally framed by the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The SPS Agreement defines the "legitimate

[150] Jack, "Enforcing Member State Compliance," p.10.
[151] Joseph Murphy and Les Levidow, *Governing the Transatlantic Conflict over Agricultural Biotechnology: Contending coalitions, trade liberalization and standard setting* (London: Routledge, 2006): 147.

grounds for restricting trade in agricultural products," which places a serious burden of providing comprehensive, scientific evidence on states that wish to refuse market-access to products they deem risky.[152] This means that "hypothetical" or "theoretical" risks will not be considered as legitimate claims. Negotiated during the Uruguay Round and entering into force in 1995, the SPS Agreement rests on the foundation of trade liberalization, and it seeks to prevent trade protectionism from occurring under the guise of risk regulation. In the case of the EU and the weight it gives to the precautionary principle, adherence to the SPS Agreement means that EU regulators must provide scientifically-supported, expert opinions to substantiate trade-restrictive measures and that will hold up under WTO scrutiny.

To counter the prioritization of the SPS Agreement on trade liberalization, environmental groups, civil society groups, and different governments began negotiations in the late 1990s on the Biosafety Protocol to the United Nations Convention on Biological Diversity.[153] Finalized in January 2000 in Cartagena, the Biosafety Protocol established a framework for regulating the trade of living modified organisms (LMOs); it applies not only to assessing the environmental impacts of LMOs in the form of genetically modified crops, but also to LMOs that are intended for food, feed, or processing.[154] Although the EU's precautionary principle is not explicitly stated in the Biosafety Protocol's Articles, precautionary language is repeated throughout. Compromises were made on the included language to satisfy states with strong biotechnology industries (namely the US, Canada, and Australia), which resulted in ambiguous wording that leaves whether the Biosafety Protocol is subordinate to the WTO rules open to interpretation.[155]

[152] Murphy and Levidow 148.
[153] Murphy and Levidow 150.
[154] Murphy and Levidow 151.
[155] Murphy and Levidow 151-152.

In the end, however, the US, Canada, and Australia abstained from becoming parties to the Protocol.

In contrast to the SPS Agreement and the Biosafety Protocol, which were crafted after GMOs had appeared on policymaking agendas, the UN's Codex Alimentarius has been a long-running effort to create global standards for food safety. Created in 1963 by the UN's Food and Agricultural Organization (FAO) and the World Health Organization (WHO), the Codex Alimentarius is a set of food standards, guidelines, and related texts, whose main purposes of "protecting health of the consumers and ensuring fair trade practices in the food trade, and promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations."[156] Thus, it too frames the global governance of agricultural biotechnology. The original set of standards of the Codex Alimentarius obviously did not address GMOs. But with the failure of the main agricultural biotechnology states to sign on, the EU and other parties to the Biosafety Protocol turned to the Codex Alimentarius as another forum in which they could develop more precautionary standards for agricultural biotechnology.

After long negotiations, the Codex Alimentarius task force on genetically engineered organisms (GEOs) formally adopted three documents in 2003; these included a global framework for evaluating the safety and nutritional aspects of GEOs and guidelines for risk assessment and labeling.[157] Although it appeared to be an attempt by the EU and other Biosafety Protocol signatories to reinforce their more cautious approach to GMOs, the new standards in the Codex Alimentarius do not go as far as the Biosafety Protocol in that they lack specific references to precautionary decision-making.[158] However, while its version of precaution is not as

[156] FAO/WHO, "Home Page," *FAO/WHO Food Standards Codex Alimentarius* (http://www.codexalimentarius.net/web/index_en.jsp) (accessed February 2011).
[157] Peter Andrée, *Genetically Modified Diplomacy* (Vancouver: University of British Columbia Press, 2007): 228.
[158] Andrée, *Genetically Modified Diplomacy*, 229.

strong as the Biosafety Protocol, the Codex does allow risks regulators to take some precautionary measures in the face of limited or uncertain risk assessment data.[159] This is still a far cry from accepting "precaution" as a factor in decisionmaking and it continues to fuel contentious debates in Codex meetings.[160]

Conclusion

Although the European food safety scandals of the 1990s played a significant role, they were not alone in shaping the EU regulatory system for agricultural biotechnology. Institutional structures and processes within the EU and its member states, as well as external pressures, also influenced how the EU has handled agricultural biotechnology regulation. The result is a risk assessment system based on the scientific evaluation of public health, food safety, and environmental risks. Yet, as noted and especially when considering the positions of EFSA and DG ENV, the EU is not a singular, reluctant actor in the GM approval debate. McGiffen and Cahill both argue, for example, that EU authorities do not have a particularly negative view of the agricultural biotechnology industry, and instead European leaders, like Barroso, are pushing to catch up in research, development, and trade opportunities.[161] Nevertheless, while EU authorities attempt to promote agricultural biotechnology as important to economic growth, they have not reformed their risk assessment process to include considerations for social and economic impacts.

Despite the promotion of biotechnology as a pathway to competitiveness, the EU continues to face resistance to the GMOs, particularly from its member states. But in the same way that an analysis of the actors involved at the EU-level reveals variation in their respective

[159] Andrée, *Genetically Modified Diplomacy* 230.
[160] Andrée, *Genetically Modified Diplomacy* 230.
[161] Steven McGiffen, *Biotechnology: Corporate Power versus Public Interest* (London: Pluto Press, 2005), p.6; Ann Cahill, "Cultivating a New Idea," *E!Sharp* (Sept/Oct 2010), http://www.esharp.eu/issue/2010-5/Cultivating-a-new-idea (accessed July 2011).

stances on GMOs, variation among the member states in public opinion and the regulatory systems for GM products becomes more evident upon closer examination. Chapter 4 now turns to a detailed analysis of the French regulatory regime as a case study of this variation, in order to more fully explore hot the differences in the evolution of the two levels of regulatory systems (EU and French) have led to the current regulatory deadlock over GMO approvals.

Chapter 4. French Agricultural Biotechnology Regulation

Before the EU claimed competence in the domain of agricultural biotechnology, member states had developed and were implementing their own policies for GMOs. In the case of France, early efforts to create a regulatory framework can be traced to the mid-1970s, when the Ministry of Research created an ad hoc group to oversee recombinant DNA experiments.[1] In the 1980s, France established its "regulatory frontline" for dealing with GMOs, by adding to its existing *Commission du Génie Génétique* (CGG) with the creation of the *Office Parlementaire d'évaluation des choix scientifiques et technologiques* (OPECST) and the *Commission du Génie Biomoléculaire* (CGB).[2] As such, when the EU began to assert its authority with Directive 90/220/EEC on the deliberate release of GMOs, many member states, like France, had already developed their own individual regulatory systems in this issue area.

Chapter 4 begins with a brief overview of the political system and institutions in France. It then turns to a review of the regulatory framework that was in place in France at the time when the EU began to develop its own system to address genetic engineering. In order to trace the development of the regulatory framework, the review is organized into six phases of the framework's development, which also coincide with significant events in the GMO debate. Thus, Chapter 4 looks at both the original regulatory framework in France and the passing of Directive 90/220/EEC by the EU in 1990 and its transposition into French law in 1992. The chapter also looks at the context of Novartis' decision to select France as the first EU market in which to introduce GMOs. It addresses how this proved to be a fateful mistake, because of the controversy

[1] Suzanne de Cheveigné, Daniel Boy, and Jean-Christophe Galloux. 2002. *Les Biotechnologies*. Paris: Balland. p. 28, as cited in Kerry Whiteside. 2003. "Humanisme et Terroir. The Culture of Genetically Modified Crops in France." *French Politics, Culture & Society*. Vol. 21, No. 3: 73-90. Here p.76.

[2] Whiteside. "Humanisme et Terroir." 76. In English, the CGG, OPECST, and CGB are respectively known as the Genetic Engineering Committee, the Parliamentary Office for the Evaluation of Scientific and Technological Choices, and the Biomolecular Engineering Committee.

over the risks of GMOs that erupted in the public sphere in 1996, and examines the ensuing changes in the regulatory framework.

Chapter 4 builds on the historical context of the European public health and food safety scandals of the 1990s to show the response of French domestic institutions to agricultural biotechnology regulatory issues. Like the actors at the EU-level, French domestic political institutions are not uniform in their stance on GMOs. The chapter looks at the different positions of France's domestic actors, and the role that they play in the policymaking and transposition processes. In particular, this analysis focuses on the phase in which GM soy arrived from the US and Greenpeace's challenge of the French approval of Bt maize (*Phase III: 1996-1998*). It also focuses on the subsequent governmental responses, including the formation in 1998 of the first of several public forums to debate the merits of GMOs; the creation of the French Food Safety Authority, the *Agence Française de Sécurité Sanitaire des Aliments* (AFSSA), in 2000; and the formation of the *Haut Conseil des Biotechnologies* (HCB) in 2008. To finish, Chapter 4 reviews the promising rapprochement that developed between the anti- and pro-GM actors later in the decade, and its subsequent destruction along with the destruction of an Alsatian vineyard field trial in 2010.

While the chapter is not completely inclusive in reviewing every event that could be considered part of the GMO debate in France, the selected events help illustrate the key stages in the French debate over GMOs. Organization of the chapter around these phases provides insight into how the issue was framed and which actors were involved in the debate during different time periods. Moreover, a selection of events from the time period of this case study allows us to observe the evolution of the debate in the last two decades.

After reviewing the French regulatory framework for GMOs, I argue that as the framework developed, the French government's decisions at critical junctures led to the institutionalization of dissent in the policymaking process. In response to the public health and food safety scandals in the 1990s, the French government appointed GMO opponents to serve on regulatory committees. The intent was to make the regulatory process more transparent by opening up approvals to conflicting opinions, with the long-term goal of creating a framework that would provide clear advice to the government, after weighing scientific and socio-economic assessments of potential risks. But instead of constructing an efficient process, the framework went through several phases of fragmentation and restructuring. The end result is the HCB – an institution whose two committees regularly provide contradictory assessments of GMO dossiers. As a consequence, *le dialogue des sourds* exists within France, as well as between the state and the European Union. On one side, GMO advocates believe that sound scientific risk assessments will result in approvals. On the other side, GMO detractors emphasize the uncertainty of scientific assessments and the potential socio-economic consequences of GMO approvals.

The French Policy Process

In order to understand the evolution of the regulatory framework within France, one must first have an understanding of the Fifth Republic's rule of law and its institutions. France is a semi-presidential democracy, meaning that the executive has both a president and a prime minister, in addition to the ministerial administration and affiliated bureaucracies. A new constitution in 1958 created the Fifth Republic, which is the current incarnation of the French government. The advent of the Fifth Republic was supposed to end the chronic constitutional instability that marked the preceding Republics.[3] To that end, under the Fifth Republic, the

[3] Gilles Champagne. 2001. *L'essential du Droit constitutionnel. Tome 2: Les institutions de la V^e^ République*. Paris: Gualino éditeur. 11.

executive branch was strengthened.[4] Since 1958, the institutions created by the constitution and the mandates for public authorities have evolved. Although this work does not examine the development of each element of the French political system in exhaustive detail, it does provide a brief overview of France's legal framework, which underlies the regulatory process for agricultural biotechnology.

The legal framework

The constitution of the Fifth Republic provides the legal basis for French governmental institutions and laws. Its foundation is a republic that is "indivisible, secular, democratic, and social."[5] The constitution transformed the French political system from a pure parliamentary regime to its semi-presidential structure. This is one of the features that make the French political system unique:

> It is neither a parliamentary system like the British one, where the executive emerges from Parliament, nor a system of separation of powers like the American one, where the President must take account of Congress: the French Fifth Republic is a hybrid system characterised by a Presidency that is oversized in the absence of adequate counterweights.[6]

France is also different than most modern democracies in that it uses "two-round single-winner voting rather than one-round (United States, United Kingdom) or proportional representation (continental Europe), which encourages a large number of parties (in the first round) and two major electoral coalitions (in the second), left and right."[7] The unique structure of France's semi-presidential regime influences institutional creation within its bureaucracy and the policymaking

[4] US Department of State. 2012. "Government." *Background Note: France*. February 15. http://www.state.gov/r/pa/ei/bgn/3842.htm#gov (accessed August 2012).
[5] Ministère des Étrangères. 2008. "From a President above the fray...to a President who governs." *The French Political System. France Diplomatie.* http://www.diplomatie.gouv.fr/en/france/institutions-and-politics/the-french-political-system/article/from-a-president-above-the-fray-to (accessed August 2012).
[6] Ministère des Étrangères. 2008. "Introduction." *The French Political System. France Diplomatie.* http://www.diplomatie.gouv.fr/en/france/institutions-and-politics/the-french-political-system/article/introduction-12286 (accessed August 2012).
[7] Ministère des Étrangères. "Introduction."

process. In the issue area of biotechnology, the executive, legislative, and judicial branches all play a role in regulation.

French institutions

Although the 1958 Constitution empowered the executive, the purpose was not to make it stronger than the legislature, but rather to create a better equilibrium between the two branches n the shift from a parliamentary system to a presidential one.[8] The power of the executive branch, and more specifically the office of the president, has ebbed and flowed over different presidencies. But the end result has been a stronger role for the president of the Republic than originally imagined at the creation of the 1958 Constitution.[9] The prevailing notion in 1958 was that the prime minister would work alongside the president as his principal collaborator. It became clear almost immediately following the inauguration of the new republic, however, that the president was the head of the executive branch, a role confirmed by the switch in 1962 to his election by universal suffrage.[10] Yet this primacy can shift back to the prime minister and the parliament during periods of cohabitation – years when the president hails from one party and the prime minister and the majority of parliament hail from the opposition.

During the time period studied (1990-2010), France has had three presidents and two periods of cohabitation.[11] Periods of cohabitation were an unintended consequence of the 1958 Constitution, which mandated seven-year terms presidents and five-year terms for parliamentarians. During conventional presidencies, the president is responsible for naming the

[8] Champagne. *L'essential du Droit constitutionnel.* 11.
[9] Champagne. *L'essential du Droit constitutionnel.* 11. Champagne does note that while a stronger role for the president was not originally envisioned by most, General de Gaulle (the Fifth Republic's first president) was an exception.
[10] Champagne. *L'essential du Droit constitutionnel.* 11.
[11] François Mitterrand was president of France from 1981 to 1995; Jacques Chirac was president from 1995 to 2007; and Nicolas Sarkozy was president from 2007 to 2012. In total, the French government has experienced three periods of cohabitation. The first was under Mitterrand when Jacques Chirac was prime minister from 1986 to 1988; the second also occurred during Mitterrand's tenure when Éduoard Balladur was prime minister from 1993 to 1995; and the third was during Chirac's presidency when Lionel Jospin was prime minister from 1997 to 2002.

prime minister, presiding over the cabinet, commanding the armed forces, and concluding treaties.[12] The president can also submit questions to a national referendum and dissolve the National Assembly.[13] The prime minister is considered the head of government, meaning that he oversees domestic administration (the ministers, ministers-delegate, secretaries of state, and ministerial staff).[14] Under the Fifth Republic, presidents have generally "tended to leave day-to-day policy-making to the prime minister and government."[15] Although the Constitution details the different responsibilities and powers of the president and prime minister, exactly how executive power is shared in practice depends on who occupies those offices. Different factors, such as the politicians' personalities and their respective party affiliations and politics affect the balance of power between the two offices.[16]

During periods of cohabitation, the prime minister's position is strengthened relative to the presidency. Cohabitation restores the powers attributed in the Constitution to the prime minister, which have in practice been appropriated by the president.[17] During the longest period of cohabitation, when Lionel Jospin (*Parti Socialiste* – PS) served as prime minister under Jacques Chirac (*Rassemblement pour la République* – RPR), the presidency was weakened.[18] The relations between the two men for the first three years of Jospin's cohabitation were mostly cordial, with both the president and the prime minister working together to amend the Constitution to reduce the presidential mandate from seven to five years.[19] But from September

[12] US Department of State. "Government."
[13] US Department of State. "Government."
[14] Premier Ministre. 2012. "La Fonction du Premier ministre." *Portail du gouvernement.* May 15. http://www.gouvernement.fr/premier-ministre/la-fonction-de-premier-ministre (accessed August 2012).
[15] US Department of State. "Government."
[16] Premier Ministre. "La Fonction du Premier ministre."
[17] Premier Ministre. "La Fonction du Premier ministre."
[18] Champagne. *L'essential du Droit constitutionnel.* 40.
[19] Champagne. *L'essential du Droit constitutionnel.* 40-41. US Department of State. "Government." The purpose of the constitutional amendment was to prevent future periods of cohabitation from occurring. The amendment passed

2000 until the end of the cohabitation period in May 2002, the relationship between Chirac and Jospin was quite contentious.[20] Both sides publicly disparaged the other's policies. For example, Jospin was highly critical of Chirac's efforts to make changes to the Constitution regarding social democratic issues, and Chirac badgered Jospin with alarmist declarations about the handling of the mad cow crisis.[21] As a consequence, during the third period of cohabitation, the posturing of the Left and the Right affected policymaking decisions. The Chirac-Jospin cohabitation came to an end in 2002, when Chirac won a second term as president, and the Right won a parliamentary majority.

The French Parliament is split into two houses: the *Assemblé nationale* (National Assembly) and the *Sénat* (Senate). Members of the National Assembly are directly elected through universal suffrage. The National Assembly is the only institution that has the power to remove a government in power, but only "if an absolute majority of the total Assembly membership votes to censure."[22] The National Assembly is the principal legislative body, and in cases of disagreement with the Senate, the Assembly has the final vote.[23] Assembly members have three main responsibilities: to represent the French people, to create legislation, and to monitor the administration.[24] Senators are also charged with creating legislation, and they have the right to initiate legislation. And, while the Assembly gets the last word on passing legislation, both houses must agree on the text of all laws.[25]

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a referendum in 2000, and entered into force for the 2002 presidential elections. The five-year term of office was also expected to make presidents more accountable for the results of domestic policies.

[20] Champagne. *L'essential du Droit constitutionnel.* 41-42.

[21] Champagne. *L'essential du Droit constitutionnel.* 42.

[22] US Department of State. "Government."

[23] US Department of State. "Government."

[24] Assemblée nationale. "Connaissance de l'Assemblée nationale." *Accueil.* http://www.assemblee-nationale.fr/connaissance/index.asp (accessed August 2012).

[25] Sénat. "Le Sénat et la loi." *Rôle et fonctionnement*. http://senat.fr/role/senatloi.html (accessed August 2012).

In addition to its unique political system, the French have a distinctive judicial system because it has both the *Conseil d'Etat* and the *Conseil constitutionnel*. The *Conseil d'Etat* protects "basic rights when they might be violated by actions of the state," whereas the *Conseil constitutionnel* "protects basic rights when they might be potentially violated by new laws."[26] This means that the *Conseil constitutionnel* reviews legislation before it is passed, deciding whether it conforms to the constitution. Moreover, it can only consider legislation that is "referred to it by Parliament, the prime minister, or the president."[27] The *Conseil d'Etat* functions differently than the *Conseil constitutionnel*; it "provides recourse to individual citizens who have claims against the administration."[28] It is the *Conseil d'Etat* that has been called upon to settle disputes about GMO regulations.

Legislative forms

The French political system has four main forms of legislation: *règles générales* (general rules), *ordonnances* (ordinances), *lois* (laws), and *décrets* (decrees). The *règles générales* provide the general rules for how legislation should be passed in other formats (who can initiate it, vote on it, and when it enters into force, for example).[29] Ordinances are used in special cases when the government asks parliament for "a limited period of time to take measures of a legislative nature," and as such are not initially voted on by members of parliament.[30] Ordinances are considered "regulations" until they are formally ratified by the parliament, and therefore may

[26] US Department of State. "Government."
[27] US Department of State. "Government."
[28] US Department of State. "Government."
[29] Legifrance. 2007. "2.1.1. Le rôle du Secrétariat général du Gouvernement et du Conseil d'Etat." *Règles générales*. October 20. http://www.legifrance.gouv.fr/Droit-francais/Guide-de-legistique/II.-Etapes-de-l-elaboration-des-textes/2.1.-Regles-generales/2.1.1.-Le-role-du-Secretariat-general-du-Gouvernement-et-du-Conseil-d-Etat (accessed August 2012).
[30] European Justice. 2011. "Member State law – France." *Law.* August 10. https://e-justice.europa.eu/content_member_state_law-6-fr-en.do?member=1 (accessed August 2012).

be challenged in the administrative courts pending ratification.[31] *Lois ordinaires* or *lois simples* (ordinary or simple laws) are the most common form of legislation. They are initiated in the Senate and must pass both houses of the legislature.[32] Decrees are implementation measures for laws or ordinances that must be signed by the president and/or the prime minister, and depending on the policy domain by relevant ministers. In the issue area of biotechnology, this study addresses the institutions and policies created by laws or decrees.

French Regulation of Agricultural Biotechnology

Initial actions to regulate agricultural biotechnology in France can be traced to the mid-1970s, when an ad hoc group was created to oversee recombinant DNA experiments being performed in laboratory settings.[33] Efforts to improve the government's ability to evaluate "techno-scientific matters" in general were advanced when the National Assembly in France created the *Office Parlementaire d'évaluation des choix scientifiques et technologiques* in 1983.[34] Other developments specific to GMO regulation followed.

The development of the current French framework specific to GMO regulation can be split into six phases.[35] Phase I begins in 1986, when the *Commission du Génie Biomoléculaire* was first created, and it ends in 1992 when France responded to three EU Directives related to GMO regulation with legislation that clarified the roles and responsibilities of the different institutions charged with GMO regulation, including the CGB.[36] Phase II (1992-1996) is

[31] European Justice. "Member State law – France."
[32] Sénat. "Les Diverses catégories de lois." *La Loi.* http://senat.fr/role/fiche/loi.html (accessed August 2012).
[33] Whiteside. "Humanisme et Terroir." 76.
[34] Whiteside. "Humanisme et Terroir." 76.
[35] The conceptualization of these phases is based on Christophe Bonneuil and Pierre-Benoît Joly's analysis of the evolution of the *Commission du Génie Biomoléculaire* (CGB) from 1986 to 2006. Bonneuil and Joly. 2006. "Plantes transgéniques, expertise et action publique: évolution de la place et du rôle de la Commission du Génie Biomoléculaire de 1986 à 2006." draft.
http://hal.archives-ouvertes.fr/docs/00/17/59/92/PDF/Histoire_CGB_BonneuilJoly.pdf (accessed June 2012).
[36] Three EU Directives prompted the passing of *Loi n°92-654 du 13 juillet 1992 relative au contrôle de l'utilisation et de la dissémination des organismes génétiquement modifiés* (Law n°92-654 of July 13, 1992 on the regulation of

delineated as a period of relative calm before public debate in France erupted over Novartis' application for market approval of Bt maize and the arrival of American GM soy in European ports.

In contrast to the relative calm of the second phase, the third phase (1996-1998) was highly contentious, and it marked the introduction of anti-GMO interest groups into the public debate. Phase III was capped off by the *Conférence des Citoyens sur les OGM* (Citizens' Conference on GMOs) in 1998. Following the *Conférence des Citoyens*, Phase IV (1998-2003) still included serious debate over GMO regulation; however, French and EU institutions also attempted to address the public's concerns regarding potential risks. Phase IV ended in 2003 when the EU lifted its moratorium on GMO approvals. At odds again with EU legislation in Phase V (2003-2008), France found itself a target of complaints brought by the Commission to the European Court of Justice (ECJ) for failure to fully implement EU GMO legislation. By 2008, when Phase VI began, France had attempted to break the impasse in its domestic debate on GMO regulation with the creation of the HCB. The thawing of the tensions between the two sides of the debate was abruptly shattered, though, with the destruction of field trials in Alsace in 2010.

A review of the phases of development of France's "regulatory frontline" for GMOs illustrates how France initially dealt with the issue separately from the EU. It also shows how French GMO regulation evolved over time in response to internal and external influences. This

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use and on the dissemination of genetically modified organisms) in France: Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified microorganisms; Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms; and Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work. Jérôme Da Ros and Diahanna Lynch. 2001. "Science and Public Participation in Regulating Genetically-Modified Food: French and American Experiences." Paper presented for presentation at the European Community Studies Association, Seventh Biannual Conference. Madison, Wisconsin. May 31-June 2, 2001: and at "European and American Perspectives on Regulating Genetically Engineered Food," Center for the Management of Environmental Resources, INSEAD, Fontainebleu, June 8-9, 2001. http://aei.pitt.edu/2132/1/002186_1.PDF (accessed June 2012).

section establishes the timeline of that evolution and the developments that resulted from domestic policymaking (see Table 4.1 for an overview of the Phases).

TABLE 4.1

Timeline of the French Regulatory Framework for GMOs		
Phase	**Years**	**Major Developments**
I	1986-1992	• *Commission du Génie Biomoléculaire* (CGB) created • France passes legislation in response to EU Directives related to GMO regulation • *Commission du Génie Génétique* (CGG) and CGB formalized
II	1992-1996	• Novartis selects France as the first EU member state in which to seek market approval for its Bt maize
III	1996-1998	• American GM soy arrives in Europe • Anti-GMO interest groups enter public debate • French government vacillates on GMO approvals • *Conférence des Citoyens sur les OGM*
IV	1998-2003	• Changes made to CGB • *Comité de Biovigilance* created • *Agence Française de Sécurité Sanitaire des Aliments* (AFSSA) created • Public debates on the issue of GMOs
V	2003-2008	• EU lifts moratorium on GMOs • European Commission challenges French noncompliance in the ECJ • *Grenelle Environnement* (Environment Roundtable) launched
VI	2008-2010	• *Haut Conseil des Biotechnologies* (HCB) created • Ministry of the Environment takes the lead on issue of GMOs • Destruction of GM vineyards in Alsace

Phase I: 1986-1992

The basis of France's regulatory framework for GMOs was established in the mid-1970s. At that time, France created an informal ad hoc group in response to the Asilomar Conference,[37] and it relied exclusively on scientific experts to respond to questions of risk and hazard in genetic engineering experimentation. The precedent of this early reliance on scientific expertise and preference for voluntary self-governance persisted in the subsequent regulatory developments in the 1980s until 1992.

