CRISIS OF DEMOCRATIC GOVERNANCE AND CENTRIFUGAL FORCES IN THE EU:

The Struggle between Periphery and Center over the Governance of Genetically-Modified Organisms[1]

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Abstract:

This paper focuses on the governance of genetically-modified organisms in the European Union in the post-moratorium phase (2004-2006). It sees GMOs as a prototype arena for a growing number of multi-functional policy issues, issues such as cloning, nanotechnology, and biometric security policies. The puzzle raised in this paper relates to the continued instability and weak legitimacy of GMO governance, despite the establishment of the most rigorous assessment, traceability, and labeling regulations in the world. Why does the EU remain unable to develop a coherent and stable policy toward agriculture biotechnology?

We argue that the European GMO policy is evolving in a piecemeal fashion through the exploitation of an institutional stalemate by peripheral policy entrepreneurs. The management of GMOs by the EU is emblematic of a situation of contested multi-level governance. Facing simultaneously a mutation of dominant paradigms, a diffusion of power among more actors, and a multiplication of member states through enlargement, the governance structure of the EU has fallen in a situation of institutional crisis. In this context, the quick fix of comitology backfires and publicly exposes the poor legitimacy of decision-making. This has opened political space for new actors, such as NGO coalitions, small member states, external inputs (such as the Swiss referendum of November 2005) and, most recently, a network of GM-free regions within Europe to develop legitimacy and repeatedly rock the policy-making boat.

Outline:

Introduction

Since the mid-1990s, the governance of genetically-modified organisms (GMOs) has undergone a major transformation: from being a purely technical and scientific topic with a relatively high degree of global consensus, it has become a central battlefield in a large confrontation over the setting of global rules in the context of globalization and technological change. In fact, GMOs can be seen as a prototype arena for a growing number of multi-functional policy issues, issues such as cloning, nanotechnology, and biometric security policies. What makes GMO policy so contentious is the fact that it cuts across multiple policy lines and involves high-stake tradeoffs. GMOs are simultaneously a matter of research and development, national competitiveness, industrial policy, agriculture policy, health policy, food safety, environmental policy, consumer information, intellectual property rights, trade policy, foreign affairs, development, consumer rights, and democracy. They involve tradeoffs between efficiency and transparency, competitiveness and democracy, and culture and technology. GMOs raise questions about the responsibility of society in managing progress, the uncertainty of scientific knowledge, and national identity. At the same time, they involve bread and butter issues of trade flows, protectionism, and short-term economic interests. This unprecedented level of multi-functionality pushes the matter of GMO policy out of the hands of bureaucrats and regulatory committees and into the sphere of high politics in a growing number of countries. Usual separations between policy fields and bureaucratic responsibilities fall apart, as the issue reemerges in different clothes in parliamentary hearings, elections, or international summits. Understanding how political systems deal with such a multi-functional issue is crucial, as GMOs may be harbinger of things to come in a growing number of fields.

Since 1990, the development of GMO policy in the EU has gradually shifted from a responsibility of member states to that of EU level regulations. The EU trajectory on GMO policy is particularly noticeable at the global level, both because of its enormous impact and for its volatility. Although the EU identified agriculture biotechnology as a separate field that required its own regulations as early as 1990, it remained within the emerging global consensus crafted by the OECD and the WTO in the early 1990s. In particular, EU countries supported the OECD focus on "substantial equivalence", a concept that implied that GMOs should not be treated in a more restrictive way than conventional breeding techniques. They supported the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) in 1994, which enshrined scientific evaluation (with undue delay) as the only basis for safety assessment of all agricultural products.[2] Further, the EU began authorizing the consumption and planting of GMOs in 1996, following trends in the US, Canada, and Japan. Meanwhile, the DG Research and DG Enterprise had identified biotechnology as a top economic priority since the early 1980s and were promoting the sector.

In 1997-1999, a major transformation took place. In the midst of NGO mobilization, high public opinion concern, and political uncertainty, the EU started adopting more stringent regulations. In June 1999, the council of ministers, led by a few key member states, decided to apply a de facto moratorium on new product approvals until strict regulations on safety and environmental assessment and labeling could be put

[2] For a more thorough analysis, see (Tiberghien 2006)

in place. By 2003, these new regulations were adopted, turning the EU into the global regulatory pace-setter on GMOs. In particular, the EU adopted the strictest traceability and labeling rules in the world, imposing the labeling of GMOs based on the production process, i.e. irrespective of whether modified DNA remained in the end product or not. Although the moratorium was formally lifted in late 2003 and approvals resumed early 2004 (with 9 new products approved to date), it wroke havoc on trade relations with the US, redirecting much of the EU imports of soy and corn toward Brazil and Argentina. It led to a high-profile WTO panel in 2003-2006, in which the WTO ruled that the EU had violated its SPS commitments. These earlier moves of the EU toward a tight regulatory position (with a temporary moratorium) and the rift with the US over GMOs have been much analyzed. Scholars have advanced a range of reasons for this divergence: in particular, interest group mobilization patterns, institutional variations, or differing norms and culture.[3]

This paper focuses on the next phase in the development of GMO policy in the EU: the post-moratorium phase of 2004-2006. Strikingly, despite the end of the moratorium and the unveiling of strict regulations on safety, environment, and labeling, GMO policy remains unstable and disputed. The Commission's efforts to return to the promotion of science, long-term industrial competitiveness (the Lisbon agenda) and stable trade relations are facing mounting political obstacles. In 2006, the Commission has found itself pushed into organizing a major EU-wide conference on the coexistence of GMOs with other crops, a conference that involved all 25 governments and over 700 representative participants. The pressure to develop further regulations on coexistence and seeds remains high. Uncertainty remains as high as ever.

This situation stands in sharp contrast with that of Japan, for example. Although the Japanese government followed a similar path to that of the EU until 2001, adopting strict safety, environmental, and labeling regulations under civil society and political pressures, it has been able to keep the situation under control since then. In other words, the regulatory outcome appears stable in Japan and the political debate has quieted down since its high point of 1997-2000. The government has also been able to answer citizens' demands through new regulations, without disrupting trade relations with the US and Canada.

Consequently, in this paper, we raise one main question:
Why is the EU unable to develop a coherent and stable policy toward agriculture biotechnology? In particular, why is it unable to put the lid on opposition to its policy line, in the context of its official Lisbon strategy (focusing on competitiveness, science and technology, R&D, industrial policy, and trade development)? This question matters for at least three reasons. The GMO issue constitutes a test for the post-Nice, post-enlargement EU regulatory apparatus. A full battery of directives and regulations has been put in place under the co-decision procedure, attempting to be more efficient and democratic. Has the process worked and what can it tell us about the EU policy-making process? Which actors end up having an advantage in the process and which ones are losing? Further, the issue of GMO policy-making has been seen as a test case for the transition from a closed regulatory game in the EU to a more inclusive and transparent

[3] In particular, see (Ansell and Vogel 2006; Bauer and Gaskell 2002; Bernauer 2003; Bernauer and Erika 2003; Dunlop 2000; Gaskell, Bauer and Science Museum (Great Britain) 2001; Jasanoff 2005; Meins 2003; Miller and Conko 2004; Skogstad 2003; Vogel 2001; Vogel 2002; Young 2003)

game. It is this transition successful? Further, because EU GMO policy has emerged as standard-setter for other countries,[4] understanding who shapes the EU standards on this key multi-functional issue and whether the EU has the capacity to develop a stable standard has much to say about the potential global role of the EU.

We argue that the EU GMO policy is not driven by interest group politics or economic considerations. Nor is it shaped by culture and norms. Rather, the European GMO policy is evolving in a piecemeal fashion through the exploitation of an institutional stalemate by peripheral policy entrepreneurs. The management of GMOs by the EU is emblematic of a situation of *contested multi-level governance*. Since the mid-1990s, the EU governance structure is simultaneously experiencing a transition of governing paradigms (from expert-led to more participatory) and a fragmentation of the institutional structure (rise in power of European Parliament and European Council, creation of new independent agencies, entry of new states through enlargement). In this context, the quick fix of comitology backfires and publicly exposes the institutional divisions and poor legitimacy of decision-making. This opens political space for new policy entrepreneurs to develop legitimacy and rock the policy-making boat. In the case of GMO policy, these actors appear in various successive forms: NGO coalitions (with linkages in the European Parliament in particular), coalition of sub-state regions (as the GM-free regional coalition), small individual states with agenda capture capability (particularly Austria), and even external inputs (Swiss referendum of November 2005, WTO ruling).

Given the weak level of legitimacy in the central institutions, intense competition between the supranational poles (EU Council, EP, Commission, and ECJ), inter-DG disagreements within the Commission, and inter-state competition within the Council, new actors that are often excluded from the policy game are able to shape the public agenda and influence policy-making in novel ways. In sum, the policy outcome in a multi-functional arena like GMOs, is fragile, disputed, and perpetually evolving.

The rest of this paper proceeds in six steps. Section 1 reviews the puzzling path of GMO policy in the EU since the 1980s and discusses some of the dominant theories developed to explain this pathway. The second section advances our framework of contested multi-level governance. It draws upon theories of institutions and of institutional crisis developed by Douglas North and Masahiko Aoki, while incorporating insights from social movement theories. In turn, section three presents some of the novel actors involved in the most recent pulling and hauling of EU GMO policy. Section four turns to the empirical analysis and focuses on the voting records of states in the EU council on post-2003 GMO approvals. It unpacks the growing dysfunctionalities of comitology procedures for such a politicized issue as GMOs. Section five focuses on three main episodes of GMO policy since 2004: the debate over the legitimacy of the European Food Safety Agency (EFSA), the debate over coexistence and the Vienna Summit of April 2006, and the EU defense process at the WTO.

