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Risk regulation, GMOs, and the challenges to deliberation in EU Governance

Politicization and scientification as co-producing trends

Dr Maria Weimer

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Abstract

This paper analyzes the problems of EU risk regulation of agricultural biotechnology through the lens of deliberative theories of EU law and governance, such as deliberative supranationalism and experimentalist governance. Previous research had suggested that the GMO issue is not conducive to deliberation in both Council of Ministers and comitology because of its high politicisation. This paper argues that another equally salient factor is the scientification of the EU authorization process. Scientification stands for the Commission's overreliance on regulatory science, and therefore on epistemic legitimacy as the sole basis for risk management. Given the deadlock of comitology in this field, scientification is exacerbated by a reversion to top-down regulation by the Commission. As a result, political responsibility for GMO authorisations gets lost. Through an in-depth analysis of both legal rules and institutional practices this contribution reframes the problem of GMO regulation as one of a precarious co-production between scientification and politicisation. It shows that both processes are mutually accelerative ultimately leading to a break down of dialog at EU level. This contradicts the assumption that deliberation is fostered by technocratic 'behind closed door' decision-making. In the GMO case the top-down imposition of epistemic authority has only increased politicization contributing to the de-legitimation of all EU institutions involved in GMO regulation (i.e. European Food Safety Authority, Commission, comitology committees, and Council of Ministers).

Keywords: risk regulation, GMOs, EU governance, deliberation, deliberative supranationalism, experimentalist governance

Introduction

Risk regulation has often been considered as a domain favorable to the occurrence of deliberation, and a promising testing field for deliberative theories in public regulation, especially in the transnational space¹. The underlying assumption is that the scientific and technical questions arising in the regulation of risk-entailing products and technologies, as well as the accompanying scientific uncertainty, are likely to encourage a collective search for truth and for the best policy.² In the EU the networked system of governance in *comitology* and the Council has often been considered as fulfilling the special pre-conditions for successful deliberation.³

Back in 2001 Christian Joerges in an article on the role of science within democratic risk management has re-stated the thesis that "the regulation of transnational markets should be guided by "transnational deliberative *fora*" which would become the basis of legitimate transnational governance; among the three levels of governance – the nation-state, the EU, WTO - the EU comes closest to that ideal."⁴ This defense of deliberative supranationalism⁵ has become the basis for the second dimension of the successor theory of European Conflicts Law Constitutionalism (CLC): namely the claim that European law in general and European transnational governance in particular can be re-interpreted as European *conflicts-law*, because they derive their legitimacy from existent deliberative practices, which are constitutionalized through procedural norms of transnational cooperation.⁶ In a similar vein, other theorists of EU governance have identified the

¹ See P. Dabrowska, 'EU Governance of GMOs: political struggles and experimentalist solutions?' in C. Sabel and J. Zeitlin (eds.), *EU Governance: Towards a New Architecture?* (Oxford: Oxford University Press, 2010); A. Spina, 'European Networks in the Regulation of Biotechnologies' (2010) 35 (2) *European Law Review* 197; S. Murphy, 'Biotechnology and International Law' (2001) 42 *Harvard International Law Journal* 47.

² For a critical view see M. Pollack & G. Shaffer, 'Risk Regulation, GMOs, and the Limits of Deliberation' in D. Naurin & H. Wallace (eds) *The European Union Council of Ministers* (Palgrave MacMillan, 2008).

³ See T. Risse, 'Let's argue!: Communicative Action in World Politics' (2000) 54 (1) *International Organization* 1 at 19-20; C. Joerges and J. Neyer 'From Intergovernmental Bargaining to Deliberative Political Processes: The Constitutionalisation of Comitology,' (1997) 3 *European Law Journal* 273.

⁴ C. Joerges, 'Law, Science, and the Management of Risks to Health at the National, European and International Level – Stories on Baby Dummies, Mad Cows and Hormones in Beef' (2001) 7 *Columb. J. Eur. L.* 1 at 15-16.

⁵ Joerges & Neyer, *Constitutionalisation of Comitology*, supra n. 3.

⁶ See C. Joerges, 'The Idea of a Three-Dimensional Conflicts Law as Constitutional Form,' in C. Joerges & U. Petersmann (eds). *Constitutionalism, Multilevel Trade Governance and Social Regulation* (Oxford; Portland Oregon: Hart Publishing, 2nd ed 2011); and C. Joerges, P. Kjaer

deliberative, self-transformative nature of European regulation as the core of the EU's legal and regulatory architecture. According to Charles Sabel and Jonathan Zeitlin, the EU is a functioning novel polity without a state due to the fact that 'its decision-making is at least in part deliberative: actor's initial preferences are transformed through discussion by the force of the better argument.' The EU has developed a new architecture of experimentalist governance, which reconciles centralized decision-making with local diversity by networking various types of decision-makers.⁷

This chapter looks at European regulation of agricultural biotechnology as a particularly instructive example of both the potential and the limits of deliberation as the legitimation basis for supranational regulation. At the latest since Ulrich Beck's *Risk Society*⁸ it is recognized that regulating technological risks has a strong political dimension, because it raises re-distributional conflicts. In other words, it raises essential political questions as to who should bear the economic, environmental, and social costs (the 'bads' rather than the 'goods') of globalization, economic interdependence, and technological progress. Over the last 20 years, the issue of GMO regulation in the EU has divided not only agricultural land (namely, into GM and non-GM cultivation), but with it also the politics, societies, and even identities in Europe.⁹ Deliberation holds out the promise of legally enabling unity in diversity in European governance via the creation of institutional frameworks within which comprehensive conflict resolutions become conceivable. In other words deliberative transnational *fora* are seen as counteracting purely science-based technocratic governance, because they are able to balance various concerns (e.g. trade, health, environment, socio-economic and ethical factors), thereby managing the political dimension of risk regulation. This paper, however, will show that EU institutions have been failing to do precisely this in the field of agricultural biotechnology. The failure of European risk governance in this field, therefore, presents itself as a

& T. Ralli 'A New Type of Conflicts Law as Constitutional Form in the Postnational Constellation,' (2011) 2 (2) *Transnational Legal Theory* 153.