The ad hoc group from the 1970s eventually became formalized as the *Commission du Génie Génétique*.[38] Initially created as an informal commission to review research dossiers on the classification of and experimentation in genetic engineering, the Michel Rocard (France's Prime Minister from 1988-1991) formally established the CGG by decree in 1989. The CGG was then institutionalized in French law in 1992, with the passing of *Loi n° 92-654 du 13 juillet 1992* as part of the French response to the EU directives related to GMO regulation.

The CGG was a twenty-member committee composed of nineteen scientists and one representative from OPECST,[39] under the purview of both the Ministry of Research and the Ministry of the Environment. The scientists were selected based on their competence in genetic engineering, public health, or environmental protection. Of the nineteen, at least one third were

[37] The Asilomar Conference was held in California in the winter of 1975, and it mainly brought together American and European scientists working in genetic engineering to discuss safety issues in recombinant DNA research. In particular, the participants addressed questions of potential hazard for recombinant DNA experiments and established guidelines for self-governance among scientists in the field. Marcia Barinaga. 2000. "Asilomar Revisited: Lessons for Today?" *Science*. Vol. 287, No. 5458, pp. 1584-1585. http://www.biotech-info.net/asilomar_revisited.html (accessed June 2012).

[38] Jean Bizet. 1998. "B. Les Principes d'évaluation de ces risques." *Transgéniques: pour des choix responsables*. Rapport d'information 440 (97-98). Commission des Affaires Economiques. http://www.senat.fr/rap/r97-440/r97-44023.html (accessed June 2012).

[39] Jean Bizet. 1998. "1. Les instances françaises d'évaluation des risques, b) La commission de génie génétique (CGG)." *Transgéniques: pour des choix responsables*. Rapport d'information 440 (97-98). Commission des Affaires Economiques. http://www.senat.fr/rap/r97-440/r97-44025.html#toc158 (accessed June 2012).

required to be specialists in environmental protection and public health.[40] The Ministries of Research and the Environment were each tasked with appointing four scientists to the CGG. The Ministry of Health proposed another four scientists, while the remaining seven were selected by the Ministries of Agriculture, Consumption, Defense, Higher Education, Industry, Labor, and the Interior, respectively.[41] Legally, the CGG was responsible for evaluating the risks posed by GMOs and the guidelines used in their procurement, as well as the potential dangers of genetic engineering processes and products. The CGG established classification systems for risks, and it proposed measures for the GMO containment procedures. In short, the CGG's main responsibilities were to evaluate the release of biotechnology products in confined environments[42] and to advise the Ministers of the Environment and of Research on authorizations for the contained use of GMOs for industrial applications.

The CGG worked alongside OPECST, after OPECST was established in 1983 by *Loi n°83-609 du 8 juillet 1983*. OPECST resulted from the French Parliament's desire to "endow itself with its own structure of assessment" regarding the "government's decisions on the major directions of scientific and technological policy."[43] As such, OPECST is comprised of eight members from the French Senate and eight members from the National Assembly. The sixteen members are selected based on proportional representation of the political parties in the Parliament.[44] The members of OPECST maintain that they act as "an intermediary between the

[40] Jean Bizet. "b) La commission de génie génétique (CGG)."
[41] Michel Rocard (Prime Minister). 1989. *Décret n°89-306 du 11 mai 1989 portant création d'une commission de génie génétique* [Decree n°89-306 on May 11, 1989 establishing the creation of a genetic engineering commission]. Les autres textes législatifs et réglementaires. http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=LEGITEXT000006067077&dateTexte=20090821 (accessed June 2012).
[42] Marie-Cécile Hénard. 2006. "France Biotechnology Annual 2006." GAIN Report. Report no. FR6039. Paris: USDA Foreign Agricultural Service. 6.
[43] Sénat. "Parliamentary Office for Evaluation of Scientific and Technological Options Presentation." *Offices – Delegations*. http://www.senat.fr/opecst/english.html (accessed June 2012).
[44] Sénat. "Parliamentary Office for Evaluation of Scientific and Technological Options Presentation."

political world and the world of research," by listening to researchers and requesting authorized opinions.[45] In order to make its decisions, OPECST is supported by a Scientific Committee. Thus, even though OPECST members are not scientific experts, their assessments rely on scientific expertise as provided by the fifteen members of the Scientific Committee.

OPECST is not limited to evaluating agricultural biotechnology, however; its responsibilities include reporting to Parliament on a range of scientific and technological assessments in order "to control technical progress while, at the same time, anticipating its consequences."[46] OPECST "collects information, launches study programmes and carries out assessments" for varying scientific activities within four main areas: energy, environment, new technologies, and sciences of life.[47]

OPECST's gradually expanding mandate of oversight on a range of scientific activities led the French government to create a new committee – the *Commission du Génie Biomoléculaire* – to act as a more specific "expert advisory body regarding the risks associated with the release of genetically modified organisms."[48] The then-Minister of Agriculture, François Guillaume, created the CGB in 1986. Under the jurisdiction of the Ministry of Agriculture, the Minister selected the president of the CGB, with the help of the Minister of the Environment. At first, fifteen members sat on the CGB: "ten scientists, two representatives of industry, one lawyer, one representative of consumer interests, and one labor representative."[49] The CGB was later expanded in response to issues raised in the *Conférence des Citoyens* in 1998 (discussed below in *Phase IV: 1998-2003*).

[45] Sénat. "Parliamentary Office for Evaluation of Scientific and Technological Options Presentation."
[46] Sénat. "Parliamentary Office for Evaluation of Scientific and Technological Options Presentation."
[47] Sénat. "Parliamentary Office for Evaluation of Scientific and Technological Options Presentation."
[48] Whiteside. "Humanisme et Terroir." 76.
[49] Herbert Gottweis. 1998. *Governing Molecules: The Discursive Politics of Genetic Engineering in Europe and the United States*. Cambridge, MA: MIT Press. 313, as cited in Whiteside. "Humanisme et Terroir." 76.

In addition to serving as the advisory body to the Parliament on the risks of GMOs, the CGB also devised "criteria and procedures regarding GMO safety" that companies were required to follow well before the commission evaluated their products for market release.[50] Christophe Bonneuil and Pierre-Benoît Joly characterize the role of the CGB in its earlier years as three inextricably-linked functions: to provide research, expertise, and decisions.[51] During Phase I of the development of the GMO regulatory framework, the CGB's scientific experts were also performing research in agricultural biotechnology, evaluating each others' work, and writing reports on biotechnology issues for OPECST.[52] As a result, the experts charged with evaluating the risks of GMOs for the government and with setting research priorities for biotechnology were the very same experts that were performing the research activities.

Furthermore, up until 1996, the Minister of Agriculture accepted and followed every CGB opinion on GMO dossiers submitted by biotech corporations.[53] The opinions were then "directly conveyed to the petitioning organization under the signature of the President [of the CGB]."[54] Thus, in Phase I, scientific experts in genetic engineering had a significant role in shaping the committees' risk assessments and the risk management of GMOs, and their opinions were always adopted as decisions. There was no separation between risk assessment and risk management for GMOs.

In 1990, the EU passed three directives that would impact the French regulatory framework: Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified microorganisms; Council Directive 90/220/EEC of 23 April 1990 on the deliberate

[50] Whiteside. "Humanisme et Terroir." 76.
[51] Bonneuil and Joly. "Plantes transgéniques, expertise et action publique."
[52] Bonneuil and Joly. "Plantes transgéniques, expertise et action publique."
[53] Bonneuil and Joly. "Plantes transgéniques, expertise et action publique."
[54] Bonneuil and Joly. "Plantes transgéniques, expertise et action publique." Original text: "Pendant les 10 premières années, ces avis sont toujours suivis d'une décision conforme du Ministère et sont même, jusqu'en 1992, transmis directement au pétitionnaires sous la signature du Président." (my translation).

release into the environment of genetically modified organisms; and Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work. In order to comply with the requirements of the EU legislation, France passed *Loi n° 92-654 du 13 juillet 1992 relative au contrôle de l'utilisation et de la dissémination des organismes génétiquement modifiés* (Law n°92-654 of July 13, 1992 on the regulation of use and dissemination of GMOs). This law amended the existing French regulatory framework in order to meet the standards set by the EU legislation.

Loi n° 92-654 formally institutionalized both the CGG and the CGB, and the law constituted the "keystone of biotechnology regulation in France" until 1998.[55] The formal institutionalization of these commissions meant that "prior governmental authorisation for both the confined use and the deliberate release of GMOs" became a statutory requirement;[56] previously it had been voluntary, though strongly encouraged by the French government. In addition, the transposition of Directive 90/220 resulted in the distribution of the different authorization responsibilities to separate institutions in France.[57] Thus, risk assessment and risk management responsibilities for GMOs were institutionally separated, though the link between the experts' opinions and the final decision was even further strengthened.[58]

Under the new law, the general responsibilities of the CGG remained the same; it was tasked with evaluating the risk of GMOs as organisms and the risks inherent in genetic engineering procedures and techniques. *Loi n° 92-654* modified the areas of competence

[55] Da Ros and Lynch. "Science and Public Participation in Regulating Genetically-Modified Food." 10.
[56] Alexis Roy and Pierre-Bénoît Joly. 2004. "France. Broadening Precautionary Expertise." [series] *Safety Regulation of Transgenic Crops: Completing the Internal Market? A study of the implementation of EC Directive 90/220.* Main contractor: The Open University, contract no. BIO4-CT97-2215, 1997-1999. This report forms part of the overall final report for the DGXII/RTD biotechnology programme on the Ethical, Legal and Socio-economic Aspects (ELSA). http://technology.open.ac.uk/cts/srtc/FR-NATReport.pdf (accessed June 2012). here p. 39.
[57] Roy and Joly. "France. Broadening Precautionary Expertise." 39.
[58] Bonneuil and Joly. "Plantes transgéniques, expertise et action publique."

assigned to the CGG by giving the commission the authority to send its members to visit the biotech firms that requested approval for their genetic engineering procedures and GMOs.[59] This was a power that the CGG did not have under the original decree. The emphasis on scientific expertise remained the same as it had been with the original configuration of the committee; all the members, besides the one representative from OPECST, were selected based on their expertise in genetic engineering, public health, or environmental protection.

Loi n° 92-654 also maintained that the majority of the CGB's members would be scientific experts in the area of biotechnology. As before, the rest of the CGB was composed of one lawyer, one representative from OPECST, and representatives of industry, consumer interests, and labor. However, the new law required a representative from an authorized environmental group to sit as a member of the committee as well. The CGB's responsibilities stayed the same. It continued to evaluate the risks of GMOs that were to be intentionally introduced into the environment and the risks of products that were derived in whole or in part from GMOs.[60] Yet, *Loi n° 92-654* gave the CGB a more official status in the regulatory system, both domestically and at the European level.[61]

The foundation and subsequent institutionalization of the CGG and the CGB in Phase I created the "regulatory frontline" in France for GMO policy. Besides launching the institutions responsible for risk assessment and risk management, the developments in Phase I established the legitimacy and influence of scientific experts in regulatory decisionmaking for agricultural biotechnology. Though the CGG and CGB were dominated by experts, the French government

[59] Parlément. 1992. Art. 3. -1. *Loi no 92-654 du 13 juillet 1992 relative au contrôle de l'utilisation et de la dissémination des organismes génétiquement modifiés et modifiant la loi no 76-663 du 19 juillet 1976 relative aux installations classées pour la protection de l'environnement*. JORF n°163 du 16 juillet 1992 page 9523. NOR: RESX9100142L. http://legifrance.gouv.fr/affichTexte.do;jsessionid=2000BE387AB051CA100ED0A062077B1F.tpdjo05v_2?cidTexte=JORFTEXT000000161523&categorieLien=id (accessed June 2012).
[60] Parlément. 1992. Art. 3. -1. *Loi no 92-654*.
[61] Bonneuil and Joly. "Plantes transgéniques, expertise et action publique."

also clearly established that these committees were subordinate to government officials. As Kerry Whiteside notes, the government claimed that it was the "public authorities who [made] the final decision on the dissemination of GMOs."[62] To that end, OPECST – made up of members of Parliament – monitored the issue of GMOs and maintained a presence on the other committees specific to evaluating the risks of genetic engineering. Despite the supervision of "public" officials, these regulatory institutions were not structured to solicit public participation or to engender public debate on the subject of GMOs.[63] Thus, the initial decisionmaking process for GMO regulation in France consisted of close relationships between the scientific experts and political elite, while public opinion was left out.

Phase II: 1992-1996

The second phase of the development of the French regulatory framework for GMOs can be characterized as the calm before the storm. The CGG and CGB were left largely unchallenged and unchanged from 1992-1996. The absence of public challenges to GMO approvals at the time made France the "main gateway into Europe for GMOs."[64] By 1996, "more than 30% of all EU field tests had taken place in France and 9 of the first 15 applications to commercialise GMOs in the EU were submitted in France."[65]

[62]Ministère de Finances. 2000. "Brefs rappels sur les OGM." http://www.finances.gouv.fr/ogm/ogm_bref.htm (accessed June 2012), as cited in Whiteside. "Humanisme et Terroir." 77.
[63] Whiteside. "Humanisme et Terroir." 77.
[64] Bonneuil and Joly. "Plantes transgéniques, expertise et action publique."; Claire Marris, Stéphanie Ronda, Christophe Bonneuil, and Pierre-Bénoît Joly. 2004. "Precautionary Expertise for GM Crops. National Report – France: Battling with Expertise." [series] Quality of Life and Management of Living Resources. Key Action 111-13: socio-economic studies of life sciences, Project n° QLRT-2001-00034. Paris, France: CNRS. p.7. http://technology.open.ac.uk/cts/national/france%20national%20report%20PEG.pdf (accessed June 2012).
[65] Marris et al. "Precautionary Expertise for GM Crops." 7.

During this period, the number of GMO dossiers presented to the CGB for approval skyrocketed; submissions quadrupled from 1992 to 1996.[66] Over its first ten years, the CGB saw the number of annual submissions increase from slightly more than 20 in 1987 to over 120 dossiers in 1996.[67] Between 1987 and 1997, the CGB reviewed a total of 593 dossiers.[68] The overwhelming majority of those submissions were for GM plants, with a smaller minority for gene therapies, vaccines, and other recombinant organisms. For example, from among the over 110 dossiers submitted for plants in 1996, over 80 of them had been genetically modified to resist pests or herbicides.[69]

It was into this regulatory environment that Novartis chose to submit an application for its GM maize in 1994. The decision was in part based on a strategy of using France as a gateway to the larger EU market. Novartis was "pleased to find a government supportive of biotechnology and a public seemingly prepared to accept the new products without qualms,"[70] and thus expected the approval to proceed smoothly. And, at first, it did. Novartis (then called Ciba-Geigy) submitted an application for market approval of Bt maize to the CGB in 1994. In April of 1995, the CGB passed the dossier onto the EU, without raising any objections.[71] Yet, Novartis' decision to submit the dossier in France "turned out to be a gross miscalculation."[72] By December of 1996, when the EU approved the dossier, the storm of public controversy in France had arrived.

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[66] Jean Bizet. 1998. "2. La situation française, a) Les dossiers examinés par la Commission du génie biomoléculaire." *Transgéniques: pour des choix responsables*. Rapport d'information 440 (97-98). Commission des Affaires Economiques. http://www.senat.fr/rap/r97-440/r97-44016.html#toc97 (accessed June 2012).
[67] Bizet. "2. La situation française, a) Les dossiers examinés par la Commission du génie biomoléculaire."
[68] Da Ros and Lynch. "Science and Public Participation in Regulating Genetically-Modified Food." 10.
[69] Bizet. "2. La situation française, a) Les dossiers examinés par la Commission du génie biomoléculaire."
[70] Claire Marris and Pierre-Bénoît Joly. 1999. "La gouvernance technocratique par consultation? Interrogation sur la première conférence de citoyens en France." *Les Cahiers de la Sécurité Intérieure* 38, 4. p.102, as cited in Whiteside. "Humanisme et Terroir." 73.
[71] Roy and Joly. "France. Broadening Precautionary Expertise." 7.
[72] Whiteside. "Humanisme et Terroir." 73.

Phase III: 1996-1998

Before the first wave of the BSE crisis and *Libération*'s "Alerte au soja fou"[73] headline heralded the beginning of Phase III, there had been some signs that controversy over the potential risks of biotechnology was brewing. Although no public debate on GMOs occurred in the first two phases, some experts in the scientific community had begun to question the possible environmental and agricultural impacts of GMOs.[74] In addition, other experts raised concerns regarding the involvement of the biotech industry as the coordinators of GMO risk assessment research.[75] At the time though, these issues were discussed within the scientific community and regulatory institutions, rather than in the public domain.

Bonneuil and Joly attribute this closed dialogue to two elements. First, the French framework privileged scientific expertise as the foundation of regulatory decisionmaking. Therefore, there was no opportunity built into the evaluation process to solicit public participation or to present dissenting opinions. The evaluation and decisionmaking processes were "invisible" to the public.[76] Moreover, the media and the environmental groups that would later become key in stimulating the public debate on GMOs were absent during the early phases. In the case of the environmental groups, they had not yet been able to effectively mobilize public interest in the issue. And without wide-scale public interest, media coverage of GMOs was scarce.

This atmosphere of "low-profile regulation" drastically changed between 1996 and 1998 when "media coverage increased massively, public debate in the form of a consensus conference

[73] Loosely translated as "Warning: Mad Soy," the "alerte" on the front page of the November 1, 1996 issue of *Libération* referenced the mad cow crisis and warned of the impending arrival of American GM soybeans. For a more detailed discussion, see Chapter 2.
[74] Bonneuil and Joly. "Plantes transgéniques, expertise et action publique."
[75] Bonneuil and Joly. "Plantes transgéniques, expertise et action publique."
[76] Bonneuil and Joly. "Plantes transgéniques, expertise et action publique."

was organised, regulation changed again and again, and public awareness of biotechnology naturally became more acute."[77] As discussed in Chapter 2, media coverage of the HIV-tainted blood scandal and the mad cow crisis increased the saliency of the policy domains of public health and food safety in 1996, just as American GM soy was arriving from the US. Daniel Boy and Suzanne Cheveigné argue that the announcement of the cloning of Dolly the sheep in February 1997 also motivated the media to cover biotechnology issues more extensively.[78]

As media coverage picked up and anti-GMO groups began to mobilize,[79] the French government began to vacillate on its original support for market approval of Novartis' Bt maize. By December of 1996, the EU had approved Bt maize for the market.[80] At that time, Jacques Chirac was President of France and Alain Juppé served as his Prime Minister of a right-wing coalition government. In response to the growing public controversy, Juppé followed established regulatory procedures and consulted the CGB regarding the cultivation of Bt maize within France's borders.[81] The CGB recommended that the government allow the maize to be grown.

Despite the CGB's recommendation for approval, the then-Minister of the Environment, Corinne Lepage, voiced doubts about allowing GMO cultivation; she was specifically concerned about the potential for transgenic crops to contaminate conventional ones through cross-pollination.[82] As a result of Lepage's influence, as well as increasing public outcry, Juppé decided "to ban the cultivation of the Bt maize, while still allowing its import for consumption."[83] The basis of this decision rested on fears that some risks related to cross-

[77] Daniel Boy and Suzanne de Cheveigné. 2001. "Biotechnology: a menace to French food," in *Biotechnology 1996-2000: the years of controversy*, George Gaskell and Martin W. Bauer, eds. London, UK: NMSI Trading Ltd.: 181-190. Here: 181.
[78] Boy and Cheveigné. "Biotechnology: a menace to French food." 181.
[79] Media coverage and anti-GMO mobilization are covered in more detail in Chapter 5.
[80] Roy and Joly. "France. Broadening Precautionary Expertise." 7.
[81] Whiteside. "Humanisme et Terroir." 79.
[82] Whiteside. "Humanisme et Terroir." 78.
[83] Whiteside. "Humanisme et Terroir." 79; Roy and Joly. "France. Broadening Precautionary Expertise." 7.

pollination were still unknown and that scientific assessments were still evolving.[84] The decision led not only to the resignation of the CGB's director, Axel Kahn (who argued that his credibility had been undermined), but it also marked a halt to the unspoken rule that the committees' opinions would be adopted as political decisions.[85]

Whiteside argues that the importance of this "first skirmish" cannot be underestimated. It meant "that early in the development of the GMO debate in France, the Government leant its authority to those who called into question the adequacy of regulatory measures surrounding agricultural biotechnology."[86] Following this decision, the "media, NGOs, and politicians invited themselves into the confined and routine process of evaluation and decisionmaking over which the CGB had long maintained control."[87]

Thus, the "Juppé decision" was a critical juncture in the evolution of the French regulatory framework for GMOs. It established the legitimacy of opinions outside the scientific community, and especially beyond the group of molecular biology experts who led the CGB. In addition, it broke the unofficial rule that, in practice, all scientific opinions from the regulatory institutions would be accepted by public policy makers in their decisions. This opening up of the evaluation and recommendation process to outside opinions and to questioning became a new hallmark of the decisionmaking process as the regulatory framework developed. It also led to public demands for more democratic participation in the risk assessment process.

The "Juppé decision" certainly did not help to quiet the growing concerns about the government's ability to effectively regulate issues of public health and food safety. With the first

[84] Roy and Joly. "France. Broadening Precautionary Expertise." 7; Whiteside. "Humanisme et Terroir." 78.
[85] Bonneuil and Joly. "Plantes transgéniques, expertise et action publique."
[86] Whiteside. "Humanisme et Terroir." 79.
[87] Original text: "… les médias, les ONG et les politiques s'invitent dans un processus routinier et confiné d'évaluation et de décision dont la CGB était maître du jeu." (my translation). Bonneuil and Joly. "Plantes transgéniques, expertise et action publique."

wave of the BSE crisis cresting, the French public was increasingly distrustful of the government's motives in regulatory decisionmaking. What they needed was a clear decision on whether GMOs were safe. Instead they got a "contradictory" one: "If GMOs were dangerous, it was asked, why allow their importation at all? If they were not dangerous, why prohibit their cultivation?"[88] Even with this glaring contradiction and the unease it provoked, the policy remained in place for the rest of Juppé's tenure.

In June of 1997, a period of cohabitation began in the French government. Chirac remained in power as the President, but the *Parti Socialiste* (PS) won the parliamentary elections in May, bringing Lionel Jospin to the position of Prime Minister. The return of the Socialist majority to power within the government came with an alliance with the Green Party (*Les Verts*). *Les Verts* had agreed to support the PS in the first round of voting in exchange for twenty-nine constituencies "reserved" for Green candidates and for particular policy commitments.[89] The two parties also signed a programmatic agreement that included moderate measures concerning agricultural biotechnology, such as a proposal at the EU-level for a moratorium on GMOs.[90] The Greens' support for the PS led to its success as well; *Les Verts* won eight parliamentary seats and the party's leader, Dominique Voynet, became the Minister of Planning and the Environment.[91]

Although environmental issues tend to have greater support from left-wing governments, in France the ecological movement had, for a long time, tried to remain unaffiliated with any particular party on the right or left.[92] It was not until the alliance with the PS for the 1997

[88] Whiteside. "Humanisme et Terroir." 79.
[89] Andrew Knapp and Vincent Wright. 2006. *The Government and Politics of France*. 5th edition. New York: Routledge. 209.
[90] Boy and Cheveigné. "Biotechnology: a menace to French food." 181.
[91] Knapp and Wright. *The Government and Politics of France*. 209.
[92] Boy and Cheveigné. "Biotechnology: a menace to French food." 181; Knapp and Wright. *The Government and Politics of France*. 207.

parliamentary elections that *Les Verts* clearly delineated themselves as a left-wing party.[93] The ascendancy of the left in 1997, however, did not ensure a more precautionary approach to GMOs from the French government.

Jospin inherited the contradictory and "troubled" GMO dossier in the spring of 1997.[94] As Whiteside notes, Jospin's government was faced with two choices: promoting GMOs, thus running "afoul of the people's worries, or [balking] at GMO distribution and possibly [damaging] the future of French agriculture."[95] In an attempt to resolve the contradictory policy, Voynet turned to a group of scientific experts and environmental groups for their advice on the cultivation of the Bt maize. She also sought the opinion of the newly created *Comité de la Prévention et de la Précaution* (CPP) on the risks associated with the cultivation of several transgenic crops, including Bt maize.[96] The CPP advised approval of Novartis' maize for cultivation, though it presented a negative opinion on the other GM crops (oilseed rape and sugar beet) under consideration.[97] With this information, the government responded by "bringing consistency back to French policy by allowing *both* the importation and cultivation" of the approved GM maize.[98] However, it placed a two-year moratorium on the cultivation of oilseed

[93] Knapp and Wright. *The Government and Politics of France*. 207.
[94] Whiteside. "Humanisme et Terroir." 79.
[95] Whiteside. "Humanisme et Terroir." 79.
[96] The CPP is an impermanent commission, created on July 30, 1996, that requires renewal every five years. It acts as a consultative commission that answers to the Ministry of Environment. The CPP is composed of twenty scientists who are experts in the fields of public health and environment. The commission's responsibilities are: to help ground ministerial policies in the principles of precaution and prevention; to provide early warnings, alerts, and expertise on health problems associated with environmental issues; to create links between scientific research and regulatory action; and to formulate opinions, either at the request of the Minister or by its own initiative. Ministère de l'Écologie, du Développment durable et de l'Énergie. "Le comité de la prévention et de la précaution." *Les comités techniques*. http://www.developpement-durable.gouv.fr/Le-comite-de-la-prevention-et-de,15001.html (accessed June 2012).
[97] Boy and Cheveigné. "Biotechnology: a menace to French food." 182; Roy and Joly. "France. Broadening Precautionary Expertise." 7.
[98] Whiteside. "Humanisme et Terroir." 79 (italics in original).

rape and sugar beet pending further research on the risks of cross-pollination. In addition, the government decided to require market stage monitoring of all GM crops, including the maize.[99]

From this example, it is clear that political party affiliation cannot be used as a shortcut to explain the position of the government regarding GMO regulation. Regulation under left-wing governments[100] appeared to favor approvals for GMOs, while leaders from the right (Juppé and later Sarkozy) made decisions that opposed them. Boy and Cheveigné maintain that this is not unusual in French politics, stating that, "In practice, changes in the political majority have had little effect on the evolution of public policy."[101]

Although party affiliation did not seem to have an impact on the evolution of the regulatory framework, the period of cohabitation did. Boy and Cheveigné argue that having a right-wing president cohabitate with a left-wing government set up a type of competition, with "each side systematically invoking the precautionary principle" in a number of cases.[102] In the case of the embargo on British beef during the BSE crisis, "the rule of prudence set up by the prime minister [appeared] to be partially motivated by the fear that the 'presidential adversary' might take political advantage of an error or lack of precaution by the government."[103] With the Conservative government across the Channel falling in May of 1997 due to its mishandling of mad cow, French politicians had every reason to fear electoral repercussions if they mishandled the GMO issue. Moreover, they only needed to look to the HIV-tainted blood scandal and the subsequent criminal trials to know that there would be domestic consequences for any

[99] Roy and Joly. "France. Broadening Precautionary Expertise." 7.
[100] Here, I am referring to François Mitterrand's tenure (a member of the PS, he was president of France from 1981-1995), as well as Lionel Jospin's period of cohabitation from 1997-2002.
[101] Boy and Cheveigné. "Biotechnology: a menace to French food." 181.
[102] Boy and Cheveigné. "Biotechnology: a menace to French food." 181.
[103] Boy and Cheveigné. "Biotechnology: a menace to French food." 181.

missteps.[104] Neither side wanted to be blamed – electorally or criminally – for mistakes due to a lack of precaution.

