Contested Accountability Claims and GMO Regulation in the European Union

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Abstract
This article investigates the EU’s regulation of GMOs (genetically modified organisms) to argue the potential for difficult-to-reconcile conflicts to arise between the internal accountability standards of Member State citizens and external accountability obligations to fellow WTO (World Trade Organization) members. Tracing the internal–external accountability conflicts to the distinct EU–WTO political cultures of GMO risk regulation, the article documents EU decision-makers’ attempts to reconcile internal and external accountability claims in the redesign of the EU GMO regulatory framework and the continuing internal and external controversy that surrounds its implementation.

Introduction
Perceptions that supranational organizations are not accountable can impair their legitimacy and undermine their regulatory authority. Yet accountability can be elusive for supranational institutions. There is no single conception of what it means to render an account; thus, the accountability standards by which Member States judge the behaviour of supranational institutions can differ and be in conflict. A supranational regional institution like the EU juggles the internal accountability claims of its Member State citizens and external accountability obligations to others impacted by EU decisions – such as fellow members of the WTO (World Trade Organization) (Grant and Keohane, 2005).
When the standards by which internal and external parties appraise the accountability of regional institutions like the EU are difficult if not impossible to reconcile, the very legitimacy of these supranational bodies can be at stake. This article examines just such a case of conflicting internal and external accountability standards and one with negative consequences for the regulatory authority and legitimacy of supranational institutions. The case under investigation is the regulation of GMOs (genetically modified organisms), the products of plant biotechnology. EU policies and their outcomes with respect to regulating the risks of GMOs have been under attack for some time both within the EU and outside it from EU trading partners and fellow WTO members like the US. Both internal and external criticisms fault the failure of the EU GMO regulatory regime to conform to ‘rendering account’ standards. These internal and external accountability standards are rooted in distinct political cultures of risk regulation and logics of legitimate decision-making with respect to GMO risk regulation. The ascendant precautionary EU political culture of risk regulation, emphasizing the uncertainty of GMO risks and sceptical of scientists’ capacity to assess GMO risks, is reluctant to delegate regulatory authority to scientific experts and measures the accountability of EU decision-makers against democratic principles of popular control. By contrast, the political culture of GMO risk regulation embedded in the WTO is consistent with a scientific rationality political culture. It assumes that the risks of GMOs are scientifically knowable, delegates regulatory authority to unelected scientific experts, and judges the latter’s accountability by efficacious policy outputs as measured by consistency with legal and scientific principles of risk management. EU decision-makers’ efforts to strike a balance between internal and external accountability standards – of, respectively, popular control and output performance – have come up short in satisfying both internal and external accountability claimants. The very legitimacy of the EU to regulate GMO risks remains an issue as some EU Member States ignore EU regulatory decisions and the EU’s trading partners criticize it as protectionist and in violation of WTO rules.

These outcomes warrant close scrutiny of the EU GMO risk regulation case for how it highlights the possibility of conflicting internal and external accountability standards and the difficulty of reconciling them. The case also invites speculation on whether and how such accountability conflicts might be minimized and managed. To pursue both objectives, the article is organized as follows. Section I develops the theoretical concepts central to the argument. It distinguishes between popular and delegated/fiduciary concepts of legitimate authority and the role of horizontal accountability norms in bolstering the legitimacy of the delegated authority exercised by EU institutions. It also addresses accountability standards specific to two distinct political cultures of
CONTESTED ACCOUNTABILITY CLAIMS AND GMO REGULATION IN THE EUROPEAN UNION

GMO risk regulation: the precautionary and scientific rationality political cultures. Section II describes the ascendance of the precautionary GMO risk regulation culture in the EU, the loss of legitimacy of the EU regulatory regime in the late 1990s, and the institutional and policy reforms undertaken to restore it. It argues that the reformed EU regulatory regime incorporated elements of both the precautionary and scientific rationality political cultures in an effort to respond to internal and external accountability standards.