[4] See for example (Rifkin 2004)

I/ THE PUZZLING PATHWAY OF GMO POLICY IN THE EU UNTIL 2003 AND RELATED THEORETICAL FRAMEWORKS

The European Union's response to the GMO debate has been primarily formulated through the legislative capacity of the union and the creation of a new and thorough regulatory framework. However, against expectations that this muscular response might end the debate and assuage consumer and public fears, the high degree of politicization over GMOs has endured. Emblematic of this politicization is the inability of member states in the EU Council since 2003 to come to a qualified majority (against of in favor) as part of the procedure for the approval of new GMOs. This stalemate triggers the rarely used direct authorization of these products by the Commission, as part of the "Comitology" procedure. In the process, however, the confrontation between member states gets publicly exposed and the legitimacy of the decision is publicly put of question. In fact, this systematic occurrence with GMO authorizations had led states such as Austria, Greece, and Italy to question the entirety of the "comitology" process in EU policy-making. This, in turn, threatens to unravel the compromise of the Single European Act across the board of EU regulatory politics.[5]

In addition, individual member states are still imposing bans, enacting safeguard clauses, and systematically opposing the Commission proposals notwithstanding positive recommendations by EFSA. To understand why the impasse has not been resolved, we thus must survey the biotechnology regulatory framework of the EU prior to the moratorium and following the moratorium.

EU Regulatory Milestones until 2003

The cornerstone of EU's GMO regulatory policy prior to the 1999 Moratorium was the Directive 90/220/EEC, which specifically dealt with the Deliberate Release into the Environment of Genetically Modified Organisms. The release and marketing procedure established by 90/220/EEC was considerably complicated and confusing. The onus was on the manufacturer to conduct all the safety studies and then submit the application to a member state, which would decide on whether to permit the GMO release or not. The European Commission and EU member states were given an opportunity to raise objections to the proposal, in which case they would initiate a European-wide decision-making procedure.[6]

Since Directive 90/220/EEC was primarily designed to regulate the release of GMOs into the environment for research purposes, the Commission proposed a new regulation in the summer of 1992 that would later be adopted as the 1997 Novel Foods Regulation (258/97). Under 90/220/EEC, 18 authorizations were granted and two GMO events were authorized for food and thousand of research field trials went ahead.[7] Since no separate legislation existed governing feed prior to the Regulation 1829/2003, eight

[5] Source: Personal interview (YT) with high official of the EU Council in April 2006. The EU Environmental and Agricultural Councils of April 2006 were both dominated by a multi-hour discussion over the legitimacy of the comitology procedure.

[6] Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, *Official Journal of the European Communities* L117 of 08/05/1990, pp. 15-27.

[7] (Skogstad 2003, 321). See also Annexes A and B of this paper.

feed events were also authorized under 90/220/EC.[8] Annex A provides a table of all GMOs authorized since 1996 and Annex B provides a record of field tests authorized in the EU since 1990.

Directive 90/220/EEC was drafted by DG Environment, a young and untested DG at that point, and did not contain any mandatory labeling requirements. The first EU-wide labeling requirement was adopted in mid-1997, as an amendment to directive 90/220/EEC. However, the introduction of 1997 Novel Foods Regulation, meant to simplify the application procedure and regulate GM-*food* products, further highlighted the emerging cleavages regarding GM product approvals. It did not include enzymes, vitamins, flavorings and food additives in its scope. Furthermore, it was difficult to operationalize, as there were no specifics as to how regulation was to be implemented. Member states were left with the power to decide thresholds, testing methods, products subject to testing and the content of labels. Another problem with the Novel Food Regulation was the fact that it did not try to regulate the already approved Bt corn and Roundup Ready soybeans, approved by the EU in 1996.[9]

Outlining the process that led to the adoption of the 1997 Regulation, Meins points out that the provisions for mandatory labelling were the most divisive. The initial Commission proposal suggested labelling on a case-by-case basis. States traditionally aligned with consumers and concerned with environmental issues, such as Denmark, Germany, the Netherlands, Finland, Sweden and Austria rose in opposition.[10] The final 1997 decision was a classic compromise: all food would be labelled (although rules for labelling were not clear), but not the products already approved under 90/220/EEC.

The final straw that broke the back of the EU GMO regulatory framework was the Novartis GM maize, approved in 1997, albeit with considerable opposition from Austria, the UK, Sweden and Denmark. The maize was approved under 90/220/EEC and since the 1997 Novel Foods Regulation did not provide for labelling of products approved under 90/220/EEC, the labelling of the Novartis maize was up to individual member states. Immediately following the approval on December 18th, 1996 Austria, Luxemburg and Italy imposed national bans. The Austrian and Luxembourg bans were examined on April 9th 1997 by the Scientific Committees on Pesticides, Foods and Animal Nutrition under the Article 16 of the Directive 90/220/EC and were found to be unjustified. However, the Council, which now had to act and remove the bans as per decision of the committee, refused to make a decision, forcing the Commission to subsequently demand in September 1997 that Austria, Luxembourg and Italian bans be dropped.

By 1998, 16 GMOs had been approved and another 11 were pending. Many member states felt that the regulations in place were insufficient and were using their rights to impose country-specific safeguards, thus eroding the common market. In this context, EU Environmental Council of June 25, 1999 adopted a moratorium on new approvals (on a proposal pushed by Greece, France, and a core group of countries),[11] with the aim of creating a time window and enabling EU institutions to pass more advanced regulations. While member states were stepping in with the highly political decision of a moratorium (with the aim of assuaging their public opinions), they also accepted the

[8] (Garcia 2006, 4)
[9] (Chege 1998, 179)
[10] (Meins 2003, 122)
[11] For details, see (Kempf 2003)

Commission proposal to amend the 90/220/EEC Directive. Therefore, the Council opted to impose a moratorium in order to allow the Commission to come up with more coherent and agreeable set of regulations that would respond to the concerns of Member States skeptical of GMOs (with the aim of protecting the common market).

The first step toward a new regime came with Directive 2001/18/EC on environmental release, the first directive to explicitly incorporate the precautionary principle. It was drafted by DG Environment. The directive introduced a complex dual-level approval process for research field tests and crop approvals. It also introduced a 0.9% threshold for mandatory labeling. It was adopted on April 17, 2001 and became applicable on October 17, 2002. Many states, however did not transpose it until 2005. The last member state, France, has still not transposed it to date. (The Senate passed the law on March 24th 2006, but it now has to pass the Assemblee Nationale, on whose agenda it is apparently only in June).[12]

The second step came with Regulations 1830/2003 and 1829/2003 regarding the placement of food and feed on the market. The regulations were drafted by DG Sanco (health and consumer rights) and codified the mandatory traceability and labeling of all GMOs. This new regulation (which did not require transposition into national law) introduced the "one key, one door policy" enabling applicants to pass the food safety assessment and environmental safety assessment with one application, the provisions of 2001/18/EC still regulated the release into the environment.[13]

Under Directive 2001/18/EC, applicants submit their application to the national authority in one country. The application can be rejected; in which case the applicant may chose to submit the GMO application in another member state (thus allowing biotechnology firms to pick and chose the most GM friendly national authority). If the assessment (which is meant to include delayed effects on human health and environment) is favorable, then the application is forwarded to the other member states, which may chose to voice their concerns. In case of objections from member states, the Commission submits the application for assessment to European Food and Safety Authority (EFSA). In either case, the approval process moves into the comitology procedure: the Commission makes a proposal (based on EFSA' recommendation). Next, a regulatory committee chaired by the European Commission needs to agree to make a decision. In the absence of qualified majority (QMV), the approval moves up to the level of the Coreper and to the relevant Council of Ministers.

Since December 2003, the Commission has started making decisions on GMO approvals. All of these decisions have been reached without QMV in favor or against in either the regulatory committee or the Council. It is fascinating to note that the current situation is in many ways very similar to the one pre-moratorium. This essentially means that the legislation enacted by the EC has apparently failed in resolving the pre-moratorium impasse. The introduction of EFSA into the equation has clearly done little to reassure Member States opposed to the GMO approvals, indicating that scientific proof was not the key issue and that the Commission's attempts to improve the "quality" of scientific evidence will be futile in the future. The issue still remains politicized and since the Comitology process has not been altered, the outcomes of committee votes remain divisive and fail to reach a QMV decision. One notable difference is that Sweden,

[12] Personal Interview with Office of Senateur Bizet (April 2006) and with Eric Meunier (Inf'OGM).
[13] Personal interviews with officials of DG Sanco and DG Environment, Brussels, June 2005.

Finland and the Netherlands, initially very concerned by lack of provisions for labeling in Novel Foods Regulation, have started voting in favor of GMO approvals. This could mean that at least some member states truly were concerned by labeling and thus were satisfied with the changes enacted by the post-moratorium regulations. On the other hand, the vast majority of the 10 new member states has lined up against GMO approvals (with the notable exception of Estonia).

Existing Theoretical Lenses to Understand the EU Pathway

How can we explain the gradual move of the EU toward a restrictive regulatory framework, particularly in contrast to other advanced industrial countries, such as the US, Canada, or even Japan? A number of theoretical lenses are often used to explain the EU pathway. This section examines their findings.

A/ Economic Interests

Scholars and policy-makers alike have suggested that the EU actions were driven by trade considerations and showed a return to some degree of protectionism against US imports.[14] In 1999, Pascal Lamy, the new EU trade commissioner met with US President Clinton and was later grilled by the US Congress. Both meetings focused partly on the GMO regulations, regulations clearly framed as an intentional trade obstacle for domestic purposes.[15] Anderson and Jackson (2006) argue that European industry is lagging in biotech research and thus advantaged by any slowdown. They further argue that European farmers welcome the ban, given their structural inadaptability to GMO farming (due to small farm size and difficulties to implement large buffer zones).

B/ Interest Groups and Collective Action Models

Meins (2003) sees regulation as a "function of material interests of interest groups and their power to influence the regulatory process"(22). She largely agrees with the economic theories of regulation, arguing that regulations usually reflect the demands of the industry because producers take greater interest in the issues and are better able to organize. However, when public outrage is involved, this balance can be altered.