And, while party affiliation did not have a significant impact on the regulatory framework for GMOs, the way that the Socialist government framed the issue made a difference. Jospin believed that the public outcry over agricultural biotechnology was related to indecision on the part of the public and a lack of education on the issue.[105] As a consequence, Jospin announced that the government would hold a "citizen's conference," organized by OPECST, to allow public debate on the issue and to help educate the public.

Modeled on consensus conferences held in Denmark, the *Conférence des Citoyens sur les OGM* was held in 1998. OPECST convened a group of biotechnology experts, sociologists, and a lawyer to educate a group of fifteen French citizens on the topic of GMOs over the course of two weekends. The group considered questions such as:

> What is gene transfer? Why is it used in agriculture? What are the potential risks of ingesting GMOs to human and animal health? Could wide-scale cultivation of GMOs endanger the environment? How should consumers be informed? What is the current state of the national and international regulatory frameworks for GMOs?[106]

The laypeople were also given the opportunity to question the experts on the potential benefits and disadvantages of GMOs.

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[104] The first round of criminal trials in the HIV-tainted blood scandal, with three of the four public officials charged receiving convictions, were held in 1992. The second round of trials for the former Ministers were held in February and March 1999. See Chapter 2 for a more detailed discussion of the HIV-tainted blood scandal.

[105] Da Ros and Lynch. "Science and Public Participation in Regulating Genetically-Modified Food." 10; Whiteside. "Humanisme et Terroir." 79-80.

[106] Original text: "Qu'est-ce qu'un transfert de gênes? Pourquoi est-il utlisé dans l'agriculture? Quels sont les risques potential pour la santé humaine et animale de l'ingestion de plantes transgéniques? La culture à grande échelle de plantes transgéniques fait-elle courir des risques à l'environnement? Comment informer les consommateurs? Quelle est aujourd'hui l'état de la réglementation nationale et internationale dans le domaine du transgénique?" (my translation). Daniel Boy. 1999. "Politiques de la Science et Démocratie Scientifique." *Revue Internationale de Politique Comparée*. vol. 6, no. 3. 613-625. Here: p.624.

The public conference was held a month after the second training session at the National Assembly on June 20-21, 1998, and included a panel of twenty-six experts, who represented the academic world, private corporations, and non-profit organizations, as well as the fifteen laypeople.[107] The experts publicly answered questions posed by the citizen panel during the two days. When the debate was completed, the citizen panel spent twenty-four hours writing its conclusions.[108] The panel did not conclude that moratorium on GMOs was necessary, though the members did present a number of measures to develop more scientific research and to improve control over GM plants.[109] For one, they called for the CGB to become more open to experts from fields that had gone underrepresented and for "a strengthening of public research in the particular domain of risks assessment."[110] The panel advocated more transparency in the decisionmaking process, recommending that all advice be made publicly available including dissenting opinions.[111]

The panel also recommended that the CGB should be split into two committees: a scientific committee and a general committee. The scientific committee would provide scientific expertise and research, whereas the general committee would advise on the social and economic impacts of biotechnology products.[112] One of the reasons for this conclusion was that the panelists did not believe that scientific experts have "all the means to assess risk comprehensively."[113] As such, the general committee would help "ensure that the final advice would not be based solely on the normative judgements which underlie experts' assumptions."[114]

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[107] Da Ros and Lynch. "Science and Public Participation in Regulating Genetically-Modified Food." 8; Boy. "Politiques de la Science et Démocratie Scientifique." 624.
[108] Da Ros and Lynch. "Science and Public Participation in Regulating Genetically-Modified Food." 9.
[109] Boy and Cheveigné. "Biotechnology: a menace to French food." 183.
[110] Da Ros and Lynch. "Science and Public Participation in Regulating Genetically-Modified Food." 9.
[111] Roy and Joly. "France. Broadening Precautionary Expertise." 10.
[112] Roy and Joly. "France. Broadening Precautionary Expertise." 10.
[113] Roy and Joly. "France. Broadening Precautionary Expertise." 10.
[114] Roy and Joly. "France. Broadening Precautionary Expertise." 10.

Another benefit to a two-committee system would be increased transparency. Finally, the panel also "urged a 'clear, reliable and accountable' labeling policy, including the separation and traceability of GM and non-GM products throughout the food chain."[115]

The French government had deferred making any further decisions on GMO policy until after the *Conférence des Citoyens*. Jean-Yves Le Déaut, the President of OPECST at the time, had been tasked with seeking out expert advice, speaking to company representatives, consumers, and researchers in the eight months leading up to the Conference, and then compiling a report when the Conference had finished.[116] For the most part, Le Déaut's report agreed with the majority of the panel's recommendations. However, Le Déaut notably disagreed with the suggestion of creating two committees within the CGB. He feared that two committees would lead to permanent disputes within and paralysis of the CGB.[117] Le Déaut did acknowledge the importance of including representatives from civil society in the decisionmaking process, though. In place of two internal CGB committees, he recommended that the government create a separate commission with representatives from consumer associations, environmental groups, unions, and members of Parliament, under the purview of the Prime Minister's office. This commission would be responsible for providing its opinion on GMOs at the behest of the Prime Minister or Parliament. It could also seek contact with the relevant regulatory institutions, which would remain staffed by scientific experts. Le Déaut envisioned the function of this citizen committee as being responsible for providing warnings, rather than expertise, on the submitted dossiers.

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[115] Da Ros and Lynch. "Science and Public Participation in Regulating Genetically-Modified Food." 9.

[116] Jean-Yves Le Déaut and Henri Revol. 1998. "Préface." *L'utilisation des organismes génétiquement modifiés dans l'agriculture et dans l'alimentation.* Rapport 545 (97-98), Tome 1. Office Parlementaire d'Evaluations des Choix Scientifiques et Technologiques. http://www.senat.fr/rap/o97-5451/o97-54511.html (accessed June 2012).

[117] Jean-Yves Le Déaut and Henri Revol. 1998. "Recommandations Générales." *L'utilisation des organismes génétiquement modifiés dans l'agriculture et dans l'alimentation.* Rapport 545 (97-98), Tome 1. Office Parlementaire d'Evaluations des Choix Scientifiques et Technologiques. http://www.senat.fr/rap/o97-5451/o97-545117.html (accessed June 2012).

The developments of Phase III were incredibly important to the evolution of the regulatory framework for GMOs. The efforts to increase public participation in the decisionmaking process gave legitimacy to both expert opinions outside of the field of molecular biology and to the opinions of members from civil society. The Citizens Conference validated the idea that the French public should be involved in the decisionmaking process. As a result, not only were public interests in the process legitimized, their place at the decisionmaking table was institutionalized. This opening in the process for outside interests surfaced in the context of the concurrently occurring public health and food safety scandals of the 1990s, which had seriously heightened the public's doubts in the government's ability to make regulatory decisions in the interest of the public good. The scandals also generated the idea that scientific choices and techniques should be democratized.[118] In light of the HIV-tainted blood scandal and the BSE crisis, French politicians needed to restore the public's trust in their ability to regulate risk. In order to achieve that goal, public officials responded with reforms to the regulatory system in Phase IV.

Phase IV: 1998-2003

Following the Citizens Conference, the government convened a new CGB. The reconfiguration of the commission created a more distinct separation of risk assessment and risk management responsibilities. It also incorporated elements of "conflicting expertise": more weight was given to the opinions of civil society representatives; the scientific experts were selected from diverse disciplinary backgrounds; and experts critical of GMOs were nominated as members.[119] To increase transparency in the CGB's activities, commission members were required to declare any possible conflict of interests that they might have when reviewing a

[118] Boy. "Politiques de la Science et Démocratie Scientifique." 620.
[119] Bonneuil and Joly. "Plantes transgéniques, expertise et action publique."

dossier[120] and to share opinions on dossiers with the public in a timely manner.[121] Finally, the CGB shifted away from its previous method of forming an opinion based on consensus among the scientists, and it implemented rules requiring a vote on each dossier. The results of each vote would then be made public, though the minutes of the meeting, which could reveal the specific concerns of the dissenting members, would remain private.[122]

Although there were no real institutional changes to the CGB's structure of function, the government did attempt to broaden the commission's composition by making the scientific expertise more interdisciplinary and by including more representatives from civil society.[123] There were also several reforms that attempted to increase the transparency of the commission's activities and to incorporate elements of "conflicting expertise." Yet, because of fears that conflicting scientific opinions would alarm the public, the reasons for dissent were kept hidden; the CGB did not publish the minutes of its meetings, nor did it include minority opinions in the final opinions expressed to the Ministries.[124] While a step toward a more transparent process, the reforms of the CGB's internal rules still left the public in the dark on how the opinions were crafted. The reform measures were aimed at encouraging "'conflicting' debate within the confines of the CGB, but [the CGB did] not wish to expose conflicting opinions to the outside world."[125]

The inclusion of an expert critical of GMOs on the CGB also had mixed results. Some members reported that the anti-GMO expert, at the time Gilles-Eric Séralini, played an important role on the commission by asking challenging questions and pushing the other members further

[120] One of the critiques of the CGB that came out during the Citizens Conference was the concern that commission experts might have conflicts of interest in cases where the commission's opinion, and the subsequent governmental decision, would have an impact on the expert's own research.
[121] Bonneuil and Joly. "Plantes transgéniques, expertise et action publique."
[122] Marris et al. "Precautionary Expertise for GM Crops." 47.
[123] Da Ros and Lynch. "Science and Public Participation in Regulating Genetically-Modified Food." 12.
[124] Marris et al. "Precautionary Expertise for GM Crops." 47.
[125] Marris et al. "Precautionary Expertise for GM Crops." 47.

in their reasoning.[126] Other CGB members complained that Séralini's constant anti-GMO position was based on "'other', non-scientific reasons," and that he did not contribute anything positive to the process.[127] Although CGB members were originally optimistic about the new "culture" at the CGB in 1998, the commission seemed to have returned to "a more closed culture" by 2003.[128]

At the same time that the French government was reorganizing the CGB, it was also working to create institutions that would become the new cornerstone of the GMO regulatory system in France.[129] In 1999, the Parliament passed the *Loi d'orientation agricole n° 99-574 du 9 juillet 1999* (Agricultural Framework Law), which created a provisional committee known as the *Comité de Biovigilance*. This committee was responsible for monitoring GMOs once they were released into the environment for experimental or commercial reasons.[130] There were three goals for monitoring GMOs: to ensure traceability of the different varieties of GMO seeds; to collect information on GM plant performance and the possible, unintentional effects of cultivation; and to ensure monitoring of potential negative environmental impacts of widespread cultivation of GMOs.[131] The *Comité de Biovigilance* was primarily created to "examine the environmental risks of GMO test plots" and to monitor GM crops planted in open field tests plots and for commercial production.[132]

Phase IV also marked the creation of AFSSA, the French food safety authority. In order to promote transparency and independent expertise within the regulatory framework even

[126] Marris et al. "Precautionary Expertise for GM Crops." 48.
[127] Marris et al. "Precautionary Expertise for GM Crops." 47-48.
[128] Marris et al. "Precautionary Expertise for GM Crops." 48.
[129] Bonneuil and Joly. "Plantes transgéniques, expertise et action publique."
[130] Hénard. "France Biotechnology Annual 2006." 6.
[131] CETIOM. "Biovigilance." *Dossier OGM*. http://www.ogm.cetiom.fr/OGM/OGMSite/pages/05_reglementation/biovigilance.htm (accessed June 2012).
[132] Hénard. "France Biotechnology Annual 2006." 6.
By 2001, the point of controversy over GMOs had mostly shifted from a push for more public participation in the decisionmaking process to the issue of the safety of open air field trials. Whiteside. "Humanisme et Terroir." 80.

further, particularly with regard to public policy makers, the government created the *Agence française de sécurité sanitaire des aliments* in 1998, and it became operational in 1999.[133] AFSSA was also a response to the major food scandals of the 1990s; its functions were to provide independent scientific risk assessment in food safety, with the goals of assisting in setting regulation, improving transparency in decisionmaking, and implementing the precautionary principle when necessary.[134] Unlike the modified CGB, the plan for AFSSA was that it would have competency in both risk assessment and risk management. However, initially it was weak because it had little means or legitimacy to introduce economic, political, or social considerations in its risk assessment.[135] In the end, it suffered from the same issues as the CGB; it had been created as an institution for scientific expertise, and efforts to take "other," non-scientific factors into consideration were seen as overreach. While it was tasked with evaluating risks to food safety, ultimately it was the government that made the policy decisions.[136]

To ensure that the best possible experts were appointed to the agency, the government held a public call for applications to attract talented candidates from a variety of fields, in order to help address the range of issues to which AFSSA would need to respond.[137] The public call was a drastic departure from the ministerial appointments that were used to staff the other regulatory committees. In addition, appointed experts were required to declare any possible conflict of interest – direct or indirect – before each AFSSA committee meeting.[138] These measures were intended to reinforce the independence of the agency from the Ministries. As the

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[133] Conseil national de l'alimentation (CNA). 2001. "Concertation et débat public en matière de politique alimentaire: enjeux et aspects méthodologiques." June 30, Avis n°29. 10. http://agriculture.gouv.fr/IMG/pdf/Avis_n29.pdf (accessed June 2012).

[134] Olivier Borraz, Julien Besançon, & Christophe Clergeau, "Is It Just about Trust?" in Ansell and Vogel (eds.), *What's the Beef? The Contested Governance of European Food Safety*, (Cambridge, MA: The MIT Press, 2006), p.128.

[135] Borraz *et al.*, "Is It Just about Trust?" 134.

[136] CNA. "Concertation et débat public en matière de politique alimentaire." 10.

[137] CNA. "Concertation et débat public en matière de politique alimentaire." 10-11.

[138] CNA. "Concertation et débat public en matière de politique alimentaire." 11.

former Executive Director of AFSSA, Martin Hirsch, has noted, however, "it is somewhat paradoxical to describe AFSSA as an 'independent agency' – as government spokespeople often do – when it is in fact under the tutelage of three ministries (agriculture, health and consumers)."[139] Instead, AFSSA could "best be described as 'a dependent body charged with conducting independent expertise.'"[140] The "independence" of the agency was supposed to be the independence of the scientific experts from political and economic pressures. To that end, the responsibility of AFSSA was to evaluate GMOs in the context of human and animal health, not with considerations for economic, political, or environmental interests.

Within the regulatory framework for GMOs, AFSSA carried "out risk assessment prior to market authorizations for different products, including GMOs used for human food or animal feed."[141] AFSSA created specialized committees of experts (CES) in 2000 to provide scientific expertise in ten main areas, including biotechnology (Biotechnology CES).[142] The Biotechnology CES was always responsible for evaluating GMOs, even if the GM product could also be considered under one of the other nine areas.[143]

As mentioned in Chapter 3, despite its lack of national power, AFSSA legitimized France's more precautionary position at the EU-level when the Commission attempted to lift the moratorium on GM crops in 1998. At that time, AFSSA opposed the risk assessment of Bt-11 maize by the EU's scientific committees and the subsequent assessments by the European Food Safety Authority (EFSA), on the grounds that the data was not sufficient to determine whether

[139] Martin Hirsch. 2001. "L'expertise scientifique indépendante dans un établissement public: l'exemple de l'Agence française de sécurité sanitaire des aliments." *Conseil d'Etat, Etudes & Documents*. 427-440, as cited in Marris et al. "Precautionary Expertise for GM Crops." 54.
[140] Hirsch. "L'expertise scientifique indépendante dans un établissement public," as cited in Marris et al. "Precautionary Expertise for GM Crops." 54.
[141] Marris et al. "Precautionary Expertise for GM Crops." 53.
[142] Marris et al. "Precautionary Expertise for GM Crops." 53.
[143] Marris et al. "Precautionary Expertise for GM Crops." 53.

the GM maize posed risks to human health.[144] France delayed implementation of the approval process for GMOs as a result of AFSSA's opinion on the matter.[145]

The legacy of Phase III guided the regulatory developments of Phase IV. In response to the conclusions of the Citizens Conference, the government reformed the CGB and created new institutions to share the responsibility of evaluating the risks of GMOs at different points along their production cycle (during fields trials and pre- and post-market authorizations). The creation of AFSSA and the *Comité de Biovigilance* weakened the central role in the GMO regulatory framework that the CGB had held in the first three phases.[146] Yet, it is also important to note that despite reforms to increase transparency and independence, the regulatory institutions still relied heavily – or in the case of AFSSA, exclusively – on scientific expertise to form their opinions.

Despite the persistent supremacy of scientific expertise in risk evaluation within the committees, the precedence of more public participation in the GMO debate, established in Phase III, continued in Phase IV. For example, the French government continued to organize public debates on the issue of GMOs. In November and December of 2000, several ministers held a series of public forums to discuss food quality and food safety, in addition to conducting a national opinion poll on the topic.[147] Known as the *États généraux de l'Alimentation* (EGA), the forums specifically dedicated to agricultural biotechnology and the national poll results "confirmed unambiguously the massive opposition of French consumers to GMOs."[148]

Additionally, when the debate over GMOs shifted in focus to questions about the safety of open air field trials, the Agricultural Minister announced a new "débat public," which was

[144] Borraz *et al.*, "Is It Just about Trust?" p.149.
[145] Borraz *et al.*, "Is It Just about Trust?" p.149.
[146] Bonneuil and Joly. "Plantes transgéniques, expertise et action publique."
[147] Direction Générale de l'Alimentation (DGAL). 2001. *Bilan d'Activité 2000*. 47. http://agriculture.gouv.fr/IMG/pdf/2000bilan.pdf (accessed June 2012).
[148] Whiteside. "Humanisme et Terroir." 80. The *États généraux de l'Alimentation* can be loosely translated as the "General State of Food."

held in February of 2002. This public debate differed from the format of the original Citizens Conference on GMOs in that it expanded the number of laypeople included, from 15 to 120 participants.[149] Known as the "Four Wise Men's Debate" (so named because it was organized by the presidents of four consultative commissions on food policy, technology assessment, bioethics, and sustainable development), the resultant final report emphasized that field trials occurred in a social space, and as such, field trial authorizations needed to be considered by an audience wider than scientific experts.[150] Although the Wise Men's debate was "an important moment in the public controversy on GMOs" and contained specific policy recommendations, a change in government shortly after its publication led to it having little impact on public policy decisionmaking.[151]

In general, although the increased efforts to include public participation through forums created a new space for public interests in the decisionmaking process, the public voice had little to no impact on the decisions taken by the French government.[152] At that time, the French government did not take seriously the recommendation to create a permanent committee that would represent socioeconomic concerns and expertise. And the proliferation of new scientific committees and agencies in an attempt to ensure transparency and independence only led to a fragmented regulatory system, making coordination between the different bodies more difficult than ever.[153]

[149] Whiteside. "Humanisme et Terroir." 80.
[150] Marris et al. "Precautionary Expertise for GM Crops." 32.
[151] Marris et al. "Precautionary Expertise for GM Crops." 33.
[152] Pierre-Bénoît Joly and Claire Marris. 2003. "A la recherche d'une démocratie technique. Enseignements de la conférence citoyenne sur les OGM en France." *Natures, Sciences et Sociétés*. vol. 1. 3-15, as cited in Olivier Borraz and Julien Besançon. 2009. "Uncertainties in regulating food safety in France," in *Uncertain Risks Regulated*, Michelle Evenson and Ellen Vos (eds.). New York: Routledge-Cavendish. p. 49-67. Here: p.63.
[153] Borraz and Besançon. "Uncertainties in regulating food safety in France." 65.

Phase V: 2003-2008

The turbulence that characterized Phase III, and that resulted in regulatory responses in Phase IV, was not just a domestic disturbance. Outside of France's borders, storms were also brewing. International pressures to lift an EU-wide moratorium on GMO approvals and GM imports were coming to a head. In addition, negotiations on regulatory guidelines and standards for GMOs were being hashed out in different international forums.[154] The EU, and by extension France as an EU member state, were under pressure to unlock the approval process and to accept GMOs within their borders.

In 1998, the French government had spearheaded the movement at the EU-level to implement a *de facto* moratorium on GMO approvals until a more stringent regulatory system was developed. Within the EU, the moratorium blocked all new GMO approvals in the Council. In terms of international trade, EU member states refused to import GM products. In 2003, the US challenged the EU in the World Trade Organization (WTO), claiming that the EU was "illegally restricting imports" by refusing entry to American GMOs.[155] After the WTO ordered the EU to allow GM products into the European market, the EU lifted its ban in 2003.

Despite the lifting of the EU moratorium, France continued to ban the importation of GM food. This stance left France at odds with the EU's policies, and thus vulnerable to legal action. Because of its noncompliance with EU law, the European Commission brought two cases to the ECJ against France during Phase V. The first, in 2004, was for France's failure to properly transpose Directive 2001/18/EC, resulting in the ECJ ruling that France had infringed Community law and was therefore required to pay penalty payments to the EU. The Commission pursued a second case in 2007 because France still had failed to transpose the Directive

[154] For a more detailed discussion of international negotiations, see Chapter 3.
[155] West. *Biotechnology Policy Across National Boundaries*. 57.

completely following the first ruling. The 2007 case finally motivated France to transpose Directive 2001/18/EC fully, though France had to pay a lump sum penalty of 10 million euros for failure to comply with the 2004 judgment.[156]

At the same time that the French government struggled at the EU-level to justify its more precautionary position, it was also struggling domestically to overcome the impasse in the GMO debate. The CGB and AFSSA were regularly producing conflicting opinions regarding GMO approvals; in 2003, for example, they disagreed on five out of six products evaluated under 2001/18/EC.[157] In addition, attempts to collect more research on GMOs and their potential effects were continually stymied by the so-called *faucheurs volontaires*.[158] Since 1999, anti-GMO interest groups had orchestrated campaigns to destroy GMO field trials.[159] The intensity of the field-trial destruction increased in the following years, and by the summer of 2005, "activists [had] destroyed half of the open field tests."[160] Consequently, although the CGB had approved several GMOs for cultivation for test purposes, the number of test plots for field trials plummeted – from 366 plots in 1999 to only 48 in 2004.[161]

Around that time, the French government announced a potential solution to the deadlock. In November of 2004, President Chirac revealed that he would present biotechnology legislation to Parliament, in an effort to transpose Directive 2001/18/EC into national law.[162] The proposed

[156] For a more detailed discussion of the WTO and ECJ cases, see Chapter 3.
[157] Claire Marris, Pierre-Bénoît Joly, Stéphanie Ronda, and Christophe Bonneuil. 2005. "How the French GM controversy led to the reciprocal emancipation of scientific expertise and policy making." *Science and Public Policy*. Vol. 32. No. 4. August. pp.301-308. Here: 30
[158] *Faucheurs volontaires* are "volunteer reapers": anti-GMO individuals who destroy GM crops as a form of protest.
[159] Claire Marris et al. "How the French GM controversy led to the reciprocal emancipation of scientific expertise and policy making." 303.
[160] Hénard.. "France Biotechnology Annual 2006."
[161] Mark Cantley. 2007. "An Overview of Regulatory Tools and Frameworks for Modern Biotechnology: A Focus on Agro-Food." *OECD International Futures Project on "The Bioeconomy to 2030: Designing a Policy Agenda."* OECD Report. OECD International Futures Programme. 73.
[162] N.A. "French President Announces Framework Law on Biotech Crops (USDA-FAS GAIN report)." *Biofuels Journal*. Original post date: November 2, 2004.

legislation included provisions on the coexistence for GM and non-GM crops and a plan to create a new biotechnology council to assess GM products at the national level in France.[163] The new council would be under the control of the Ministry of Agriculture, with the assistance of the Ministries of the Environment and of Research. Rather than adding a new scientific committee to evaluate GMOs to the already existing regulatory institutions, the proposed council intended to replace several of the existing regulatory institutions (the CGG, CGB, and *Comité de Biovigilance*) with one inclusive scientific committee. The legislation would also have created a second committee within the new council, but rather than offering scientific evaluations, that committee would be responsible for evaluating the sociological and economical aspects of GM products.[164]

The proposed changes to the regulatory framework by Chirac recalled the suggestions made in the conclusions of the Citizens Conference, namely that a new committee was necessary to evaluate the non-scientific factors associated with potential GMO risks. The intent of the progressive fragmentation of the regulatory framework in the wake of the Citizens Conference was to incorporate "conflicting expertise" into a closed system, with the greater goal of creating more transparency. The result was, indeed, that AFSSA and the CGB regularly produced conflicting opinions. But the consequence of those conflicts was a paralyzed regulatory system, rather than a coherent regulatory framework.