⁷ C. Sabel and J. Zeitlin (eds), *Experimentalist Governance in the European Union* (Oxford: Oxford University Press 2010) 2. On both similarities and differences between CLC and experimentalist governance see J. Corkin ... in this volume.

⁸ U. Beck, *Risk Society: Towards a new modernity* (London: SAGE, 1992).

⁹ For example regional identities that are either "GMO-free" or not. See <http://www.gmo-free-regions.org/>.

challenge to deliberative theories such as CLC and experimentalist governance. At the same time, it also offers important insights into the pre-conditions of successful deliberation in European decision-making. By analyzing the problems of EU governance of GMOs as well as their causes this chapter seeks to enhance our understanding of the scope conditions of successful deliberation in transnational governance.

I. Re-framing the problem of GMO regulation: politicization and scientification as co-producing trends

Since the establishment of the first EU harmonizing measures for the cultivation of GMOs back in the 1990s this area has developed from a low-profile technical into a political issue of high salience on the EU agenda. The authorization of genetically modified organisms (GMOs)¹⁰ as food, feed and agricultural products in the EU continues to be one of the most gridlocked policy fields on the Union's agenda despite continuous reform efforts. "... a political agreement on the GMO dossier is not possible" concluded the Danish EU presidency in 2012 referring to its failed attempt to push forward the adoption of new legal rules on the agricultural cultivation of GMOs in the EU.¹¹ The proposed reform aims to grant the Member States more freedom to restrict or ban GMO cultivation on their territories,¹² and thereby to resolve the yearlong stalemate in the EU authorization of GMO crops.¹³ Over the last 20 years the controversy¹⁴ surrounding this policy area has divided the EU not only politically, but also geographically. At the moment there are over

¹⁰ Article 2 of Directive 2001/18 defines GMO as 'organism(s), with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.'

¹¹ The Council of the European Union (2012), *Progress report from the Danish presidency*, Interinstitutional File 2010/0208 (COD), 6.

¹² See See Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, COM (2010) 375 final from 13.7.2010; see M. Weimer (2010) 'What price flexibility? - The recent Commission proposal to allow for national "opt-outs" on GMO cultivation under the Deliberate Release Directive and the comitology reform post-Lisbon' (4/2010) *European Journal of Risk Regulation*, 347.

¹³ Since the introduction of new GMO rules in 2001-2003 only one GMO has been authorized for cultivation. This product was the 'Amflora' potato, which following a recent judgment of the EU General Court is no longer authorized; see General Court judgment in Case T-240/10 of 13 December 2013.

¹⁴ See for an overview M. Lee, 'EU Regulation of GMOs: Law and Decision Making for a New Technology' (Cheltenham/Northampton: Edward Elgar 2008), 19.

hundred voluntary 'GMO-free regions' in the EU.¹⁵ Preferences (and as their basis beliefs, risk perceptions and socio-economic interests) with regard to GMO cultivation differ greatly among the Member States. Moreover, several *Eurobarometer* surveys have indicated that a majority of European citizens opposes the use of GMOs as food and in agriculture.¹⁶ All these factors make EU agreement on common authorizations difficult, if not impossible, as evidenced by the yearlong deadlock in both *comitology* and the Council of Ministers.

Conflicts (i.e. legal and political disagreement) are perpetuated in the post-authorization phase. Several MS have banned GMO cultivation on their territory in response to strong anti-GM movements at home. While the Commission considers these bans to be unlawful it is powerless to lift them against a qualified majority of national representatives in the Council and *comitology*. The only issue MS were able to agree upon over the past decade (since the enactment of the reformed GMO framework in 2001-2003) was that the Commission should not be entitled to lift national GMO bans against the will of the Member States, and their citizens.¹⁷ This is a profound contestation of the Commission's authority to decide on GMO cultivation for the Union as a whole.

All this seems to suggest that the high politicization of decision-making on GMO cultivation is the main factor preventing successful deliberation in Council and *comitology*. Mark Pollack and Greg Shaffer, indeed, have argued that the GMO issue is not conducive to the sort of deliberative decision-making in the *comitology* process advocated by Joerges due to the intense politicization of the issue in public opinion. According to them, politicization

'... has severely limited the ability of member-state representatives to engage in the sort of deliberative search for better policy depicted in the Habermasian literature. In this sense, our analysis lends further support to the view that transparency and politicization *decrease* the prospect for deliberation in transnational bodies, which appears to function most effectively in closed, *in-camera* settings. If confirmed by other studies, this finding suggests a stark normative trade-off between transparency and openness,

¹⁵ Not counting GMO-free provinces, departments or municipalities. See a map of GMO regions in 2012 at http://www.gmo-free-regions.org/fileadmin/pics/gmo-free-regions/conference_2012/map/EU_map_0912.png.

¹⁶ The last survey indicated 58 % opposing GMOs, see Eurobarometer (2008), *Attitudes of European citizens towards the environment*, at 65.

