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Supranational Regulation and Contested  
Accountability:  
The Case of GMO Risk Regulation in the European  
Union

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**Abstract**

The regulation of genetically modified organisms in the EU has become embroiled in a tension between agency and fiduciary principles of delegated authority and the alternate understandings of political accountability they imply. Fiduciary principles have gained the upper hand in a regulatory process expected to legitimize GMO risk regulation by respecting agency principles of delegated authority. Amidst continuing scientific debate and uncertainty about the environmental safety of GM crops, the EU's precautionary political culture of risk regulation adds to the controversy of relying on non-majoritarian bodies to regulate GMO risks. Albeit contentious, the fiduciary model of regulation is compatible with the external accountability commitments of EU member states not only to EU law but also to fellow WTO signatories. The incentives, and indeed imperatives, to embrace fiduciary principles of authoritative decision-making explain why the European Commission is exercising its legal authority to authorize some GMOs on the advice of its scientific advisors but without the support of a qualified majority of member states

**Keywords**

Accountability, Genetically Modified Organisms, Supranational Regulation, Risk Regulation, Fiduciary Logic of Delegation, Agency Logic of Delegation

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## **Introduction**

In the late 1990s, European Union (EU) policies to license genetically modified (GM) products for cultivation and marketing across member states lost the support of swaths of the European public and their national governments. The EU undertook major legislative reforms to restore its regulatory authority by responding to criticisms about existing procedures for the licensing of genetically modified organisms (GMOs). Controversy, nonetheless, persists with the implementation of these reforms. Every GMO approved under the new legislation has failed to secure the support of a qualified majority of member states. A handful of member states continue to disregard EU regulations for GMOs. Little wonder, then, that two analysts have worried that GMO controversies 'risk becoming disputes over the legitimacy of EU law itself' (Pollack and Schaffer 2005: 350).

Attacked from within, the application of the EU GMO regulatory regime has also been challenged from without. In late 2006, the World Trade Organization sided with the United States, Canada and Argentina and ordered the EU to bring itself into conformity with its obligations under international law. Eighteen months later, a handful of member states were still resisting EU law and the EU had yet to comply fully with the WTO ruling.<sup>1</sup>

Why has it been so difficult to secure an internal EU consensus that is also compatible with external/WTO legal obligations on the regulation of GM products? In some respects, the answer to this question is straightforward. Consensus has been elusive because the majority views of the EU public--who reject GM foods regardless of scientific experts attesting to their safety--are in conflict with WTO laws that prohibit restrictions on food imports on grounds other than scientific evidence of their lack of safety. For democratic governments, whose electoral fortunes rest on being responsive to public opinion, the choice of staying onside that opinion and being offside international law is obvious.<sup>2</sup> And yet, however correct this answer, it is not fully satisfying. Scholars of European integration have pointed to EU-level governing norms and structures that, first, seek to build compromises responsive to the social concerns of member states even while enabling internal market integration to proceed (Heritier 1999, 2003; Joerges and Neyer 1997; Scharpf 2006); and second, vest supranational bodies like the European Commission and the European courts with the legal authority to uphold external commitments to foreign countries and international bodies (Majone 2000, 2001). It is important to ask, therefore, why these governing structures and norms appear to be less than effective in managing the controversy over the regulation of GMOs in the EU.

The answer provided here is that the GMO controversy has become embroiled in a tension within the EU between agency and fiduciary principles of delegated authority and the alternate understandings of political accountability they imply. Whereas agency-based principles of delegated authority regard decision-makers as accountable when they act consistent with the delegating party's preferences and can be brought under control in order to do so, fiduciary-based principles give delegated decision-makers independence in order to be accountable in procuring valued policy outcomes. The two principles of accountability exist in tension in polities in which agency-based principles of accountability are seen as the more legitimate basis for the exercise of political authority (Majone 2001).

Two factors make the tension between agency and fiduciary principles of regulation particularly vexatious in the case of GM product regulation in the EU. The first is that fiduciary principles have gained the upper hand in a regulatory process expected to legitimize GMO risk regulation by respecting agency principles of delegated authority. Decisions to license GM products are being made by the European Commission on the basis of non-elected experts' appraisals of their safety, despite the expressed legislative intent of the GMO regulatory framework to leave regulatory decisions in politicians' hands and the expectation that the decision-making process will procure this result. A second reason for member states to challenge the integrity of the EU regulatory approval process and its regulatory outcomes is

the precautionary political culture of risk regulation that is embedded in EU law and predominant in GMO discourse. Amidst continuing scientific debate and uncertainty about the environmental safety of GM crops, opponents of GM products have been effective in undermining the authority of the fiduciary model of regulation by criticizing its scientific risk assessments for failing to respect the precautionary principle.

If the fiduciary model of regulation is so contentious, a third factor helps to explain why it is nonetheless prevailing. That factor is the external accountability commitments of EU member states not only to EU law but also to fellow WTO signatories. WTO law obliges the EU and other WTO members to base their GMO risk regulations on scientific knowledge of GMO risks. The fact that EU decision makers have not just incentives but also imperatives to embrace fiduciary principles of authoritative decision-making explain why the European Commission is exercising its legal authority to authorize some GMOs on the advice of its scientific advisors but without the support of a qualified majority of member states.

As an illustration of the contested nature of accountability principles in a context of supranational governing, the EU GMO controversy also demonstrates how accountability controversies can have feedback effects. The disputed legitimacy of fiduciary-based regulation has resulted in efforts to shore up political accountability. First, consistent with EU governing norms of horizontal accountability, supranational decision makers have left scope within the parameters of EU and WTO law for member states to respect norms of democratic accountability to their electorates. Second, with its authority challenged, the EU supranational body entrusted with determining the risks posed by GM products, the European Food Safety Authority, has been required to become more accountable in democratic procedural terms.