Sections III and IV examine the efficacy of the EU to balance internal and external accountability standards since 2004. Section III focuses on continuing contested internal accountability of the EU as its institutions approve imports of GM products for processing and animal feed without the support of a qualified majority of Member States. Some Member States continue to disregard EU regulations for GMOs. Moreover, the EFSA (European Food Safety Authority), the agency delegated authority for scientific assessments of the risks of GMOs, has come under attack for not being accountable as measured by the standards of the precautionary risk regulation political culture. Section IV reiterates the importance of external accountability obligations, as confirmed by the WTO ruling in EC Communities-Biotech in 2006. The WTO ruling reduced the EU’s capacity to be accountable as judged by standards of the precautionary risk regulation culture. Even so, external accountability obligations remain elusive. In 2006, the WTO ordered the EU to bring itself into conformity with its obligations under international law to end Member States’ prohibitions on GMO approvals. While the EU has struck agreements with Canada and Argentina to end the trade dispute, a similar agreement with the US is still outstanding.

The concluding section considers options for reducing inconsistencies between internal and external accountability claims.

I. Accountability, Supranational Institutions and Political Cultures of Risk Regulation

Those who regulate and govern the behaviour of others do so conditional on the latter’s acceptance of their right to do so (Bentham, 1991). In liberal democracies, this perception of political legitimacy – the belief that those who make and/or enforce binding rules have the right to do so and their actions should thus be obeyed – is closely related to the belief that decision-makers can be held to account for their actions.1 However, just what ‘holding to account’ entails – in terms of who can hold whom to account and for what

1 Some argue 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). Here, public participation is folded into one set of accountability standards.
and by what means – is not necessarily a matter of consensus either within or across liberal democracies. As Bovens (2007, p. 106) states, standards for accountable behaviour ‘differ from role to role, time to time, place to place’. They do so because concepts of accountability are discursively constructed in specific institutional and social contexts and these contexts afford social and political actors with varying incentives and opportunities to advance different accountability claims based on different logics of legitimate political authority (Black, 2008).

Contestation around what constitutes legitimate governance makes accountability ‘a contested concept’ in the EU (Fisher, 2004, p. 510). There is a division between participation and delegation logics of legitimate political authority and their accompanying accountability standards (Majone, 2000, 2001; Grant and Keohane, 2005). The participation logic is usually equated to models of democratic politics that vest authority in the hands of elected governments who are representatives of the people and can be sanctioned by them. Popular representation and popular control are the accountability mechanisms. By contrast, delegated authority models of governing eliminate the possibility for direct popular control of decision-makers and define accountability in either agency or trustee/fiduciary terms. Accountability standards that measure the behaviour of delegated authorities as agents judge these decision-makers’ behaviour in terms of its consistency with the preferences of the delegating party (be it the electorate or elected politicians). As trustees or fiduciaries, decision-makers’ measure of accountability is their effectiveness to perform the functions assigned them (Majone, 2001). On the fiduciary logic, the accountability of the decision-maker is not weakened by being beyond the delegating party’s control; indeed, such independence may be crucial to accountability as measured by effective performance (Majone, 2001). The accountability of non-majoritarian fiduciary bodies is further checked by controls on their discretionary behaviour: for example, membership by virtue of expertise and professionalism, requirements to give reasons and make transparent the bases for their decisions, and judicial review of these decisions (Majone, 1994, pp. 2, 22–3; Dyrberg, 2002, p. 83; Harlow, 2002, pp. 162–92).

Like most political systems, the institutions of supranational governing in the EU incorporate both participation and delegation logics of accountability (Majone, 2000, 2001; Menon and Weatherill, 2002). Legislative processes – of formulating and agreeing on directives and regulations – are subject to models of shared political authority across the EU institutions that reinforce participation and popular control standards of accountability. By contrast, the implementation of these same regulations by comitology procedures that involve unelected officials from the European Commission, and their legal
enforcement by the European Court of Justice, shifts to a logic of delegated authority (Majone, 2000, 2001).