While the government acknowledged that the system was deadlocked within France, members of Parliament were in no rush to pass the legislation. Only the French Senate had voted on the biotech bill by March of 2006. And reports from that time indicate that the French

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http://www.biofuelsjournal.com/articles/french_president_announces_framework_law_on_biotech_crops__font_size__2___usda_fas_gain_report___fon_-24110.html (accessed June 2012).

[163] "French President Announces Framework Law on Biotech Crops (USDA-FAS GAIN report)."

[164] "French President Announces Framework Law on Biotech Crops (USDA-FAS GAIN report)."

National Assembly was reluctant to bring the bill up for a vote so close to the presidential and parliamentary elections scheduled in May and June of 2007, despite the threat of heavy fines from the EU for failure to transpose the EU Directive.[165] Politicians were not interested in making agricultural biotechnology a campaign issue.

In late spring of 2007, Nicolas Sarkozy and his party – *Union pour une Majorité Populaire* (UMP) – won decisive victories for the presidency and in the parliament.[166] Sarkozy's early endeavors in office seemed to continue the previous efforts to free up the regulatory impasse regarding GMOs. For example, he organized a series of workshops on the environment, known as *Le Grenelle Environnment* (the Environment Roundtable), to help "define the key points of government policy on ecological and sustainable development issues" for his term in office.[167] The then-Minister of the Environment, Jean Louis Borloo, and the then-Under-Secretaries of the Transportation and Environment Ministries, Dominique Bussereau and Nathalie Kosciusko-Morizet, organized the Roundtable. They brought together panels of civil society and public service delegates, who represented five interest groups: national government, unions, corporations, NGOs, and local authorities.[168]

The roundtable events occurred in five phases. Between July and September of 2007, six workgroups with representatives from all panels "met to propose concrete action [regarding environmental issues] to be implemented at [the] national, European and international level."[169]

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[165] Hénard. "France Biotechnology Annual 2006."; Cantley. "An Overview of Regulatory Tools and Frameworks for Modern Biotechnology." 72-73.

[166] The *Union pour une Majorité Populaire* is known at the "Union for a Popular Majority," in English. Bruno Cautrès with Alistair Cole. "The 2007 French Elections and Beyond," in Alistair Cole, Patrick Le Galès, and Jonah D. Levy (eds.), *Developments in French Politics 4*. New York: Palgrave Macmillan, 2008: 22-41. Here: 37-38.

[167] Le Ministère de l'Ecologie, du Développement durable et de l'Energie. *Le Grenelle Environnement*. http://www.legrenelle-environnement.fr/-Version-anglaise-.html?rubrique33 (accessed June 2012).

[168] Le Ministère de l'Ecologie. *Le Grenelle Environnement*.

[169] Le Ministère de l'Ecologie. *Le Grenelle Environnement*; Le Ministère de l'Ecologie, du Développement durable et de l'Energie. *Présentation du Grenelle Environnement*. http://www.legrenelle-environnement.fr/Presentation-du-Grenelle.html (accessed June 2012).

The second phase began in October, when the government solicited public feedback by opening up the proposals to the general public for debate, through public meetings and internet forums.[170] On October 24-25, 2007, negotiations among the five panels took place to identify "the major guidelines for action in all theme areas."[171] Sarkozy closed the negotiations with a speech presenting the Roundtable's conclusions.[172] The direct result of the negotiations was the creation of thirty-four operational committees charged with developing guidelines for the implementation of the Roundtable's conclusions in the fourth phase of *Le Grenelle* (December 2007). The final phase and result of *Le Grenelle Environnement* was the passing of five *lois Grenelle* (the Grenelle laws) between 2008 and 2010. These laws created the legal basis for the Roundtable's environmental action plans.

The first law of the *lois Grenelle* to pass through Parliament was the *Loi OGM* on June 25, 2008.[173] Among the principal measures of the *Loi OGM* were: a guarantee of the right to produce and consume GM-free products; an assurance that farmers whose crops had been contaminated by GMOs would be compensated; and the declaration that the destruction of GM fields would be punishable by two years in prison.[174] In addition, the *Loi OGM* finally created

[170] Le Ministère de l'Ecologie. *Le Grenelle Environnement*; Le Ministère de l'Ecologie. *Présentation du Grenelle Environnement*.
[171] Le Ministère de l'Ecologie, du Développement durable et de l'Energie. *Round Table.* http://www.legrenelle-environnement.fr/-Round-Table-.html (accessed June 2012). The "themes" of the different workgroups were: "fight climate change and control energy demand; preserve biodiversity and natural resources; create an environment conducive to health; adopt sustainable modes of production and consumption; construct a green democracy; and promote green development favouring employment and competitiveness." Le Ministère de l'Ecologie, du Développement durable et de l'Energie. *Workgroups.* http://www.legrenelle-environnement.fr/-Workgroups-.html (accessed June 2012).
[172] The English version of Sarkozy's speech can be found here: http://www.legrenelle-environnement.fr/IMG/pdf/Discours_GrenelleEnvironnement_Anglais-4.pdf.
[173] The *Loi OGM* is officially known as *Loi n° 2008-595 du 25 juin 2008 relative aux organismes génétiquement modifiés* (Law n° 2008-595 of June 25, 2008 related to genetically modified organisms).
[174] Le Ministère de l'Ecologie, du Développement durable et de l'Energie. *Loi OGM.* http://www.legrenelle-environnement.fr/Loi-OGM.html (accessed June 2012).

the *Haut Conseil des Biotechnologies* (HCB – High Council on Biotechnology): the two-committee council that had been proposed by Chirac.[175]

Phase VI: 2008-2010

The final incarnation of the HCB did share some characteristics with Chirac's proposal, though there were also a few significant differences. In terms of similarities, the HCB did replace the CGG and the CGB, as Chirac had proposed. The HCB also absorbed a provisional committee that the Ministry of the Environment had created in 2007 to evaluate the potential environmental impacts of Monsanto's GM maize (MON810).[176] The provisional *Comité de Biovigilance* did not become subsumed into the HCB; however, the *Loi OGM* did create a "new" commission to replace it – the *Comité de surveillance biologique du territoire* (CSBT).[177]

As proposed by Chirac and the Citizens Conference report, the HCB is made up of two committees: one responsible for scientifically evaluating the effects of GMOs on the environment and public health (the *Comité scientifique* – CS), and another responsible for evaluating the social, economic, and ethical implications of GMOs (the *Comité économique, éthique et social* – CEES).[178] Unlike Chirac's recommendation that it be housed in the Ministry

[175] The *Haut Conseil des Biotechnologies* was further defined legally in December of 2008 by the *Décret n° 2008-1273 du 5 décembre 2008.*

[176] HCB. "Missions." *A propos du HCB.* http://www.hautconseildesbiotechnologies.fr/spip.php?article42 (accessed July 2012). The provisional committee was called the *Comité de Préfiguration de la Haute Autorité sur les OGM* (CPHA). At the time, MON810 was the only GM maize that had been approved for cultivation within France. Agnès E. Ricroch, Jean Baptiste Bergé, and Marcel Kuntz. 2010. "Is the Suspension of MON810 Maize Cultivation by Some European Countries Scientifically Justified?" *ISB News Report*. April. http://www.isb.vt.edu/news/2010/Apr/Suspension-of-MON810-Maize-Cultivation.pdf (accessed July 2012).

[177] The CSBT took over the responsibilities of the provisional committee, in that it is responsible for evaluating and monitoring the impacts of the cultivation of GM plants on the environment. But, more broadly, the CSBT is responsible for monitoring the potential impacts of agricultural practices on the environment and for establishing the protocols for collecting data on the appearance and proliferation of harmful organisms. In addition, the CSBT must consult with the HCB at least once a year to provide its opinion on the guidelines for surveillance practices used to monitor the environmental effects of GM crops. Le Ministère de l'Ecologie, du Développement durable et de l'Energie. 16/09/2011 "CSBT: missions et avis." *Surveillance du territoire*. http://agriculture.gouv.fr/CSBT-missions-et-avis,1645 (accessed July 2012).

[178] In English, they are known as the Scientific Committee and the Economic, Ethical, and Social Committee. HCB. "Comités." *Accueil du site*. http://www.hautconseildesbiotechnologies.fr/spip.php?rubrique2 (accessed July 2012).

of Agriculture like the CGB had been, with assistance from the Ministries of the Environment and of Research, the HCB is instead affiliated with several ministries: Environment, Consumption, Agriculture, Health, and Research.[179]

The CS of the HCB is made up of a minimum of 26 and no more than 40 members, including its president. At least 22 members must be specialists from a range of scientific backgrounds: genetics (3), microbiology (3), human and animal health (10), agronomy (3), and environmental sciences (3). To meet the minimum number of members, the scientific committee must also include at least one specialist from each of the following fields: statistics, law, economics, and sociology.[180] Like the reformed CGB, the composition of the HCB's scientific committee is interdisciplinary, with a broad range of scientific expertise included. The interdisciplinarity of the HCB, however, goes even further than the reformed CGB by including representatives from more fields in both the sciences and social sciences. And, it is staffed similarly to AFSSA; the French government solicits applications for membership on the CS through a public call. Each member serves a five-year term, which can be renewed.

In addition to its president, the CEES is required to have 26 members who represent 17 different categories of civil society, industry, labor, and local, regional, and national government. Members are nominated to the CEES by their respective organizations.[181] The pertinent Ministers present nominations for the president of each committee and of the HCB as a whole. The Finance Committees in both the French National Assembly and the Senate must then

[179] François Fillon. 2008. *Décret n° 2008-1273 du 5 décembre 2008 relatif au Haut Conseil des biotechnologies.* http://www.legifrance.gouv.fr/affichTexte.do;jsessionid=?cidTexte=JORFTEXT000019876045&dateTexte=&oldAction=rechJO&categorieLien=id (accessed July 2012).

[180] Marie-Cécile Hénard. 2009. "France Biotechnology French Biotechnology Policy Measures Bogged Down 2009." GAIN Report. Report no. FR9003. Paris: USDA Foreign Agricultural Service. 2; Fillon. *Décret n° 2008-1273*.

[181] Fillon. *Décret n° 2008-1273*. For example, the representative from the National Ethics Consultative Committee is nominated by the president of that committee; the five farmers' union representatives are nominated by their respective unions; the two representatives from consumer rights organizations are nominated by their respective organizations, etc.

approve the presidential nominations. The three presidents make up the leadership of the HCB, along with the vice-presidents of the CS and the CEES who are elected by an absolute majority of their committee's members.[182]

The mission of the HCB is "to provide advice to the French Government on a wide range of issues relative to biotech products."[183] Moreover, the HCB is responsible for "proposing a definition of non-biotech products; recommending coexistence measures for biotech and non-biotech crop cultivation; and reviewing applications on the confined use of [GM] products and on the release into the environment (cultivation) of a large number of [GM] products."[184]

As part of its work, the HCB receives dossiers regarding GMO approvals. When the submitted dossier refers to a question on the use of an already approved GMO, only the CS provides an opinion. However, when the submitted dossier concerns a new request to disseminate a GMO voluntarily (as in a field test, through cultivation, or the market entry of a product with GM content), both committees respond. First, the CS gives its opinion after evaluating the potential health and environmental impacts of the GMO. Then, the CEES gives its own recommendations after reviewing the opinion of the CS and performing an analysis of the potential economic, ethical, and social implications of the GMO.[185] The HCB president communicates the opinions to the competent authorities and to the petitioner. For dossiers where both committees respond, the president presents the HCB's opinion as the *avis du CS – recommandation du CEES* (CS opinion – CEES recommendation).[186]

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[182] Fillon. *Décret n° 2008-1273*.
[183] Hénard. "French Biotechnology Policy Measures Bogged Down 2009." 2.
[184] Hénard. "French Biotechnology Policy Measures Bogged Down 2009." 2.
[185] HCB. "L'instruction des saisines." *Fonctionnement*. http://www.hautconseildesbiotechnologies.fr/spip.php?rubrique25 (accessed July 2012).
[186] HCB. "Les avis." *Fonctionnement*. http://www.hautconseildesbiotechnologies.fr/spip.php?rubrique25 (accessed July 2012).

In this way, the opinions of the two committees may diverge, and they often do. For example, the CS and the CEES differed over the first dossier that the HCB received – a request to review GM maize by Monsanto (MON810) for which EFSA was considering reauthorization. The CS noted that the scientific data provided was limited, but that the GMO did not seem to pose significant risks to human or animal health. In addition, the committee found that the GM maize would help reduce the amount of pesticides used by up to 50%. However, the CS also recommended that Monsanto should continue to monitor the GMO, in conjunction with the CSBT, after approval and during cultivation.[187] In contrast, the majority of the members of the CEES found that the benefits of MON810 did not outweigh its disadvantages.[188]

The HCB acknowledges that it provides contradictory opinions, but does not perceive its contradictions as inherently problematic. Its website states that: "The [HCB's] opinions may express the conflicting positions formulated within each committee, [but] they do have consultative value."[189] The HCB goes on to note that it is only an advisory body; its opinions are not meant to replace the state in the decisionmaking process. This hesitancy to provide a clear-cut opinion is evident in the way in which the CEES presents its recommendations. In the case of the MON810 dossier, 14 of the 26 members voted "no" to the question of whether the benefits of the GMO outweighed its disadvantages; yet, the committee also provided recommendations on

[187] Comité scientifique du HCB. "Avis sur les réponses de l'AESA aux questions posées par les Etats membres au sujet de la culture et de la consommation du maïs Mon810, Dossier EFSA-GMO-RX-MON810." December 22, 2009. http://www.hautconseildesbiotechnologies.fr/IMG/pdf/091222_Mais_MON810_Avis_CS_HCB.pdf (accessed July 2012). 7.

[188] Comité économique, éthique et social du HCB. "Recommandation relative à la demande de renouvellment des autorisations de culture, importations et transformation du maïs MON810." December 22, 2009. http://www.hautconseildesbiotechnologies.fr/IMG/pdf/091222_Mais_MON810_Recommandation_CEES_HCB.pdf (accessed July 2012). 8.

[189] HCB. "Les avis." Original text: "Les avis peuvent faire état de positions divergentes exprimées au sein de chaque comité. Ils ont une valeur consultative : le HCB étant une instance de concertation et de conseil, il ne se substitue pas à la puissance publique pour la prise de décision." (my translation).

the standards and monitoring methods that should be required if the state decided to authorize MON810 anyway.

For other dossiers, the CEES has provided appendices in its recommendations to catalogue dissenting opinions. One such example is the *avis du CS – recommandation du CEES* on the authorization of field trials to study the Grapevine fanleaf virus (GFLV). After its evaluation of the dossier, which was presented by the *Institut National de Recherche Agronomique* (INRA),[190] the CS stated that there were no identifiable risks to human or animal health or to the environment.[191] In turn, the CEES concluded that the dossier met the standards of the three criteria used for its evaluation. And, though the recommendation does not explicitly state that the tests should be authorized, the dissenting opinions imply that meeting the criteria was seen as positive support for the authorization.[192]

The formation of the HCB was supposed to reduce the bottleneck in the regulatory approval process for GMOs, by streamlining a fragmentary system into one major council that would be responsible for providing the government with a comprehensive opinion. The HCB's structure reflected previous regulatory reforms with its efforts to engender interdisciplinary, scientific expertise and to include a range of public interests. The internal rules of the CS, however, were a return to the consensus-style of scientific evaluation that characterized the CGB

[190] INRA is the number one agricultural research institute in Europe. It is a public research institute, and it carries out "mission-oriented research for high-quality and healthy foods, competitive and sustainable agriculture and a preserved and valorised environment." INRA. *The Institute*. http://www.international.inra.fr/the_institute (accessed July 2012).

[191] Comité scientifique du HCB. "Avis sur le dossier B/FR/09.11.01." March 15, 2010. http://www.hautconseildesbiotechnologies.fr/IMG/pdf/100410-Vigne-Avis-CS-HCB.pdf (accessed July 2012). 2.

[192] Representatives from four NGOs offered reasons for their dissent in the appendix. Three of the four dissenters represented environmental protection groups (Greenpeace, Les Amis de la Terre, and France Nature Environnement). The remaining dissenter was a representative from the Confédération Paysanne.
Comité économique, éthique et social du HCB. "Recommandation relative à la demande d'expérimentation de porte-greffes de vigne génétiquement modifiés (demande B/FR/09.11.01)." April 10, 2010. http://www.hautconseildesbiotechnologies.fr/IMG/pdf/100410-Vigne-Recommandation-CEES-HCB.pdf (accessed July 2012). 7-11.

before the reforms in Phase IV. In its first years, the opinions of the CS have all been based on unanimity, except in the case of determining coexistence guidelines.[193]

Yet, consensus has not developed between the two committees, and frequent conflicting opinions from the CS and the CEES mean a lack of clear-cut advice for the Ministries. As a result, the Ministries must decide whose opinion to follow. The HCB has not opened up the approval process as hoped. Although the anti-GMO groups have generally worked well with the HCB, pro-GMO groups have been more critical because they had expected "science to come first."[194]

Sarkozy's government was also not successful in promoting a coherent stance on the issue of GMOs. The American government interpreted Sarkozy's position to be anti-GMO,[195] partly because he maintained a domestic ban on MON810 and partly because he consistently voted negatively or abstained on new GMO approvals at the EU-level.[196] Furthermore, early in Sarkozy's tenure, there was a shift in the leader of the GMO portfolio, from the Minister of Agriculture to the Minister of the Environment. Between 2007 and 2010, the Ministry of the Environment spearheaded a number of policy initiatives that seemed to take a more negative approach to the biotechnology issue.[197]

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[193] Jean-Pierre Bompard. 2/21/12. "Lecture de l'histoire du HCB." *Alternative Economiques*. http://alternatives-economiques.fr/blogs/bompard/archives/150 (accessed July 2012).
[194] Olivier Borraz, from interview with the author (March 12, 2012).
[195] Marie-Cécile Hénard. 2008. "France Biotechnology GOF Action on Biotech – One-Year Review 2008." GAIN Report. Report no. FR8008. Paris: USDA Foreign Agricultural Service. 2, 3.
[196] The French government temporarily suspended the cultivation of the GM maize MON810 at the end of October 2007. Following protests from over a thousand scientists, the government formed a provisional committee – CPHA – to assess the potential impacts of MON810's cultivation. Despite only providing a draft report, which did not find new scientific data on MON810 to be "negative," the government decided to uphold the ban, and on February 7, 2008, cultivation of MON810 was officially suspended. Ricroch, Bergé, and Kuntz. "Is the Suspension of MON810 Maize Cultivation by Some European Countries Scientifically Justified?"
[197] Hénard. "GOF Action on Biotech – One-Year Review 2008." 2; Marie-Cécile Hénard. 2010. "France Approves New Biotech Corn, Biotech Vine Destructions Extremely Unpopular." GAIN Report. Report no. FR9046. Paris: USDA Foreign Agricultural Service. 4.

But there were several public inconsistencies that suggested Sarkozy might compromise on the GMO issue. For example, when Environmental Minister Borloo suggested that France might halt new plantings of GM crops, "he was immediately contradicted by an Élysée spokesman."[198] One of Sarkozy's aides further clarified that the "GMO question should not be treated 'cavalierly' and that the ultimate decision would be made by 'the President of the Republic and the Prime Minister.'"[199] Sarkozy even went as far as to announce in a 2008 speech at the annual *Salon de l'Agriculture* that France must change its environmental protection methods in agricultural practices, stating that he would not "sacrifice French agricultural interests" to others' standards.[200] This declaration angered environmentalists, who felt "betrayed" by Sarkozy just a few months after the success of his *Grenelle Environnement*.[201]

Despite its, at times, inconsistent message, the French government realized that something needed to be done to resolve the GMO issue, particularly in the face of renewed pressure and penalty payments from the EU. To that end, the law that created the HCB also transposed the outstanding portions of the EU Directive 2001/18/EC. With the transposition, France avoided more penalty payments to the EU. But the creation of the structure of the HCB only ensured that the letter of the law was met, not the intent. One of the main purposes of the Directive was "to make the procedure for granting consent for the deliberate release and placing on the market of genetically modified organisms (GMOs) more efficient and more transparent,"

[198] The "Élysée" refers to the French presidential palace. Article from the September 24, 2007 issue of *Libération*, as cited in Jonah D. Levy and Cindy Skach. "The Return to a Strong Presidency," in Alistair Cole, Patrick Le Galès, and Jonah D. Levy (eds.), *Developments in French Politics 4*. New York: Palgrave Macmillan, 2008: 111-126. Here: 124.
[199] *Libération* (September 24, 2007), as cited in Levy and Skach. "The Return to a Strong Presidency." 125.
[200] Elodie Bousquet. 2010. "Nicolas Sarkozy s'assoit sur le Grenelle de l'environnement." *L'Express*. March 9. http://www.lexpress.fr/actualite/environnement/nicolas-sarkozy-s-assoit-sur-le-grenelle-de-l-environnement_853994.html (accessed July 2012).
[201] Bousquet. "Nicolas Sarkozy s'assoit sur le Grenelle de l'environnement."

in order to help establish "a common methodology for risk assessment."[202] But France continued to maintain its national GMO bans, which violated EU approvals.

The HCB was further tested in August 2010, when approximately 60 *faucheurs volontaires* destroyed the INRA open air field trials of GM grapevines. The HCB's *avis du CS – recommandation du CEES* had been generally positive regarding INRA's petition for a ten-year field trial. The CS wholly agreed with the dossier that INRA submitted, noting not only that there seemed to be no identifiable risks to the environment or to public health, but also that INRA had presented "the characteristics of the trial, the environment, and the measures taken to control the risks in a precise manner."[203] In most of its opinions, the CS details the measures that need to be taken by the petitioner to ensure the protection of the environment and of public health. In the case of INRA's dossier, the CS made no major suggestions. The CEES was also much more positive in its assessment of INRA's proposal than in other recommendations it had provided. The CEES observed that INRA had already worked closely with the local community (researchers, professionals, and members of civil society) to solicit feedback and to provide information regarding the trials.[204] The recommendation even went as far as to state that, despite not all members being in agreement, the CEES believed that an open air trial could provide useful data regarding plant life and viruses in general.[205]

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[202] European Commission, "Summaries of Legislation: Deliberate Release of Genetically Modified Organisms (GMOs)," http://europa.eu/legislation_summaries/agriculture/food/l28130_en.htm (accessed July 2012).

[203] CS du HCB. "Avis sur le dossier B/FR/09.11.01." 10. Original text: "Les caractéristiques de l'essai, l'environnement et les mesures prises pour contrôler le risque sont décrites de façon précise. Il n'y a pas d'indication d'effet indésirable des produits des transgènes sur la santé publique ou l'environnement." (My translation).

[204] CEES du HCB. "Recommandation relative à la demande d'expérimentation de porte-greffes de vigne génétiquement modifiés (demande B/FR/09.11.01)." 6.

[205] As mentioned above, dissenting opinions from four anti-GMO NGO representatives were included in the appendix of the CEES recommendation. CEES du HCB. "Recommandation relative à la demande d'expérimentation de porte-greffes de vigne génétiquement modifiés (demande B/FR/09.11.01)." 5-6.

The INRA open air trials in Alsace had been viewed by the anti- and pro- sides as something of a rapprochement.[206] Both the CS and the majority of the CEES seemed positive that risks were minimal and that they would be well-managed. The fact that INRA is a public research institution, and not a private biotech corporation, also soothed fears that commercial interests would trump public health and environmental concerns. INRA's engagement of the local community had already led to meetings between the anti-GMO and pro-GMO camps to develop a protocol on how experimental trials should be conducted and how the results should be interpreted.[207]

The rapprochement was shattered, however, when *faucheurs volontaires* destroyed the GM vines a few months into the new trial period. The president of the INRA unit in Alsace, Jean Masson, reacted strongly to the destruction: "'It's extremely serious for the research. We work for a public institution and these psychos come destroy it all. They stop knowledge from advancing, that's all they do.'"[208] For their part, the *faucheurs volontaires* emphasized that they were engaging in non-violent acts of civil disobedience, and that although it was public money that had financed the trials, the public did not want GMOs.[209]

Several public figures condemned the destruction of INRA's test field, including the Ministers of the Environment, of Research, and of Agriculture. Frédéric Bach, the director of the wine-growers association in Alsace (*Association des viticulteurs d'Alsace*), also spoke out against the destruction and in support of INRA's work.[210] The HCB published a press release a

[206] Olivier Borraz, from interview with the author (March 12, 2012).
[207] Olivier Borraz, from interview with the author (March 12, 2012).
[208] Original text: "C'est gravissime pour la recherche. On travaille pour un établissement public et ces malades viennent tout détruire. Ils empêchent la connaissance d'avancer, c'est tout ce qu'ils font." (my translation). "Les faucheurs volontaires s'en prennent aux vignes de l'INRA." *Le Monde.* August 15, 2010. http://www.lemonde.fr/planete/article/2010/08/15/les-faucheurs-volontaires-s-en-prennent-aux-vignes-de-l-inra_1399165_3244.html (accessed July 2012).
[209] "Les faucheurs volontaires s'en prennent aux vignes de l'INRA."
[210] Hervé Morin. "La vigne transgénique, nouvelle cible des 'faucheurs'." *Le Monde*. August 17, 2010.

week after the vineyard's destruction, entitled "The High Council on Biotechnology deplores the disruption of INRA's experiments on the genetically modified vines in Colmar."[211] But in the months following the destruction of the Alsatian field test and during the ensuing trial, the respective organizations of the CEES members who had dissented on INRA's dossier all publically supported the *faucheurs volontaires*.[212] In addition, *France Nature Environnment* and Greenpeace France publically condemned the HCB for issuing the press release that spoke against the destruction. Both organizations claimed that the HCB did not speak for them, and that their representatives on the HCB had not been consulted on the press release.[213] The HCB was just two years old at that time, and already it seemed to be troubled.