To develop its argument that the GMO controversy is one of contested accountability principles, with fiduciary-based principles gaining ascendancy, the paper is organized as follows. Part I reviews perspectives on political accountability in the EU, examining the distinction between agency and fiduciary-based logics of delegated authority and accountability, the governing norms and practices that are sensitive to principles of democratic political accountability, and the endemic tension between agency and fiduciary delegation logics in the comitology procedures under which GM products are approved. Part II examines the precautionary political culture of GMO risk regulation in the EU, the loss of legitimacy of the regulatory framework in the late 1990s, and subsequent legislative reforms to recover it through strengthened accountability of fiduciary and agency principles of authority. Part III examines how the implementation of the regulatory framework via the functioning of comitology procedures and norms, and risk assessment by the European Food Safety Authority, has elevated fiduciary logics even while failing to stem controversy. Part IV examines how external legal accountability obligations of both the Commission and the member states have been made explicit in the WTO ruling in *EC Communities-Biotech*. Part V provides a brief conclusion to the paper.

## **I. Accountability and Supranational Governing**

Accountability, observes Fisher (2004: 510), is 'a contested concept.' Not only are discussions about accountability fundamentally about 'the standards that decision makers should be held to,' they 'cannot be disentangled from debates about the legitimacy of European governance and in particular what the role of democratic processes and principles should be' (Ibid. 514). Fisher's observations reflect the scholarly debate on accountability in the EU.

The dominant perspective on accountability and supranational governing among EU scholars is, as Harlow (2002: 172) phrases it, 'an unhappy one' characterized by perceptions of 'a yawning accountability gap' in EU governing structures. Those who adhere to this



perspective define accountability in democratic terms as the obligation of those who wield political power to account for their behaviour to those on whose behalf they govern and to face sanctions when the latter judge their performance wanting. The accountability chain of popular control is broken when political authority is delegated from elected national governments to supranational institutions like the European Commission and opaque procedures like comitology. The citizens governed by the latter institutions have little ability to call these bodies to account and to sanction them for their decisions. A slightly different perspective but still within the 'unhappy' accountability view is provided by Schmidt (2006). She faults elected representatives who share authoritative decision making at the supranational level (in the Council of Ministers) for passing the buck to the Commission for unpopular EU-level decisions.<sup>3</sup>

A second and alternate perspective on accountability in the EU points to governing norms and practices norms of horizontal accountability that require supranational political actors constantly to account for their actions to others prior to acting. Horizontal accountability norms require efforts to accommodate the views of member states who are not part of the majority. Heritier (2003: 818) describes the goal of supranational decision-making to be 'reaching policy decisions which satisfy as many of the concerned interests as possible.' She points to efforts within institutions like the Council of Ministers to give national governments 'escape routes' to accommodate popular concerns (Heritier 1999). Such mechanisms are clearly crucial to elicit tacit, if not explicit, member state endorsement for EU decisions. Joerges and Neyer (1997) argue that deliberative supranationalism within the comitology procedures ensures decision makers' sensitivity to member state interests. Although comitology rules permit a qualified majority of member states to impose their will on a dissenting minority of states, in practice, representatives of member states in committees and the Council work toward consensus-building. Joerges (2002:143) argues that the comitology system requires national bureaucracies 'to face up to the positions of their neighbour states' and not to 'filter out' their interests and concerns. And Scharpf (2006: 99) observes that 'In the face of legitimate diversity, ... intergovernmental disagreement cannot be overcome by majority rule.' Such horizontal accountability norms and practices are viewed as a way to promote democratic accountability and legitimacy for supranational decisions by providing member state governments with scope to be responsive to their constituents.

A third body of literature argues that even if democratic accountability via popular control is unlikely or impossible in a supranational governing context, other forms of non-majoritarian accountability exist in the EU (Bovens 2006). A prominent example is legal accountability as rendered when those who exercise authority are required to explain and justify their actions as consistent with law and juridical values such as fairness (Harlow 2002: chapter 6). Menon and Weatherill (2002: 129) argue that legal accountability as entrusted to the Commission and enforced by EU courts is a way of ensuring member states do not 'take decisions which are neglectful of costs imposed on parties who are not able to gain (adequate) access to the (domestic) market for votes.' This accountability has been described as external accountability (Grant and Keohane 2005).

Consistent with this line of reasoning is the more general argument of Majone (2000, 2001) who distinguishes between agency and fiduciary logics of delegated authority and their attendant conceptions of political accountability. Majone (2000, 2001) argues that supranational bodies like the European Commission and the European Court of Justice are intended to act as fiduciaries—not as agents of member states subject to their control. Fiduciary institutions can only procure valued policy outcomes—usually of a longer-term nature—because they operate largely independently of the parties (member states) who have delegated them their authority. The independence of the fiduciary, by depriving the delegating parties of the possibility to renege on a commitment, strengthens the credibility of that commitment.

Distinct accountability principles accompany the agency-fiduciary delineation. A delegated authority that acts as an agent renders accountability when it acts consistent with the preferences of the delegating party (be it the electorate or elected politicians). A delegated authority that acts as a fiduciary is accountable when its actions serve to achieve policy outputs desired by the delegating party.