Public outrage and public perceptions in general are rarely modeled into regulatory outcomes, and save for William T. Gormley's concept of saliency, are never mentioned by the economic theories of regulation. Meins expands upon saliency to develop the variable of public outrage: "In a political context, saliency is the degree of public interest and attention devoted to a particular issue. I define public outrage as the degree of fear or anger an issue induces in a significant part of a country's population."[16]

[14] Cf presentation by Dr. Chris Sommerville, Director of the Carnegie Institute and Professor of Biology at Stanford University, on 2/15/2001 at Stanford University. See also international trade lens used in Falkner 2000 and Newell and Mackenzie 2000.
[15] See (Lamy 2002, 123)
[16] (Meins 2003, 29)

For Meins, two components determine the development of public outrage: contextual and issue-related. Issue-related aspect assumes that public outrage is higher when the risk in question is "involuntary, personally uncontrollable, invisible, memorable, scientifically uncertain, personally uncontrollable, invisible, memorable, scientifically uncertain, poorly understood, unfamiliar, unfairly distributed, a consequence of technological failure, has unclear benefits and a delayed, catastrophic, or dreaded effect"[17], whereas contextual lens refers to variables that make the risk become "exceptionally imaginable or memorable such as recent disasters, intensive media coverage".[18]

Meins concludes that public outrage essentially alters the distribution of power between producers and consumers, helping consumer groups overcome collective action problems, especially the environmental NGOs.

Likewise, Bernauer (2003) introduces an Olsonian variant to the interest group model, by focusing not on the preferences and power of key groups, but on their "collective action capacity" (10). In particular, he contrasts the respective collective action capacities of biotech groups and agri-biotech adverse groups and finds that environmental and consumer groups have had a higher capacity to organize in Europe than in North America, due to a lower degree of trust in regulatory institutions (11).

C/ The Limits of Economic and Interest Group Approaches:

However, explanations rooted in economic and trade interests have important empirical limitations in the case of the EU. First, it is important to note that there is a strong biotechnology industry in the European Union and that this industry has received government support both at the national and the European level since the early 1980s. Europe's biotech industry has closed links with its US counterparts and is integrated into an effective EU-level lobbying organization, Europabio. Companies, such as Aventis, Bayer Life Crop Sciences, or Syngenta (Novartis) have made strong investments into biotechnology and see it as a priority. They would stand to gain significantly if the industry took off. As of December 2000, it was reported that the 15 EU members plus Switzerland counted over 2092 independent dedicated biotechnology firms.[19] Some of the biggest global firms in agriculture biotechnology are based in Europe (Syngenta, Bayer Life Crop Science, and Limagrain among others). Interestingly, the countries leading the pack are Germany (504 firms), the UK (448), France (342), Sweden (235), and Switzerland (93). Of these five top countries, at least three (Germany, France, and Switzerland) have been leading the moves restricting agriculture biotechnology and going against the interest of industry. A first fact is clear: regulatory moves on GMOs have occurred against the interests and opposition of a strong and growing biotech industry, one that has been deemed strategic by all levels of government.

Farmers would appear as the most obvious beneficiaries of restrictions on foreign-grown GM crops. However, even there, the position is not that clear. All significant large

[17] Ibid, p. 28
[18] Ibid, p. 30
[19] Source: Pamolli and Ricaboni, 2001, University of Sienna data, quoted by Euroapabio at http://www.europabio.org/images/DBFS-HR.jpg.

farmers organizations, beginning with ECOPA (the EU peak organization) have supported GMOs and still do. For large farming lobby groups in France, Germany, Spain, or at the EU level, it is simply suicidal to lag behind a core technology that is transforming agriculture. At a recent EU summit on GMOs in April 2006, possibly the most visible clash pitted pro-GMO farmers against anti-GMO NGOs, such as Friends of the Earth and Greenpeace. Only in countries with very small average farm size and a high-value added agriculture such as Austria, Switzerland, and Greece have farmers unions clearly positioned themselves against GMOs. And even then, it was after a long and protracted process. In the Swiss case, during the long negotiations leading to the Gen-tech law of 2001, members of parliament with strong ties to farmers (or part-time farmers themselves) long hesitated to side with socialists and break their usual coalition with industry and business. Growers initial saw cheaper GMO feed as a good idea that would improve competitiveness and would not affect the quality of meat. In larger countries, such as France, the federation of corn growers (AGPM) has taken a pro-GMO position since the mid-1990s. Given the production surplus and export situation of France, corn growers are concerned about losing out in a competitive battle over technology. Given the possibility that the next generations of GMOs become acceptable to consumers, corn growers cannot afford to miss the boat of this new farming revolution, especially in a country that has historically been at the forefront of farming innovations in Europe. In France, the peak farming organization representing the majority of farmers (about 80%), the FNSEA (Federation Nationale des Syndicats d'Exploitants Agricoles) has taken a neutral and prudent position, although in action it did not take any lobbying step against GMOs. On the other hand, the union representing small farmers (Confederation Paysanne) became the leader of the anti-GMO coalition in France after 1999. The GMO issue allowed them to move from a minority position to the center of public debate and to build unprecedented direct links with urban voters and consumers.

Regarding economic actors in the food processing industry (from millers down to supermarkets), most moved against GMOs (although at different speeds), although they only did so after getting under pressure from consumer groups (a pressure which trickled down from the supermarkets to first stage processors). Initially, most were neutral, given that GMOs did not affect them directly. On the other hand, the heavy regulations of labeling and traceability did bring important burdens and costs to all intermediary actors.

The slow process of GM approval in Europe has affected trade flows between Europe and North America. Corn imports from the US collapsed (from $400 Million in 1996 to $15 Million in 1999 and $10 Million in 2004)[20] and soybean imports decreased significantly ($2.3 Billion in 1996 or 1997; $1.0 Billion in 1999 and $0.9 Billion in 2004). Import flows were mostly redirected toward Brazil and other GM-free producers, although Brazil's shift to GMOs after 2003 raises question about the sustainability of this change. The EU may yet return to imports from the US in the near future. It is hard to believe, however, that the EU has gained from such redirection of trade flows. With an increase in the price of feed, the impact on the meat industry may have been negative. On corn (maize) as well, the main impact of the EU moratorium and EU regulations has been to redirect imports from the US to Argentina and Brazil. In 1995, before the introduction of GMOs, 62% of EU corn imports were internal (from other EU countries), 32% from

[20] Source: United States Department of Agriculture, Foreign Agriculture Service.

the US, 5% from Argentina, and 0% from Brazil.[21] By 2004, the portion of EU internal imports had modestly increased to 68%; the US share had collapsed to only 1%, while Argentina took 12% and Brazil 13% (with Romania also gaining a 2% share). Regarding canola, the EU started with a 100% self-sufficiency situation as of 1995 (literally no import). By 2004, the US had actually gained a 2% import share but Canada stayed at 0%. Other beneficiaries were Belarus (2%) and Russia (1%), with the EU internal share at 94%.

Clearly, the main anti-GMO drivers have not been traditional economic interest groups. Rather, the opposition was led by environmental and health NGOs (the first movers in 1996), and anti-globalization NGOs (after 1997-1998). In parties that had Green parties (such as Germany, Austria, Switzerland, France, and the European Parliament), Green parties became core political vectors for the opposition. To some degree, consumer associations have lent a voice to the coalition. Unlike Japan or Korea, however, consumer associations were not in the lead. These actors were successful in capturing media attention and shifting public opinion against GMOs, despite initially pro-biotech politicians and bureaucrats.

What has to be explained, therefore, is how groups that are usually external to regulatory policies have managed to take a dominant voice and disproportionately influence GMO policy-making.

D/ Institutions:

Several other scholars have developed explanations rooted in institutions to explain the variance between EU and US GMO policy.

Skogstad (2003) focuses on the institutional weaknesses of the EU regulatory processes in generating legitimacy. In an issue area such as GMOs, both input and output legitimacy are necessary, given the disputed nature of the domain and the lack of trust in officials. In a situation of joint (multi-level) decision-making, such a double legitimacy is best attained with a process of network governance where integrative processes dominate over aggregative ones. However, due to formal institutional rules regulating links between the supranational poles of the EU and low coherence among the various actors, aggregative politics end up dominating and legitimacy remains in question. This approach brings the right focus on issues of legitimacy and institutional set-ups. However, this paper demonstrates that the institutional crisis may go beyond features of network governance.

As for Bernauer (2003), he focuses on access to policy-making provided by institutions to interest groups. He argues that, in the EU, anti-GMO groups have enjoyed higher "institutional access due to multilevel and decentralized policy-making" (11). Bernauer further argues that the very institutional structure of the EU has played a role in the creation of strict regulations. According to him, regulation among constituencies in a

[21] Percentages calculated on total quantities, using statistics from the United Nations Statistics Divisions:http://unstats.un.org/unsd/comtrade/dqBasicQuery.aspx

free, integrated market leads to the adoption of the most stringent set of regulatory practices because a non-agreement would lead to a complete market breakdown.[22]

An institutional focus on decentralized and multilevel decision-making forms a useful foundation for the analysis of GMO policy in the EU. At the same time, the institutional weaknesses may be more systemic than the relatively narrow focus taken by Bernauer and may relate as much to the ability of external actors to the usual decision-making procedures to capture the agenda.

Ansell and Vogel (2006) introduce the concept of *contested governance:* "a pervasive sense of distrust that challenges the legitimacy of existing institutional arrangements" (10). *Contested governance* seeks to highlight institutional conflict regarding the "fundamentals of governance", rather than the normal, day-to-day, conflict over policy outcomes. In terms of food safety regulation, Vogel and Ansell identify four key questions that contested governance involves: on what basis should food safety be regulated (science vs. consumers vs. precaution…), by whom, where (at which level, national, regional or international) and how. Searching for the underlying causes that brought the issue of food safety to the level of *contested governance*, Vogel and Ansell conclude that triggering events (for them clearly the BSE affair) and longer-term trends or tensions (such as anti-globalization and tensions regarding European level regulation) are to blame. Finally, with *contested governance* spillover and contagion are difficult to prevent, as distrust spreads from regulatory agencies into government and the private sector, "loss of trust and legitimacy is probably a critical mechanism producing a snowballing effect in which conflict begets conflict" (21).