Analysts observe that fiduciary-based authority vested in the European Commission and the EU courts is an important element in the EU’s ability to meet the internal accountability obligations of Member States to one another (to maintain an internal market, for example) but also external accountability obligations to third parties. Delegating authority to non-elected politicians, say Menon and Weatherill (2002, p. 129), is a way to ensure 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’. Moreover, such performance-based accountability can be an important source of legitimacy for the EU, capable of generating support for it (Scharpf, 1999).

Still, democratic/popular control standards dominate the accountability discourse in the liberal democracies of EU Member States and weaken the legitimacy of supranational institutions that can escape ‘rendering an account’ directly to voters or to elected politicians. This situation, says Schmidt (2006), means that Member State governments are the major conduit to European publics for legitimizing the decisions of supranational decisions and sharing accountability for them. What incentives do national governments have to take responsibility for EU-level decisions rather than to compete for leadership with the Commission? In answer to this question, analysts point to norms and practices of horizontal accountability that require supranational political actors constantly to account for their actions to others prior to acting and to accommodate the views of Member States that are not part of the majority. Héritier (1999, 2003) points to efforts within institutions like the Council of Ministers to give national governments ‘escape routes’ to accommodate popular concerns. Joerges and Neyer (1997) argue that comitology procedures are a site of deliberation that makes decision-makers sensitive 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, p. 143) believes 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. When such horizontal accountability norms and practices are operative, they should be a source of legitimacy for supranational decisions by resulting in policy outcomes for which Member State governments are willing to render an account.

2 Harlow (2002, p. 172), like other academics who equate accountability with democratic controls, speaks of ‘a yawning accountability gap’ in EU governing structures.
These polity-wide institutional norms and practices are one component of what Jasanoff (2005) calls political cultures of biotechnology risk regulation: that is, the amalgam of ideas and institutional practices in a political community that pertain to the roles of science, experts, the state and the public in democratic decision-making for biotechnology. In addition to the formal and informal methods of ensuring accountability and legitimacy in decision-making, as discussed above, cultures of risk regulation also incorporate beliefs about the appropriate processes for producing and validating ‘credible knowledge claims’ about the risks and benefits of plant biotechnology (Jasanoff, 2005, p. 249). ‘Credible knowledge claims’ for GMO risk regulation are discursively constructed by social and economic actors, and reflect socially embedded values. The discourses that dominate reflect these values, historic contingencies and the bias of institutional settings that allow some but not other discourses to become ascendant (Gottweis, 1998; Gaskell et al., 2001; Toke, 2004; Jasanoff, 2005).

A useful distinction can be drawn between political cultures that grant cognitive authority to scientific methods and scientists to produce reliable knowledge about a novel technology’s risks, and those which do not. The former can be labelled a scientific rationality political culture (Isaac, 2002); the latter, a precautionary political culture of risk regulation. Whereas a scientific rationality political culture accepts and respects scientists’ ability to calculate a novel technology’s risks, 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. Whereas a scientific rationality political 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. Rather, it is likely to contest experts’ knowledge as an exclusive basis for risk regulation, advocating, instead, a view of reliable knowledge as that which society has a role in co-producing (Borrás, 2006).

As the next section of the article argues, a precautionary political culture of GMO risk regulation has emerged in the EU. It constitutes a weak basis for a fiduciary-based model of risk regulation by scientific experts.

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 species (plant) 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. The task of risk regulation entails assessing any potential human health and environmental risks posed by GM products. Potential risks to human health include the allergenicity of the GM plant, and environmental risks include the possibility that the GM plants may cross-pollinate with non-GM crops as well as with wild relatives, with potentially negative consequences for biodiversity.