¹⁷ The Council on several occasions voted with qualified majority against Commission proposals to lift national safeguard measures on GMOs. See M. Weimer, 'Applying Precaution in EU Authorisation of Genetically Modified Products - Challenges and Suggestions for Reform', 16(5) *European Law Journal* (2010), 624.

on the one hand, and deliberative decision-making on the other (last emphasis added).'

While politicization certainly hampers a deliberative problem-oriented type of decision-making, how appropriate is it to draw a causal link from transparency to politicization and, further, to failure of deliberation? Are we in this way not omitting a part of the problem analysis? In this chapter it is submitted that the problems of GMO regulation in the EU are rooted *not only* in the politicization and decisional deadlock within *comitology*. Along with this goes another equally salient dimension of the GMO governance failure: namely the *de-facto* shift from de-centralized to unilateral top-down decision-making combined with the *scientification*¹⁸ of the authorization process.

This other dimension points us to a sort of 'parallel reality' of GMO regulation. The two main EU institutions responsible for GMO authorizations, the European Commission and its expert agency, the European Food Safety Authority (EFSA), continue to approve GMOs. Despite strong opposition from several Member States and the public,¹⁹ under the current legal framework²⁰ the Commission has authorized every GMO application submitted to it following in each case a positive EFSA opinion finding no risks to human or animal health or the environment. Moreover, high-ranking EU officials have publicly taken a pro-GMO stance in an attempt to end what some perceive as a 'GMO psychosis.'²¹ Anne Glover, the chief scientific advisor of Commission President Barroso, has publicly criticized opposition to GMOs on grounds of health protection and environmental safety as lacking robust scientific evidence and declaring the precautionary principle as being no longer relevant with GMO foods or crops.²² Last year, a report of the European Academies Advisory Council, a body representing national science academies in the EU and

¹⁸ The notions of politicisation and scientification, although in a slightly different form, in M. Everson & E. Vos, 'The scientification of politics and the politicisation of science' in *idem* (eds) *Uncertain risks regulated* (Routledge-Cavendish 2009) 1.

¹⁹ See F. Seifert, 'Synchronised national publics as a functional equivalent of an integrated European public. The case of biotechnology' (2006) 10 (8) *European Integration online Papers* (EIoP).

²⁰ See *infra* at II.1..

²¹ See a statement by former Commissioner for Health and Consumer Protection David Byrne in 'Risk versus benefit' European Voice Conference 'Farm to Fork', SPEECH/01/565, Brussels, 22 November 2001.

²² See interview with EurActiv, *EU science advisor: 'Lots of policies are not based on evidence'*, 24 July 2012, available at <http://www.euractiv.com/innovation-enterprise/chief-scientific-adviser-policy-p-interview-514074>.

seeing itself as the 'collective voice of European science',²³ has called European countries to rethink their rejection of the technology. Using strong terms, the Advisory Council warned of the 'grave scientific, economic and social consequences of current EU policy towards GM crops' including disadvantages for the Union's global competitiveness in agricultural research and innovation. It also criticized claims of adverse effects as based on 'contested science.'²⁴ Hence, this parallel reality is one in which regulatory science²⁵ plays a crucial role constituting a powerful basis for Commission decisions on GMOs.

It follows that Pollack and Shaffer's analysis does not consider the arguably very important role, which top-down decision-making combined with scientification plays in contributing to the increased politicization of GMO regulation. In fact, the EU experience with GMO authorization over the last 20 years is strongly marked by the clash between these two above-described trends, namely between politicization on the one hand and scientification on the other hand. Until today no settled view exists on how to define the actual problem with regulating GMOs. While some blame the polarized public debate calling for more science-based regulation, others see the over-reliance on science as the root of the problem. To understand the problems of GMO regulation in Europe (and importantly also to draw lessons for other fields of risk regulation) it is, therefore, of crucial importance to analyze the interconnection between both politicization and scientification as dynamic processes. In other words, we need to analyze the ways in which both processes are interrelated, and are potentially co-producing²⁶ each other. The following sections begin to address this task by analyzing the dynamics of GMO regulation between legislative ideals and institutional practices (II.). A subsequent section (III.) considers the potential of the 2010 reform proposal to re-nationalize GMO cultivation to offer an escape route out of the regulatory stalemate. The chapter concludes with some final remarks (IV.) on the promise of deliberation in European risk governance.

²³ See <http://www.easac.eu/about-easac/what-is-easac.html>.

²⁴ <http://www.euractiv.com/science-policy-making/chief-eu-scientist-backs-damning-news-530693>.

²⁵ For an explanation of the term S. Jasanoff, *The Fifth Branch: Science Advisers as Policymakers* (Cambridge, MA: Harvard University Press, 1990).

²⁶ The notion is being adapted from S. Jasanoff (ed), *States of Knowledge, The co-production of science and social order* (London: Routledge, 2004), 1.