This paper builds on the concept but sees the dysfunctional GMO policy as a consequence of a general crisis of EU institutions, rather than a special case (food policy). The authors also tend to overplay triggering events such as BSE (more below).

In the same volume, Skogstad (2006) sees the "authoritative basis" on which food safety is regulated on as the main point of conflict upon which *contested governance* is initiated in terms of GMOs. Therefore, the most important issue is whether politically responsible actors, private firms or scientists should regulate food safety. She argues that in the specific case of the EU (with its "multilevel governance, construction of an internal common market, and supranational (EU) institutions with fragile legitimacy", p.234), the emphasis is placed on democratic norms and lower priority is given to scientific expertise. This is because the issue of food safety is really part of a larger debate regarding legitimacy of European institutions and integration.

This paper agrees with the focus on democratic legitimacy, but argues that recent reforms, including the creation of EFSA continue to face the same limitations. While the precautionary principle and public consultations are written into various EU regulations on GMOs, the Commission has seemed hesitant to implement them, which is part of the problem fueling the current post-moratorium impasse.

E/ Culture

[22] On pages 104 and 105, Bernauer describes potential outcomes of regulation by one state in a federal system and applies it to the EU case.

It is often argued that responses to GMOs are tied to culture. According to such an argument, European attachment to quality food explains the gut-level rejection of GMOs. Gottweis (1995) and Andree (2002) have argued that the value framing of science in different settings dominate the political response to GMOs. Cultural arguments are often used in public forums and in the press. Such views, however, face major empirical problems. How can one explain the fact that France, the archetypical case of cultural exceptionalism, held on as one of the most pro-GMO state in the EU until 1998-1999, only to turn into the leader of the anti-GMO fight after 1999?
Jasanoff (2005) develops a much more sophisticated approach, introducing a "dynamic concept of political culture" (15). Political culture shapes the frames and meanings used by actors and thus shapes the politics of science and technology in general (21). The political culture, however, is a dynamic concept that is shaped by the interactions of events, social entrepreneurs, and existing social structures. Jasanoff focuses on the rise of different civic epistemologies in various national settings.

This approach has much to say regarding the ability of novel actors to create new narratives and combat dominant narratives, shaping a changing political agenda. However, it may underplay the interactions with institutional features in enabling these new narratives and agendas to come to the fore.

F/ International Norms

One could advance a constructivist argument based on international norms to explain the EU's anti-GMO attitude. Much has been written about the rise of international norms and of global regimes on human rights, gender, and environmental protection.[23] Likewise, a global social movement has clearly come about in the field of GMOs with cross-linked anti-GMO NGOs active in nearly every country. Indeed, as this paper shows, one global NGO, Greenpeace, had a major impact in 1995-1996 in shaping public opinion in Northern Europe on the issue of GMOs. However, such an explanation has one major flaw: why is there is such cross-national variation in the GMO regulatory stance of various countries? Why are the US and Canada so impervious to such international norms and NGOs while the EU is so penetrable? Why is Japan, a notoriously state-dominated polity, more responsive to such international norms and movements than Canada?

G/ Unintended Events

Other arguments have emphasized the impact of one single event: the mad cow (BSE) crisis in the UK and later in the EU (Vogel 2001; Vogel 2002; Vogel and Cadot 2001). According to such views, the mad cow crisis dealt a terrible blow to the safety of food regulation in Europe and turned Europeans against GMOs. There is indeed a clear correlation in the timing of the big turn against GMOs (1996) with the high point of the BSE crisis. The explanation is particularly strong in the case of the UK. However, key countries such as Denmark, Austria, and Germany saw an anti-GMO movement that preceded the BSE crisis. In addition, current polls show a clear increase in the trust of

[23] See, for example, (Boli and Georges 1999).

Europeans in beef regulation and food safety in general, while the mistrust for GMOs continues unabated. NGO networks have built upon arguments that were independent from the BSE crisis in their fights against GMOs: issues such as the patenting of life, the threat to biodiversity, and the risks of mutations. The mad cow crisis may have given a "lift" to the anti-GMO movement in the UK (and partially in France), but the anti-GMO movement in Europe builds upon much deeper political roots and has come to encompass a much bigger symbol.

II / Contested Multi-Level Governance: the Rise of new Policy Actors in the Midst of Multipolar Competition and Institutional Crisis

Theoretical framework – Institutional Crisis and Social Policy Entrepreneurs

This paper connects recent work in comparative institutional analysis (CIA) with work on social movements and policy entrepreneurs. It argues that the voice of social movements can find itself enhanced in a situation of institutional stalemate and shifting legitimacy.

The current literature on comparative institutional analysis and institutional change builds upon Douglas North's path-breaking work (1990). North defined institutions as "rules of the game" and "humanly devised constraints that shape human interaction". According to North, institutions serve to reduce uncertainty and transaction costs. At the same time, institutions are "created to serve the interests of those with the bargaining power to devise new rules" (16). North includes a limited analysis of institutional change. According to him, changes in relative prices lead key actors to renegotiate contracts and change rules in an incremental way (86). Aoki (2001) goes much further in his monumental work, *Comparative Institutional Analysis*, as his analysis integrates the role of cognitive aspects. Aoki starts out by defining an institution as an equilibrium outcome of a game. More specifically, he sees institutions as a "self-sustaining system of shared beliefs" (10). This approach allows for a new approach to institutional change. According to Aoki, environmental and internal changes can trigger an "institutional crisis" in the cognitive sense: "the shared beliefs regarding the ways in which a game is played may begin to be questioned and the agents may be driven to reexamine their own choice rules based on new information not embodied in existing institutions" (18). Aoki defines as a *"general cognitive disequilibrium"* a situation when "the gap between aspiration and achievement occurs in a critical mass" (240). Examples of factors that could trigger such a general disequilibrium include new technological innovation, external shocks, or a change in the distribution of assets and power among key actors.

Aoki identifies an interactive mechanism between triggers of change and accumulation of internal tensions. He writes: "external shocks alone may not be sufficient to trigger institutional change. Without the accumulation of the seeds of change, agents may adapt their subjective game models only marginally (…)" (240). The disequilibrium

phase entails a period of competition, where different actors generate novel ideas. In turn, a new institution may emerge that is more consistent with the internal state of the domain (242). This approach to institutional change not only integrates external triggers and cognitive gaps, it also allows for discontinuous change.

At these critical moments of tension, questioning, and competition, there is room for novel actors to gain disproportionate voice. Aoki's framework can be further developed through the inclusion of policy entrepreneurs, and particularly the role of social movements in that capacity.

The concept of political entrepreneurs builds on a large literature.[24] Who are politicy entrepreneurs and what do they do? Simply put, they are self-appointed individuals who have the ability to influence others and to shift positions of voters or of societal groups. Policy entrepreneurs thrive on the fertile ground of uncertainty and interest group fragmentation. These individuals grasp the existence of arbitrage opportunities between a suboptimal present situation and a potential transformed future.

In a competitive political environment, emerging new political leaders seek novel issues to build a visible reputation and persuade voters that they are the most qualified. An emerging leader needs to spot an opportunity for arbitrage under uncertainty and offer a clear solution, betting that he may gain power if he manages to stir institutional change successfully in the new direction. Political entrepreneurs are indispensable catalysts in the process of institutional change. They solve the transaction cost problem of institutional reforms by temporarily enlarging the pro-reform coalition and influencing the shape of social forces. They resort to two main tools: persuasion and manipulation.[25]

Social movements and the leaders of these movements can find themselves in the situation of policy entrepreneurs when they participate in the generation of competing narratives and agendas. An institutional crisis can provide an ideal "political opportunity" or window for such social movements.[26] This focus on the entrepreneurial capacity of civil movements in periods of crisis mirrors (at a different level of analysis) findings of scholars who work on transnational civil society (TCS) at the global level. In particular, the literature identifies four kinds of roles played by transnational civil society: agenda setting, creation of new solutions, network building, and implementation of new solutions (through persuasion, pressures, shaming mechanisms, or nudging compliance with norms).[27]

Application to the EU in state of transition: Contested Multi-Level Governance

In its post-Nice, post-Enlargement, but pre-constitution incarnation, the European Union (EU 25) is in a state of *contested multi-level governance* and quasi-institutional crisis. In this situation, the EU has retained some features of supra-nationalism in the form of a well-developed Commission with a strong influence over agenda setting, a

[24] See in particular, (Downs 1957; Ellickson 2001; Geddes 1994; Kingdon 1984; Moe 1980)
[25] For a more thorough treatment of the concept, see (Tiberghien forthcoming 2007).
[26] (Giugni, McAdam and Tilly 1999; Imig and Tarrow 2001; Kriesi and Wisler 1996; McAdam, McCarthy and Zald 1996; Tarrow 1976, 1998, 1999, 2000; Tilly 2004)
[27] (Price 2003, 584).

growing European Parliament, and a more assertive European Court of Justice (ECJ).[28] The key decisions, however, remain in the hands of the member states, be it in the various Councils of Ministers or at the occasional meetings of the EU Council. This feature supports an inter-governmental bargaining model of the EU. However, the simultaneous occurrence of these two processes, in addition to the growing interdependence of decision-making at different levels has given rise to a literature of multi-level governance.[29]

What is striking, however, is how the various components of the EU system are increasingly in competition with each other and how internal rifts and differences increasingly individually weaken them. This process has happened at all levels and is traceable to the multiplication of member states (enlargement), the growing inclusions of new actors (interest groups at all levels finding more access in the various institutions), and to the spread of EU competences.