Built-in tensions between agency and fiduciary logics of delegation in EU level institutions create the very real possibility for contestation around accountability principles. The comitology procedures, under which representatives of national governments collectively make decisions pertaining to the implementation of EU laws, are a case in point. Comitology procedures for regulatory committees are generally seen to rest on agency principles of delegated authority. These procedures allow national representatives of member states to retain some control over the supranational policy process, even while their expertise helps to improve the quality of decisions (Dogan 1997; Majone 2001, 104; Pollack 2003; Bergstrom, 2005). Just how regulatory committees do so can be illustrated by the comitology procedures that pertain to the authorization of GM products. The decision-making process begins when the Commission, as chair of the Standing Committee on the Food Chain and Animal Health, asks its member state representatives to give an 'opinion' on a draft authorization proposal to market a GM food or feed. A qualified majority vote (QMV) of the committee members in favour of the Commission's proposal allows the Commission to adopt its draft measure and to require member states to implement it.<sup>5</sup> Without this requisite degree of member state support at the regulatory committee, the Commission must submit its proposal to the Council of Ministers. The Council of Ministers can stop the Commission proposal with a QMV against it. In short, member states exercise control as a blocking minority<sup>6</sup> to stop the Commission from acting at the regulatory committee stage, and/or as a qualified majority to stop the Commission from acting at the Council of Ministers' stage.

However, under certain conditions, the regulatory comitology procedures revert to fiduciary principles of delegated authority. When member states cannot agree—in the requisite numbers required for a qualified majority—to vote against the Commission proposal, the Commission has not only the power, but also the obligation to implement its proposal. When the Council of Ministers is unable within the stipulated three month period to issue an opinion on the Commission's proposal (neither adopt nor oppose it), the Commission, acting as a College of Commissioners, must approve it. Comitology rules put an onus on the Commission to still try to find a compromise acceptable to a significant majority in the event of such a voting outcome. However, if that compromise cannot be found, decision-making rules require the Commission to be a fiduciary at this final stage in the comitology process.

Nor do changes to comitology procedures agreed to in 2006 change the balance of the agency-fiduciary logic when it comes to the authorization of GM products. The European Parliament acquires powers of 'scrutiny' (in effect, a veto) over decisions of regulatory committees that have a 'legislative impact.' For GMOs, the scrutiny powers of the EP with regard to the Standing Committee on the Food Chain and Animal Health will include decisions concerning labeling regulations, but not specific product approvals.<sup>7</sup>

Even if fiduciary-based authority is part of the institutional fabric of the EU (Majone 2000, 2001; Menon and Weatherill 2002), whether it can be a legitimate source of decision-making authority is unclear. Those who regard democratic political accountability, in the form of popular control, as a crucial base of legitimacy reject the possibility. However, others see performance-based accountability as capable of generating support for the belief that those who make and/or enforce binding rules have the right to do so, and moreover, that their actions are appropriate and desirable. Scharpf (1999) has observed that delegating policy-making authority to non-elected bodies can be an important source of (output) legitimacy when technical or specialized expertise is requisite to efficacious public policies. Wallace

(2005: 493) goes further to argue that the EU's legitimacy 'depends very heavily on the quality of its output for popular support.' Nonetheless, notions of accountability that define it in terms of 'rendering an account' either to voters or to elected politicians are sufficiently strong that there are usually controls to check the discretionary behaviour of non-majoritarian fiduciary bodies. They include judicial review; requirements of expertise, professionalism and reason-giving; political oversight; monitoring by civil society organizations and opportunities for public participation (Majone 1994: 2, 22-23). Given the close association of transparency and accountability, making transparent the bases on which non-elected bodies decide is generally seen to be a way to improve their accountability (Dyrberg, 2002: 83).

Even so, there can be no guarantees that even in policy domains where high quality outputs or credible commitments are desired, fiduciary-based principles of accountability will be viewed as appropriate. The legitimacy of output or performance based accountability depends on agreement within the political community on what constitute good performance/desired policy outputs, as well as confidence or trust in the delegated body to secure these desired outcomes. The policy legacy of regulating GMOs in the EU has created a precautionary political culture that constitutes a weak foundation for a fiduciary science-based model of risk regulation.

## **II. Regulating GM Products in the EU: A Precautionary Culture of Risk Regulation**

Genetically modified products are products of modern biotechnology that are created by transferring a gene from one organism (seed) to another in order to produce a product with a new desirable trait. The desired trait of most GM plants is their resistance to pests or insects and, as a result, their expected higher yields. There is some risk that the toxins built into GM plants to make them insect/pest resistant can harm those who consume them. There are also concerns of environmental risks; GM plants, for example, may cross-pollinate with non-GM crops as well as with wild relatives, with potentially negative consequences for bio-diversity.

Jasanoff (2005: 21) argues persuasively that political communities are characterized by distinct political cultures of biotechnology risk regulation that can be differentiated on at least two dimensions. Who/what is authoritative when it comes to producing and validating collective knowledge of the risks and benefits of the novel technology? By what methods can accountability and legitimacy in decision-making be assured? On the first dimension of risk assessment, politicians necessarily rely on the expertise of scientists (and, indeed, are required to do so under international law, as elaborated more fully in Part IV). However, a two-fold distinction can be made between deferential or technocratic political cultures and precautionary political cultures in terms of the faith they put in scientific experts to accurately appraise the risks, costs and benefits of scientific discoveries.<sup>8</sup> A deferential/technocratic political culture respects scientists' judgements of a technology's risks whereas a precautionary political culture is more inclined to stress the limits of scientific knowledge and to view scientific claims as indeterminate and uncertain and not necessarily a reliable basis for decisions on how to manage a technology's risks. The two political cultures have different implications for risk management. Whereas a deferential/technocratic culture is likely to sustain a science-based fiduciary model of risk regulation with little political contestation, a precautionary political culture is much less likely to do so. Risk regulation in a precautionary political culture is more likely to be subject to political contestation (Jasanoff 2003) and only secure public support when it is in the hands of decision makers who are directly accountable to citizens (Christoforou 2003).