II. GMO regulation between legislative rules and administrative practices

The current EU legal framework for GMOs²⁷ underwent significant reform in the years 2001 to 2003 as part of a wider overhaul of the Union's food safety regime in the aftermath of the BSE crisis.²⁸ The current rules, firstly, respond to the institutional failures²⁹ of EU food safety regulation uncovered by the BSE and other food safety crises, which occurred during the 1990s.³⁰ Secondly, reforming the authorization procedure for GMOs was an essential pre-condition to ending the then EU *de-facto* moratorium on the authorization of GMOs,³¹ and thereby the transatlantic conflict over GMO trade.³²

Since its establishment in the academic literature the legal framework has been assessed as a promising example of precautionary transnational governance³³ for its effort to reconcile two potentially conflicting notions of legitimacy, namely the scientific and the political legitimacy of GMO authorizations. Mindful of the disastrous experiences with relying on scientific advice during the BSE crisis, the EU legislator based the new GMO rules on the precautionary principle,³⁴ which requires

²⁷ It covers the import, export, and production of GMOs; their deliberate release into the environment for both marketing and other purposes; labeling and traceability of GMOs; and their placing on the market as food and feed products. The main legal acts are Directive 2001/18 on the deliberate release into the environment of genetically modified organisms, OJ 2001 L 106/1; Regulation 1829/2003 on genetically modified food and feed, OJ 2003, L 268/1 and 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms, OJ 2003, L 268/24; see also see T. Christoforou, 'The Regulation of Genetically Modified Organisms in the European Union: The Interplay of Science, Law and Politics', (2004) 41 Common Market Law Review 637.

²⁸ See E. Vos, 'EU Food Safety Regulation in the Aftermath of the BSE Crisis' (2000) 23 Journal of Consumer Policy 227.

²⁹ See Report of the Temporary Committee of Enquiry of the European Parliament on alleged contraventions or maladministration in the implementation of Community law in relation to BSE (Medina Ortega Report) PE 220.544/fin/A.III.

³⁰ E. Vos, 'EU Food Safety Regulation in the Aftermath of the BSE Crisis' (2000) 23 Journal of Consumer Policy 227.

³¹ The *de-facto* moratorium lasted between 1998 and 2004, see M. Lee, 'EU Regulation of GMOs: Law and Decision Making for a New Technology' (Cheltenham/Northampton: Edward Elgar 2008), 2.

³² See M. Pollack and G. Shaffer, *When Cooperation Fails: the International Law and Politics of Genetically Modified Foods* (Oxford; New York: Oxford University Press, 2009).

³³ See Lee, EU regulation of GMOs, *supra* n. 14; Dabrowska, 'EU governance of GMOs' *supra* n. 1; D. Chalmers, 'Risk, Anxiety and the European Mediation of the Politics of Life,' *European Law Review* 30, no. 5 (2005): 649.

³⁴ See M. Weimer, 'Applying Precaution in EU Authorisation of Genetically Modified Products - Challenges and Suggestions for Reform', 16(5) *European Law Journal* (2010), 624; see also Communication from the Commission on the Precautionary Principle COM (2000) 1.

justifying authorization decisions along two different trajectories.³⁵ On the one hand, authorizations have to be based on a scientific risk assessment, and thus follow a scientific rationality. On the other hand, the Commission adopts the final decision in cooperation with national representatives according to the *comitology* procedure. It is not bound by EFSA's risk assessment, but has to take into consideration both possible scientific uncertainties and other legitimate factors.³⁶ Risk management, therefore, is essentially a political process aiming at mediating scientific and non-scientific (e.g. consumer-related, socio-economic, ethical or cultural) aspects of GMO cultivation.

As this chapter will show, however, the implementation practice of GMO authorization in the EU is far from realizing this ideal. The reality of GMO regulation is instead characterized by the failure on the part of the participating institutions to achieve a balanced and cooperative decision-making able to reconcile scientific and political legitimacy. Instead, regulation is caught in-between two conflicting trends, namely that of scientification of the Commission's risk management, on the one hand, and that of politicization and resulting deadlock of comitology decision-making, on the other hand (see below at 2.).

1. The legal framework: cooperative problem solving and precautionary risk governance

The 2001-2003 EU legal framework seems to recognize the complexity both in societal and in scientific terms of decision-making on GMO authorizations.³⁷ It responds with a procedural solution, which aimed at structuring the process of authorization as a cooperative effort of various actors through which both the scientific and political legitimacy of GMO regulation ought to be reconciled. The matrix of the new legislative design for GMO authorization is de-centralized administrative cooperation.³⁸ As noted in the literature, it constitutes 'a transnational governance regime which cuts across national/supranational and public/private

³⁵ See M. Weimer, 'Legitimacy through precaution in European regulation of GMO? From the standpoint of Governance as Analytical Perspective' in C. Joerges and P. Kjaer (eds) *Transnational Standards of Social Protection* (Oslo, RECON Report No 4, 2008) 159.

³⁶ See e.g. Article 7 of Regulation 1829/2003.

³⁷ As a reaction to previous protests and GMO opposition, see L. Levidow, S. Carr & D. Wield, 'Genetically modified crops in the European Union: regulatory conflicts as precautionary opportunities,' (2000) 3 (3) *Journal of Risk Research*, 189.

³⁸ On administrative cooperation see E. Schmidt-Assmann, *Der europäische Verwaltungsverbund Formen und Verfahren der Verwaltungszusammenarbeit in der EU* (Tübingen: Mohr Siebeck, 2005).

distinctions, and which both guides and is accountable to scientific communities, national food authorities and civic society.’³⁹ Shared responsibility and, in fact, shared authority for GMO authorizations is therefore a key feature of this regulatory regime.⁴⁰

The legal framework, however, does contain some important features of centralized top-down regulation.⁴¹ Firstly, it almost totally harmonizes national provisions concerning GMO commercialization both as food and as plants for agricultural cultivation.⁴² Moreover, the legislation has introduced the principle of prior-authorization for all GMO products on the EU market requiring every GMO to undergo an individual safety assessment before it can be placed on the market.⁴³ In this administrative process of prior-authorization, the Commission has been granted the exceptional competence of direct implementation (Article 291 (2) TFEU) of GMO rules.⁴⁴ It, therefore, acts as the central EU administrative authority adopting (following *comitology*) legally binding decisions directly vis-à-vis private companies applying for authorisation.⁴⁵ At the same time, however, the private applicant (i.e. a biotech company wanting to market a GM product) has been granted an active co-regulatory⁴⁶ role within the authorization procedure. This is due to the shift of the burden of proof⁴⁷ for the safety of the GMO product to be authorized to the applicant. Seen as an expression of the precautionary principle, the reversed burden of proof entails that, not the regulatory authority (i.e. the Commission) has to

³⁹ D. Chalmers, “‘Food for Thought’: Reconciling European Risks and Traditional Ways of Life,” *Modern Law Review* 66, no. 4 (2003): 538.