Thus, on issues such as GMOs, the commission itself falls prey to classic bureaucratic differences. Thus, the DG Environment (particularly under Commissioner Dimas) has not hesitated to voice positions that were openly contrary to those of the DG Agriculture or Trade (as evidenced in the Vienna Conference of April 2006). Further, as a whole, the European Parliament is more receptive to social and environmental concerns than the Commission, setting the stage for further rifts. As for the EU Council, the differences among member states are so stark that if often finds itself paralyzed, exposing publicly its inability to decide and forced to pass on the hand to the Commission, as per the Comitology procedures. Individual member states, such as Germany or Poland or Spain (for the GMO case) are often divided themselves between coalition members and unable to even express a position at the Council. The ECJ also steps in the game, often at the request of the Commission to enforce EU law on reluctant member states. This inability to come to collective stable decisions by the various poles of EU institutions opens a large political space for social groups and novel actors who have traditionally had a weaker say in EU decision-making.

This situation of contested and unstable multi-level governance can be characterized as a state of institutional crisis in the Aokian sense and the ability of novel peripheral actors to rock the boat can be seen as successful policy entrepreneurship.

III / Frontier Actors on the Rise: Civil Society, Regional Network, and the Uninvited Swiss input

A/ Civil Society Networks on GMOs

As early as 1996, associations and civil society groups that had remained peripheral to core decision-making in the EU managed to organize effectively and have a profound impact on public opinion. On the basis of the INRA/Eurobarometer opinion data, Bonny (2003) states that opposition to GMOs started to spread in 1996, when the first GM seeds arrived in Europe and in the midst of the EU debate over the approval of

[28] See work by Kellemen on the power and influence of the ECJ.
[29] (Comella 2004; Gualini 2004; Hooghe and Marks 2001)

the Novartis Bt corn. She identifies as crucial, the "strong influence of associations that focus on risks". These associations cluster in four groups: ecologist organizations (Greenpeace, Friends of the Earth), groups working for citizens' rights (Ecoropa, the Natural Law Party), farmers' unions (particularly the Confédération Paysanne led by Jose Bové), and anti-globalization organizations (such as ATTAC). At the EU level, the 1999 Eurobarometer data showed that the actors judged most often by respondents as "doing a good job for society " with respect to GMOs were consumers' unions, doctors, the media, and environmental groups. Industry, on the other hand garnered a negative score in most EU countries (51% negative opinion vs. 25% positive opinions in the case of France).[30] Finally, Bonny links negative opinions about GMOs to a low "confidence in institutions" at the time of the crisis.

The European anti-GMO civil society network grew in phases. The first movers were environmental groups such as Greenpeace, with the support of Green MPs in the European Parliament (e.g. Benedikt Haerlin). Anti-globalization groups and small farmer unions joined in the movement beginning in 1998. Consumer movements never took a central leadership role, but increasingly lined up on the same side as civil society groups. Increasingly, in key countries such as France, civil society groups were successful in making GMOs the proxy for a larger battle on the role of society against economic globalization.

How were NGOs successful in constructing GMOs as a proxy for unbridled economic globalization? Interestingly, it did not start that way. Arnaud Apoteker, the French Greenpeace leader on GMOs, had to fight a long battle with the Greenpeace leadership in 1993-1996 before being allowed to launch a campaign on GMOs. Greenpeace initially saw GMOs as a wrong battle. They surmised that GMOs were a narrow and technical matter that would not enthrall the public and foresaw some positive environmental impact through the use of biotechnology. The success of the November 1996 campaign in France and related campaigns in Northern Europe came as a big surprise for the leadership. The framing of GMOs as a key vector of globalization came in a piecemeal fashion and gradually. In Europe, it occurred through the enlargement of the NGO coalition beyond Greenpeace toward farmers' unions (e.g. Confederation Paysanne) and anti-globalization NGOs (such as ATTAC), a process that did not take place in Japan for example. This second wave of NGOs focused on two main aspects of the GMO controversy: property rights and the ownership of life by large (foreign) corporations; and the industrialization of agriculture (moving toward a productivist model). These two dimensions carried the GMO issue beyond a mere food safety issue or an environmental issue and made it a symbol of globalization.

B/ The Impact of Small States

At the level of states, three states acted consistently against GMOs and managed to have a disproportionate impact on the EU GMO policy throughout the 1990s: Denmark, Greece, and Austria. Denmark initiated the EU regulatory process through its own 1986 *Environment and Gene Technology Act*, while Greece and Austria consistently acted as first movers and initiators of EU-level anti-GMO regulations during the 1990s.

[30] Bonny 2003:53

In 1997, an Austrian public petition against GMOs garnered signatures from 20% of voters.

On the other hand, the big states, particularly France, Germany, and the UK, wavered back and forth. Steeped in its role as agricultural powerhouse in Europe and its strong presence in the biotech industry, France took a position as the sole pro-GMO state in 1997 and 1998, allowing the EU to approve the notorious Novartis corn Bt-11. By 1999, France had turned resolutely anti-GMO, leading the battle against the US in words and at the WTO.

The position taken by each country is the result of a combination of interests and embedded values. The Austrian position seems rooted in a rejection of eugenics, strong environmental awareness, and a rejection of the domination of the EU by big countries. The Greek position is more ad-hoc and seems heavily influenced by a successful Greenpeace campaign in the country before public opinion was formed.

In France, by contrast, strong industrial and agricultural interests have formed a de facto pro-GMO elite position (still present to this day). The national position was forced to move by the (unexpected) bottom-up mobilization of civil society groups and the strong response of public opinion. The UK situation is similar (without the strong agricultural interests).

Thanks to crafty leadership or good luck, Denmark ended up having a big impact on the drafting of the first EU regulations; Greece was the state that proposed the moratorium at the EU Council on June 24, 1999; and Austria has been shaping the agenda as president of the EU in 2006, organizing the major Vienna conference and landing voice to civil society groups and to the new regional alliance.

C/ The Rise of the GM-Free Regional Network

In 2003, a new anti-GMO actor came on the European political map. At the initiative of two key European regions, Tuscany (Italy) and Upper Austria (Austria), a network of "GMO-Free" European Regions and Local Authorities was born. The formal act of birth came with a conference in Brussels on November 4, 2003. Ten regions stemming from 7 different countries participated in this initial foundational act: Aquitaine (France), Basque Country (Spain), Thrace-Rodopi (Greece), Limousin (France), Marche (Italy), Upper Austria (Austria), Salzburg (Austria), Schleswig-Holstein (Germany), Tuscany (Italy), and Wales (UK). The process gradually grew in strength and coverage. At the second conference in Linz (Austria) on April 28, 2004, the GMO-free regions numbered 12. At the third conference in Florence (Italy) on February 4, 2005, the then 20 regions adopted the formal "Florence Charter", defining their list of objectives. At the fourth conference in Rennes on November 30, 2005, the number of GMO-free regions totaled 40, including most of Italy, Spain, France, and Greece. They set mid-term and long-term objectives and took stock of the just-accomplished mission to Brazil to procure GM-free soybeans. This marked the first international initiative of the movement.[31] In

[31] The mission to Brazil included 32 participants from 11 regions (representing 4 countries) and met a large number of political, economic, and agricultural actors. The mission aimed at giving a truly autonomous capacity to the network of regions (source: "Region Bretagne. Mission des regions Europeennes du GM-Free Region Netwok au Bresil, 17-21 octobre 2005, Rapport Provisoire")

Rennes, the regions also adopted a formal organizational structure, with a presidency (from Tuscany), a vice presidency (Upper Austria), and seven working groups (with the external cooperation led by Bretagne). As of 2006, the network is extending into Finland, Hungary, Poland, and Croatia.[32]

The network is a particularly unusual actor, as it brings together political entities with extremely large differences among them. Despite similar motivations regarding GMOs, the regions differ on three crucial dimensions. First, they have different legal positions and degrees of autonomy: the Austrian Laender, Italian regions, Spanish regions, or even more so, Wales, have the capacity to legislate in a wide range of arenas, By contrast, French regions are nearly powerless. Second, some regions have conservative governments with nationalist aims (e.g. Austrian Laender aiming at protecting the purity of their culture and national identity; see also Polish regions); others have leftist-green coalitions with a focus on anti-globalization and the need for stronger regulations of the market (French regions). Finally, some regions already grow GMOs (especially Spanish regions and Lazio in Italy), while most others have no GMOs yet.[33] What unites these regions is the protection of right to choose at the local and regional level.

A formal acknowledgement of this new actor came in the form of a meeting with the European Commissioner for Agriculture, Mariann Fischer-Boel on April 7, 2005. A further meeting with the DG Agriculture took place on September 28, 2005. The actors of the network also figured prominently among the invitees of the Vienna Conference of April 2005. An entire panel was devoted to regional approaches. It is also noteworthy that a key backer of the movement in France has been Segolene Royal, president of the Poitou-Charentes Region and currently the leading presidential candidate for the socialist party.

The objectives and principles contained in the Florence Charter are rather far-reaching. Technically, they focus on issues of coexistence, biodiversity, and responsibility for contamination. Thus, they demand strict rules to prevent the "contamination" of organic and conventional crops by GM crops (with a threshold of "technical zero") and the setting aside of entirely GM-free regions. They demand the protection of GM-free seeds (with a threshold set at the technical zero) and the setting of sanctions in cases of contaminations.[34] The main demand of the GM-free network, however, is the recognition of regions as the "appropriate" level to implement coexistence measures, rather than individual farms. Regions also demand the right to set their own guidelines. This set of demands consists in an attempt to devolve power over GMO policy from the EU and states down to regional level. Regions make this claim on the basis of a higher degree of democratic legitimacy and closeness to citizens. The breadth of the network, its fast growth and development, and the reach of their claim make it one of the rising stars in the anti-GMO galaxy in Europe. It potentially constitutes an unprecedented shift in the EU balance of power. *For the first time, a transnational sub-state coalition of democratically elected regional leaders is organizing and presenting EU institutions and member states with a coherent set of demands, on the basis of a democratic claim.*

[32] Personal Interview with Renaud Layadi, Region Bretagne, January 6, 2006.
[33] Ibid.
[34] Source: (Network of "GM-Free" European Regions and Local Authorities 2006)

Who is the actual driver of the network is and what are its institutional relays? While it is clear that the process started at the initiative of local governments in Austria and Italy, the second stage in the process (the diffusion phase) can lead to a debate. For some, after the initial catalyst, the process became a reincarnation of the NGO campaign through a different vector.[35] Thus, four key NGOs, Friends of the Earth Europe (FOE), Greenpeace Europe, GENET (led by Hartmut Meyer), and Save our Seeds (led by the well-known Benedikt Haerlin) have been particularly active behind the regional network and served as think tanks of ideas. Two conferences of the GM-free Region network were organized in Berlin by Save our Seeds, most recently on January 14-15, 2006. At the same time, some key regions have taken a real entrepreneurial role in developing and extending the network in the defense of their own interest. For example, the Bretagne region has taken the lead in developing a region-based GM-free procurement source from Brazil. Both the Green vice-president of the Region, Pascale Loget, and the president himself (Le Drian) have used the issue prominently as a way to transform the positioning of Bretagne, to take part in the regulation of globalization, and to court voters on these issues. For Loget, "we cannot dissociate GMOs and contestation of globalization. Resistance to GMOs can be seen as a strong totem of the questioning of the WTO and of this financial globalization that has opaque aspects".[36] Loget insists that the regional opposition to GMOs is a symbol of a democratic resistance to globalization. Economically also, Bretagne see the GM-free angle as a key way to invest into a high-value added agricultural base in Bretagne.