Analysts characterize the EU political culture of GMO regulation as a precautionary one whose epistemological underpinnings are scepticism in the capacity of science to know and assess the risks of this novel technology and, understandably therefore, less willingness to

grant scientific experts exclusive authority in risk regulation (Toke 2004; Skogstad 2005; Jasanoff 2005; Murphy and Levidow 2006). This political culture is both a cause and consequence of a policy legacy in the EU. EU legislation since 1990 has been underpinned by the premise that the *process* of genetic engineering is a novel one and GMOs cannot be assumed to be equivalent to their traditional counterparts (Ibid.). The precautionary approach, says Noiville (2006: 312), is reflected in the requirement of a case by case assessment of the risks of GMOs prior to their licensing ‘for the sole reason that they [GMOs] derive from new techniques and that this innovation has spawned scientific uncertainty.’ The precautionary principle—whose aim is to require decision-makers to take action ‘in the event of a potential health risk, .. without waiting for the risk to be confirmed by scientific evidence’—has since been incorporated into EU law and jurisprudence as a justification for protective measures when there exists doubt and uncertainty concerning the safety of a product (Ibid: 309)

If compliance with rules is the foremost indicator of legitimacy, by the late 1990s the EU GMO regulatory framework had lost legitimacy. Beginning in 1997, member states (Austria, Italy, and Luxembourg) invoked the legislative ‘safeguard clause’ to ban the import and use in their territory of a GM maize that the Commission had approved via comitology procedures. When the Commission sought member state support, again via comitology procedures, to require the safeguard bans to be lifted, a qualified majority (QM) of member states rejected its proposal. In a display of respect for norms of horizontal accountability, they voted to allow their partner member states to maintain their national bans (Bradley 1998). Although seven GMOs were approved by QMV in the regulatory committee between 1996 and October 1998, thirteen applications for authorization were pending, and authorizations had ground to a halt. In June 1999 member states in the Environment Council announced that they would not authorize any new GM products until existing procedures were reformed (Lieberman and Gray 2006; Murphy and Levidow 2006).

Accountability concerns played an important role in the loss of governance legitimacy. The backdrop to the blockage in regulatory approvals was a consumer revolt against GM foods amidst an anti-biotechnology coalition that argued that GM products were neither safe to humans or the environment, nor desirable (Isaac 2002; Toke 2004; Jasanoff 2005; Kurzer and Cooper 2007). In the context of the mobilization against GM products, risk management decisions at the EU-level to approve GM products for licensing throughout the Community were seen as failing to meet agency principles of member state accountability to electorates. The Commission’s approval of a GM maize against the wishes of all but one member state (as it was then authorized to do under Directive 90/220) was criticized as inconsistent with democratic (agency) principles of political accountability. For its actions, the Commission was ‘roundly condemned’ by consumer, environmental and farm groups; the European Parliament; and member states (Bradley 1998: 214).<sup>9</sup>

The precautionary political culture also played a role in the loss of legitimacy and reforms to restore it. The unwillingness to respect the Commission’s legal right to authorize GM products in the absence of unanimous opposition of member states was based in part on negative perceptions of the science/risk assessment it relied upon in making the risk management decision. The European Commission exercised discretion on whether to consult scientific advisors and the quality of advice it received was viewed with suspicion (Joerges and Neyer 1997).

A series of regulatory and institutional reforms over the period 2002-2004 were implemented to restore legitimacy to EU-level regulation of GMOs.<sup>10</sup> These reforms were also made in the shadow of external accountability obligations to WTO members; the United States was threatening to bring action against the EU regulatory framework (Skogstad 2003; Pollack and Schaffer 2005). The most important elements of the regulatory framework are laid out in four pieces of legislation.<sup>11</sup> First is Directive 2001/18, the Deliberate Release

Directive. It replaced Directive 90/220 in April 2001 and specifies the conditions under which GMOs can be released into the environment for field trials or for cultivation, import or transformation into industrial products (CEC 2001). Its objective is to ensure the environmental safety of GMOs. It applies to GMOs that are 'live', like GM maize kernels or rapeseed, but not to processed products like cornstarch or rapeseed oil made from GM plants. Second is Regulation 1829/2003, the Food and Feed Regulation (CEC 2003a). It replaced the 1997 Novel Food Directive. Its regulatory procedures are designed to ensure the human and animal health and safety of any genetically modified food and feed, and processed food made from GMOs (like cornstarch) that are marketed in the EU. Third is Regulation 1830/2003 on the labeling and traceability of GMOs and food and feed produced from GMOs (CEC 2003b). Labelling is intended to ensure consumer choice; traceability provisions, to track and recall GM products in the event of a safety issue. Fourth, and not specific to GM products, is Regulation 178/2002 on European food law and the European Food Safety Authority. It is discussed further below.

This package of reforms incorporates both agency and fiduciary-based principles of accountability. The fiduciary principles are most evident in risk assessment whereas the agency principles predominate in risk management. The risk assessment principles are dealt with here; the risk management principles in Part III.

The procedures for scientific risk assessment of GMOs are intended to strengthen fiduciary-based principles of performance accountability. Directive 2001/18 requires a case-by-case environmental risk assessment before the release of a GMO into the environment and provides detailed and extensive information for applicants on how to do such risk assessments.<sup>12</sup> It also requires the consultation of scientific committee(s), affirms the precautionary principle as a guide to risk regulation, and strengthened measures in keeping with the principle.<sup>13</sup> The fiduciary role at the EU level is played by the scientific committees of the European Food Safety Authority (EFSA). Since it began operations in 2003 as an advisory body to the Commission on food safety issues, EFSA, with its independent scientific experts, has been expected to provide supranational regulators with more authoritative risk assessments than did its predecessor EU scientific committees (Skogstad 2001; Buonano 2006).<sup>14</sup>

Risk assessment is centralized at the EU-level under the Food and Feed Regulation (Regulation 1829/2003). The company that wishes to market a GM food or feed in the EU begins its application by notifying the competent authority in the member state. National authorities can ask for further information of the company but *must* pass the GMO application directly to the EFSA for a risk assessment. Only EFSA, not the national authority, is mandated to issue an opinion on whether the GM food or feed product will have adverse effects on human health, animal health or the environment and/or should be placed on the market. Writing in 2004, Poli (2004:36, 26) observed that EFSA's role in risk assessment had decreased the scope for national authorities to make critical comments in the pre-marketing stage of the authorization process. Chalmers (2005:654) concurs, arguing that the impact of bringing EFSA 'forward' in the regulatory approval process under the food and feed regulation allows it to 'frame the debates.' For its part, the Commission is not bound by EFSA opinions, but it must provide an explanation when its authorization draft differs from the opinion of EFSA.