⁴⁰ For a more detailed analysis see M. Weimer, *Democratic Legitimacy through European Conflicts-Law? The case of EU administrative governance of GMOs* (PhD thesis, EUI: Florence, 2012).

⁴¹ On the hybrid nature of GMO regulation from the governance perspective see Dabrowska, *EU governance of GMOs*, supra n. 1.

⁴² In the case of Regulations 1829/2003 and 1831/2003 there is exhaustive harmonization, since both regulate all aspects of the placing of GM food on the market. See Christoforou, ‘The regulation of GMOs’, supra 31.

⁴³ See Article 4 (2) Regulation 1829/2003 and Articles 6 and 13 of Directive 2001/18.

⁴⁴ As a rule, implementing powers lie with the Member States, see Article 291 (1) TFEU.

⁴⁵ On the differences between the procedures under Regulation 1829/2003 and Directive 2001/18 see Christoforou, ‘The regulation of GMOs’, supra 31.

⁴⁶ See F. Fleurke & H. Somsen, ‘Precautionary Regulation of Chemical Risk: How REACH Confronts the Regulatory Challenges of Scale, Uncertainty, Complexity and Innovation,’ (2011) 48 *Common Market Law Review* 357 who describe similar arrangements under the REACH legal framework.

⁴⁷ Article 4 (3) of Regulation 1829/2003. Directive 2001/18 does not contain a similar explicit provision on the burden of proof, but the shift of burden follows from a combined reading of Dir 2001/18, Arts 4(2) and 13.

demonstrate the existence of risks, but the applicant, as the risk producer, has to demonstrate the safety of its product adequately and sufficiently.⁴⁸

At the same time, a remarkable feature of the GMO framework is the mitigation of these top-down and command-and-control elements by both the legal indeterminacy of the substantive safety requirements for GMO products and the strong proceduralization of the authorization process. In other words, the legal provisions lay down a dense procedural and institutional framework for GMO authorisation whereas substantive requirements for authorisation are rather indeterminate, and need further definition and concretization in the process of administrative implementation. Notions, such as that GMOs should not have 'adverse effects on human health and the environment' or not be 'nutritionally disadvantageous' are highly technical and require scientific expertise. To decide whether a product fulfils them, and has, therefore, to be authorised, pre-supposes a set of prior decisions and activities, such as the generation of knowledge about the possible effects of GMOs, of conventions about when these effects will be considered as adverse, etc. In this way the Commission, as the final administrative authority, is granted a wide epistemic discretion when authorizing GMOs, which means that it is left to the Commission, together with its expert agency, to determine how the requirement of GMO safety should best be measured or realized.⁴⁹ In other words, the concretisation of the substantial safety requirements laid down in the legislative rules is being 'outsourced' to the administrative process of rule implementation with EFSA's regulatory scientists playing a crucial role in this process (see below 2.1.).

In order to compensate for their loss of ex-ante substantive control, the EU legislator has provided for a dense procedural framework to 'orchestrate'⁵⁰ the input of various actors into the authorization process. Two interconnected institutional principles were crucial in shaping this framework. On the one hand, the legal

⁴⁸ Therefore also carrying the financial and personal burden of proving safety. In practice, however, this gives the applicant strong de-facto influence over the safety assessment process. See analysis in M. Weimer 'Democratic Legitimacy through European Conflicts-Law? The case of EU administrative governance of GMOs', (Florence, EUI PhD thesis, 2012).

⁴⁹ See P. Craig 'Review, risk, legality and damages' (3/2013) *European Journal of Risk Regulation*, 399 at 402 where, in a case note, Craig describes this as a phenomenon of risk regulation more generally.

⁵⁰ A limited role of the legislator as an organiser or orchestrator has been described as typical for the governance age. See O. Label, (2004) 'The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought,' 89 *Minnesota law review* no. 2 342 and K-H Ladeur, *Das Umweltrecht der Wissensgesellschaft : von der Gefahrenabwehr zum Risikomanagement* (Berlin: Duncker & Humblot, 1995).

framework has been based on the precautionary principle.⁵¹ On the other hand, and as an expression of the latter,⁵² the GMO authorization procedure is governed by the principle of risk analysis.⁵³ Seen together these principles express the idea that GMO authorization decisions should be able to reconcile two potentially conflicting rationalities: a scientific and a political rationality.⁵⁴ The former underlies the process of risk assessment as an independent, objective and transparent process of scientific evaluation of GMO risks, thereby providing the overall administrative process with cognitive or functional legitimacy.⁵⁵ The latter, in contrast, should govern the process of risk management, which is seen as a process of ‘weighing policy alternatives in consultation with interested parties’, and which not only takes into account the outcome of risk assessment, but also other non-scientific legitimate factors,⁵⁶ as well as the precautionary principles and scientific uncertainty.⁵⁷ Political rationality can therefore be seen as securing both the normative and democratic legitimacy of GMO authorisations in the EU.⁵⁸

⁵¹ See Article 1 and recital 8 of Directive 2001/18 and Article 1 of Regulation 1829/2003 together with Article 7 of Regulation 178/2003; see also M. Weimer, *Applying Precaution* supra n. 28.