Conclusion

The HCB has thus failed to provide a solution to the regulatory deadlock in France. The CS and the CEES continue to present conflicting opinions on GMO approvals, leaving the relevant Ministry to make the final decisions. The Ministries still need to evaluate the conflicting opinions and then decide whether to approve the submitted GMO dossier. This situation leaves public officials vulnerable to claims of political manipulation of the outcome and to blame if

[211] HCB. "Le Haut Conseil des biotechnologies déplore l'interruption de l'expérimentation de l'INRA sur des porte-greffes de vigne génétiquement modifiés à Colmar." *Communique de Presse*. August 23, 2010. http://www.hautconseildesbiotechnologies.fr/IMG/pdf/CP_HCB_230810_Colmar-2.pdf (accessed July 2012).

[212] Greenpeace France. 2010. "OGM: le HCB prend des positions partisanes sans consulter ses membres: Greenpeace proteste." *OGM*. August 23. http://ogm.greenpeace.fr/ogm-le-hcb-prend-des-positions-partisanes-sans-consulter-ses-membres-greenpeace-proteste (accessed July 2012); Christian Vélot. 2011. "Vigne transgénique de Colmar : quand les vilains faucheurs s'attaquent à une recherche innocente..." *Les Amis de la Terre*. October 13. http://www.amisdelaterre.org/Vigne-transgenique-de-Colmar-quand.html (accessed July 2012); France Nature Environnement. 2010. "Vignes OGM : l'argent du contribuable investi à perte dans une recherche inutile." *Notre actualité*. August 27. http://www.fne.asso.fr/fr/vignes-ogm--largent-du-contribuable-investi-a-perte-dans-une-recherche-inutile.html?cmp_id=33&news_id=1768 (accessed July 2012); La Confédération Paysanne. 2011. "La Confédération paysanne regrette vivement la condamnation de 60 Faucheurs Volontaires par le Tribunal de Colmar." *Dossier OGM*. October 19. http://www.confederationpaysanne.fr/confederation-paysanne-regrette-vivement-cond_23.php&actualite_id=1892 (accessed July 2012).

[213] Greenpeace France. "OGM: le HCB prend des positions partisanes sans consulter ses membres."; France Nature Environnement. 2010. "Essai de vigne OGM: le Haut Conseil des Biotechnologies sort de son rôle." *Notre actualité*. August 23. http://www.fne.asso.fr/fr/essai-de-vigne-ogm--le-haut-conseil-des-biotechnologies-sort-de-son-role.html?cmp_id=33&news_id=1794 (accessed July 2012).

something goes wrong. Moreover, it undermines policymakers' efforts to shift responsibility to "independent" agencies. As long as the French policymakers continue to hold onto their decisionmaking power in risk management, they are also directly responsible for those decisions.

The path-dependent evolution of the regulatory framework in France has led to the current deadlock. The first two developmental phases emphasized scientific expertise as the foundation for risk assessment and risk management. The Ministry of Agriculture accepted the decisions of the CGB without issue from 1986 to 1997, leaving molecular biologists predominantly in charge of genetic engineering regulation with no real external, independent oversight of the field. The development of the regulatory system took a turn in Phase III, however, when the public health and food safety scandals of the mid-1990s acted as triggering events. Public trust in the ability of government to regulate risk effectively in these policy domains plummeted. Additionally, the French public began to doubt that scientists could comprehensively assess the risks associated with GMOs because the experts had failed to anticipate the problems with BSE.

In response to the public outcry, Juppé's decision to disregard the CGB's opinion and to ban the cultivation of Bt maize became a critical juncture for the institutionalization of the regulatory authorities of agricultural biotechnology. Juppé's decision legitimized the consideration of non-scientific opinions as part of the decisionmaking process. Consequently, the ensuing reforms to the regulatory system incorporated public participation and non-scientific expertise into the risk assessment process. The proliferation of these authorities in Phase IV aimed to create more transparency and dialogue within the risk assessment process. Instead, the regulatory system became fragmented and deadlocked.

In Phase V, internal and external pressures to resolve that deadlock escalated. Decisions by the WTO and by the ECJ motivated the French government to attempt a solution in the form of the *Loi OGM*. The creation of the HCB as part of the law was originally expected to alleviate some of the pressure, especially from the EU's threats of penalty payments. Yet, despite France meeting the EU's transposition requirements, the risk assessment process remained cumbersome in Phase VI. Even when both committees of the HCB produced generally positive assessments of a dossier, anti-GMO interest groups wrecked the tenuous rapprochement of the two camps with the destruction of INRA's test fields.

A consequence of this developmental trajectory is that the French government has institutionalized the need to evaluate GMOs on two levels: 1) scientific expert assessment of the impacts on the environment and public health, and 2) non-scientific expert assessment of the social, economical, and ethical impacts. Because the evolution of the regulatory system in France has been a path-dependent process, the French government can no longer move away from this arrangement and back toward solely science-based assessment. The inclusion of anti-GMO interest group representatives in the HCB foretells continued deadlock within France and at the EU-level, where regulatory authorities employ a science-based assessment only. The representatives' dissenting opinions on the INRA dossier and the supportive responses from their organizations for the *faucheurs volontaires* of the Alsatian vineyards reveals the significant role that anti-GMO organizations play in the GMO debate in France. Chapter 5 explores the evolution of these groups and public opinion in France more closely.

Chapter 5. French Resistance to GMOs

The *faucheurs volontaires* responsible for the destruction of the Alsatian vineyards in 2010 did not represent any one anti-GMO interest group or region.[1] The protesters were a collection of individuals from across France, and they covered a wide range of ages and a variety of professions.[2] The diversity of the *faucheurs volontaires* in Alsace anecdotally confirms how widespread anti-GMO sentiment is in France. A 2010 Eurobarometer survey confirms it statistically: the majority of French respondents do not believe that GM food is good for human health, the environment, or the French economy.[3]

When examined closely, however, French feelings towards biotechnology are more complicated than unmitigated anti-GMO sentiment. The French tend to have a mainly negative outlook on "green" biotechnology (GMOs in agriculture and food applications), while having a more positive outlook on "white" and "red" biotechnologies (industrial and medical applications, respectively). Moreover, their views have shifted over time, with French attitudes about biotechnology ranking as particularly pessimistic in the late 1990s when compared to other years.[4]

Anti-GMO interest groups have contributed to the entrenched opposition to GMOs among the French public, in part because they have been able to maintain continued support for their positions with frequent, highly visible actions. In addition, their respective messages are not only appealing to the French public, but they are compatible among the diverse interest groups

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[1] *Faucheurs volontaires* can be loosely translated as "volunteer reapers." See Chapter 4 for a more detailed discussion of their actions in Alsace.

[2] The age range of the *faucheurs volontaires* was from 22 to 76 years old, and many had careers in education or agriculture or were retired. Annick Woehl. 2012. "Vignes OGM. 54 faucheurs volontaires jugés en appel à Colmar." *L'Alsace*. June 20. http://www.lalsace.fr/actualite/2012/06/20/54-faucheurs-volontaires-juges-en-appel-a-colmar (accessed July 2012).

[3] TNS Opinion & Social. 2010. "Biotechnology." *Special Eurobarometer 341 / Wave 73.1*. Brussels, Belgium: European Commission. 29, 30, and 20. http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_en.pdf (accessed July 2012).

[4] TNS Opinion & Social. "Biotechnology." 13.

themselves. In this way, environmental, consumer rights, and public health interest groups do not compete for public support; rather, they collaborate with and reinforce each other's actions.

Chapter 5 examines responses to Eurobarometer surveys from 1991 to 2010 on the topics of biotechnology and risk. The survey data help illuminate the intricacies of the general anti-GMO position in France. The data show how the French compare to the "average" European as well. Although the French are more likely to have heard of biotechnology and GM food when compared to their neighbors, they exhibit a similar level of objective knowledge about genetics and biology compared to other Europeans. In general, the French embrace technological and scientific progress, but they remain fiercely anti-GM food. Worries about food-related risks over which they have no control rank high on the list of concerns for the French, and biotechnology applications in food production (GMOs, cloning, and nano particles) figure among them. Worries about a lack of personal control over food risks also indicate a larger fear about the loss of food sovereignty – the right of individuals to choose their own food. Despite the French expressing high levels of worry about biotechnology and food-related risks, over the last decade they have become less likely to take action – either private or political – in reaction to their concerns.

Yet, public concerns have played a central role in the institutionalization of dissent within the domestic agencies that assess GMOs. To explain the high levels of French awareness and apprehension about agricultural biotechnology, Chapter 5 also reviews several anti-GMO interest groups (*l'association Consommation, Logement, Cadre de Vie*; *Comité de Recherche et d'Information Indépendantes sur le genie Génétique*, Greenpeace France, and *la Confédération Paysanne*) that have been at the forefront of French resistance. The chapter examines the different conceptualizations these groups put forward: GMOs as an issue of safety and health,

consumers' rights, farmers' rights, and globalizing corporate forces. By reviewing these groups and their framing of the GMO issue, I explore the different strands of anti-GMO sentiment in French public opinion that have been revealed in the Eurobarometer data and how GMOs have become a proxy for globalization. In doing so, I demonstrate how efforts to unlock the regulatory approval process for GMOs in France must address all parts of the anti-GMO movement.

French Public Opinion of Biotechnology

In order to gain insight into European public opinion, the European Commission has been performing surveys of member state populations since 1973. The ultimate goal of the Commission's data collection is to assist in the preparation of its texts, decisions, and evaluations of its work.[5] Thus, the Eurobarometer surveys and studies address a range of major topics concerning European citizenship, including EU enlargement, health, culture, technology, the environment, and the euro.[6]

The Commission began a series of Eurobarometer surveys on biotechnology in 1991. In total, there are six surveys, with data collected in 1991, 1993, 1996, 1999, 2002, and 2005. The Directorate General (DG) for Research also commissioned a special Eurobarometer in 2010, separate from the series, to "gain a deeper insight into Europeans' views on biotechnology" within the context of the Commission's "Europe 2020 Strategy."[7] All of the surveys include questions that deal broadly with the concept of biotechnology, as well as questions about specific applications, such as GM food, cloning, and pharmaceuticals. They provide data for each

[5] European Commission. "Public Opinion." *Public Opinion Analysis Sector.* http://ec.europa.eu/public_opinion/index_en.htm (accessed July 2012).
[6] European Commission. "Public Opinion."
[7] TNS Opinion & Social. "Biotechnology." 5, 3. In March 2010, the Commission launched the Europe 2020 Strategy, which was "designed to help the Union to come out stronger from the [then] current economic and financial crisis and to prepare its economy for the next decade's challenges." Biotechnology was identified as an area where efforts should be made to stimulate and coordinate development to help with economic growth and to create more jobs.

member state, as well as an aggregate of the data from the member states to paint a picture of the "average" European.[8]

In addition to the surveys on biotechnology, the European Food Safety Authority (EFSA) requested two special Eurobarometers on food-related risks in 2005 and 2010.[9] The Health and Consumer Protection DG and EFSA commissioned the original survey "to assess how people in the EU perceive risk, focusing in particular on food safety," which was an area of "shared interest" for the two bodies.[10] For the 2010 survey, EFSA wanted to obtain data to help determine how European consumers' "views on food-related risks have evolved" between 2005 and 2010.[11] The surveys questioned Europeans about their perceptions of and reaction to food-related risks, including concerns about GM food.

The focus of my review of these nine Eurobarometers is to gauge European citizens' awareness of and attitudes towards: biotechnology in general, GM food in particular, and biotechnology governance. Additionally, this work examines the opinions and attitudes of French citizens on these topics. I compare the data collected from French participants to the "average" European response and in some cases to the data from other individual member states, in order to explore the complicated relationship that the French have with biotechnology, food-related risks, and GM food. I also compare the data over time to illustrate how French public opinion has shifted at critical junctures in the development of the regulatory framework for GMOs, and how lurking fears about globalization are inherent to French concerns about GMOs.

[8] The surveys also take into consideration the successive enlargements of the EU. During the time period studied, the EU has grown from 12 member states in 1990 to 27 member states in 2010.
[9] TNS Opinion & Social. 2006. "Risk Issues." *Special Eurobarometer 238 / Wave 64.1*. Brussels, Belgium: European Commission; TNS Opinion & Social. 2010. "Food-related risks." *Special Eurobarometer 354 / Wave 73.5*. Brussels, Belgium: European Commission.
[10] TNS Opinion & Social. "Risk Issues." 2.
[11] TNS Opinion & Social. "Food-related risks." 5.

Awareness of biotechnology

The first of the Eurobarometer series on Europeans and biotechnology, undertaken on behalf DG Research in 1991, focused on four points: the reputation and knowledge of biotechnology/genetic engineering; attitudes and opinions of biotechnology/genetic engineering applications; information sources that people use to gain knowledge about new technologies; and information sources that people trust with regard to biotechnology/genetic engineering.[12] These themes remained central to each survey in the series. The surveys also contextualized European opinions on and attitudes about biotechnology by including questions about other technological advancements, like solar energy or information technologies. Some adjustments have been made over the course of the series to account for new technologies. For example, the original 1991 survey contained questions regarding "new materials or substances" and "telecommunications." By 2005, those categories had been dropped, and questions on "mobile phones," "wind energy," "nuclear energy," and "nanotechnology" had been added.

The introduction to the 1991 survey notes that there was "a great deal of confusion" surrounding the definitions of "biotechnology" and "genetic engineering."[13] For some people, "biotechnology" refers to "modern (post-1974) techniques of genetic engineering, i.e. methods of recombining segments of DNA."[14] For others, "biotechnology" has a "far wider scope," including all applications of the life sciences, fermentation industries, and modern applications.[15] Thus, the decision was made to use a "split ballot" – half of the questionnaires would use the term "biotechnology" and the other half would use "genetic engineering" – to help determine if

[12] INRA (Europe). 1991. "Opinions of Europeans on Biotechnology in 1991." *Eurobarometer 35.1*. Brussels, Belgium: European Commission. 3.
[13] INRA (Europe). "Opinions of Europeans on Biotechnology in 1991." 3-4.
[14] INRA (Europe). "Opinions of Europeans on Biotechnology in 1991." 3.
[15] INRA (Europe). "Opinions of Europeans on Biotechnology in 1991." 4.

there were different perceptions attached to the terms.[16] In general, the two terms seem to have different connotations for Europeans; Europeans appear to respond more favorably to "biotechnology." On average over the six surveys, about 5% more of respondents agree that "biotechnology" will improve their way of life in 20 years compared to respondents who were asked if "genetic engineering" will improve their way of life.[17] While the difference between the two terms has remained fairly constant over the course of the series, the total number of respondents agreeing has fluctuated over time.

To gain more information about the public's knowledge of biotechnology and its applications, interviewers asked respondents to identify topics that concerned biotechnology/genetic engineering from a list of seven choices for the 1991 survey.[18] In this way, the survey provided a crude measure of Europeans' "objective" knowledge of biotechnology and genetic engineering. The French exhibited a level of knowledge comparable to the EU average by correctly identifying approximately four out of seven items.[19] The authors of the survey report also noted that a high level of objective knowledge about biotechnology corresponded to higher levels of optimism about biotechnology: "Among the 21% of people having replied correctly to the seven items proposed, this degree of optimism reaches 69%."[20] They went on to state,

[16] INRA (Europe). "Opinions of Europeans on Biotechnology in 1991." 4. The subsequent surveys in the biotechnology series maintained the split ballot format.

[17] The authors of the 2005 Eurobarometer report attribute this trend to the term "bio" with its more positive connotation of "healthy and natural things"; whereas "engineering" has a connotation of "manipulating or tampering." George Gaskell et al. 2006. "Europeans and Biotechnology in 2005: Patterns and Trends." *Final Report on Eurobarometer 64.3*. Brussels, Belgium: European Commission. 11.

[18] INRA (Europe). "Opinions of Europeans on Biotechnology in 1991." 21-22. The question used was: "I have here a list of some developments where new technologies are actually developed [sic]. In your opinion, which of these are linked to biotechnology and genetic engineering and which are not?" Approximately half of the respondents were asked the question with the term "biotechnology" used, and the other half heard "genetic engineering." The list of items for identification included such statements as: "Research on early detection and treatment of cancer" (Item 1) and "Treating hereditary human diseases by modifying the tissue involved" (Item 2). In fact, all seven items were related to biotechnology.

[19] INRA (Europe). "Opinions of Europeans on Biotechnology in 1991." 22, 24. Correct responses were marked with a 1, and incorrect and "don't know" responses were marked 0, providing a scale of 0-7.

[20] INRA (Europe). "Opinions of Europeans on Biotechnology in 1991." 24.

however, that when looking at the average level of objective knowledge of the two groups, the score of the "pessimists" (4.42/7) was only very slightly lower than that of the "optimists" (4.8/7).[21]

The subsequent Eurobarometers in the series continued to measure Europeans' objective knowledge of biotechnology, though the format changed. Starting in 1993, interviewers presented a list of twelve items to participants and asked them to determine whether the statements were true or false.[22] Researchers now wanted to extract two types of objective knowledge of biotechnology/genetic engineering: "an 'elementary' knowledge and a 'thorough' knowledge" so that they would be able "to analyse more carefully the 'knowledge' variable."[23] Like the 1991 survey, the results of the 1993 survey showed a positive correlation between a higher level of objective knowledge and optimism about biotechnology, but the average level of objective knowledge of "pessimists" (6.53/12) still was only slightly lower than that of the "optimists" (6.73/12). In the 1993 report, the authors thus concluded that, because of the similarity among the knowledge level of both the optimists and pessimists, "one should not look for automatic links between cause (knowledge) and effect (optimism) in these knowledge/optimism relationships."[24]

The format of the "objective knowledge" section of the questionnaire became a list of ten items in 1996, and remained that way through the rest of the series.[25] By maintaining a more consistent format, researchers were able to assess the public's knowledge over time. They concluded that a "small upward trend in the genetics items, contrasted with stability in the other

[21] INRA (Europe). "Opinions of Europeans on Biotechnology in 1991." 24.
[22] Eric Marlier. 1993. "Biotechnology and Genetic Engineering. What Europeans Think about It in 1993." *Eurobarometer 39.1*. Appendix 2. Brussels, Belgium: European Commission. 4. The prompt used was: "Here are some statements. For each of them, please tell me whether you think it is true or false. If you don't know, say so, and we will skip to the next statement." A split ballot was not used in reference to this specific question.
[23] Marlier. "Biotechnology and Genetic Engineering. What Europeans Think about It in 1993." 26.
[24] Marlier. "Biotechnology and Genetic Engineering. What Europeans Think about It in 1993." 30.
[25] Eight of the items were kept constant from 1996 to 2005, while two items were changed in each survey.

questions, provides some evidence that Europeans' knowledge of genetics and biotechnology… increased" between 1996 and 2005.[26] In 2005, the majority of Europeans (over 60%) answered four of the ten questions correctly.[27] Only slightly more than half of all EU15 respondents correctly identified two statements about GM fruit and embryonic stem cells.[28] The majority of Europeans misidentified the remaining four items. French respondents followed a similar pattern to the EU in 2005; over 60% correctly identified the same four statements.[29] In addition, the majority of the French made mistakes on the same four items that the majority of Europeans misidentified. Slightly more than half of the French respondents correctly identified the statement about the consequences of eating GM fruit, like most Europeans, but slightly less than half were able to correctly identify the statement about embryonic stem cells.

The authors of the study assert that seven of the ten items on the list were included in order to test "textbook" knowledge of biology and genetics. These items included the statements: "Human cells and human genes function differently from those in animals and plants," and "It is not possible to transfer animal genes into plants."[30] The survey also included three statements that were supposed to tap into "menacing images":

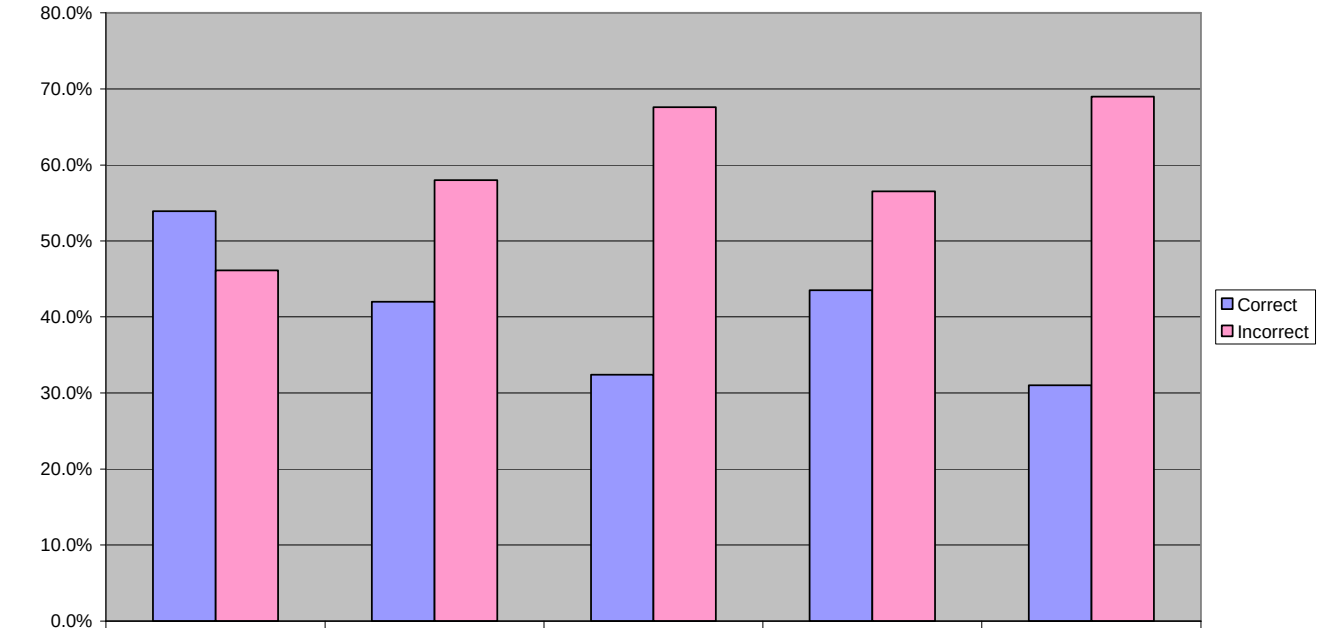
- Ordinary tomatoes do not contain genes, while genetically modified tomatoes do;
- By eating a genetically modified fruit, a person's genes could also become modified;

[26] Gaskell et al. "Europeans and Biotechnology in 2005." 58.
[27] Gaskell et al. "Europeans and Biotechnology in 2005." 57. Europeans correctly identified statements about pregnancy tests for Down's Syndrome, cloning, yeast used in fermentation, and chimpanzee and human genes as true. See Appendix B for the complete statement list.
[28] The abbreviation EU15 refers to the fifteen member states that comprised the EU after the 1995 enlargement. Citizens from twelve member states (EU12) were interviewed for the 1991 and 1993 Eurobarometers on biotechnology; citizens from fifteen member states (EU15) were interviewed for the 1996, 1999, and 2002 Eurobarometers. In 2004, the eastern enlargement brought the number of member states up to twenty-five (EU25). Citizens in the eastern enlargement member states were interviewed for the 2005 Eurobarometer, but there is no previous national data with which to compare their responses. The 2010 Eurobarometer interviewed citizens in twenty-seven member states (EU27).
[29] Gaskell et al. "Europeans and Biotechnology in 2005." Codebook 8-9.
[30] Gaskell et al. "Europeans and Biotechnology in 2005." 57.

– Genetically modified animals are always bigger than ordinary ones.[31]

The inclusion of these three statements was to determine if there is an "inclination to assent to the idea that food biotechnology is associated with fears about adulteration, infection, and monstrosities."[32] Figure 5.1 illustrates the French response to these items and two of the "textbook" items.[33]

Figure 5.1. French Knowledge about Biology & Genetics



	GM Fruit	GM Animals	GM Tomatoes	Human Genes	Gene Transfer
Correct	53.9%	42.0%	32.4%	43.5%	31.0%
Incorrect	46.1%	58.0%	67.6%	56.5%	69.0%

For the "menacing image" of the potential consequences of eating GM fruit, approximately 54% of French respondents correctly identified that statement as false. This response rate matched the European average. Less than half (42%) were able to correctly identify the statement about the size of GM animals as false. The French rate was slightly lower than the EU15 average of 45%. Even fewer French citizens (32.4%) were able to correctly ascertain that

[31] All of these statements are false. Gaskell et al. "Europeans and Biotechnology in 2005." 55.
[32] Gaskell et al. "Europeans and Biotechnology in 2005." 55.
[33] Figure 5.1 was created from data in the 2010 Eurobarometer Codebook, 8-9. The "incorrect" response category contains both incorrect and "don't know" answers.

the statement about ordinary tomatoes and GM tomatoes was false. Although a majority of European participants also were incorrect on this item, 40.9% did get it right, leaving the French well below the average.

The French struggled with two of the "textbook" questions as well. More than half believed (incorrectly) that human cells and human genes function differently than those in animals and plants. Yet, in contrast to the statement about tomatoes, the response rate for this item was much better than the EU15 average: 66.2% of Europeans were incorrect versus 56.5% of the French. Still, the lower rate of incorrect responses for the French compared to the European average was more the exception than the rule. Almost seven in ten French respondents (69%) incorrectly believed that it is not possible to transfer animal genes into plants, a rate almost exactly the same as the EU15 average (69.4%).