If these provisions suggest an imbalance in risk assessment authority to the advantage of supranational bodies at the expense of member states, it nonetheless remains the case that member states have important risk regulation powers. Under the Deliberate Release Directive, they regulate field trials of GMOs in their home territory. Moreover, under the Food and Feed Regulation, EFSA must ask a national competent authority to carry out the environmental risk

assessment when the application concerns GMOs to be used as seeds or other plant-propagating material (Christoforou 2004: 660, fn.93).

The regulatory framework also requires regulators to be directly accountable to the European public. They must consult the public on both experimental and commercial releases of GMOs and publish details of GMO trials as well as the results of scientific risk assessments.

### **III. Risk Management, Fiduciary-Based Accountability and Contestation**

Legitimation norms, argues an EU official, required that risk management decisions remain with elected governments rather than be placed in the hands of a politically independent body like EFSA (Christoforou 2004). National governments do have some independent capacity for risk management within their borders. They are responsible for conducting field trials of GM products and determine the rules for co-existence of GM and non-GM crops within their borders.<sup>15</sup> Moreover, Article 23 of the Deliberate Release Directive allows member states to restrict the marketing within their borders of a GMO authorised under the Directive if they can provide 'new or additional information made available since the date of the consent' relating to the human health and/or environmental risk of the GMO. This 'safeguard' clause for GMOs is more onerous than that in the earlier 1990 Directive (Directive 90/220) which allowed the safeguard clause to be invoked with 'justified reasons.'

The authorization of a GM product for input and marketing in the EU is a collective decision taken under regulatory comitology procedures. However, the functioning of comitology procedures has not produced their intended effect: to enable elected governments to collectively control risk regulation for GMOs in the EU. In the period between the implementation of the Food and Feed Regulation in April 2004 and February 2008, more than a dozen GMOs were authorized for import into the EU for use as *animal feed and/or processing*.<sup>16</sup> In no case, however, was a GMO approved by a QM of member states. The functioning of the comitology procedures was such that, at the regulatory committee, a blocking minority of member states denied the Commission the QMV to implement its authorization proposal. At the Council of Ministers, divisions among member states (some supporting the proposal, others voting against it, and others abstaining) left the Council unable to muster the QMV either to reject or support the Commission proposal. As it is required to do so under EU legislation, the College of Commissioners then implemented its own authorization proposals.

Over this same period, no new applications to authorize a GMO for *cultivation* were approved.<sup>17</sup>

The functioning and outcomes of the comitology procedures can be interpreted as consistent with governing norms of horizontal accountability of member states to one another. Joerges (2002: 141) has described the role of committees to make 'the logic of market integration... compatible with the social regulatory concerns and interests in Member States.' The 'social regulatory concerns' are evinced in public opinion data showing persistent antipathy toward GM products. The majority view in every EU member state is that GM foods are not useful, not morally acceptable, and a risk for society (Gaskell et al. 2006; European Commission 2008: 66). Although the opposition to GM foods is stronger in some countries—Austria, Greece, Germany and France—than in others like Italy or Spain, in no EU member state does a majority believe that GM food should be encouraged (Ibid.). In the face of this hostile public opinion, some member states have been reluctant to impose a decision to authorize the cultivation of a GM crop on recalcitrant fellow national governments and to require member states to lift safeguard bans that prohibit EU-approved GMOs in their country.<sup>18</sup>

Horizontal accountability norms have been evident in the reluctance of member states to support Commission proposals to require Austria to lift its safeguard bans on GMOs. Austria's population voted in a nation-wide referendum in the mid-1990s to ban the cultivation of GMOs in its territory (European Environmental and Packaging Law Weekly, 2007: 21) and member states are sensitive to the Austrian government's predicament.<sup>19</sup> On three occasions (June 2005, December 2006, February 2007), the Council rejected by the requisite QMV the Commission proposal to require Austria to end its ban on the two GM maize varieties that had been approved for cultivation under Directive 90/220. In November 2007, the Commission did score a victory of sorts when it reworded its proposal to require Austria to end its ban on the two GMOs in question for feed and food processing but not to authorize their *cultivation*. The absence of a QMV in the Environment Council in opposition to the Commission proposal left the Commission with the legal right to oblige Austria to lift the safeguard bans on the marketing and import of the GM crops in question. Still, the Commission's moral authority to do so was questioned by Austria and others.<sup>20</sup>

Escape routes that would respond to Austria's desire to remain GMO-free have, however, been eliminated by the Commission and reinforced by the European Court of Justice. In March 2003, relying on EFSA advice, the Commission rejected Austria's proposal to prohibit GMO cultivation in Upper Austria. In 2005, the European Court of Justice agreed with the Commission that such a ban was illegal and could not be scientifically justified (AgraFocus November 2005: 37).