⁵² The Commission Communication on the Precautionary Principle describes the so-called structured approach to risk analysis as an expression of the precautionary principle in the EU, see COM (2000) 1.

⁵³ By virtue of Article 1 Regulation 1829/2003 that refers to Article 3(10) and Article 6 of Regulation 178/2003.

⁵⁴ See also T. Christoforou, ‘The Precautionary Principle and Democratizing Expertise: A European Legal Perspective’, (2003) 30(3) *Science and Public Policy* 205. In the Pfizer case, Case T-13/99, *Pfizer Animal Health SA v Council* [2002] ECR II-3305 the EU General Court has confirmed this interpretation of the precautionary principle stating that the latter is based on the idea that scientific legitimacy is not sufficient to underpin regulatory decisions on risk, but must be complemented by a political legitimacy provided for by the risk manager who is democratically accountable and has the discretion to take into consideration other factors than the results of the scientific risk assessment.

⁵⁵ See J. Black, ‘Constructing and contesting legitimacy and accountability in polycentric regulatory regimes’ (2008) 2 *Regulation & Governance*, 137 at 146: ‘functional legitimacy claims focus on the outcomes and consequences of the organization (for example efficiency, expertise or effectiveness) and the extent to which it operates in conformance with professional or scientific norms.’

⁵⁶ Following Preamble 19 of Regulation 178/2003 laying down the general principles and requirements of food law and establishing the European Food Safety Authority such factors can include societal, economic, traditional, ethical, and environmental factors and the feasibility of controls.

⁵⁷ See Article 6 (2) & (3) of Regulation 178/2003. And Article 3 (12) of Regulation 178/2003 defining risk management.

⁵⁸ According to Black, ‘Legitimacy and accountability,’ supra n. 56, regulators often aim at satisfying various legitimacy claims. Normative legitimacy is achieved when the goals and/or procedures of a regulatory activity are perceived as morally appropriate, at 144.

In institutional terms, while the Commission acts as risk manager of GMO authorizations, EFSA, a quasi-regulatory EU agency, is the risk assessor. At the same time, both actors have been embedded in a de-centralised transnational network, which essentially aims at involving other actors in the decision-making thereby preventing unilateral action of the EU institutions. On the one hand, before authorizing GMOs the Commission is obliged to follow the *comitology* examination procedure (former regulatory committee procedure). Ideally, the involvement of a *comitology* committee representing the Member States should compensate for the loss of national regulatory competences by serving as a forum for them to express their concerns, and to raise arguments about, for example, socio-economic or long-term environmental impact of GMO commercialisation on their national economies, agricultures, biodiversity, etc.⁵⁹ The new *comitology* rules adopted in 2010 explicitly stress the deliberative element of this administrative process.⁶⁰ On the other hand, EFSA has been designed not as superior to national scientific authorities, but as a networked agency that promotes networking and scientific co-operation between national authorities while mediating divergent scientific risk assessments.⁶¹

Another important instance of de-centralised governance within the GMO framework is the management of so-called co-existence measures after an EU authorization has been granted. Co-existence refers to problems of admixture between different agricultural production systems, namely between GM, conventional and organic crops. Because of the diversity of farming conditions across the EU national, regional and local aspects (e.g. small family farms or big agribusiness, different preferences for organic farming etc) are particularly important for co-existence. To ensure that critical geographical, ecological and climatic conditions that affect crop production can be taken into account this area has been explicitly excluded from the scope of EU harmonisation.⁶²

Democratic legitimacy is achieved when the regulatory activity complies with certain models of democratic governance, for example, representative, participatory, or deliberative, at 146.

⁵⁹ Preamble (9) of Regulation 1829/2003 speaks of 'close cooperation between the Commission and the Member States.'

⁶⁰ Article 3 (4) and a corresponding provision in Article 6 (2) of Regulation 182/2011.

⁶¹ See Articles 22 (7), 23, 30 and 36 of Regulation 178/2003. See also See for a similar analysis Vos, "Responding to Catastrophe: Towards a new Architecture for EU Food Safety Regulation?" in C. F. Sabel & J. Zeitlin (eds) *Experimentalist Governance in the European Union* (Oxford; New York: Oxford University Press, 2010).

⁶² Article 26a of Directive 2001/18: "Member States may take appropriate measures to avoid the unintended presence of GMOs in other products."

However, GMO rules have also foreseen that national co-existence measures should be coordinated by the Commission. The Commission shall gather and coordinate information, observe developments and develop guidelines on co-existence. The main instrument used for this purpose so far has been a 'soft' Commission recommendation (hereinafter Co-existence Recommendation).⁶³ Therein the Commission formulated non-binding general principles for the development of national co-existence measures. In order to coordinate national co-existence strategies the Commission established two networks,⁶⁴ within which both national and EU experts are supposed to exchange information, develop best practices and advice on co-existence.

As a consequence, the management of co-existence has been described as proceeding by way of multi-level expert networks, which resemble governance structures characteristic for the European Open Method of Coordination (OMC).⁶⁵ National and regional diversity was declared an important value, and top-down control through EU harmonisation and centralisation of authority was to be avoided. Arguably, this could be seen as an attempt to ensure diversity of solutions and national autonomy in this area while at the same time enabling regulatory convergence.