The network has also (initially) benefited from the logistical support of the Association des Regions d'Europe (ARE), the Brussels-based association that federates most regions of Europe and supports their interest in Brussels. The ARE saw in the movement a genuinely democratic initiative and a rare cross-national one that had the capacity to turn regions into potent actors. The ARE also supported the anti-GMO regions' argument that the comitology procedure was not legitimate any longer, given that the council was unable to take a QMV decision.[37]

D/ The Impact of Swiss Direct Democracy on EU Governance

Somewhat surprisingly, another actor who gained significant leverage in the EU policy process has been Switzerland, and more precisely its well-organized anti-GMO campaign. The November 2005 referendum in which 55% of Swiss voters and the majority of its cantons approved a 5-year constitutional ban on the production of GMOs in Switzerland dramatically enlivened all anti-GMO actors in the EU and boosted their legitimacy. The referendum also served as the explicit reason for the Austrian presidency of the EU to convene the April Vienna Conference on Coexistence. The Austrian Agricultural Minister Josef Proell immediately stated that the Swiss referendum emphasized how sensitive European people were to the issue and how the EU regulatory system remained insufficient.[38]

[35] Personal Interview with FOE, April 2006, Vienna.
[36] Personal Interview with Pascale Loget in Rennes, January 6, 2006. Translation from French by Author.
[37] Personal Interview with ARE official, April 2006, Vienna.
[38] See USDA's GAIN Report of 11/30/2005 (#AU 5029). "Austria to Lead GMO Debate".

The case of the Swiss referendum further illustrates the power of direct democracy and presents a powerful example upon which European anti-GMO coalitions can build their strategies. Despite a strong opposition to the referendum from both the scientific and business communities as well as the government and the parliament, including a formal declaration right before the vote by the Economics Minister Joseph Deiss that a referendum would be disastrous for farmers and consumers, the Swiss public voted in favor of a five year moratorium on GMO crops on 27th November 2005 with a 55% majority. The ban was also approved in every single of the 26 canton, including Basel, the headquarters of Novartis and of the Swiss biotech industry.

The Gentechfrei Schweiz campaign started with the collection of 120,000 signatures initiating the referendum. Part of the leadership of the campaign consisted of Schweizerische Arbeitsgruppe Gentechnologie SAG and its President Maya Graf, a Swiss Green Party parliamentarian. The strategy of the campaign was to "combine town and country", the "produce-free" and the "enjoy-free" slogans were used to indicate the desire of the farmers and the consumers to be GMO-free. With a broad alliance of town and country, the Gentechfrei campaign was capable of defeating the government and the scientific community.

The successful strategies from the Swiss referendum elicited a lot of interest at the January 2006 GMO-Free Region Conference in Berlin. Fellow European anti-GMO NGO members greeted Ms. Graf and her Swiss colleagues as rock-stars. The GMO-Free Region movement is slowly turning to the type of local campaigning that the Swiss made successful, targeting local farmers and working from the bottom up. The institutional impasse at the European top is opening avenues for these more local approaches that deliberative democracy illustrated can be so successful. In fact, the Swiss referendum had impact beyond Europe. At a conference of the anti-GMO network in Tsukuba, Japan, in early February 2006, the anti-GMO leader Amagasa Keisuke presented flags from the Swiss campaign and used the Swiss example as a model for civil society action in Japan.

These four novel inputs in the EU institutional process have all gained a higher leverage over the agenda than expected due to the existing state of institutional crisis. Nothing is more emblematic of the institutional crisis than the continuing impasse in the Council of Ministers on GMO approvals since the end of the moratorium.

IV / Voting Record of GMO Approvals since 2004: Implosion of Comitology[39]

Genetically modified products are submitted for approval through the so-called Comitology procedure of the EC. The Commission drafts a proposal, based on a positive EFSA study that it then submits to a regulatory committee, usually the Standing Committee on the Food Chain and Animal Health (SCFCAH) under the "Genetically Modified Food, Feed and Environmental Risk" section of the SCFCAH committee. GMO products also are often discussed in other sections of the SCFCAH and also in other regulatory committees, with a prominent example being the Standing Committee on Agricultural, Horticultural and Forestry Seeds and Plants (SCPS). It was in SCPS that the May 18th, 2005 vote on various national bans took place. Votes are not necessarily secret,

[39] This section draws on (Papic 2006)

summary reports of all committee meetings can be accessed on the EU website, however, the actual voting preferences of member states cannot be discerned in the final tabulations.

The regulatory committee uses QMV procedure to make a decision, either approving or rejecting the Commission proposal. If a decision is not made either in favor or in opposition, the proposal goes to the Council level. It is this procedure that is referred to as Comitology decision-making system. In this procedure, the Commission is the *agent* acting on behalf of the *principle*, the member states. In an attempt to limit the "bureaucratic drift" in regulatory decision-making of the Commission, the member states impose post-facto controls on the agency, in this case the regulatory committees. The Council decides when a Comitology committee should be utilized for a certain regulatory legislation. Original intention of the Comitology procedure was for policy areas for which the member states wanted to retain considerable regulatory control, such as foodstuffs, health and veterinary regulations. More than 65 per cent of all expenditure-related legislation uses the Comitology procedure for implementation[40], illustrating the importance that the Council places on this tool.

The Comitology procedure begins with a Commission proposal, in the case of GMOs it is also preceded by an EFSA safety assessment. The vote of the regulatory committee through the QMV procedure can have three possible outcomes:

1. Proposal is adopted through QMV majority (committee votes in favor of the Commission proposal) > Proposal adopted by the Commission;
2. Proposal is turned down through QMV majority (committee votes against the Commission proposal) > Referral to the Council;
3. Proposal is not decided on as no QMV majority is established (committee fails to reach a decision on the Commission proposal) > Referral to the Council.

The first scenario ends the Comitology procedure as the Commission proposal is adopted by a favorable vote of the regulatory committee, while the second and the third scenario leads to a referral to the Council for further deliberation. The Council has three possible decision outcomes as well:

1. Proposal is adopted through QMV majority > Proposal adopted by the Commission;
2. Proposal is turned down through QMV majority > Commission can resubmit the proposal to the committee as either a) amended proposal or b) same proposal or can c) initiate a legislation change through a proposal for a new legislation;
3. Proposal is not decided on as no QMV majority is established > Commission is entitled to adopt the proposal unilaterally.

Of considerable interest to this research is the third scenario, where the Council, along with the regulatory committee before it, fails to reach a QMV majority. There is no concrete evidence that this decision in fact forces the Commission to approve its own proposal. In fact, the Commission has previously declared that in "'particular sensitive sectors' [it] would not go against 'any predominant position, which might emerge within the Council against the appropriateness of an implementing measure.'"[41] This statement

[40] (Dogan 2000, 52)
[41] (Pollack 2003, 133)

clearly indicates that a legal option does exist for the Commission to not approve its proposal following the failure of the Council to reach QMV majority. The hand of the Commission is therefore *not* forced once the member states fail to reach a decision.

The voting record of regulatory committees and the Council post-moratorium are surprisingly uniform in outcome. Of the 18[42] votes taken since December 8th, 2003, all have failed to reach a QMV decision (see Annex C for details of the votes, based on a release of the records by Friends of the Earth, corrected by interviews at the EU Council). Out of the 18 votes, 3 votes had a majority in weighted votes against the Commission proposal (however still not enough to overturn the proposal). Furthermore, if we take both an abstention and a vote against a Commission proposal to introduce a GM product to indicate opposition towards such a policy, then we can conclude that an astounding number of 15 votes had a majority of votes in either the no or the abstention category. Most of the votes show a 35-40% qualified vote in favor of GMO approval, not enough to confer legitimacy to the decision. Annex C also reveals the voting profile of the different member states. The Netherlands, Sweden, Finland, the UK, and the Czech Republic systematically vote in favor of GMO approvals. France, Ireland, Belgium, and Estonia also mostly vote in favor. On the other hand, Austria, Italy, Greece, Denmark, Lithuania, Cyprus, Malta, and Luxembourg systematically vote against new GMO approvals. Spain and Germany almost systematically abstain.

The failure of QMV approval in the Council is particularly intriguing when one considers the fact that food safety was one of the original regulatory fields for that the Comitology procedure was implemented. The member states are clearly incapable of reaching a decision using QMV voting in the Comitology procedure. Furthermore, the Commission keeps adopting their proposals on GMO product approvals despite a clear opposition within the Council and regulatory committees and despite it not having to do so, as is illustrated by its own commitment not to adopt unpopular measures.