In its proposals to authorize GMOs and to end member states' safeguard bans, the Commission is relying closely on EFSA's risk assessment data and its advice that the products in question are safe and there are no new data to warrant the bans.<sup>21</sup> Jasanoff (2003: 160) warns that 'science invoked to support policy tends to unravel under the stresses of politics: those wishing to question a given scientific interpretation can generally find errors, hidden biases or subjective judgements that undercut their opponents' claims to truth and objectivity.' Not surprisingly, then, EFSA itself has become a target of criticism by member states and environmental organizations who have questioned the integrity of its scientific opinions, including its failure to recognize the uncertain state of the scientific knowledge of GMOs' environmental risks (Friends of the Earth Europe 2004; Levidow 2006). Member state criticism likely arose also in response to what Chalmers (2005:661) described in 2005 as EFSA's 'more aggressive...treatment of national [risk assessment] work' over time in 'not only rejecting some methodologies but also, even where it agreed with the methodology, rejecting the standards used by national authorities.' Another factor fueling contestation over GMO authorization is the still uncertain state of knowledge of the environmental risks of GMOs.<sup>22</sup>

These criticisms have had feedback effects for accountability principles. The Commission has taken steps to require EFSA to be more accountable to the Commission, member states, and public critics for the quality of its scientific risk assessments. Environment Minister Dimas has been especially sensitive to charges of failing to take a precautionary approach. On more than one occasion, he has asked EFSA to re-do its risk assessment of a GM product and caused a delay in the regulatory approval process itself (AgraFocus 2007). In 2006 the Commission directed EFSA and its GMO Panel to work more closely with member states' competent authorities and to be more transparent in the basis for its opinions. EFSA's GMO Panel was required to take into consideration all the scientific comments from member states prior to finalizing its scientific opinion, to explain in more detail when its opinion differs from member state agencies, and to look into the longer term studies of the environmental and health effects of GMOs (AgraFocus June 2006: 36).<sup>23</sup>

The success of these efforts to strengthen the legitimacy of GMO risk regulation via more transparent and procedurally accountable risk assessments is unclear. On the one hand,

Eurobarometer data indicate that EU-level regulators are trusted as much or more than national level regulators in regulating biotechnology (Gaskell et al. 2006: Figure 20, p. 51).<sup>24</sup> On the other hand, the visible public divisions, including within the Commission and across member state governments, on whether GMOs are safe or unsafe serve to remind all of the contestation over appropriate GMO risk regulation processes.

#### **IV. The WTO Biotech Case and External Accountability**

The contestation around accountability principles within the EU has also been fueled by external accountability pressures that lend support to fiduciary-based principles of political accountability.<sup>25</sup> These external accountability pressures came in the form of the threat, and then, action by the United States, Canada and Argentina—all major producers and exporters of GM crops—to challenge the suspension of GMO authorizations in June 1999 as inconsistent with the EU's WTO obligations. The ruling of the WTO Panel in *European Communities-Biotech Products* (World Trade Organization 2006) has reiterated the imperative of external accountability legal obligations to those affected by EU activity but who have not empowered it.

In *EC-Biotech*, the WTO supported the complainants' claim that the EU failed to uphold its obligations under the WTO Sanitary and Phytosanitary (SPS) Agreement when it suspended its procedures to license GMOs after October 1998 (the date of the last GMO approval decision). The WTO panel ruled that this de facto moratorium on licensing GMOs and the suspension of approvals of some specified GMO products contravened SPS Agreement provisions and EU treaty obligations. It reached the same conclusion with respect to the safeguard measures of six member states

The WTO Panel blamed both the Commission and the member states' competent authorities for stalling the approval procedures. In the face of clear member state opposition, the Commission had not followed authorized comitology procedures. The initial step in these procedures required the Commission to submit draft measures to approve GMOs to the regulatory committee of member states. The Panel ruled that the Commission took an unjustifiably long time to forward a draft measure to the committee, despite a favourable opinion from the EU-level scientific committee (WTO 2006: Paras 7.2142, 7.2244 ). When it did submit authorization proposals to the regulatory committee, and was denied the support necessary to authorize the GMO, the Commission failed to proceed to the next step in the authorization process of asking the Council to vote on the draft measure. Without a Council vote to approve or reject the GMO application within the prescribed time limit, the approval process was de facto suspended, and the Commission was in violation of its own comitology rules as well as WTO obligations.

In addition to their success in challenging the de facto moratorium, the complainants also prevailed in their challenge of the safeguard measures of six member states. The complaint was that the particular bans of six member states on the import and marketing of nine biotech products were inconsistent with SPS obligations that prevent import bans in the absence of scientific risk assessments. All the GMO products in question had been authorized at the EU-level on the basis of scientific committees' advice as to their safety. Member state studies in defense of these safeguard bans, ruled the WTO Panel, did not qualitatively or quantitatively assess the risks of GM products and so did not meet the threshold of a risk assessment. Nor could the safeguard bans be justified on the basis of precautionary measures (as allowed by the SPS Agreement) because extensive risk assessments for the relevant GMOs had been carried out at the EC level. Accordingly, relevant scientific evidence was not insufficient (WTO 2006: paras 7.3232-7.3261). The WTO Panel did not consider relevant the



national studies that questioned the EU-level risk assessments and stressed the scientific uncertainty surrounding GMOs' safety.

The WTO ruling thus limited the precautionary principle as an effective escape hatch to accommodate member state concerns. In its view, the fact that scientific information and data on GMO risks were still limited did not *per se* justify the general moratorium and the halt in approval of product-specific measures. The Panel's decision thus implies that at a certain point a country has to decide whether a product is safe or not, regardless of the degree of uncertainty surrounding it (Poli 2007; Franken and Burchardi 2007). As with the EU legislation, member states who wish to ban the entry of GMOs on grounds of uncertainty about their risks face a difficult hurdle. Poli (2007:721) observes that 'when a risk assessment has been carried out and it supports the granting of an authorisation to place a GMO on the market, it is exceptionally difficult to invalidate it on the basis of new scientific information provided by assessors other than the original ones.' Member states have little option but to accept a GM product vetted as scientifically safe at the EU unless they can furnish new scientific evidence as to its risk.