The French exhibit knowledge of biology and genetics comparable to their neighbors – approximating the EU15 response rate with no more than a 3% difference on eight of the ten items. But the data also reveal that the French lack a more widespread, basic understanding of genetics. Like other Europeans, the French are susceptible to the "menacing images" of "monstrous" GM foods: almost 70% do not know that non-GM tomatoes contain genetic material; 58% think that GM animals are bigger than non-GM ones; and 46% believe that eating GM fruit will modify their own genes.

A lack of knowledge regarding biology and genetics directly influences perceptions of biotechnology. As the 1991 survey notes, the curiosity and enthusiasm of biotechnology specialists are far from being shared by the rest of the population, public authorities, or the political world.[34] And, the present lack of knowledge of biotechnology among the public – leading to misunderstandings about GM plants and animals – is one of several factors that have

[34] INRA (Europe). "Opinions of Europeans on Biotechnology in 1991." 2.

an impact on attitudes towards biotechnology.[35] The EU15 average has shown small increases in correct responses over time for the questions on cloning and genetics, but EU citizens have room to gain a better understanding of the processes that are involved in biotechnology. French citizens are no exception.

Attitudes towards biotechnology

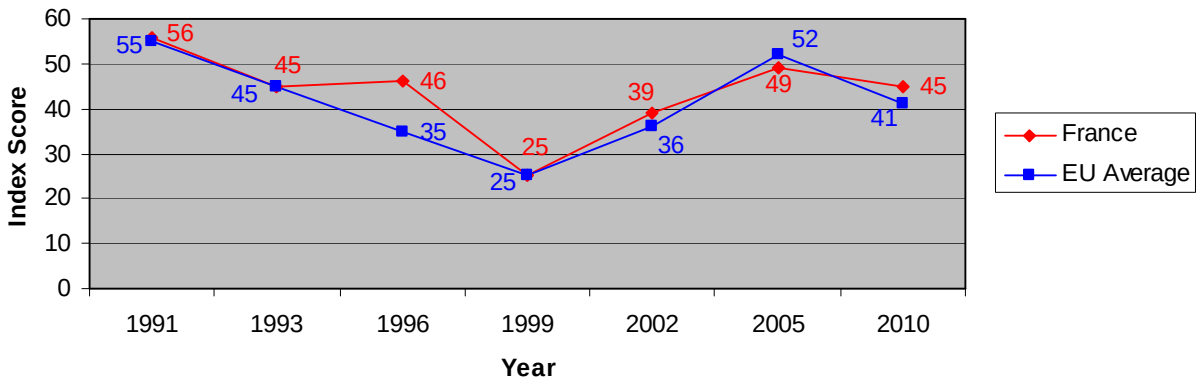
In order to assess the changes in optimism and pessimism over time, the authors of the Eurobarometer surveys created an "index of optimism."[36] The index revealed some distinctive trends in European opinions on different technologies. For example, levels of optimism about information technology and solar energy remained high and stable from 1991 to 2005, while there were consistently more pessimists than optimists regarding the topic of nuclear energy during that time period.[37] In contrast to the stability of the index scores for other categories of technologies, optimism about biotechnology has shown more significant shifts. European optimism about biotechnology declined steadily from 1991 to 1999, falling about 30 percentage points during those years.[38] After 1999, the downward trend reversed, and by 2005, the level of European optimism about biotechnology had climbed back up to 52%, almost to the same level it was in 1991.[39] Numbers from the 2010 report on biotechnology do not show that this upward

[35] INRA (Europe). "Opinions of Europeans on Biotechnology in 1991." 2.
[36] The summary index was created by subtracting the percentage of pessimists from the percentage of optimists, and then dividing that value by the combined percentage of optimists, pessimists, and respondents who stated that the technology will have no effect on their life. The index was thus based on the respondents who expressed an opinion about the technology. The exclusion of the "don't know" responses was because of wide variation across the member states in that category. As a result of the variation, the raw scores were misleading. The report combines the responses to genetic engineering and biotechnology from the split ballot to determine the optimism index for biotechnology. Gaskell et al. "Europeans and Biotechnology in 2005." 12.
[37] Gaskell et al. "Europeans and Biotechnology in 2005." 12.
[38] In 1991, the index level of optimism among all Europeans was around 55%; by 1999, it had dropped to around 22%. Gaskell et al. "Europeans and Biotechnology in 2005." 12.
[39] Gaskell et al. "Europeans and Biotechnology in 2005." 12.

trend continued, however; when adjusted for the summary index, the level of optimism about biotechnology among EU27 citizens had fallen to approximately 41%.[40]

Data collected from French respondents follow a pattern similar to the "average" European response. Figure 5.2 illustrates the index of optimism about biotechnology for both France and the EU over the period of 1991 to 2010.[41] Like the European average, the optimism index score for the French regarding biotechnology was over 50% in 1991. From its high of 56% in that year, the French optimism index score fell to 25% by 1999. The French decline in optimism was more staggered than the steady decline of European optimism about biotechnology.

Figure 5.2. Index of Optimism about Biotechnology (1991-2010)



[40] Data from the 2010 Biotechnology Report was used to determine the EU and French optimism index scores for that year. TNS Opinion & Social. "Biotechnology." 9. The 2010 report lists the raw scores to the question QB1.3 (I am going to read out a list of areas where new technologies are currently developing. For each of these, do you think it will have a positive, a negative or no effect on our way of life in the next 20 years? – Biotechnology and genetic engineering) as: 53% positive effect, 20% negative effect, 7% no effect, and 20% don't know. The summary index score was determined using the authors' formula: the percentage of pessimists was subtracted from the percentage of optimists and the result divided by the combined percentage of optimists, pessimists, and those who say the technology will have no effect [((53-20)/(53+20+7)) = 33/80 = 41.25 ≈ 41%].

[41] Index scores for the EU average for 1991 to 1999 are based on estimates from Figure 2 included in *Eurobarometer 64.3* (12). Neither calculated index scores nor raw figures were provided in the 1991, 1993, 1996, and 1999 Eurobarometers. Index scores for 2002, 2005, and 2010 were calculated from raw data from their respective Eurobarometers, using Gaskell et al.'s formula (see footnote 19).

While the European average consistently fell about 10 percentage points every few years between 1991 and 1999, France experienced a plateau between 1993 and 1996, and then a sharp drop in optimism of 21 percentage points between 1996 and 1999.

The plateau in public optimism toward biotechnology coincided with Phase II (1992-1996) of the development of the French regulatory framework, which was a period of calm in the GMO debate in France. The plunge coincided with critical years for public health and food safety in Europe and in France. In 1996 – the *annus horribilis* of food safety – the first wave of the mad cow crisis was cresting and the French media was beginning to report on the potential risks of GM food. By the end of 1999, when *Eurobarometer 52.1* participants were being interviewed,[42] over 3.3 million cattle had already been destroyed as a response to mad cow disease, and Europeans were watching television reports on the fatal cases of young Europeans who had been infected with the human variant of the disease. At that time in France, the government was refusing to lift a ban on British beef with the support of its newly formed food safety authority (AFFSA), even though the EU had announced the beef was safe and had lifted an EU-wide ban. The final trials of the HIV-tainted blood scandal had come to a close as well, with former Health Minister Edmond Hervé convicted of manslaughter in March 1999. Additionally, Europe had faced the dioxin contamination episodes just months before the survey.

While France is similar to the overall EU average of optimism, an examination of the individual member states reveals different domestic stories. France's decline in optimism was steep between 1996 and 1999, but it was not the most severe when compared to the other

[42] Interviews for *Eurobarometer 46.1* were performed in October and November of 1996. INRA (Europe). 1997. "The Europeans and modern biotechnology." *Eurobarometer 46.1*. Brussels, Belgium: European Commission. Interviews for *Eurobarometer 52.1* were performed in November and December of 1999. INRA (Europe). 2000. "The Europeans and Biotechnology." *Eurobarometer 52.1*. Brussels, Belgium: European Commission.

fourteen member states of the EU at that time. Table 5.1 shows the index of optimism for biotechnology for the EU15 over the period of 1991 to 2010.[43]

TABLE 5.1

Trends in the index of optimism for biotechnology in the EU15 (1991-2010)								
Index Score	**1991**	**1993**	**1996**	**1999**	**2002**	**2005**	**2010**	**Difference from 1996 to 1999**
Spain	82	78	67	61	71	75	75	-6
Sweden	-	-	42	-	61	73	73	NA
Portugal	50	77	67	50	57	71	70	-17
Italy	65	65	54	21	43	65	65	-33
Denmark	26	28	17	-1	23	56	56	-18
Luxembourg	47	37	30	25	29	55	55	-5
Ireland	68	54	40	16	26	53	53	-24
UK	53	47	26	5	17	50	50	-21
Netherlands	38	20	29	39	39	47	47	+10
Belgium	53	42	44	29	40	46	46	-15
France	56	45	46	25	39	49	45	-21
Finland	-	-	24	13	31	36	36	-11
Germany	42	17	17	23	24	33	33	+6
Austria	-	-	-11	2	25	22	23	+13
Greece	70	47	22	-33	12	19	19	-55

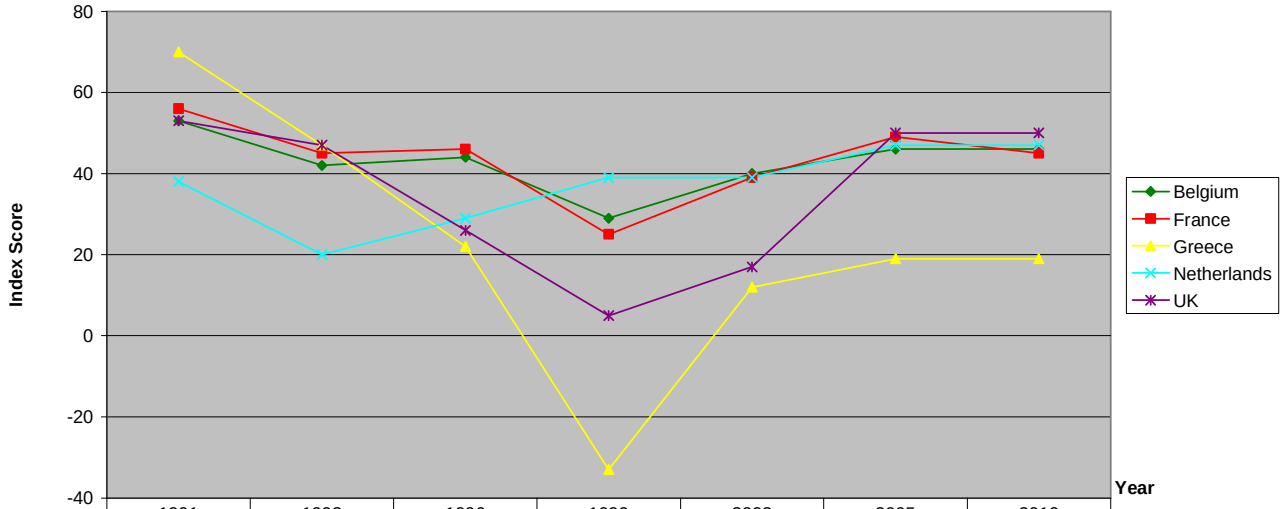
The final column of Table 5.1 shows the change in the optimism for biotechnology score for the individual member states between 1996 and 1999. For example, Greek optimism declined the most, plummeting 55 percentage points in three years and resulting in a higher level of pessimism than optimism about biotechnology. Italian optimism also dropped significantly in the same time period, falling 33 percentage points.

In contrast to the overall European trend, three member states experienced positive changes in their index scores: the Netherlands (+10), Germany (+6), and Austria (+13). It should

[43] A version of Table 5.1 appears in *Eurobarometer 64.3* without the 2010 figures or the calculated differences between 1996 and 1999 (Gaskell et al. "Europeans and Biotechnology in 2005." 13). Figures for 2010 have been calculated using Gaskell et al.'s formula and raw data from the 2010 Eurobarometer Codebook. The countries are ordered from the most to the least optimistic in 2010. Positive values indicate that there are more optimists than pessimists in a given member state; negative values indicate that there are more pessimists than optimists. Data for the remaining twelve member states of the EU were not collected until after the 2004 and 2007 enlargements, and thus cannot be compared over time.

be noted, however, that these states recorded much lower starting index scores than France in 1996. As a consequence, their upward turn in optimism is tempered by the fact that their overall levels remain lower than the EU average. The UK also exhibited a trend different from both the European average and France. The British experienced an earlier drop in optimism when compared to France, falling 21 percentage points (47% to 26%) from 1993 to 1996. This was followed by a drop of another 21 percentage points (26% to 5%) in 1999 to an all-time low for the UK. France is not the only member state who mirrors the European average, though; levels of optimism in Belgium also closely follow the French path. Figure 5.3 plots the trends of five member states from 1991 to 2010 to illustrate the differences in national levels of optimism about biotechnology.

Figure 5.3. Index of Optimism about Biotechnology in Five Member States (1991-2010)



	1991	1993	1996	1999	2002	2005	2010
Belgium	53	42	44	29	40	46	46
France	56	45	46	25	39	49	45
Greece	70	47	22	-33	12	19	19
Netherlands	38	20	29	39	39	47	47
UK	53	47	26	5	17	50	50

In general, the trends for the EU15 can be split into two phases: pre- and post-1999.[44] From 1991 to 1999, the majority of EU member states showed a decline in levels of optimism about biotechnology, with the exception of the Netherlands, Germany, and Austria. From 1999 to 2005, the EU15 member states, with the exception of Austria, showed an upward trend in optimism.[45] Several states even exhibited significant increases of more than 20 percentage points in their levels of optimism from 2002 to 2005.[46] Yet, it appears that the levels of optimism are leveling off across the EU15 member states, with little or no change in those states' index scores from 2005 to 2010.[47] Data collection after 2010 will be required to determine whether this plateau is a trend in levels of optimism.

An exception to the apparent trend of stability in the EU15 is France, which dropped 4 percentage points in its levels of optimism between 2005 and 2010. The drop coincided with the end of Phase V (2003-2008) and with Phase VI (2008-2010) in the development of France's GMO regulatory framework. These phases were characterized by new efforts to resolve the regulatory deadlock on GMO approvals in France, such as the *Le Grenelle Environnment* (the Environment Roundtable), the subsequent *Loi OGM* (the Biotech Law), and the creation of the *Haut Conseil des Biotechnologies* (HCB – High Council on Biotechnology).[48] During the same time, however, France instituted a ban on the cultivation of GM maize (in violation of EU law) and was penalized by the European Court of Justice (ECJ) for failure to transpose EU directives

[44] Gaskell et al. "Europeans and Biotechnology in 2005." 13.
[45] Gaskell et al. "Europeans and Biotechnology in 2005." 13-14.
[46] Five member states recorded increases of over 20 percentage points in their index of optimism scores: Italy (+22), Denmark (+23), Luxembourg (+26), Ireland (+27), and the UK (+33).
[47] When accounting for all 27 member states (EU27), the EU average indicates an overall decline between 2005 and 2010 of 11 percentage points from 52% to 41% (see Figure 5.1). This indicates that levels of optimism in the eastern enlargement states have contributed to the downturn in the EU average. When only the EU15 are considered, France is the only member state that shows more than a percentage point of change.
[48] See Chapter 4 for a detailed discussion of the phases of development of the French GMO regulatory framework.

on GMOs.[49] Thus, the drop in French optimism corresponds to a period when the French government struggled to implement a consistent policy position on GMOs.

While two periods of decline in French levels of optimism about biotechnology (1996-1999 and 2005-2010) coincide with higher levels of conflict in the domestic debate over GMOs, the period of decline in French optimism from 1991 to 1993 occurs during the end of Phase I and the beginning of Phase II, which had little to no public debate on GMOs. The drop in optimism during this period can be attributed to an increase in awareness of the issue. As the 1993 report notes: "If we look at the overall results, the fairly general drop [in the European Community mean average] does not correspond so much to a decline in favourable opinions as to an increase in neutral and negative ones. This increase has also been accompanied by a fall in ["don't know"/"no answer" responses]."[50] As a consequence of increased awareness, more respondents offered an opinion on their outlook for biotechnology, and as the denominator of the summary index (the sum of the optimistic, pessimistic, and neutral responses) increased, the weight of the optimistic responses as part of the index score decreased. This was not a factor when comparing 1996 to 1999, as "don't know" response rates were similar.

Unfortunately, although the Eurobarometer surveys provide insight into the awareness and attitudes of Europeans – and more specifically French citizens – during key moments in time, I cannot argue that there is direct causation between the food safety and public health crises of the 1990s and the decline in optimism about biotechnology from this dataset. The Eurobarometer surveys did not inquire as to the reasons respondents believed that biotechnology would or would not improve their quality of life. The surveys also did not include questions particular to mad cow disease or other food safety concerns. Nonetheless, the Eurobarometers on

[49] Data collection for the 2010 Eurobarometer report on biotechnology was collected in January and February, months before the destruction of the INRA vineyard in Alsace.
[50] Marlier. "Biotechnology and Genetic Engineering. What Europeans Think about It in 1993." 12.

biotechnology and risk did include questions about GM food, which allow us to examine the awareness of and attitudes about GMOs within the context of food safety.

Attitudes towards food-related risks

The Eurobarometers on risk in 2005 and 2010, commissioned by EFSA, provide insight into Europeans' attitudes towards food and food-related risks. In general, a comparison of the survey responses reveals that Europeans' levels of worry about food-related risks have increased over time; yet the likelihood that Europeans will take action in response to their concerns has diminished. Europeans are more likely to worry about risks perceived to be out of their direct control, such as chemical contamination or animal infections occurring in the supply chain, when compared to diet-related risks like high fat intake and cholesterol levels. In the same way, they are the least confident in their ability to avoid risks associated with new technologies, like nanotechnology and animal cloning.[51]

When we examine individual member state responses, these patterns of behavior and of concern hold true for France as well. In 2010, when interviewers read a list of potential risks and asked how likely these risks might occur in respondents' personal lives, over half of the French respondents believed that it was "likely" that the food they eat would damage their health.[52] The French responses reveal an 8% increase in the belief of potential food-related risk over time: in 2005, 48% found the risk of food damaging their health to be likely versus 56% in 2010. And, when prompted about particular problems or risks associated with food, the overwhelming

[51] TNS Opinion & Social. "Food-related risks." 38-39.

[52] TNS Opinion & Social. "Food-related risks." 17. The "likely" category includes "very likely" (14%) and "fairly likely" (42%) responses. The question used was: QF2 I will read out a list of potential risks. For each of them please tell me how likely you think they are to happen to you personally. OPTIONS: Being a victim of a crime; The food you eat damaging your health; Environmental pollution damaging your health; The economic crisis negatively affecting your life; Being injured in a car accident; Getting a serious illness. ANSWERS: Very likely; Fairly likely; Not very likely; Not at all likely; Do not know.

majority of EU citizens worry about chemical residues (like pesticides or antibiotics), pollutants (like dioxin contamination), and animal cloning.[53]

Moreover, levels of worry are fairly high across all categories. Of the seventeen issues listed for the survey, more than half of the EU's citizens expressed worry about thirteen (ranging from 52% to 72%), with the remaining four issues garnering levels of worry between 46 to 48%. Similarly, over half of all French respondents expressed worry about thirteen issues, though with slight variations on which issues were the most worrisome. French levels of worry, however, were higher for many issues when compared to the European average. See Table 5.2 for both the EU-average and French levels of worry for the top thirteen issues.[54]

[53] TNS Opinion & Social. "Food-related risks." 20-21. The average shows that 70% or more of the EU's citizens are worried about pesticide, antibiotic, and hormonal residues in food; 65% or more are worried about pollutants and cloning animals for food products. These three issues also ranked the highest for "very worried" responses: 31% of Europeans stated that they were very worried about pesticide residues; 30% were very worried about antibiotic and hormone residues; and 30% were very worried about cloned animals for food products.

[54] Data for Table 5.2 is from: TNS Opinion & Social. "Food-related risks." 21, 19/78. The "percentage worried" values include "very worried" and "fairly worried" responses. The issues are listed in descending order of level of worry.

TABLE 5.2

Top Thirteen Food-Related Problems & Risks: EU and France (2010)				
Issue	**EU average Percentage Worried**		**France Percentage Worried**	**Issue**
Pesticide residues in fruit, vegetables, or cereals	72%		80%	Pesticide residues in fruit, vegetables, or cereals
Residues like antibiotics or hormones in meat	70%		80%	Pollutants like mercury or dioxins
Pollutants like mercury or dioxins	69%		77%	Residues like antibiotics or hormones in meat
Quality & freshness of food	68%		***72%***	***Cloning animals for food products***
GMOs found in food or drinks	***66%***		70%	Quality & freshness of food
Additives like colors, preservatives, or flavorings	66%		66%	Additives like colors, preservatives, or flavorings
Cloning animals for food products	***65%***		65%	Food poisoning from bacteria
Welfare of farmed animals	64%		65%	Welfare of farmed animals
Food poisoning from bacteria	62%		***64%***	***GMOs found in food or drinks***
New viruses found in animals	60%		64%	Substances contained in plastics or other materials coming into contact with food
Getting a diet-related disease	59%		62%	Getting a diet-related disease
Substances contained in plastics or other materials coming into contact with food	59%		54%	Not having a healthy and balanced diet
Not having a healthy and balanced diet	52%		***52%***	***Nano particles found in food***

Like the average European, French respondents expressed considerable worry about food-related risks over which they feel they have little control, such as chemical contamination of their food and the risks of new technologies. The top issues also reflect concerns about the consequences of the ever-increasing industrialization of the food supply. For example, the use of

pesticides in agricultural production and the use of additives and preservatives to improve taste, appearance, and shelf-life are causes for concern among many consumers.[55]

In the 2010 survey, the French expressed more concern about new technologies than the European average. Overall, 63% of French participants stated they were worried about the risks of new technologies (animal cloning, GMOs, and nano particles) used in food production, compared to the European average of 59%.[56] When separated out by issue, the French exhibited more worry than the European average on the subjects of animal cloning (72% to 65%) and the presence of nano particles in food (52% to 47%).[57] The French response rate was slightly lower than the European average regarding GMOs in food and drinks (64% to 66%), though it still demonstrates that almost two out of three French citizens are worried about GM food. In addition, the levels of serious concern are high among French respondents: 36% said they were "very worried" about cloning animals for food products, 23% were "very worried" about GMOs found in food and drinks, and 17% were "very worried" about nano particles found in food.[58]

Despite the increasingly high levels of worry that were recorded in 2010, the likelihood that Europeans will take action in response to their concerns has decreased since 2005. Most EU citizens take no action when hearing something about unsafe or particularly unhealthy food.[59] When asked in 2010 how they reacted to the last information that they had "heard, saw, or read about a type of food being unsafe," 50% of Europeans took no action (up from 42% in 2005), while 46% made some adjustment to their eating habits (down from 53% in 2005).[60] French

[55] TNS Opinion & Social. "Food-related risks." 5.
[56] TNS Opinion & Social. "Food-related risks." 36/78.
[57] See the highlighted figures in Table 5.2.
[58] TNS Opinion & Social. "Food-related risks." 32/78, 20/78, 35/78.
[59] TNS Opinion & Social. "Food-related risks." 57, 76/78.
[60] "No action" includes the responses: "You ignored it, and did not change your eating habits" and "You got worried about the problem but finally you did nothing about it." "Action" includes the responses: "You have permanently changed your eating habits" and "You avoided the food mentioned in the story only for a while." TNS Opinion & Social. "Biotechnology. 58.

responses showed similar trends; in 2010, 47% made no adjustment to their eating habits (up from 39% in 2005) and 48% made some adjustment (down from 57% in 2005).