Analysts characterize the EU political culture of GMO regulation as a precautionary one whose epistemological underpinnings are scepticism about 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; Jasanoff, 2005; Murphy and Levidow, 2006). This political culture is the outcome of the history of GMO regulation in the EU. Since 1990, it 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 (Toke, 2004; Jasanoff, 2005; Murphy and Levidow, 2006). The precautionary approach, says Noiville (2006, p. 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 exist doubt and uncertainty concerning the safety of a product (Noiville, 2006, p. 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. The backdrop to their doing so 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). Despite this mobilization against GM products, the Commission used its legal authority to approve a GM maize against the wishes of all but one Member State. When the Commission sought Member State support, again via comitology procedures, to require the safeguard bans to be lifted, a QM (qualified majority) of
Member States rejected its proposal. The vote to allow partner Member States to maintain their national bans is consistent with norms of horizontal accountability. Although seven GMOs were approved by QMV (qualified majority vote) in the regulatory committee between 1996 and October 1998, 13 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 based on both standards of popular control and fiduciary standards of good performance played an important role in the loss of governance legitimacy. The Commission’s behaviour in overriding Member State concerns was criticized as inconsistent with democratic principles of political accountability. It was ‘roundly condemned’ by consumer, environmental and farm groups, the European Parliament and Member States (Bradley, 1998, p. 214). The condemnation was also related to criticisms of the reliability of the risk assessments that the Commission used to authorize GMOs. The Commission’s discretion on whether to consult scientific advisers contributed to this criticism (Joerges and Neyer, 1997).

A series of regulatory and institutional reforms over the period 2002–04 were implemented to restore legitimacy to EU-level regulation of GMOs. Reforms were also made in the shadow of external accountability obligations to WTO members; the US was threatening to bring action against the EU regulatory framework (Pollack and Shaffer, 2005). An intensive process of societal input attempted to bridge internal and external accountability claims and bridge the schism within the EU between social and political actors (most prominently, the biotechnology industry) arguing for a GMO regulatory framework closer to a scientific rationality model and those (most prominently, environmental and consumer groups) arguing for a risk-averse precautionary approach (Skogstad, 2003; Borrás, 2007).

The most important elements of the regulatory framework are laid out in four pieces of legislation. First is Directive 2001/18, the Deliberate Release Directive. Its objective is to ensure the environmental safety of ‘live’ GMOs, like GM maize kernels or rapeseed. Like Directive 90/220 which it replaced in April 2001, Directive 2001/18 requires a risk assessment of every GMO before it is released into the environment. It provides detailed and extensive

3 In deciding to authorize the GM maize, the Commission followed the advice of three committees who determined that the corn would have no adverse effects on the environment, animal health or human health.
4 The 1997 Novel Food and Novel Food Ingredients Regulation remains in effect, but it does not apply to GM foods authorized under Regulation 1829/2003.
information for applicants on how to carry out such risk assessments, affirms the precautionary principle as a guide to risk regulation, 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 (Commission, 2001).

Second is Regulation 1829/2003, the Food and Feed Regulation (Commission, 2003a), which replaced the 1997 Novel Food Directive. Its regulatory procedures are designed to ensure the human and animal health and safety of any GM food and feed, and processed food made from GMOs (like cornstarch) that are marketed in the EU. Third is Regulation 1830/2003 on the labelling and traceability of GMOs and food and feed produced from GMOs (Commission, 2003b). Labelling is intended to ensure consumer choice, and traceability provisions are intended to track and recall GM products in the event of a safety issue.

The fourth pillar in the EU GMO regulatory framework is not specific to GM products. It is Regulation 178/2002 which laid out European food law and the role of EFSA (Commission, 2002). Since it began operations in 2003 as a permanent body dispensing advice to the Commission on food safety issues (and GMOs’ risks), EFSA has replaced Commission-appointed scientific committees. Although the European Commission is not bound by EFSA opinions, it must provide an explanation when its recommendation on whether to license a GMO or not differs from the opinion of EFSA.

This package of reforms can be read as an effort to strengthen both democratic (participation) accountability standards of popular control as well as delegated fiduciary-based principles of performance accountability. With respect to the first – popular control – regulators 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. With respect to the second, risk assessments at the EU level are performed by the scientific committees of EFSA whose members are independent of governments. The hope has been that EFSA’s professional credentials, alongside its mandate to adhere to the precautionary principle, will provide supranational regulators with more authoritative risk assessments than did its predecessor EU

5 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, p. 690). An Annex to Directive 2001/18 specifies Principles for Environmental Risk Assessment that include extensive informational requirements for effects of GMOs on non-target species and ecosystems, including the food supply for birds and other animals.