The ruling of the World Trade Organization in the *EC-Biotech* trade dispute reiterates to EU-level decision-makers in the Commission their fiduciary obligation to uphold not only EU-level laws and EU treaties, but also commitments to co-members of international organizations like the WTO. In 2008, as a handful of member states continued to resist their external accountability obligations, it appeared necessary for the Commission to call on the European Court of Justice to compel them to come into conformity with the EU's own laws.<sup>26</sup>

## V. Discussion and Conclusions

The EU GMO controversy illustrates the rife possibilities for contestation around the meaning and scope for political accountability in an arena of supranational governing. Three factors have attenuated accountability concerns in the case of GMO risk regulation. First, the dominant political discourse and institutional logic (of comitology) link political accountability to democratic norms of citizen control over elected decision-makers. In this context, performance-based accountability as rendered by non-majoritarian bodies has faced an uphill battle to gain legitimacy. Second, the widespread precautionary political culture of the European public when it comes to GMOs and their aversion to GM foods undermine non-majoritarian regulators whose professional expertise gives rise to policy outcomes at variance with public opinion. Where, as in the United States and Canada, there is greater trust in science and less skepticism of GMOs, fiduciary-based principles of accountability have met with far less resistance.

Third, the incentives for member states to lend their authority to fiduciary-based institutions like the Commission have been undermined by the dearth of escape routes that respect 'legitimate diversity' of member states (Heritier 1999, Scharpf 2003). In the GMO case, escape hatches have been elusive and certainly not sufficiently wide or frequent to generate member state majority support. Opting out options have been narrowed by EU legislation, the rulings of the European Court of Justice, and the WTO's dispute-settlement powers and its treaties. The constraint of external accountability has been especially consequential. As Victor and Weiner (2003: 158) observe and the ruling in *EC-Biotech* confirms, the dispute settlement rules under the WTO create an automatic enforcement mechanism that ensures that states will be held accountable if they 'defer inconvenient trade rules and disputes.' External accountability of EU states to those affected by their actions has chafed with norms of democratic accountability of these same member states which create an obligation on their part to respect the preferences of citizens who have empowered them.

Not surprisingly then, some member states have resisted their individual responsibility to recognize their external accountability obligations to WTO law. In challenging the

regulatory outcomes of the GMO authorization process at the supranational level, including the risk assessments on which risk management decisions are based, these contrarian states have risked putting in jeopardy the legitimacy of the EU's GMO regulatory framework and decisions. They have abdicated the burden of external accountability to the Commission. A situation in which the EU is seen to be making decisions that run contrary to the positions of their national governments and which are based on the advice of scientific experts can hardly be desirable. It carries the high risk of lending credence to unflattering perceptions of the EU as a site of unaccountable, technocratic decision-making. From the point of view of Commission officials, it would be far better if more member states recognized their own external accountability obligations to explain to their domestic publics the need to support the EU GMO regulatory institutions and its outcomes.

What are the prospects for an attenuation of the current situation whereby EU regulation of GMOS is contested? What is the likelihood that member states will assume more public accountability for decisions rendered by supranational governing bodies? In answer to these questions, two points appear to be relevant. First, the rapidly escalating costs of feed to EU poultry, hog and cattle producers in 2007-2008 gave some member states incentives to champion the legitimacy of existing regulations and the role of the Commission and EFSA in the regulatory process.<sup>27</sup> This incentive should not be exaggerated. Member states whose agricultural sectors are less reliant on imported animal feed do not have the same incentives. Second, external accountability obligations remain. The EU's GMO authorization process remains a source of tension with (American) exporters of GMOs who decry both its delays and failure to date to approve any GMOs for cultivation.<sup>28</sup> These external parties have strong incentives to prevail upon their governments to force the EU to comply with its external accountability obligations to fellow WTO members.

One of the premises of this paper is that accountability is a source of legitimacy and effort must therefore be put into constructing, explaining, and practising norms of accountability that are consistent with supranational governing. This premise is not accepted by all. Some have argued that the legitimacy of supranational political authority at the EU-level depends less on accountability norms and practices than it does on public participation and representation (Fisher 2004; Riekmann 2007). Notwithstanding this view, there is ample reason to expect that the contested accountability that seems inevitably to shroud supranational regulation is likely to remain an obstacle to legitimate supranational regulation.

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Endnotes

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1. In mid-2008, France, Austria, Poland, Hungary and Greece had bans on the cultivation of some genetically modified crops that had secured EU-level approval.
  2. Such a calculus explains the collective decision of EU member states and the EU Commission not to allow hormone-fed beef products into the EU, despite the WTO ruling that the EU ban was not supported by the requisite scientific risk assessment to demonstrate the harm of the hormones. The EU elected to pay sanctions to countries economically harmed by its ban. The EU response to the beef hormone case is not an entirely similar case to the GMO case since there was evidence that at least some of the hormones in question were unsafe and scientific dispute about the safety of others.
  3. Some cite an additional problem of discussing accountability in the EU context: the difficulty of defining to whom it is owed. These scholars argue that accountability only makes sense if there is a coherent political community-- defined group of citizens who share certain basic attributes--to which it can be delivered. Aside from their common membership in the EU, many doubt that EU citizens are sufficiently holistic for decision-making institutions to be able to be accountable to them. In the case of attitudes toward GM products, this argument is undermined by the degree of consensus across EU citizens that, at least when it comes to GM food, it is not useful and a risk for society. See Gaskell et al. (2007) reporting Eurobarometer data.
  5. In the 27 member state EU, 255 out of a possible 345 votes (73.9%) constitute a QM. Abstentions count as negative votes.
  6. A blocking minority consists of 91 votes. On GMO authorizations, a blocking minority could entail 4 countries: Germany, France, and Italy with 29 votes each, and Austria with 10.
  7. This information is based on interviews with Commission, member state, and non-governmental officials in November 2007 and February 2008.
  8. This distinction builds on Jasanoff's work.
  9. Before authorizing the GM maize, the Commission secured advice from three committees who determined that the corn would not adversely affect the environment, have adverse effects on animal health, or create human health problems.
  10. Borás (2007) provides a useful account of the political process to secure agreement on the GMO regulatory framework.
  11. Adopted in 1997, Regulation 258/97, the Novel Food and Novel Food Ingredients Regulation, continues in effect, but it will no longer apply to GM foods authorized under Regulation 1829/2003. A good overview of the new regulatory framework can be found in Christoforou (2004).
  12. Directive 90/220 required member states to ensure that GMOs did not have any adverse effects on the environment, but it 'was limited to possible environmental risks without addressing specifically the use of GMOs in food or feed' (Christoforou 2004: 690).