The data supports a trend in European "modes of engagement with biotechnology" highlighted in the 2005 Eurobarometer on biotechnology report.[61] French citizens fall into the category of "European Spectator" – someone who has "read about biotechnology in the newspapers, heard about it on TV or radio, and might have talked about it before," but is "generally neither too actively involved nor very knowledgeable concerning biology and genetics."[62] Although three out of four French citizens might read articles or watch TV programs about biotechnology, only around one in ten would definitely sign a petition about biotechnology or participate in public discussions or hearings about biotechnology. Even fewer – one in twenty – would definitely join a demonstration about biotechnology.[63]

The survey data from the 2005 and 2010 Eurobarometers on risk thus demonstrate that the French have high levels of worry concerning food-related risks, especially for risks that result from industrialized production processes and new technologies. But the Eurobarometers on biotechnology reveal that the French take little action as a result of their worries. Levels of worry across most issues increased between 2005 and 2010 at both the EU- and member state-levels. Within France, the increase in worry about food-related risks and problems coincides with a decrease in the level of optimism about biotechnology. The drop in optimism also coincides with high levels of concern about other emerging biotechnology applications for food production, like animal cloning and nanotechnology processes, in addition to GM foods. In the 2010 survey on biotechnology, the overwhelming majority of French respondents expressed the same

[61] Gaskell et al. "Europeans and Biotechnology in 2005." 63.
[62] Gaskell et al. "Europeans and Biotechnology in 2005." 63, 64.
[63] The 77.1% response rate for the statement, "Read articles or watch TV programmes on the advantages and disadvantages of biotechnology," include "Definitely would" responses (32.9%) and "Probably would" responses (44.2%). TNS Opinion & Social. "Food-related risks." 37/78.

conclusions about animal cloning and nanotechnology as they consistently have for GM food. They labeled animal cloning as unnatural, unsafe, and not good for them, their families, or France's economy.[64] They also found that nanotechnology was risky, unnatural, and unsafe.[65]

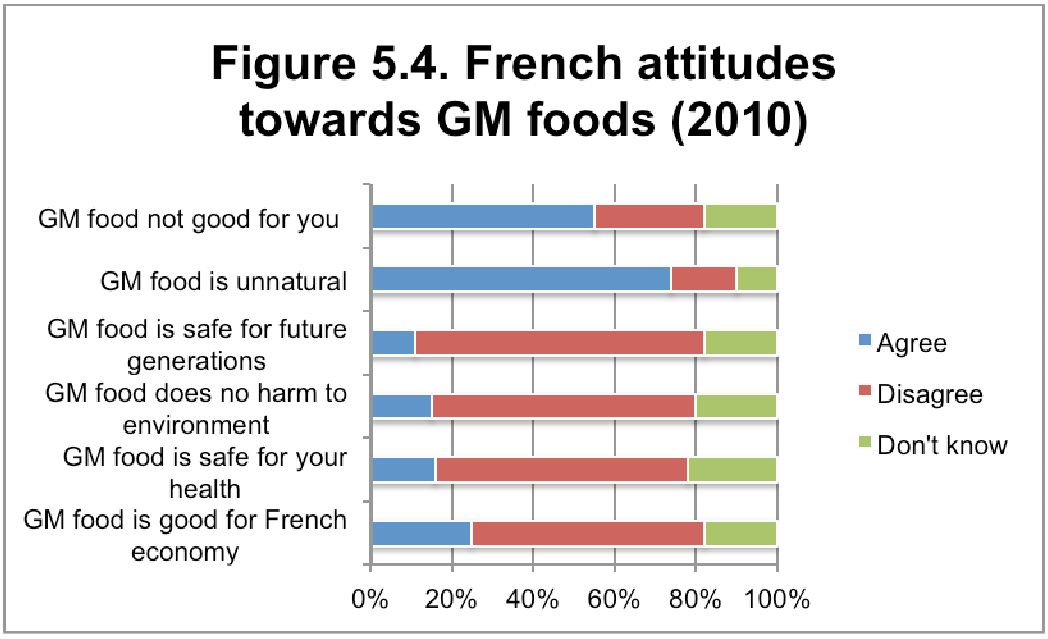
Awareness of and attitudes towards genetically modified food

Like the biotechnology applications of cloning and nano particles in food production, Europeans believe that GM food does not provide any benefits and that it is unnatural and harmful.[66] And, they have arrived at their opinion with a general awareness of the subject; the overwhelming majority of Europeans (84%) have heard of GM food.[67] The French exhibit a similar level of awareness; 86% have heard of GM food before participating in the 2010 biotechnology survey.[68] Unlike the seemingly positive relationship between knowledge of biotechnology and levels of optimism noted in 1991 and 1993, however, a higher level of awareness about GM food is linked to negative feelings about it at the EU-level. The respondents who had previously heard of GM food were more likely to think that GM food was bad for their national economy, bad for their health and the health of their families, and that it should not be encouraged.[69] Figure 5.4 illustrates French attitudes towards GM food in 2010.[70]

Overall, the French express very negative attitudes about GM food, and their negativity stretches across personal, societal, environmental, and economic domains. Over half of all French respondents (55%) agreed with the statement, "GM food is not good for you and your family." Three out of four French citizens believe that GM food is "fundamentally unnatural."

[64] TNS Opinion & Social. "Biotechnology." 66, 63, 60, 59.
[65] TNS Opinion & Social. "Biotechnology." 34, 45, 46, 48-49.
[66] TNS Opinion & Social. "Biotechnology." 7.
[67] Among all European respondents, 84% of respondents had heard of GM food; 75% had heard of animal cloning; and 51% had heard of nanotechnology. Among all French respondents, 86% had heard of GM food; 77% had heard of animal cloning; and 44% had heard of nanotechnology. TNS Opinion & Social. "Biotechnology." 14, 53, 34.
[68] TNS Opinion & Social. "Biotechnology." 14.
[69] TNS Opinion & Social. "Biotechnology." 20, 21, 29, 32.
[70] Figure 5.4 was created using survey data from: TNS Opinion & Social. "Biotechnology." 18-31.

When looking at all EU member states, one finds that the majority of respondents in each country also believe that GM food is unnatural.



Additionally, most French participants disagree with positive statements about GM food. They do not believe that GM food is safe for their health and their family's health; nor is it safe for future generations. Over half of French citizens also think that GM food harms the environment (65%) and that it is not good for the French economy (57%). French negative attitudes toward GM food have increased over time. Similarly, I find that there has been a steady decline in support for GM food across Europe among the decided public, based on data from the Eurobarometer surveys on biotechnology from 1996 to 2005.[71] French support of GM food exhibits a significant drop of 25 points, from 54 index points in 1996 to 29 index points in 2005. Other member states of the EU15 also display declines in that time period, leading to the

[71] Gaskell et al. "Europeans and Biotechnology in 2005." 20-21. Gaskell et al. note that their summary index of support for GM food is based on positive and negative responses (or those participants who stated an opinion), and does not include "don't know" responses of undecided survey participants.

conclusion that, "In 2005, fewer people [were] prepared to discount the perceived risks of GM food against prospective benefits."[72]

My examination of the Eurobarometer data demonstrates that French citizens do not believe that the benefits of GM food outweigh its risks. Indications from 1991 that higher levels of knowledge about biotechnology positively correlate with optimism for biotechnology were dismissed by the second survey of the series. Increases in knowledge of biology and genetics over the course of the survey series have not positively changed the general European or French outlooks on GM food. Instead, negativity towards GM food has intensified over the same time period. Moreover, when placing GM food within the broader context of biotechnology and a range of other technologies, "There is no evidence that opposition to GM food is a manifestation of a wider disenchantment with science and technology in general."[73] Thus, the lesson that can be learned from the data is that "unless new crops and products are seen to have consumer benefits, the [European] public will continue to be sceptical" about agricultural biotechnology.[74]

Attitudes towards biotechnology governance

Widespread disenchantment towards GM food is due to the fact that the issue is not just about food safety, although worries about food-related risks do matter. GM food also raises concerns about the environmental and long-term public health consequences of producing and consuming it, as well as about the impacts of the industrialization and globalization of food production. Furthermore, European citizens are not certain that public authorities have their best interests in mind when it comes to GM food regulations. European reactions to the statement, "Public authorities in the EU view the health of consumers as being more important than the

[72] Gaskell et al. "Europeans and Biotechnology in 2005." 21.
[73] Gaskell et al. "Europeans and Biotechnology in 2005." 3.
[74] Gaskell et al. "Europeans and Biotechnology in 2005." 3.

profits of producers," are divided: 46% agree and 42% disagree.[75] When examined individually, the French are even less convinced that public authorities prioritize public health over producers' profits: the majority of French citizens (51%) disagree with the statement, while 38% agree.[76]

The French wariness of public authorities' motivations regarding GM food is evident for both EU and national institutions. When compared to trust in other actors, such as consumer groups, medical doctors, and university scientists, fewer French citizens believe that the EU and the French government are "doing a good job for society." In 2010, over 80% of French citizens believed that university scientists, consumer organizations, and medical doctors were doing a good job for society, whereas only 56% of French citizens believed the same about their government.[77] More French participants (64%) trusted the EU than their national government.[78]

Although the majority of the French express confidence in the EU and in the national government to regulate biotechnology as of 2010, trust levels have not always been so high. The national government ranked lowest on the list of key actors in 2005, with only 39.5% of French respondents indicating that it was doing a good job for society. Nearly as many respondents (33.1%) thought the French government was not doing a good job.[79] In 2005, there was also a very high level of uncertainty; 27.4% recorded their response as "don't know." But by 2010, uncertainty about the role of the government in biotechnology had decreased to 17% of French respondents. More citizens were expressing an opinion about the government's role in

[75] TNS Opinion & Social. "Food-related risks." 65. The remaining 12% responded "don't know."
[76] TNS Opinion & Social. "Food-related risks." 55/78. The remaining 11% responded "don't know."
[77] TNS Opinion & Social. "Biotechnology." 155-165. Participants were asked: For each of the following people and groups, do you think they are doing a good job for society or not doing a good job for society? Among the list of people and groups included were: "Medical doctors keeping an eye on the health implications of biotechnology"; "University scientists doing research in biotechnology"; and "Consumer organizations checking products of biotechnology." Gaskell et al. "Europeans and Biotechnology in 2005." 46.
[78] TNS Opinion & Social. "Biotechnology." 155-165. The national and EU authorities were described as: "Our government in making regulations on biotechnology" and "The European Union making laws on biotechnology for all European Union countries." Gaskell et al. "Europeans and Biotechnology in 2005." 46.
[79] Gaskell et al. "Europeans and Biotechnology in 2005." 46.

biotechnology regulation than in previous surveys, and those opinions were overwhelmingly positive. The increases in French trust in public authorities coincide with efforts in Phase VI to resolve the regulatory deadlock in the GMO approval process.

Moreover, French levels of trust in each key actor had increased, and significantly so, for almost all actors.[80] Increases across the board meant that in 2010, the majority of French citizens indicated some level of trust for each actor, ranging from 52% for the media to 86% for university scientists. The highest levels of confidence were for university scientists (86%), consumer organizations (84%), medical experts (82%), and environmental groups (70%).[81] The French also expressed high levels of confidence in the same group of actors plus their "family and friends" when asked about sources of information on food-related risks.[82] Based on this data, it is possible to conclude that French citizens are more likely to turn to individuals in their personal lives (their doctors, family members, and friends) and to NGOs (consumer and environmental groups) for information and guidance on GMOs before they would rely on information from and the actions of EU and national authorities.

Anti-GM Interest Groups in France

Anti-GM consumer and environmental groups have worked at both the EU-level and the member state-level to influence biotechnology regulations and standards. In general, these groups seem to have had more success influencing agricultural biotechnology policymaking and

[80] On average, belief that key actors were doing a good job for society increased by approximately 17% across eight of the nine items. The smallest jump of 11% was for consumer organizations; the largest jump of 20.7% was for the EU.

[81] TNS Opinion & Social. "Biotechnology." 155-165. The environmental groups were described in the survey as: "Environmental groups who campaign about biotechnology."

[82] TNS Opinion & Social. "Food-related risks." 46. In response to question QF5 – "Suppose a serious food risk were found in a food you eat regularly, such as fish, chicken or salad. How much confidence would you have in the following sources to give you accurate information about risk?" – French participants' total "very confident" and "fairly confident" responses were the highest for "your physician/doctor and other health professionals" (92%), "consumer organizations" (85%), "family and friends" (78%), "scientists" (76%), and "environmental protection groups" (75%).

standard-setting at the national level. For example, biotech industry officials point to "hostile" campaigns by anti-GMO non-governmental organizations, like Greenpeace, and the media, such as the UK Daily Mail's campaign against "Frankenfood," as the catalyst for the refusal of national retail chains in Europe to place GM products on their shelves.[83]

As detailed in Chapter 4, however, member state governments are not unitary, anti-GMO actors. For example, President Nicolas Sarkozy pushed to get the French Parliament to transpose the required EU directives,[84] at the same time that he instituted a ban on approvals for and the cultivation of Bt maize in France.[85] In part, though, I find that French resistance is rooted in the reluctance on the part of public officials to support the approval of GMOs. Elected officials are concerned about their future electoral prospects and potential blame if they pursue politically unpopular policy decisions. The Eurobarometer polls reflect public disapproval by showing that the overwhelming majority of French respondents are opposed to the use of GMOs.[86] In addition, the French are overwhelmingly aware of GMOs as a policy issue, with only 2% claiming to have never heard of GMOs. In order to understand why awareness of this issue is so high among the French, I look to the role of anti-GM interest groups.

At a domestic level, the *Comité de Recherche et d'Information Indépendantes sur le genie Génétique* (CRIIGEN), *L'association Consommation, Logement et Cadre de Vie* (CLCV), Greenpeace France, and *La Confédération paysanne* have supported the non-implementation of

[83] European Commission Directorate General for Health and Consumers. Evaluation of the EU legislative framework in the field of GM food and feed. July 12, 2010. http://ec.europa.eu/food/food/biotechnology/evaluation/docs/evaluation_gm_report_en.pdf (accessed April 2012).

[84] N.A., "OGM : Nicolas Sarkozy fustige l'attitude des socialistes," Le Figaro (May 20, 2008), http://www.lefigaro.fr/politique/2008/05/20/01002-20080520ARTFIG00430-ogm-nicolas-sarkozy-fustige-l-attitude-des-socialistes.php (accessed August 2011).

[85] "Another Inconvenient Truth," Editorial, Nature Biotechnology vol. 25, no. 12 (December 2007), p.1330. The author of this editorial asserts that Sarkozy's proclamation was an attempt to play politics in the national sphere in an effort to curry favor with the green lobbies.

[86] Special Eurobarometer, "Attitudes of European citizens towards the environment," 295/EB68.2/2007 (2007): http://ec.europa.eu/public_opinion/archives/ebs/ebs_295_en.pdf (accessed January 2011).

EU policies in France by effectively drawing attention to their anti-GM cause.[87] They have done so by using a range of activities, from demonstrations and the "volunteered" harvesting of GM crops to independent research and lobbying. The movement has also expanded the discourse framing GMOs from one of human health and food safety to include concerns about the economic and social repercussions of industrialized and globalized food production and the effects that these trends have on food sovereignty.

Anti-GM interest groups have successfully rallied public support on three levels: as a consumer rights issue, as an environmental rights movement, and as an anti-globalization effort. While many groups in France have spoken out against the cultivation of GM crops and the introduction of GMOs into the food supply, for this study I briefly review the positions of three leading groups: CLCV, CRIIGEN, and Greenpeace France. I then look more closely at the *Confédération Paysanne*, a farmers' union. As noted above, the French have expressed both high levels of trust in the information these types of groups share and of confidence that consumer groups, scientists, and environmental groups are doing a good job for society. This means that French citizens rely on information provided by these groups to help form their opinions about biotechnology and food-related risks. The survey data illustrate how French fears echo the anti-GM statements of these groups, and how their concerns have been institutionalized in the regulatory framework. By reviewing the varying platforms, I demonstrate how the issue of GMOs has been framed within the French debate.

[87] In English, CRIIGEN is the Committee for Research and Independent Information on Genetic Engineering. Loosely translated, the CLCV is the Consumers, Housing, and Working Conditions Association, and the *Confédération Paysanne* is the Peasant Confederation, though scholars and journalists usually refer to both organizations by their French titles.

L'association Consommation, Logement, Cadre de Vie (CLCV)

The CLCV is the most prominent consumers' rights group in France. Its members engage with authorities at local, departmental, regional, and national levels within France with over 400 domestic chapters. It also engages with institutions at the EU-level, in particular as a member of the European Consumers' Union (*Bureau Européens des Unions de Consommateurs* – BEUC), which acts as an umbrella organization in Brussels on behalf of the national consumer groups.[88] Internationally, the CLCV joins forces with Consumers International, a global consumer rights organization. The CLCV's main efforts center on educating the public and mobilizing them to contact the relevant authorities about an issue. In addition, the association works with consumers in a legal capacity, promising to provide its members with information on their legal rights and access to legal specialists.[89]

In the case of GMOs, the CLCV's primary mobilization effort is to call on consumers to contact both their national and European parliamentary representatives. The association also publicly takes positions on policy decisions, such as pushing the French *Conseil d'Etat* for more transparency in GMO field tests[90] and demanding that the European Commission reevaluate its approvals for several GMOs.[91] While the CLCV recognizes that the majority of French citizens do not wish to ingest GMOs, the organization also notes that biotechnology may have some

[88] BEUC, "Welcome to BEUC, the European Consumers' Organisation," BEUC: Home (August 2011), http://www.beuc.org/Content/Default.asp (accessed August 2011).
[89] CLCV, "Nous vous défendons," CLCV : National (n.d.), http://www.clcv.org/Nous-vous-defendons.835.0.html (accessed August 2011).
[90] CLCV, "Rayonnements électromagnétiques, OGM, Nanotechnologies: Danger ou progrès?" CLCV : Thèmes / Environnement / Energie / Nos positions / Positions (November 24, 2009), http://www.clcv.org/Rayonnements-%C3%A9lectromagn%C3%A9tiques,-ogm,-nanotechnologies--danger-ou-progr%C3%A8s--[-24.11.2009-].6851.0.html (accessed August 2011).
[91] CLCV, "Appel pour une réévaluation des OGM," CLCV : Thèmes / Alimentation - Santé / Santé / Nos positions / Communiqués de presse (July 5, 2010), http://www.clcv.org/Appel-pour-une-reevaluation-de.cp93.0.html (accessed August 2011).

important uses (such as in conjunction with pesticides).[92] To this end, the CLCV has promoted several platforms: more stringent labeling requirements that allow consumers to avoid GM products; more studies on the environmental impacts of GMOs, to be performed by independent research groups and not industry; guarantees of protection for non-GM crop producers in cases of cross-contamination; and expanded evaluations of the environmental, human health, and socio-economic impacts of GMOs.[93]

The CLCV attempts to advance its platforms through its representative on the *Comité économique, éthique et social* (CEES) of the HCB. Charles Pernin, head of the food industry division of the CLCV, is one of the members of the CEES. He was selected at the HCB's inception to represent consumer associations as part of the risk assessment process and, like all committee members, he has a five-year mandate.[94] During his tenure, Pernin has publicly called for a reevaluation of GMO approvals at the EU-level, calling into question the scientific assessments performed by EFSA.[95] He also expressed his dissent on the first dossier under review by the CEES: a request to review GM maize by Monsanto (MON810) for which EFSA was considering reauthorization. Pernin was one of the fourteen members of the committee to vote "no" to the question of whether the benefits of MON810 outweighed its disadvantages.

In his dissenting opinion included in the appendix of the CEES recommendation, Pernin stated that he was against the approval of MON810 for several reasons. For one, he questioned the robustness of the scientific assessment of the GMO's risks. Second, he found the potential use of the GMO to be very narrow; MON810 would only be useful if precise conditions were

[92] CLCV, "OGM: Préserver la liberté de choix des consommateurs et des producteurs," CLCV : Pensons nous… (n.d.), http://www.clcv.org/OGM-Preserver-la-liberte-de.2715.0.html (accessed August 2011).
[93] CLCV, "OGM: Préserver la liberté de choix des consommateurs et des producteurs."
[94] For a more detailed discussion of the CEES and the HCB, please see Chapter 4.
[95] CLCV. "Appel pour une réévaluation des OGM."

met, yet those conditions (serious, recurring infestations of the corn borer) were rare in France.[96] Finally, Pernin believed that the coexistence regulations that were in place at the time would not be sufficient to prevent the contamination of non-GM crops.[97] Pernin's dissent in this dossier exemplifies his contributions to the CEES' recommendations. He represents the platforms that the CLCV promotes within France and at the EU-level: more stringent labeling requirements, protections for conventional crops, and calls for more robust scientific studies of possible effects.

Comité de Recherche et d'Information Indépendantes sur le genie Génétique (CRIIGEN)

CRIIGEN is "an independent non-profit organization of scientific counter-expertise" that was created in June 1999 "to study GMOs, pesticides and impacts of [genetic] pollutants on health and environment, and to develop non-polluting alternatives."[98] Like the CLCV, it also offers legal advice, as well as its scientific expertise. Unlike the CLCV, CRIIGEN focuses solely on genetic engineering issues. One of its main objectives is to achieve "transparency on blood analyses (crude data) of mammals having eaten GMOs in regulatory tests."[99] To that end, CRIIGEN requests that the results of research on commercial genetic engineering and on the cultivation of GMOs that might have an impact on the environment and/or health be made public.[100] Furthermore, the organization pursues its own research – not only on the impact of GMOs on the environment, agriculture, food, medicine, and public health, but also on methods

[96] The corn borer is an agricultural pest that infests grain crops, especially maize varieties. Comité économique, éthique et social du HCB. "Recommandation relative à la demande de renouvellment des autorisations de culture, importations et transformation du maïs MON810." December 22, 2009. http://www.hautconseildesbiotechnologies.fr/IMG/pdf/091222_Mais_MON810_Recommandation_CEES_HCB.pdf (accessed July 2012). 48.

[97] CEES. "Recommandation relative à la demande de renouvellment des autorisations de culture, importations et transformation du maïs MON810." 49. Coexistence regulations are standards that are set to allow for the cultivation of both conventional (non-GM) and GM crops without cross-contamination. This is to ensure that conventional crops do not contain GM content above a certain percentage of total content.

[98] HH, "Presentation of CRIIGEN," CRIIGEN - Committee for Research and Independent Information on Genetic Engineering (April 17, 2010), http://www.criigen.org/SiteEn/index.php?option=com_content&task=blogcategory&id=52&Itemid=103 (accessed August 2011).

[99] HH, "Presentation of CRIIGEN."

[100] HH, "Presentation of CRIIGEN."

for preventing "the spread of genetic pollution."[101] To achieve these objectives, CRIIGEN publicizes its research and policy positions, as well as takes legal action from time to time.

CRIIGEN does not have a representative on either of the HCB's committees. However, one of the founders of CRIIGEN, Gilles-Eric Séralini, was the anti-GMO expert who was added to the *Commission du Génie Biomoléculaire* (CGB) during reforms to the French regulatory framework in Phase IV. Although other CGB members had mixed feelings about Séralini's role on the committee, which was characterized as a constant anti-GMO position based on "'other', non-scientific reasons," he was purposefully included to present a conflicting opinion in an attempt to "open" the approval process to other opinions.[102] Séralini is also a molecular biologist like the majority of experts on the HCB's scientific committee (CS), but he argues for "independent" expertise to be included in the risk assessment process.

To that end, when the government dissolved the CGB and began to assemble the HCB, CRIIGEN – under Séralini's direction – sought to annul the HCB's founding decree. CRIIGEN claims that the HCB's scientific experts are not truly independent of industry interests, and that "conflict of interest" statements submitted by HCB experts do not amount to transparency and independence.[103] They point to several public health and food safety issues, such as the HIV-tainted blood scandal, the mad cow crisis, and the "lax evaluation of GMOs," as contributing to

[101] HH, "Articles of Association of CRIIGEN, as modified on 7 July 2008,"Articles of Association of CRIIGEN (April 17, 2010), http://www.criigen.org/SiteEn/index.php?option=com_content&task=view&id=13&Itemid=103 (accessed August 2011).
[102] Claire Marris, Stéphanie Ronda, Christophe Bonneuil, and Pierre-Bénoît Joly. 2004. "Precautionary Expertise for GM Crops. National Report – France: Battling with Expertise." [series] Quality of Life and Management of Living Resources. Key Action 111-13: socio-economic studies of life sciences, Project n° QLRT-2001-00034. Paris, France: CNRS. p.7. http://technology.open.ac.uk/cts/national/france%20national%20report%20PEG.pdf (accessed June 2012)." 47-48. See Chapter 4 for a more detailed discussion on reforms to the French regulatory framework on GMOs.
[103] CRIIGEN. 2011. "Les scandales sanitaires remettent en cause l'indépendance de l'expertise." November 15. CRIIGEN – Committee for Research and Independent Information on Genetic Engineering. http://www.criigen.org/SiteFr//index.php?option=com_content&task=view&id=370&Itemid=32 (accessed August 2012).

the need for more "independent" research and expertise.[104] To promote its platforms, CRIIGEN frequently provides its own counter-assessments of industry-provided data, and it performs its own research on GMOs for which the HCB and EFSA have presented favorable opinions.

Greenpeace France

Like the CLCV and CRIIGEN, Greenpeace France similarly claims that GMOs present risks to the environment and to human and animal health. It also emphasizes the impacts of GMO cultivation on the economic and social equilibrium.[105] The organization has been actively involved in the anti-GMO movement since 1996, when the first GM crop was approved for cultivation in Europe. However, Greenpeace France takes a stronger stance against GMOs than the CLCV, opposing any cultivation of GM crops in open air.[106] The organization's platforms include: supporting sustainable agriculture that does not include GMOs; pursuing independent studies on the effects of GMOs on the environment and human health; promoting conditions that allow consumers and producers to choose non-GMO alternatives; and requiring stringent labeling for products containing GMOs.[107]

Greenpeace also asserts that it is not against innovative research or progress; rather its members respect science that enriches everyone and respects the environment, which, from their perspective, the biotechnology industry does not do.[108] Thus, Greenpeace France shares with CRIIGEN the position that biotechnology companies are not transparent about their production processes or with their research results. To draw attention to its cause, Greenpeace France has published its own studies on the environmental and health impacts of GMOs and mobilized its

[104] CRIIGEN. "Les scandales sanitaires remettent en cause l'indépendance de l'expertise."
[105] Greenpeace France, "OGM: organismes génétiquement modifés," S'informer : les OGM (n.d.), http://www.greenpeace.org/france/fr/campagnes/ogm/ (accessed August 2011).
[106] Greenpeace France, "OGM: organismes génétiquement modifés."
[107] Greenpeace France, "Solutions," S'informer: Les OGMS – Solutions (n.d.), http://www.greenpeace.org/france/fr/campagnes/ogm/solutions/ (accessed August 2011).
[108] Greenpeace France, "OGM: organismes génétiquement modifés."

network for protests and to sign petitions expressing anti-GM sentiment to be sent to the European Commission. These organized protests have occurred around France, including a heavily-publicized 2005 demonstration in which Greenpeace and the *Confédération Paysanne* members met a cargo ship carrying GM soy into the French port of Lorient.[109]

Greenpeace France also has a representative who sits on the CEES. Until 2011, Arnaud Apoteker, a biologist and an organic foods specialist, was the original Greenpeace representative on the committee.[110] Apoteker has been a longtime anti-GMO activist in France; motivated by the arrival of American GM soy in 1996, Apoteker worked to prevent the spread of GMOs in Europe as a leader in Greenpeace France.[111] As a member of the CEES, Apoteker wrote a dissenting opinion for every positive recommendation of a GMO from the committee, often siding with representatives from the *Confédération Paysanne*, *Les Amis de la Terre* (Friends of the Earth), and the organic farmers' and beekeepers' groups.[112] In his dissents, Apoteker continually questions the necessity of using biotechnology to deal with agricultural issues. He encourages industry to research other methods to address issues like agricultural pests and yield. More importantly, he emphasizes that the advantages of GMOs only benefit the biotech industry and possibly the farmer, but not the consumer or the public at large.[113]

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[109] Greenpeace, "Greenpeace, Jose Bové protest against genetically engineered soy on high seas," Greenpeace Press Releases (January 25, 2005), http://www.greenpeace.org/international/en/press/releases/greenpeace-jose-bove-protest/ (accessed August 2011).