6 EFSA advises the European Commission on any matter that directly or indirectly affects 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. Existing scientific advisory committees were transferred to EFSA in May 2003.
scientific committees (Skogstad, 2001; Buonanno, 2006). Observers also point to the possibility for EFSA’s role in risk assessment to allow it to ‘frame the debates’ around GMO risks (Chalmers, 2005, p. 654). Only EFSA, not the competent national authority, is mandated to issue an opinion on whether a GM food or feed product will have adverse effects on human health, animal health or the environment and/or should be placed on the market.

Member States retain some important risk regulation powers. They regulate field trials of GMOs in their home territory and determine the rules for coexistence of GM and non-GM crops within their borders. They also share risk management powers with the Commission under the comitology procedures. Finally, under Article 23 of the Deliberate Release Directive, Member States can restrict the marketing within their borders of an authorized GMO 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 Directive 90/220; it allowed the safeguard clause to be invoked with ‘justified reasons’.

As the next section demonstrates, the reformed regulatory regime, including its escape hatches, has nonetheless not arrested controversy around the accountability and legitimacy of EU GMO risk regulation.

III. GMO Risk Management and Contested Internal Accountability

The decision to leave risk management decisions in the collective hands of elected governments, argues an EU official, was necessary for the legitimacy of the regulatory outcomes (Christoforou, 2004). Regulatory comitology procedures, not the politically independent EFSA, thus determine whether GMOs will be licensed for marketing in the EU.

As suggested earlier, comitology procedures are typically understood as a way for Member States to retain some control over the supranational policy process (Dogan, 1997; Majone, 2001, p. 104; Pollack, 2003; Bergstrom, 2005). Control is exercised by Member States forming a blocking minority to stop the Commission from acting at the regulatory committee stage, and/or forming a QM to stop the Commission from acting at the Council of Ministers stage. With respect to approvals of GMOs, authorization begins when the Commission, as chair of the Standing Committee on the Food Chain and

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7 The European Commission’s document on coexistence states that it is ‘imperative’ for Member States to have ‘a maximum degree of flexibility’ to develop their own coexistence measures according to their own national or regional situations. See «www.europa.eu.int/Comm/agriculture/coexistence/index_e.html».

8 A blocking minority consists of 91 votes. On GMO authorizations, a blocking minority could entail four countries: Germany, France and Italy with 29 votes each, and Austria with 10.
Animal Health, presents the committee of Member State representatives with an ‘opinion’ on a draft authorization proposal for a GM food or feed. A 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. 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.

However, when Member States cannot agree – in the requisite numbers required for a QM and 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 exercise its delegated powers as a fiduciary and approve the proposal it initiated.

It is this fiduciary role that the Commission has found itself playing since it attempted to resume GMO risk regulation under the revised regulatory framework. Since 2004, although more than a dozen GMOs have been authorized for import into the EU for use as animal feed and/or processing, none was approved by a QMV of Member States. 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 to 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.

The functioning and outcomes of the comitology procedures are consistent with norms of horizontal accountability – of Member States to one another –

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9 In the 27 Member State EU, 255 out of a possible 345 votes (73.9 per cent) constitute a QM. Abstentions count as negative votes.
10 Changes to comitology procedures agreed to in 2006 do not alter the authorization procedures for GM products.
11 As of June 2009, GMO Compass (2009) listed 15 applications (eight maize, three rapeseed, two soybean, one sugar beet and one carnation) that had been approved for import and processing and/or for use as food and feed. No products had been approved for cultivation. A handful of products were approved before Regulation 1829/30 went into effect in April 2004.
12 A GM maize produced by Monsanto, approved under the 1990 Directive, remains the only GM crop cultivated in any amount in the EU. Spain, followed by France, grows the largest amounts of GM maize. The Czech Republic, Portugal, Germany and Slovakia grow far smaller amounts.
but they have had the (unintended) effect of undermining the Commission’s authority to legitimate GMO regulatory outcomes. Joerges (2002, p. 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 that reveal a persistent antipathy towards 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; Commission, 2008, p. 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 (Gaskell et al., 2006; Commission, 2008, p. 66). 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.13