For these reasons, the Commission in fact considers the Comitology procedure as a considerable obstacle in GMO approvals procedure. The post moratorium legislation on GMO approval procedure and labeling were in part introduced because of the problems encountered through the Comitology procedure in GMO regulation throughout the late 90s. In April of 2006 the Commission tried to address the current impasse by asserting that it is vital to:

"[…] Reassure Member States, stakeholders and the general public that Community decisions are based on high quality scientific assessments which deliver a high level of protection of human health and environment. These improvements will be made within the existing legal framework, in compliance with EC and WTO law, and avoiding any undue delays in authorization procedures."[43]

In sum, the inability of member states to come to a qualified majority in the regulatory committee and at the level of the Council of Ministers, a rare case for the EU, ends up eroding the legitimacy of the final approval. It exposes to the open the embedded

[42] Not accounted for is the 19th indicative vote for Monsanto's maize 863, which only garnered 5 positive votes, but still failed to reach QMV majority against the proposal due to a high number of abstentions, nonetheless this vote has not been included in our empirical research because it was informal).

[43] Commission Press Release IP/06/498.

democratic deficit in the comitology procedure, as the Commission finds itself in the unfortunate situation of approving a decision that has often been opposed by the majority of member states in the Council. This in turn opens up space for contestation at the grassroots' level.

V / The Thin Line of Legitimacy: WTO Defense, EFSA in Question, and the Coexistence Debate

Three further events in 2005-2006 have further exposed the institutional rifts within the EU policy-process and explain why civil society movements, small states, and now the network of GM-free regions have been able to gain a larger influence of the EU policy agenda.

The Commission's Acrobatic Act: Defending the EU at the WTO

After several years of discussions and the failure of EU-US negotiations, the US, Canada, and Argentina launched a legal action against the EU's de facto moratorium on GMOs at the WTO. A panel was formed in August that year and the dispute quickly turned into one the most contentious cases in the WTO's history.[44] The EU engaged into a massive defense operation, arguing that there was no moratorium but rather a thorough evaluation process for 50 individual GMOs. The EU's legal theme brought boxes of documents to back up the process on each of these individual GMOs and the proceedings took nearly 3 years until a conclusion was reached.[45] At the same time, the WTO case resulted in a high sense of pressure within the Commission, as the DG for Trade and Legal Affairs pressed the rest of the Commission to move forward with regulations that would be more compatible with international commitments and remove the EU's exposure to a trade conflict with the US. The Commission found itself in a delicate balancing act, attempting to effectively defend the right of the EU to take its own regulations on the basis of democratic procedures, while also trying to avoid high trade sanctions or even a collapse in the legitimacy of the trade regime and the WTO.

The preliminary outcome of this WTO panel was announced in February 2006 and resulted in a relative European defeat. The outcome of the WTO panel on GMOs came out in February against the EU. Although EU regulations were not seen as illegal, the de facto moratorium on new approvals enforced by the EU in 1998-2004 was seen as illegal according to WTO (SPS) rules. The panel confirmed that the de facto EU moratorium of 1999-2004 on new GMO approvals resulted in undue delay and thus in a violation of its WTO commitments (namely, the Agreement on the Application of Sanitary and Phytosanitary Measures, or SPS Agreement). In addition, the WTO panel also found that the individual safeguard clauses taken by several countries (Austria, Luxembourg, France, Greece, and most recently Hungary) go against a science-based evaluation of the safety of GMOs and are therefore illegal. The report of the panel was the longest in the WTO's history (at 1050 pages) and both camps brace from a tense

[44] Personal Interview with WTO official in charge of GMO file, January 2006, Geneva.
[45] Personal Interview at DG Legal Affairs, Brussels, June 2005.

period ahead, beginning with a likely EU appeal and continuing with likely law suits for economic damages.

This outcome delivered an important victory to the pro-GMO camp, one that is likely to reverberate to other countries and could lead to a new case against the EU, this time challenging the core of EU regulations. However, this victory is also likely to be a pyrrhic victory, as it gives wind in the sail of anti-GMO activists and weakens the legitimacy of the WTO in the eyes of European public opinion. Moreover, the WTO decision simply fuels the notion that the Commission is pushing GMO approvals in order to escape further litigation.

EFSA in Question: Debate over the Legitimacy of Scientific Evaluation

Another pillar of the EU institutional architecture that has come under fire from many sides has been the European Food Safety Agency (EFSA). EFSA was barely established in 2003 and barely moved to its new Parma headquarters in 2005 that it already found itself under attack by several member states and civil society movements (as well as GM-free regions) for a pro-GMO bias. EFSA was initially established to develop a strong European scientific expertise in food safety. It is an independent agency that is able to make purely scientific evaluations without political or economic considerations. In accordance to its mandate, it does not include civil society members in its organization. However, because GM opponents fear a strong collusion of the scientific and business community in biotechnology and the crucial position of EFSA as a first mover in the GMO approval sequence, they have targeted EFSA for harsh criticism. The critique escalated in early 2006.

During a March 9th, 2006 Environmental Ministers meeting, EFSA was criticized heavily for not taking into account national studies and independent experts. Responding to the criticism, EU Environment Commissioner Stavros Dimas responded that, **"**I am aware of the criticism that is being directed towards its (EFSA's) working procedures… It has only recently been established and, as for any large organization, is still finding its feet," further adding that "certain changes may be beneficial".[46] Later on at the April Vienna Conference on co-existence, Commissioner Dimas took a far more critical line as he attacked EFSA's work to date, "There are questions like whether scientific opinions rendered by EFSA have relied exclusively on information provided by companies that look at short-term effects," continuing that, "EFSA cannot give a sound scientific opinion on long-term effects of GMOs. There are also questions on whether GMO companies are providing the right information to the European Commission."[47]. In his plenary speech, Commissioner Dimas linked the rise of the GM-free regional movement to the deficiencies of EFSA:

> As you are aware, the European Food Safety Authority (EFSA) plays a major role in the risk assessment procedure for GMOs under the new regulatory framework.

[46] Smith, Jeremy. "EU Ministers take Aim at Biotech Approvals Policy." Reuters March 10th, 2006, Accessed on May 25, 2006 http://www.planetark.com/dailynewsstory.cfm/newsid/35578/story.htm

[47] Smith, Jeremy. "Safety Checks on GMOs Flawed - EU Environment Chief." Reuters, April 6th, 2006. Accessed on May 25, 2006 http://www.planetark.com/dailynewsstory.cfm/newsid/35913/story.htm.

> EFSA has recently undergone an independent external evaluation to assess both its working practices and to take account of the views of stakeholders at both the Community and national level. The evaluation report, which is publicly available on the EFSA website, indicates that certain changes may be required in its practices concerning risk assessment, including those related to communication and co-operation with Member States.
>
> It is clear that this report will be taken fully into account both by EFSA and by the Commission.
>
> Indeed, if we can alleviate concerns regarding GMO products by improved risk assessment practices and making them more transparent co-existence measures can be established with more confidence. Regions may find it unnecessary to create GM-free zones and Member States may not feel the need to invoke bans to address concerns about the potential risks to the environment.[48]

Finally, on April 12th 2006, the Commission published a communiqué in which it proposed the following changes, arguing that these changes were due to the failure to reach consensus at the GMO approval level[49] (as they appear in the communiqué):

- - In the scientific evaluation phase:
- to invite the European Food Safety Authority (EFSA) to liaise more fully with national scientific bodies, with a view to resolving possible diverging scientific opinions with Member States;
- to invite EFSA to provide more detailed justification, in its opinions on individual applications, for not accepting scientific objections raised by the national competent authorities;
- The Commission will fully exercise its regulatory competences foreseen in the basic legislation to specify the legal framework in which EFSA assessment is to be carried out;
- to invite EFSA to clarify which specific protocols should be used by applicants to carry out scientific studies (for example regarding toxicology) demonstrating safety;
- Applicants and EFSA will also be asked to address more explicitly potential long-term effects and bio-diversity issues in their risk assessments for the placing on the market of GMOs;
- - In the decision-making phase:
- The Commission will also address specific risks identified in the risk assessment or substantiated by Member States by introducing on a case by case basis additional proportionate risk management measures in draft decisions to place GMO products on the market, as appropriate; and
- Where in the opinion of the Commission a Member State's observation raises important new scientific questions not properly or completely addressed by the EFSA opinion, the Commission may suspend the procedure and refer back the question for further consideration.

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[48] Speech made at the EU Vienna Conference on April 6, 2006. Transcript available at: http://ec.europa.eu/comm/agriculture/events/vienna2006/index_en.htm

[49] Commission Press Release IP/06/498. "Commission proposes practical improvements to the way the European GMO legislative framework is implemented." Brussels 12, 2006. Accessed on April 17, 2006 http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/06/498&format=HTML&aged=0&language=EN&guiLanguage=en

It is important to note that the Commission, with Environment Commissioner Dimas in the lead, takes quite seriously the inability of Member States to reach a decision through QMV procedure. However, the decision to improve the quality of scientific assessment, in this case EFSA's work, has to be evaluated through the lens that highlights the politicization of this issue. If the impasse is political at heart, how much will the improvement of scientific assessment truly matter?

Centrifugal Disorder: The Debate over Coexistence and the EU summit

The debate over coexistence forms the current frontier of the EU policy debate on GMOs. Coexistence refers to the possibility of growing side-by-side conventional crops, organic crops, and GM crops. The debate is particularly fierce when it comes to the preservation of organic agriculture, given that its survival depends on the credibility of its differentiation from other crops. Since genes can easily flow from GM plants to non-GM plants through cross-pollination, be it through the wind or bees, and since seeds cannot be full segregated, the risks are significant. At the time of the 2001/18 directive, and again in 2002 and 2003, the Commission decided that the variety of situations and positions made it impractical for the EU to legislate on coexistence. Instead, member states were left free to pass their own regulations as part of the transposition process of Directive 2001/18, within the limits of what was deemed acceptable. The end result has been a patchwork of regulation and non-regulation, with extreme variation from one country to another. The Commission, on the basis of being too extreme, rejected some stronger measures. As an example of the extreme variations among national rules, separation distances between GM crops and conventional beets have been set at 1.5 m in the Netherlands, 50 m in Denmark, 100 m in Portugal, and 2000m in Luxembourg! For maize, the distances range from 25m in the Netherlands, 50m in Spain, 200m in Denmark, and 800m in Luxembourg and Hungary.[50] All regulations have arguably be put in place on the basis of scientific evaluations! Other items that indicate major variations in rules adopted include the issue of compulsory training, licensing of the grower, approval procedure for each field, duty of grower to inform neighbors, record keeping, and, most contentious of all, the issue of liability and financial reparation.