[110] Apoteker left the HCB before his five-year tenure was complete because he was elected to the European Parliament as a member of the Greens/European Free Alliance. He left his post at Greenpeace at the same time. The Greens/European Free Alliance in the European Parliaments. "Arnaud Apoteker." (accessed August 2012). http://www.greens-efa.eu/36-details/apoteker-arnaud-164.html; Ecolopedia. 2011. "Arnaud Apoteker." *Acteurs*. May 12. http://www.ecolopedia.fr/?p=1057 (accessed August 2012).

[111] Hervé Kampf. 2005. "Portrait - Arnaud Apoteker, anti-OGM scientifique." *Inf'OGM – Veille citoyenne sur les OGM*. February 2. http://www.infogm.org/spip.php?breve360 (accessed August 2012).

[112] See the CEES' recommendations from 2010 on marigolds (*œillets*), grapevines (*vignes*), and maize (*maïs*) for examples of Apoteker's opinions (source in French). HCB. "Avis rendu in 2010." *Avis.* http://www.hautconseildesbiotechnologies.fr/spip.php?rubrique1 (accessed July 2012).

[113] HCB – CEES. 2010. "Recommandation relative à la demande de mise en culture du maïs « 1507 » (dossier Pioneer C/ES/01/01)." *Avis rendu in 2010*. May 6. http://www.hautconseildesbiotechnologies.fr/IMG/pdf/100601-Mais-1507-Recommandation-CEES-HCB.pdf (accessed August 2012).

La Confédération Paysanne

The *Confédération Paysanne* is probably the most recognizable anti-GM group specific to France. It is a farmers' union that split from the *Fédération nationale des syndicats d'exploitants agricoles* (the major farmers' union – FNSEA) in 1987 over differences in political direction. To the *Confédération Paysanne*, FNSEA represents the interests of farmers who have taken on more industrialized agricultural methods. In contrast, the *Confédération Paysanne* represents family farmers who have been marginalized by industrial agriculture.[114] The *Confédération Paysanne* also has connections to organizations with a global scope, including Greenpeace, Attac, and *La Vía Campesina*. Accordingly, the *Confédération Paysanne* is a "green" movement that takes a distinctly anti-globalization stance.[115] Its main anti-GM platforms call on governments to: prohibit the patenting of seeds; ban GMOs in Europe; stop all open air field trials of GM crops; recognize the results of independent studies on the effects of GMOs on human health and the environment; and require traceability procedures for any GM content as well as strict labeling requirements.[116]

The *Confédération Paysanne* is perhaps best known outside of France because of its leader, José Bové. Bové has been an activist since the 1970s, which is also when he was first arrested during a protest against the expansion of a military base.[117] His activism has included leading rallies for increased farm subsidies, protesting at WTO meetings, and demonstrating with Greenpeace on issues outside of agriculture, like nuclear testing. Led by Bové, the *Confédération*

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[114] Chaia Heller, "Post-industrial 'quality agricultural discourse': Techniques of governance and resistance in the French debate over GM crops," Social Anthropology 14.3 (2006), p.319.
[115] Julie Pagis, "Behind their common struggle against GMOs: Political cultures that divide," Focaal – European Journal of Anthropology 48 (2006), p.49.
[116] Confédération Paysanne, "OGM and Brevetabilité: Main basse sur le vivant," OGM : Argumentaire de la Confédération Paysanne (December 2004), http://www.confederationpaysanne.fr/images/imagesFCK/file/dossiersthematiques/OGM/4pagesOGM.pdf (accessed August 2011).
[117] Caroline Frost, "José Bové: Profile," BBC Four : Documentaries (April 20, 2002), http://www.bbc.co.uk/bbcfour/documentaries/profile/jose_bove.shtml (accessed August 2011).

Paysanne formally launched its anti-GMO campaign in 1997. But Bové's most notorious protest – the destruction of a McDonald's construction site in Millau, France in 1999 – was also the one that shot him to the forefront of the anti-globalization movement.[118] At its helm, Bové has led the *Confédération Paysanne* in acts of civil disobedience and the destruction of GMO fields.[119]

Like the CLCV and Greenpeace France, the *Confédération Paysanne* has a representative on the HCB's CEES. A long time member of the *Confédération Paysanne*, Guy Kastler also works closely with *La Vía Campesina*, *Le Réseau Semences Paysannes*, and several other anti-GMO organizations. Kastler objects to all GMOs and pesticides, regardless of quantity, and actively works through different groups to prevent their usage.[120] Like Apoteker, he has written a dissenting opinion for each positive recommendation that the CEES has submitted for a GMO dossier. He has supported acts of civil disobedience in protest of GMO cultivation, including the destruction of GM crops by the *faucheurs volontaires*.[121]

Frequently, Kastler co-authors his dissenting opinions with Apoteker and/or with the representatives from other environmental and organic farming groups.[122] In his dissents, he argues that GMOs only benefit a small group of people, either farmers or the biotech company proposing approval, and that the benefits of use do not outweigh the risks. Kastler also maintains that there is uncertainty about the potential long-term environmental, social, economic, and human health effects of GMOs. In his position on the CEES, Kastler promotes the *Confédération Paysanne* efforts to ban all GMOs.

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[118] Chaia Heller, "Post-industrial 'quality agricultural discourse,'" p.326.
[119] Franz Seifert, "Consensual NIMBYs, Contentious NIABYS: Explaining Contrasting Forms of Farmers' GMO Opposition in Austria and France," Sociologica Ruralis vol. 49, no. 1 (January 2009).
[120] Alerte environnement. "Guy Kastler." http://alerte-environnement.fr/portraits/guy-kastler/ (accessed August 2012).
[121] Alerte environnement. "Guy Kastler."
[122] For examples, see the CEES' recommendations in 2010 on marigolds (*œillets*), grapevines (*vignes*), and maize (*maïs*). HCB. "Avis rendu in 2010." *Avis.* http://www.hautconseildesbiotechnologies.fr/spip.php?rubrique1 (accessed July 2012).

The French anti-GM movement

Although each interest group's approach is rooted in a particular issue (consumers' rights, environmental protections, or farmers' rights), all four recognize the other issues as essential to their individual arguments. As such, together the anti-GM groups keep their educational efforts and protests on message and affiliated with one another, making for a stronger movement. This strength and the efforts of each group help maintain GMO regulation as an issue on the public policy agenda in France. For example, besides rallies and demonstrations, the *Confédération Paysanne* has supported the *faucheurs volontaires*, who have destroyed GM crops around the country.[123] The groups also contribute directly to the regulatory process through representatives on the HCB. These activities continually bring media attention to the anti-GM cause, and they keep the concerns about the risks of agricultural biotechnology fresh in the minds of French citizens.

But the public's concerns about "risk" have shifted over the last twenty years. Instead of focusing on the potential biological risks of GMOs and a fear of GM food, the debate has expanded to include their social and economic impacts. The anti-GM movement has effectively framed the issue of agricultural biotechnology regulation as a question of environmental rights, consumer rights, and citizens' rights in the face of globalization. Through the activism of anti-GM groups, the French population has a high level of awareness of GMO issues and, consequently, the majority of French citizens are anti-GMO. Thus, as Claire Marris points out, French resistance to GMOs is not some irrational rejection of science; rather, resistance comes

[123] The most recent instance of faucheurs volontaires at work was July 30, 2011. Confédération Paysanne, "Les paysans et notre alimentation n'ont pas besoin d'OGM : les Faucheurs volontaires mettent le projecteur sur les plantes mutées," Dossiers : OGM (August 3, 2011), http://www.confederationpaysanne.fr/paysans-notre-alimentat-n-ont-pas-besoin-ogm_23-actu_1859.php (accessed August 2011).

from suspicions that "economic interests often override health and environmental considerations" in the regulation and management of risks.[124]

Chaia Heller has written extensively on this discursive shift from a sociological approach. Her argument is that public debate has shifted from one of questions of science and "riskification" within the framework of "risk rationality" to looking at those same questions within a "rationality of sociology" framework.[125] This means that "public concerns over GMOs extend beyond food anxiety to include concerns about the rationalization of human life itself."[126] Furthermore, Heller traces this shift back to 1999 and José Bové's "dismantling" of the McDonald's in Millau. This particular act effectively linked the issue of GMOs and food quality with globalization in the French mind. Thus, the *Confédération Paysanne* and the other anti-GMO groups are no longer fighting simply for farmers' rights to less industrialized methods of production; its members are also demanding the right to "quality food" and "quality of life" for small agricultural producers.[127]

The connection between globalization and GMOs is made clearly within the concept of food sovereignty, which is defined as the right of citizens to choose their own food.[128] Globalization undermines food sovereignty by placing control over food production into the hands of a few agricultural companies. This is especially true in the case of GM crops, where seeds are patented by biotech companies, like Monsanto or Novartis, and producers have few choices but to buy stock from these global corporate entities. The *Confédération Paysanne* believes that the right to quality of life for small farmers is being destroyed by agricultural

[124] Claire Marris, "Public views on GMOs: deconstructing the myths," EMBO Reports vol. 21 no. 7 (July 15, 2001), 548.
[125] Chaia Heller, "From Risk to Globalization: Discursive Shifts in the French Debate about GMOs," Medical Anthropology Quarterly vol.15, no. 1 (2001), p.25.
[126] Heller, "From Risk to Globalization," p.27.
[127] Heller, "Techne versus Technoscience: Divergent (and Ambiguous) Notions of Food 'Quality' in the French Debate over GM Crops," American Anthropologist vol.109, no.4 (2007), p.607.
[128] Julie Pagis, "Behind their common struggle against GMOs," p.49.

industrialization (at the core of which is GMOs), with the control over the means of production being further condensed through globalization into the hands of just a few agricultural biotech companies. The *Confédération Paysanne* views its struggles from three perspectives within this discourse:

> [T]he social – based on providing employment, and fostering solidarity among farmers and among regions and farmers world-wide; the economic – by adding value so that farmers can live with relatively modest outputs which is the precondition for maintaining large numbers of people as farmers; and, finally, what is really the moral argument – the need to show respect to both consumers and nature.[129]

The *Confédération Paysanne*'s position then is that "food sovereignty – by country or by region – and the right to protect one's agriculture, and an agricultural way of life, against destruction by unbridled market forces" is the alternative to globalization that must be pursued.[130] Bové himself sums it up as such:

> Judging by the substantial social and environmental damage free trade has inflicted, before anything else, it is necessary for all of us – farmers and non-farmers alike – to make [free trade] subject to three fundamental principles: food sovereignty – the right of peoples and countries to produce their food freely, and to protect their agriculture from the ravages of global "competition"; food safety – the right to protect oneself from any threat to one's health; and the preservation of biodiversity.[131]

While protection from risk is still included, the right to food sovereignty has become the chief goal of the anti-GM movement. Resistance to GMOs then is not just about lingering fears over the government's ability to protect public health and maintain food safety. It is about the right of citizens to participate in regulatory governance, whether it is at the EU-level or within the domestic sphere.

[129] Richard Kuper, "Confédération Paysanne: French Farmers Fight Back," Social Policy (Winter 2002/2003), p.27.
[130] Kuper, "Confédération Paysanne," p. 28.
[131] José Bové, "Globalisation's misguided assumptions," Observer no. 228 (September 2001), p. 19.

Conclusion

The Eurobarometer data on biotechnology and food-related risks illustrate how the French fear that their food sovereignty is being encroached upon by agricultural biotechnology. The French express high levels of worry about risks that occur during food production. Pesticide and pharmaceutical residues and pollutant contamination are the top three concerns of French citizens. In addition, over half of French citizens worry about GM food and drink, animal cloning, and nano particles in their food. Overall, French citizens worry the most about factors over which they feel they have little or no control.

The mad cow and the dioxin contamination episodes left lingering fears about "unnatural" processes in food production. More industrialized practices in those cases directly led to negative effects on human health. And for what end? To increase producers' profits. The French find that biotechnology applications in food production are unnatural and unsafe; thus they do not believe that the benefits of agricultural biotechnology outweigh the risks. They also do not believe that the government will prioritize public health when profits are on the line. Public officials clearly did not in the case of the HIV-tainted blood scandal, and the pattern was repeated in other member states when faced with the mad cow outbreak and dioxin contamination.

The French government has responded to its citizens' worries by institutionalizing anti-GM sentiment into its regulatory framework for GMOs. Representatives from anti-GM groups now sit on one of the main committees offering recommendations to the government on GMO dossiers, and as expected they express disapproval of each GMO presented. While the Ministers could ignore the recommendations of the CEES, they might do so at their own peril. The French public has expressed high levels of confidence and trust in environmental and consumers' rights

groups, but much lower levels in public authorities. Approving GMOs that have been rejected by the CEES as a whole or by members of the CEES would reinforce the public's belief that producer profits win out over protecting public health. Thus, the GMO debate in France will continue to remain unresolved as long as anti-GMO representatives are included in the regulatory process.

Concluding Remarks

Although the European Commission's efforts to unblock the GMO regulatory process by returning final approval power to the EU member states gained some support from the majority of states, a blocking minority is preventing adoption of the "compromise" proposal.[1] France, Germany, Belgium, Slovakia, and the United Kingdom have indicated that they are opposed to the proposal on several grounds, and will not support it. In addition, Spain and Ireland have expressed reservations about this "compromise," while Cyprus and Slovenia object to the absence of environmental reasons for "restricting and prohibiting the cultivation of GMOs" in the proposal.[2] After two years of trying to move the proposal forward, the Presidency of the Council concluded in June 2012 that "a political agreement on the GMO dossier is not possible."[3]

Conclusions of the study

This dissertation has shown how the GMO regulatory process in the EU and in France has arrived at this impasse, by tracing the development of the EU and French regulatory systems from 1990 to 2010. Chapter 1 anchored this case study in three major literatures: historical institutionalist studies, multi-level governance studies, and implementation studies. Historical institutionalism provided key concepts to the study, such as path dependence, critical junctures, and a particular emphasis on the timing and sequence of events and policy decisions that lead to the "stickiness" of the French institutions that regulate GMOs. The multi-level governance framework highlighted the importance of looking at both the EU-level and the domestic-level in

[1] Council of the European Union. 2012. "Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory - Progress report." Interinstitutional File: 2010/0208 (COD). June 6. Brussels, Belgium. http://register.consilium.europa.eu/pdf/en/12/st10/st10883-re01.en12.pdf (accessed August 2012).
[2] Council of the European Union. "Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC." 5.
[3] Council of the European Union. "Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC." 6.

the case of France to understand the evolution of the different institutions that play a role in the current impasse. A multi-level governance approach also acknowledges the pressures on the policymaking process and the GMO regulatory framework from actors external to the EU and its member states, such as the United States and the World Trade Organization (WTO). Implementation studies complement each of these theoretical approaches with a focus on the policy environment during the formation and implementation of agricultural biotechnology regulation.

Together, the concepts from the reviewed literatures have allowed me to demonstrate how the timing and sequence of the European public health and food safety scandals of the 1990s set the evolution of the GMO regulatory framework at the EU-level and at the French-level on different paths. Chapter 2 explored those scandals in-depth, and established how the scandals became linked to the issue of GMOs. Acting as triggering events, they elevated the saliency of public health and food safety in the public consciousness. Chapter 2's review of the scandals also illustrated how they framed the political context in which the issue of GMOs appeared on the public policy agenda. The speed at which the crises unfolded meant that French regulatory institutions for GMOs were created and reformed at a time when public officials were eager to avoid blame and when levels of anxiety about health issues and food safety were high among the public.

Chapter 3 addressed how the EU reacted to these scandals through the creation of more stringent labeling and traceability criteria, in contrast to the American regulatory framework. It also reviewed the creation of the European Food Safety Authority (EFSA). At the EU-level, the regulatory response maintained a science-based risk assessment of GMOs within EFSA. Although economic or social risks may be considered by actors within other EU institutions, no

formal assessment mechanisms for these types of risks evolved at the EU-level. The EU's more stringent approach to GMO regulation has put it at odds with major GM crop exporters, such as the US, Canada, and Argentina. The variation in standards leads to pressure, both directly and through proceedings at the WTO, from the major GM crop exporters for the EU to relax some of its standards.

Chapter 4 explored the evolution of the regulatory framework at the French-level, and the differences of the regulatory responses at the EU-level and the domestic-level in the case of France. The French regulatory response codified anti-GMO sentiment within the institutions created to handle the risk assessment process. As a consequence, French GMO opponents have an institutionalized voice in the approval process, and French citizens have come to expect the inclusion of conflicting opinions, particularly concerning the possible social and economic risks of GMOs. The French assessment of GMOs evaluates more criteria for potential risks than assessments performed at the EU-level. This has contributed to persistent noncompliance and regulatory deadlock in this issue area. While major GM crop producers outside of Europe see EU standards and regulations as too stringent for world trade practices, anti-GM EU member states, like France, deem EU standards and regulations to not be sufficient enough for the European common market.

Chapter 5 examined French public opinion about GMOs and anti-GMO interest groups more closely, in order to illustrate the extent of anti-GMO sentiment in the state. The chapter established not only how widespread anti-GMO feelings are among the French population, but also the diversity of concerns that the French harbor about GMOs. For the French, the issue of GMOs is about health, environmental, social, and economic risks, and they do not see personal benefits to embracing agricultural biotechnology. As noted in Chapter 1, the social management

of technological development must balance the benefits of the technology to the public against the potential harm of its application.[4] In the case of GMOs, the French only see the potential benefits of agricultural biotechnology accruing to the producers of GMOs, not to the consumers.

In order to move forward, the EU will have to address the dissonance in this policy area at three levels: the global level, the EU level, and the member state level. At the global level, the EU must present a unified front to maintain the integrity of the EU as a common market. If final regulatory power is returned to the member states, individual states that maintain GMO bans will be vulnerable to WTO complaints and proceedings against them. Exposing its members to this vulnerability contradicts the EU's objective of creating and maintaining a common market.

At the EU-level, the European Commission must resolve the deadlock within the member state representative delegations that leads to *de facto* approvals for GMOs. *De facto* approvals undermine the legitimacy of the EU's authority because the decisions are made without a consensus among the member states. The current system is not working, but returning power to the member states is not the answer. Ceding power back to the member states after already asserting authority over agricultural biotechnology sets a dangerous precedent regarding the repercussions of noncompliance. It implies that if several member states hold out long enough, the EU will return authority, which would create an incentive for states to delay implementation or to refuse to comply with EU regulations.

To address this problem at the member state-level, the EU will have to appeal to the concerns of the general public and of the citizens of the member states that remain staunchly anti-GMO, France included. In the case of France, the French exhibit high levels of mistrust in the corporations that innovate and produce agricultural biotechnology and in the government

[4] Smita Siddhanti, *Multiple Perspectives on Risk and Regulation: The Case of Deliberate Release of Genetically Engineered Organisms into the Environment* (New York: Garland Publishing, Inc., 1991): 4.

institutions responsible for regulating agricultural biotechnology products. Current efforts by the EU to highlight the importance of biotechnology to economic growth and development are falling on deaf ears. European citizens are fearful that their concerns are ignored in favor of producers' profits, with producers reaping the benefits while consumers shoulder the risks. If the EU insists on promoting agricultural biotechnology, its benefits must be seen as beneficial to the public, not to private, corporate interests. In the case of France, however, turning public opinion in favor of GMOs will be a significant hurdle to clear. However, if the EU decides to scale back its promotion of agricultural biotechnology, it will face backlash from major GMO producing countries at the global-level.

Future research

By studying the hurdles to compliance in the French case and the role of domestic institutions in policy adaptation, this dissertation serves as a template for further studies on the implementation of EU legislation in other member states. Although the lessons drawn from one case cannot be applied in their entirety to other EU member states due to variation across nations in their domestic institutions, this work has highlighted the importance of understanding the role of domestic institutions during the process of national implementation or periods of non-compliance. As a result, the conclusions provide us with insight as to how the EU could move forward in order to resolve the regulatory deadlock in the issue area of agricultural biotechnology. Furthermore, they highlight the value of looking at the role of domestic institutions in the implementation phase specifically for scholars.

The conclusions of this study can be used by EU scholars as a foundation for further research into other member states. EU scholars may seek a better understanding of the structures of national regulatory institutions within anti-GMO member states. Promotion of the benefits of

GMOs may require different tactics for different states based on the evolution of their regulatory framework and the timing and sequence of triggering events particular to each state. While such research would necessitate case-by-case studies, a broad lesson learned from the French case is the need to examine the effects of the institutionalization of dissent within the risk assessment process. EU scholars may want to investigate whether other anti-GM states also have dissent codified in their regulatory process, or whether pro-GMO states consider only science-based risk assessments and not economic or social considerations. In each individual case study, scholars could explore the type of anti-GMO sentiment that may exist within a state, and whether it is based on public health, food safety, environmental, and/or social and economic concerns. In order to build support for GMOs, the EU will have to tailor its promotion of agricultural biotechnology to the institutional structures and public opinion within each state. Alternately, the EU may encourage reforms to national regulatory processes in anti-GMO states based on the institutional models from pro-GMO states.

Pressure from the WTO, and namely the US, continues to push the EU to "resolve" the regulatory deadlock by getting more GMOs approved for cultivation and the market. If EU authorities were to attempt to scale back the promotion of agricultural biotechnology, scholars would need to consider the possible repercussions from international organizations, which could affect trade agreements and EU exports. Accordingly, future scholarly studies may address the role of individual member states and EU actors in international negotiations on regulatory standards and restrictions, such as The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). These studies might look at how the differences between the promotion of agricultural biotechnology by major GM crop producers and exporters, like the US, and the more cautious position of the EU play out in international arenas. If a state

can effectively promote its own regulatory standards in other regions of the world, it has a comparative advantage in production and exportation. Future research may then also examine efforts by the EU to push its more stringent standards in other markets, such as Africa.

Additionally, scholars may use the study as a template for other single case studies of regulatory non-compliance within the EU. However, instead of looking for ways to change policies to fit specific, national conditions, future scholarship can help to build the historical institutionalist, multi-level governance, and implementation literatures. These studies could investigate the development of institutional structures within the member states compared to the institutions at the EU-level. They might also consider the impact of the timing and sequence of triggering events (or the absence thereof), which shape institutional development in particular policy issue areas.

This research contributes to the field in several ways. It provides in-depth research that explains the position of non-compliance for a particular member state. It also offers suggestions for how to address the persistence of anti-GMO sentiment and non-compliance. For scholars, this work helps to build three literatures and to create conceptual links between them. In the case of the EU studies, different approaches are imperative due to the organizational structures of the EU. Research on the EU should not be divorced from recognizing the EU's relationship to the member states or from global relations. Comparative policy studies of the EU must recognize the need to contextualize EU policy within the multi-level governance framework.

Furthermore, this dissertation has endeavored to build a dialogue among the fields by demonstrating how concepts from comparative politics, international relations, and public policy can be employed to better analyze EU policymaking and implementation. Similarly, the lesson learned from the study's conclusions is the importance of clear dialogue between the different

levels of biotechnology governance. The EU and its member states must talk to each other rather than at each other. Yet as long as the EU continues to push GMOs for economic reasons with little regard to other potential risks, the *dialogue des sourds* that characterizes the current state of the regulatory approval process for GMOs in the European Union will not be resolved.

Appendix of EU Legislation & Related Documents

Directives:

- Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms
- Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.
- Directive 2008/27/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, as regards the implementing powers conferred on the Commission

Regulations:

- Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.
- Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
- Regulation (EC) No 1946/2003 of 15 July 2003 of the European Parliament and of the Council on transboundary movement of genetically modified organisms.
- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed.
- Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.
- Regulation (EC) No 1882/2003 of the European Parliament and of the Council of 29 September 2003 adapting to Council Decision 1999/468/EC the provisions relating to committees which assist the Commission in the exercise of its implementing powers laid down in instruments subject to the procedure referred to in Article 251 of the EC Treaty.
- Commission Regulation (EC) No 65/2004 of 14 January 2004, establishing a system for the development and assignment of unique identifiers for genetically modified organisms.
- Regulation (EC) No 641/2004 of the Commission of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.
- Commission Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms.

Decisions:

- 2002/628/EC: Council Decision of 25 June 2002 concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biosafety.
- 2002/623/EC: Commission Decision of 24 July 2002 establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (Text with EEA relevance) (notified under document number C(2002) 2715).
- 2002/811/EC: Council Decision of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.
- Council Decision 2002/813/EC of 3 October 2002 establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market.
- Council Decision 2002/812/EC of 3 October 2002 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms as or in products.
- Commission Decision 2003/701/EC of 29 September 2003 establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, a format for presenting the results of the deliberate release into the environment of genetically modified higher plants for purposes other than placing on the market.
- 2004/204/EC: Commission Decision of 23 February 2004 laying down detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for in Directive 2001/18/EC of the European Parliament and of the Council (Text with EEA relevance) (notified under document number C(2004) 540).
- GMOs placed on the market in accordance with Directive 2001/18/EC
    - Decision 2004/643/EC - maize product NK603
    - Decision 2005/608/EC - maize product MON 863
    - Decision 2005/772/EC - maize product 1507
    - Decision 2005/635/EC - oilseed rape product GT73
    - Decision 2006/47/EC - maize product MON863 x MON810
- Commission Decision 2005/463/EC of 21 June 2005 establishing a network group for the exchange and coordination of information concerning coexistence of genetically modified, conventional and organic crops

Reports:

- Report from the Commission to the Council and the European Parliament of 31 August 2004 on the experience of Member States with GMOs placed on the market under Directive 2001/18/EC and incorporating a specific report on the operation of parts B and C of the Directive.
- Report from the Commission to the Council and the European Parliament, of 25 November 2006, on the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed.
- Report from the Commission to the Council and the European Parliament, of 10 May 2006, on the implementation of Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.
- Second report from the Commission to the Council and the European Parliament of 5 March 2007 on the experience of Member States with GMOs placed on the market under Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms.

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