Horizontal accountability norms of Member States to one another have also thwarted the Commission’s efforts to require Austria to lift its safeguard bans on GMOs. Austria’s population voted in a nationwide referendum in the mid-1990s to ban the cultivation of GMOs in its territory (European Environmental and Packaging Law Weekly, 2007, p. 21) and Member States are sensitive to the Austrian government’s predicament.14 On three occasions (June 2005, December 2006 and 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. The absence of a QMV in the Environment Council to a November 2007 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 – gave the Commission the legal right to oblige Austria to lift its 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.15

In its proposals to authorize GMOs and to end Member States’ safeguard bans, the Commission is relying closely on EFSA’s risk assessment

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13 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.

14 This statement is based on interviews conducted in November 2007 and February 2008 with Commission and national government officials. Several pointed to the reluctance of Member State governments to interfere with Austria’s sovereignty over its environment.

15 Austria’s response to the outcome of the vote was that it had secured 191 votes while the Commission had only 56 (European Environmental and Packaging Law Weekly, 2007, p. 1).
data and its advice that the products in question are safe and there are no new data to warrant the bans. Jasanoff (2003, p. 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 which have questioned the integrity of its scientific opinions. In their view, EFSA has adopted an unwarranted scientific rationality inconsistent with the uncertainty that surrounds GMOs’ environmental risks (Friends of the Earth Europe, 2004; Levidow, 2006). Member State criticism likely also arose in response to what Chalmers (2005, p. 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’.

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 was especially sensitive to charges of failing to take a precautionary approach. On more than one occasion, Dimas asked EFSA to redo its risk assessment of a GM product (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, 2006, p. 36).

These efforts towards more transparent and procedurally accountable risk assessments have not demonstrably strengthened the legitimacy of GMO risk regulation. Although Eurobarometer data indicate that EU-level regulators are trusted as much or more than national-level regulators in regulating

16 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.
17 For an academic critique of EFSA’s ‘uncertainty intolerance’ approach, see Van Asselt and Vos (2008), who fault EU decision-makers and EFSA for using science to provide conclusive evidence of risks when these risks are uncertain and cannot be answered by science.
18 Reuters (2007) reported that Italy called for an examination of the work of the EFSA and a moratorium on GM authorization until the examination was completed.
biotechnology (Gaskell et al., 2006, figure 20, p. 51), the behaviour of Member State governments reveals their sensitivity to discourses elevated by the precautionary risk regulation culture. For Member States in which GMOs continue to be a source of political contestation, there are few incentives to support the EU regulatory regime and plenty to attack its legitimacy in what Tiberghien (2009) describes as a display of ‘competitive governance’.

As the next section demonstrates, the EU’s difficulties in assuaging internal accountability claims are compounded by its failure to satisfy its external accountability obligations.

IV. The WTO Biotech Case and External Accountability

Analysts argue that external accountability pressures shaped not only the pace but also the substance of reforms to EU GMO regulatory policies. These external accountability pressures came in the form of the threat, and then action by the US, 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 (WTO, 2006) has reiterated the imperative of external accountability legal obligations to those affected by EU activity but who have not empowered it: in this case, co-members of international organizations like the WTO (Winham, 2009).

In EC-Biotech, the WTO supported the complainants’ claim that the EU failed to uphold its obligations under the WTO SPS (Sanitary and Phytosanitary) 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, finding them inconsistent with SPS obligations that prevent import bans in the absence of scientific risk assessments.

The WTO ruling limited the precautionary principle as an effective escape hatch to accommodate Member State concerns. In its view, the fact that

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

20 Pollack and Shaffer (2005, p. 347) state that reforms were made ‘in order to fend off a US challenge’. Lieberman and Gray (2006, p. 606) argue the trade challenge ‘concentrate[d] the mind of EU decision-makers, serving as a trigger for a change in policy stance’. Alternatively, Murphy and Levidow (2006) argue the trade challenge resulted in more stringent terms of entry for GMOs onto the EU market.
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. All the GMO products in question had been authorized at the EU level on the basis of scientific committees’ advice as to their safety. The WTO Panel ruled that Member State studies in defence of safeguard bans did not 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’s ruling is consistent with a scientific rationality model that assumes that the risks of GMOs are knowable and can be ascertained scientifically. 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 implication is 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). Poli (2007, p. 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 level unless they can furnish new scientific evidence as to its risk.