Regulation 258/97 required food safety assessments. Directive 2001/18 specifies Principles for Environmental Risk Assessment in an Annex that include extensive requirements for information of effects of GMOs on non-target species and ecosystems, including the food supply for birds and other animals.

13. These measures include rejection of 'substantial equivalence' as a means of safety assessment (Commission of the European Communities 2006) and mandatory post-marketing monitoring of GMOs.

14. EFSA's mandate is broad. It includes advising the European Commission on any matter with a direct or indirect effect on the safety of the food supply, including matters related to animal health and welfare, and plant health. It is also entrusted with a role in risk communication; that is, informing the public of the (non-)risks of a product. Existing scientific advisory committees were transferred to EFSA in May 2003. Risk assessment of GMOs is done by the Panel on GMOs.

15. The European Commission's document on co-existence states that it is 'imperative' for member states to have 'a maximum degree of flexibility' to develop their own co-existence measures according to their own national or regional situations. See: [www.europa.eu.int/Comm/agriculture/coexistence/index\\_e.html](http://www.europa.eu.int/Comm/agriculture/coexistence/index_e.html).

16. GMO Compass (2008) provides an up-to-date list of the status of GMO applications. As of June 2008, it listed 12 applications (8 maize, 2 rapeseed, 1 sugar beet and 1 carnation) as approved for import and marketing. No products had been approved for cultivation. Two cotton, 6 maize, 1 soyabean, 2 sugar beet and 2 rapeseed seed applications had been submitted.

17. A GM maize, MON810, that had been approved under the earlier 1990 Directive, remains the only GM crop cultivated in any amount the European Union. Spain, followed by France, grow the largest amounts of the GM maize with the Czech Republic, Portugal, Germany and Slovakia growing far smaller amounts. In February 2008, the Council of Ministers failed to issue an opinion on a proposal to license a GM potato to be grown for use in industrial processing and animal feed. EU Environment Commission Dimas delayed allowing the GM potato to be cultivated on the grounds that internal Environment DG studies raised environmental risk concerns about the potato. EFSA had declared the GM potato to be safe.

18. These norms did not prevent the Commission from requiring Greece to lift its safeguard measure in 2006; the Council failed to take a position within the three-month period on the Commission draft decision to that effect.

19. This statement is based on interviews held in November 2007 and February 2008 with individuals within the Commission as well as in national governments, several of whom pointed to the reluctance of member state governments to interfere with Austria's sovereignty over its environment.

20. Austria greeted the outcome of the October 2007 Council vote—which allowed the Commission to require Austria to lift its safeguard clause on import and processing of GM products—with the statement that it had 191 votes cast for it, while the Commission had only 56. And the Portuguese Council President pronounced the outcome, in which a proposal prevailed despite the opposition of a majority of member states, as having created 'an

uncomfortable situation.’ See *European Environmental and Packaging Law Weekly* (November 2, 2007: 1).

21. The Commission also relied upon an EFSA opinion when it ruled in March 2003 that Austria’s proposal to make the region of Upper Austria GM-free was illegal.

22. For instance, in February 2008, *Agence Presse France* reported on a University of Arizona stud that found evidence that some, but not all, target insect pests developed resistance to GM crops.

23. Reuters (2007) reports that Italy called for an examination of the work of the EFSA and a moratorium on GM authorization until the examination was completed.

24. Only in Finland, Denmark, Sweden and Austria are national regulators trusted more than EU regulators. These data may not capture public sentiments with respect to GMO regulation, however, since the question asks about trust to regulate ‘biotechnology’, a term which includes medical biotechnology (like stem cell research) and which is viewed positively by the EU public.

25. Pollack and Shaffer (2005: 347) state that reforms were made ‘in order to fend off a U.S. challenge.’ Murphy and Levidow (2006) argue that one substantive effect of the trade challenge was more stringent terms of entry for GMOs onto the EU market. Lieberman and Gray (2006:606) argue the trade challenge ‘concentrate[d] the mind of EU decision-makers, serving as a trigger for a change in policy stance.’

26. In late January 2008, EU regulators were reported to be launching a court case against Poland’s ban on marketing and cultivation of GM seeds. See Reuters (2008).

27. Livestock, hog and poultry farmers who rely on imported feed produced from maize or soybeans have not only faced higher feed costs but have had difficulty accessing non-GM varieties. The five countries most affected are Ireland, the United Kingdom, Netherlands, Spain and Portugal. For details, see Directorate General for Agriculture, 2007; and Brookes, Craddock and Kneil, 2005.

28. GMO companies state that it takes 2-4 years to approve a GMO in the EU versus 15 months in the U.S.A.