Overall, the 2001-2003 GMO legal framework has been evaluated positively in the academic literature. Patrycja Dabrowska has emphasized the framework's institutional capacities to induce deliberation among various supranational and local actors, thereby enhancing the potential for mutual learning and democratic experimentation both within the authorisation process and thereafter.⁶⁶ Damian Chalmers has seen in the transnational structure of the new framework the potential

⁶³ Commission Recommendation 2003/556 on Guidelines for the Development of National Co-existence Strategies and Best Practices, which has been replaced by Commission Recommendation 2010/C 200 on Guidelines for the Development of National Co-existence Measures.

⁶⁴ The Network Group for the Exchange and Coordination of Information concerning Co-existence of Genetically Modified, Conventional and Organic Crops (COEX-NET), see Commission Decision 2005/463/EC, OJ 2005 L 164/50; and the European Co-existence Bureau (ECoB), see See Mandate for a European Co-existence Bureau published at <http://ecob.jrc.ec.europa.eu/documents.html> (accessed 8 June 2011).

⁶⁵ Dabrowska, 'EU governance of GMOs' supra n. 1. A critical appraisal in Thijs Etty, "Regulating Coexistence in the EU: Moving beyond 'Subsidiarity vs Harmonisation' towards Synergetic Governance," in (presented at the 4th International Conference on Coexistence between Genetically Modified (GM) and non-GM based Agricultural Supply Chains (GMCC'09), Melbourne, Australia, 2009).

⁶⁶ See Dabrowska, 'EU Governance of GMOs' supra n. 1.

for mediation between two conflicting logics of political action in the EU; namely between the politics of hazard, which embrace uncertainty in order to realise new public goods and the politics of anxiety, which rejects uncertainty to protect the vulnerability, status and singularity of the individual subject.⁶⁷ Maria Lee, in one of the most comprehensive scholarly analyses of EU regulation of GMOs at present, concludes

‘The organisation of the legislation attempts to tread a delicate path between national and central authorities and between reaping the benefits and protecting public interests, as well as between scientific and political understandings of GMOs. The sensitivity of the balance is emphasised by the uncertainty that pervades our understanding of effects in this area, not to mention public awareness of that uncertainty.’⁶⁸

2. The practice of GMO regulation: subversion of precautionary risk governance by technocratic rule?

The idea of a cooperative and de-centralised management of GMO risks, which seems to have guided the legislative design, is far from being realized in the current practice of GMO regulation. The reality of GMO regulation is instead characterized by the failure of the legal structures described in the previous section to achieve a balanced deliberative decision-making able to reconcile scientific and political legitimacy. Instead, the institutional practice is caught in-between the scientification of the Commission’s risk management on the one hand, and the politicization of comitology decision-making on the other hand. Moreover, the following analysis shows problematic shifts of authority, which go beyond the system of shared responsibility envisaged by the EU legislator. Instead of administrative cooperation between national and supranational actors in the risk management phase, top-down decision-making by the Commission dominates the process.

⁶⁷ See Chalmers, *Risk and Anxiety*, supra n. 27, at 669.

⁶⁸ Lee, *EU regulation of GMOs*, supra n. 14 at 102. See for a more critical view with regarding to the practice of GMO authorization M. Lee, ‘Multi-level Governance of Genetically Modified Organisms in the European Un-ion: Ambiguity and Hierarchy,’ in Bodiguel, Luc and Cardwell, Michael (eds) *The regulation of genetically modified organisms : comparative approaches*, (New York, N.Y.: Oxford University Press, 2010).

2.1 EFSA as an uncertainty intolerant epistemic authority of GMO authorizations?

Since EFSA's establishment cooperation with national scientific authorities on GMO risk assessments has been hampered by lack of trust and conflicting views over GMO safety. An external evaluation report from 2011 on the EU legislative framework in the field of GMO cultivation (EPEC report)⁶⁹ has found the need to improve communication and dialogue between EFSA and the Member State authorities thereby increasing the rate of learning in the system.⁷⁰ A majority of national authorities perceive that EFSA's risk assessments do not sufficiently consider their comments, in particular with regard to the diversity of agro-ecological environments and non-target species within Europe.⁷¹ Some Member State authorities noted that they have submitted the same comments on several applications because their concerns were not sufficiently addressed the first time.⁷² A particular problem is that most applications for cultivation are now being submitted via the Regulation 1829/2003, which means that applications are being sent to EFSA directly bypassing the national evaluation stage. 'A key difference between Directive 2001/18 and Regulation 1829/2003, from Member States' point of view is that the Regulation provides fewer opportunities to engage in the risk assessment process. This adds to the demand for Member State authorities to be provided with better opportunities to comment, and to pressure for comments that are raised to be adequately addressed.'⁷³

Moreover, empirical studies of EFSA's work⁷⁴ indicate that despite the fact that legally EFSA has not been granted a superior authority over national scientific

⁶⁹ European Policy Evaluation Consortium (EPEC), Evaluation of the EU legislative framework in the field of cultivation of GMOs under Directive 2001/18/EC and Regulation (EC) No 1829/2003, and the placing on the market of GMOs as or in products under Directive 2001/18/EC, Final report, March 2011.

⁷⁰ EPEC report, *ibid*, at 75.

⁷¹ *Ibid* at 20 and 74.

⁷² *Ibid* at 24.

⁷³ *Ibid* at 17.