Conclusions

The contestation that can surround the accountability of supranational institutions is compounded by the addition of external accountability obligations. The EU experiences such a conundrum in regulating GMO risks with the standards of its ascendant precautionary risk regulation culture regarding what constitute accountable knowledge claims and regulatory processes and outcomes at odds with outcomes deemed acceptable by the EU’s trading partners and WTO principles and agreements.

What is the way forward and what lessons can be drawn? First, external accountability obligations have to be taken seriously. As Victor and Weiner (2003, p. 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’. Although external accountability obligations cannot be evaded, there may nonetheless still be incentives for countries to avoid enforcing such obligations and to seek co-operative solutions. In this regard, recent diplomatic initiatives to resolve the North Atlantic controversy over Canadian and American GMO exporters’ access to the EU are welcome.

Second, at the same time, the analyses here suggest limits to the legitimacy of delegated authorities – including supranational organizations – that rely on scientific rationality principles to promote market opening and integration goals. In a precautionary risk regulation culture, what constitutes ‘scientific principles’ and ‘sufficient scientific evidence’ – the standards in the WTO SPS Agreement needed to justify health and environmental measures that discriminate against imports – are likely to be matters of ongoing contestation. When political systems differ on these basic epistemological questions, any answers to them cannot be dictated by expert fiat – or by a WTO Panel – but rather by consensus-building across expert and social groups.

Third, contestation around internal accountability standards is likely to continue to bedevil supranational organizations – like the EU – whose dominant discourses of accountability define it in terms of democratic norms of citizen control over elected decision-makers. These discourses put bodies of delegated authority like the EU on the defensive unless those with democratic accountability credentials – Member States – assume co-responsibility for supranational regulatory performance. That an insufficient number have chosen to do so to date can be attributed in some measure to the absence of escape routes wide or frequent enough to respect the ‘legitimate diversity’ needed for Member State support for EU-level decision-making (Héritier, 1999; Scharpf, 2003). These escape hatches in GMO regulation have been narrowed not only by WTO treaties and panel rulings, but also by EU legislation and rulings of the European Court of Justice, including its 2005 decision that Austria could not ban GMO cultivation in Upper Austria. Yet some escape routes may still be found – for example, voluntary GMO-free regions – that give Member States the latitude to respond to domestic citizen preferences without undermining EU-level authority to regulate the internal market.

In July 2010, the European Commission proposed just such an escape hatch to give Member States the ability to restrict or ban the cultivation in their countries of GM crops. The proposed legislation would allow countries to restrict the cultivation of GM crops within their borders for social, economic, ethical and moral reasons; that is, on grounds other than the health and environmental risk assessments of the EU. Should this proposal be legislated into effect, it would eliminate the need for Member States to rely on the safeguard clause or scientific reasons to ban GM crop cultivation. It is not
clear, however, that such legislation would be either consistent with WTO laws or acceptable to the US.

Finally, insofar as political cultures of risk regulation, including their accountability standards, are discursively constructed, they can also be reconstructed. A discursive reconstruction of GMO risks could occur if EFSA is able to persuade critics that its risk assessments meet the accountability standards of a precautionary scientific approach. Social and economic coalitions may also shift their views of plant biotechnology. The rapidly escalating costs of feed to EU poultry, hog and cattle producers in 2007–08 has given some Member States incentives to champion the legitimacy of existing regulations and the role of the Commission and EFSA in the regulatory process. This incentive, and its capacity to lend legitimacy to the EU GMO regulatory regime, however, should not be exaggerated as long as the majority of Europeans continue to see no utility to GM food and to fear the environmental risks of GM crops.

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21 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 UK, the Netherlands, Spain and Portugal.