On March 9th, 2006 the Commission issued a Working Paper titled "Report on the implementation of national measures on the coexistence of genetically modified crops with conventional and organic farming" in which it argued against establishing Europe-wide co-existence rules. Environmentalists harshly criticized this report: Friends of Earth argued that it promotes a "wait-and-contaminate" policy, while Greenpeace opposed the threats of legal action against national co-existence laws. The report directly threatened legal action against almost half of proposed national co-existence measures on the basis that they would "create obstacles to the free movement of goods." Eric Gall of Greenpeace Europe commented on the Commission Working Paper, "People have a right to GM-free food; farmers have a right to grow GM-free crops; and regions or countries have the right to protect their land, citizens and farmers from potentially dangerous and

[50] Source: Commision of the European Communities, "Annex to the Communication from the Commission to th Council and the European Parliament. Report on the implementation of national measures on the coexistence of genetically modified crops with conventional and organic farming", March 3, 2006.

irreversible GMO contamination. The EU Commission has been using an undemocratic procedure to force GMOs onto a public that rejects them and onto governments that have regularly voted against them. The Commission is getting further from the people day by day."[51]

While the Commission (supported by Europabio and GMO proponents) is unwilling to initiate the drafting of EU-wide rules on coexistence (and on seeds), the existence of deep splits within the Commission (DG Environment), between states, and between the Commission and the European Parliament have emboldened proponents of such new regulations. The combination of the rise of GM-free regional network, the Austrian presidency of the EU, the support of the EP, and the Swiss referendum in November 2005 led to the convening of a major EU-wide conference on the topic on April 4-6, 2006 in Vienna. While the conference was officially co-convened by the Commission and the Austrian presidency, the tensions were vivid. The daily proceedings in the conference hall emphasized a debate on the freedom of choice and the dual protection of the right to move forward with GMOs and to protect organic agriculture. The lavish evening events, however, were entirely paid and organized by the Austrian presidency and openly promoted GM-free food, showcasing the fact that Vienna and most of Austrian regions had joined the GM-free regional network. Similarly, the Commission tried to restrict participation to selected interest groups. The Austrian presidency, on its side, increased the number of NGO and regional participants, overriding the choices of the Commission. The end result was one of the most open and intense debates at the official level. A panel of stakeholders brought face to face the biotech industry and large farmers and industry representatives with environmental NGOs, consumer representatives and small farmer representatives. The debate was intense and fierce. The Commission found itself under considerable pressure to initiate further regulations on the issues of seeds in particular and coexistence (particularly liability), for fear that the common market would fall prey to the decisions of regional governments and individual states.

The clash between periphery and center over the issue of policy legitimacy was vivid and remains unresolved.

Conclusion

This paper has analyzed the post moratorium GMO policy in the EU and found that this policy arena continues to be disputed, unstable, and beset by opposite counter-currents. For all its attempt to put the lid to public contestation through a series of regulations that combined strict assessment with the strictest labeling and traceability requirements in the world, the Commission has yet been unable to reduce its own internal differences or to put the lid on grassroots-led opposition.

As a quintessentially multi-functional policy issue that involves tradeoffs between science, prosperity, culture, and democracy, GMOs have become emblematic of

[51] Greenpeace Press Release. "Commission launches attack on national and regional GMO laws." March 10th, 2006. Accessed on May 25, 2006
http://eu.greenpeace.org/downloads/gmo/CoexCommunicationPR060310.pdf

a wider situation of contested multi-level governance in the EU. They reveal a state of institutional crisis, in which a fundamental paradigm shift collides with an institutional transition that has seen a changing balance of power among institutions and a multiplication in the rise of actors. With this concomitant rise in expectations and decrease in capacity, EU institutions found themselves divided and only able to produce policy decisions that enjoy weak legitimacy among the public. The situation of institutional fragmentation and crisis has opened political space for new kinds of peripheral actors who are normally excluded from decision-making. These actors have been able to use the institutional crisis to push their own agenda to the fore and act as policy entrepreneurs.

The first phase in 1996-2000 has been dominated by the unexpected impact of NGOs and civil society movements. Their actions exposed the democratic gap of the EU decision-making process and gained a large influence on the public opinion of many member states. In turn, this led to decisions by a majority of member states to act defensively and suspend the regulatory framework of the EU through a temporary moratorium in 1999-2003. Throughout this period, some key small states (Austria, Greece, Denmark) have wielded disproportionate power over GMO policy through the support of civil society movements and the adoption of the cause of democratic legitimacy.

In the more recent phase, from 2004 to 2006, a novel actor has come to the fore and continued to rock the boat of GMO policy: the network of GMO-free regions. Set up in 2003, it has grown to 40-strong and keeps expanding. It has pushed the recent EU agenda on the issue of coexistence, and, with the willing help of Austria as president of the EU, played a role in the organization of large EU-wide conference on coexistence in April 2006. The GM-free network is having an impact and worrying the commission, because it appears democratically legitimate. All these regions have democratically-elected governments who have taken public commitments on GMOs in elections or thereafter. This stands in contrast to the opacity of the comitology procedure through which GMO approvals are processed.

The net outcome of this continued multi-level governance crisis and ability of peripheral actor to act in the name of democratic legitimacy has been a fragile, disputed, and perpetually evolving GMO policy.

GMOs remain highly politicized in the EU. The poor legitimacy and coherence of the regulatory apparatus results in higher politicization and a continued transfer of regulatory politics into the sphere of higher strategic politics.

Annex A: Record of All Individual GMOs Approved in the EU for Food and Feed since 1995

[All products authorized under Regulation 258/97 (for food), Directive 2001/18/EC and 90/220 (feed and release into environment) and Regulation 1829/2003 (feed AND food)]

	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	TOTAL
Maize			1[52]	4[53]						2[54]	2[55]	1[56]	**10**
Soybean		1[57]											**1**
Oilseed rape		1[58]	3[59]		2[60]	1[61]							**7**
Cotton								2[62]					**2**
Bacillus subtilis						1							**1**
TOTAL		**2**	**4**	**4**	**2**	**2**		**2**		**2**	**2**	**1**	**21**

Source: European Commission:
http://europa.eu.int/comm/food/food/biotechnology/authorisation/index_en.htm
Most events were authorized through two EU legislative documents. If a product was authorized through one regulation in 1997 and another in 1998, only the first authorization will be counted, however, the footnote will indicate subsequent authorizations.

[52] Bt-176, approved under both 90/220 and 258/97 in January 1997.
[53] MON 810, T25, Bt11 (Novartis variety) received approvals under 258/97 in February 1998 and were also approved under 90/220 in April 1998. MON 809 was approved only for food use under Novel Foods Regulation 258/97 in October 1998.
[54] NK 603 authorized under 2001/18 in July 2004, also authorized under 1829/2003 in October 2004. Bt11 (Syngenta variety) only authorized under 1829/2003 in May 2004.
[55] MON 863 first authorized under 2001/18/EC in August 2005 and then under Regulation 1829/2003 in January 2006 (for food) and also DAS1507 maize first authorized under 2001/18/EC in November 2005 (for feed and industrial use) to then be authorized under Regulation 1829/2003 in March 2006 (for food).
[56] GA21 only authorized under 1829/2003 in January 2006.
[57] Soybean 40-3-2 only authorized for import and processing (under 90/220) and for food uses (under 258/97), both in April 1996, however it is authorized for growth in Romania and is widely grown.
[58] MS1/RF1 - In February 1996 only authorized under 90/220 for "breeding purposes", in June 1997 also authorized under 258/97 for food.
[59] TOPAS 19/2, MS1/RF2 and GT73 all authorized for food use under 258/97. Of these, MS1/RF2 authorized also in 1997 under 90/220. TOPAS 19/2 finally authorized under 90/220 in April 1998 and GT73 finally authorized under 2001/18 in August 2005.
[60] Falcon GS40/90 and Liberator L62 only authorized for food under 258/97 on November 1999.
[61] MS8/RF3 only authorized for food under 258/97 in April 2000.
[62] Both cotton varieties 1445 and 531 only authorized under 258/97 (for use in food) on December 2002.

Annex B: Record of GM Field Trial in the European Union since 1992 (covered by EU legislation on Environmental Release)

Country / Year	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	2
France		1	35	57	69	91	72	70	64	34	17	3	17	11	
Spain			3	10	11	16	44	39	39	19	19	17	40	20	
Italy			5	19	43	50	46	43	51	18	5	9	2	4	
United Kingdom		16	17	23	37	27	25	22	13	25	12	5	8	1	
Germany		3	1	8	12	17	20	18	23	7	8	7	9	10	
Netherlands	4	15	9	25	16	10	14	19	5		19	4	4	7	
Belgium		26	16	17	11	7	7	6	8	16	5	8	1	2	
Sweden					8	10	9	8	19	6	2	2	1	14	
Denmark		5	1	5	4	5	10	4	5	1					
Finland					1	3	6	3	3	3	1			1	
Portugal			2	2	1		3	3	1						
Greece						1	5	7	6						
Hungary															
Ireland							2	2				1			
Czech Republic															
Poland														1	
Austria						2	1								
Iceland														1	
Norway									1						
Total	**4**	**66**	**89**	**166**	**213**	**239**	**264**	**244**	**238**	**129**	**88**	**56**	**82**	**72**	

Source: Joint Research Center of the European Union: http://biotech.jrc.it/deliberate/dbcountries.asp Field trials approved under Regulation 90/220/EEC run until 2004 with some overlap with those authorized from 2002 onwards by the Directive 2001/18/EEC.

Annex C: EU Council Votes on GMO product approvals since 2003

See Separate File.

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