⁷⁴ See M. Van Asselt & E. Vos, 'Wrestling with Uncertain risks: EU Regulation of GMOs and the Uncertainty Paradox' (2008) 11 (1-2) *Journal of Risk Research*, 281 with further references; M. Van Asselt, E. Vos, & B. Rooijackers, 'Science, Knowledge and Uncertainty in EU Risk Regulation,' in E. Vos & M. Everson (eds) *Uncertain Risks Regulated* (Abingdon, Oxon; New York, NY: Routledge-Cavendish, 2009); D. Chalmers, "Risk, Anxiety and the European Mediation of the Politics of Life," *European Law Review* 30, no. 5 (2005): 649; For a view that cooperation problems between EFSA and the Member States are overstated see S. Poli, 'Scientific advice in the GMO area' in A. Alemanno & S. Gabbi (eds), *Foundations of EU Food Law and Policy, Ten Years of the European Food Safety Authority* (Ashgate, 2014), 111.

authorities, in practice it⁷⁵ seems to assert scientific authority by overriding national safety concerns about GMOs during the risk assessment. In this field, it therefore fails to fulfill its legally envisaged function as a mediator between different national risk assessors, and a networked agency.

Marjolein Van Asselt and Ellen Vos have shown that EFSA tends to dismiss risk claims or indications of scientific uncertainty by way of discarding certain arguments as non-scientific, or as not being part of the risk assessment – something scholars of science studies have termed ‘boundary work.’⁷⁶ For example, EFSA used boundary work in order to construct a boundary between risk assessment and risk management, or to reduce the scope of risk assessment by discarding possible uncertainties about the interference of GMOs with the European environment and regular maize crops as non-scientific concerns.⁷⁷ The exclusion of risk management and mitigation issues from the scope of EFSA’s assessment has also been criticized in the 2011 external evaluation report.⁷⁸ By drawing boundaries and dismissing competing claims EFSA manages to construct authority, and to produce authority claims. As Van Asselt and Vos have observed, ‘The GMO Panel often mobilized “the scientific literature,” but without specific references or they just agree with some particular findings or conclusions, without providing further justification. Through this *ex cathedra* style, EFSA presented itself as an authoritative voice.’⁷⁹

There also seems to be little trust between national authorities and EFSA, especially when scientific views differ. Only few bilateral meetings to discuss scientific divergences between EFSA and the Member States⁸⁰ have been held so far. Where they were held, Member States authorities felt that the outcomes of these meetings were not entirely satisfactory due, for example, to lack of sufficient time

⁷⁵ Reference is made to the operation of the EFSA scientific panel responsible for GMO risk assessments. No conclusions are being drawn with regard to EFSA’s operation in other food policy areas.

⁷⁶ Van Asselt and Vos define this term in reference to Thomas F. Gieryn as “a strategic and purposeful act in which boundaries are drawn between realms, for example, between science and non-science and between science and politics. Boundary work involves drawing and maintaining contrasts through selective attributions, which effectively demarcate in order to construct ‘self-evident’ justification and ‘superiority in designated terrains.’” See Van Asselt, Vos, & Rooijackers, ‘Science, Knowledge and Uncertainty’ supra n 75; Van Asselt & Vos, ‘Wrestling with uncertain risks’ supra n 75.

⁷⁷ Van Asselt & Vos, ‘Wrestling with uncertain Risks’ *ibid.*, at 288-289 with further references.

⁷⁸ EPEC report supra n 70 at 74.

⁷⁹ Van Asselt & Vos, ‘Wrestling with uncertain Risks’ supra n. 75, who explain this as a result of EFSA’s so-called “uncertainty intolerance”.

⁸⁰ Pursuant to Article 30 of Regulation 178/2002.

and inadequate preparation.⁸¹ As a DG Sanco official reports, scientific meetings at EFSA between national and EFSA scientists take place within a rather hostile atmosphere.⁸² There also seems to be little incentive for EFSA to strive at more consensus with its national counter-parts. EFSA often rather strives at asserting its own scientific authority in order to convince the Commission to follow its view.⁸³

Moreover, the quality of scientific risk assessment, which constitutes a meta-review by EFSA of the data and analyses provided by the applicant company, has often been strongly criticized by several stakeholders including national authorities, NGOs and independent scientific institutes. In 2008 the European Environmental Council has called upon EFSA to improve its assessment of long-term risks of GMOs, and, for example, to revise its guidelines for environmental risk assessment.⁸⁴ Furthermore, research by Van Asselt and Vos based on the study of several GMO applications⁸⁵ has suggested that EFSA's risk assessment is being characterized by what the authors refer to as the 'uncertainty paradox.' The latter is described as a situation in which scientific uncertainty is acknowledged, in principle, but the role of science is framed as one of providing certainty and definitive answers about the absence or presence of risk despite uncertainty precluding both conclusiveness and definitiveness. This situation, they argue, results from an uncertainty intolerant attitude on the part of EFSA (but also of other relevant actors such as biotech companies and the European Commission). Such attitude is characterized by EFSA's reluctance to acknowledge the existence of uncertainty in its GMO risk assessments, or at least to deem it as relevant, instead of genuinely and systematically investigating it in the practice of GMO safety assessment.⁸⁶

A wind of change in controversial cases of GMO cultivation? The example of Pioneer maize 1507

There are, however, some recent developments in EFSA's GMO risk assessment, which indicate a potential shift towards more uncertainty tolerant

⁸¹ EPEC report supra n. 70 at p. 24.

⁸² Interview with a Commission official from DG Environment on 15 December 2009.

⁸³ See in a similar vein, Lee 'Multi-level governance' supra n. 69 at 111.

⁸⁴ European Council conclusions adopted on 4 December 2008, http://www.consilium.europa.eu/ueDocs/cms_Data/docs/pressData/en/envir/104509.pdf.

⁸⁵ Three cases pertaining to the import of GMOs, namely NK 603, GT73, and MON 863 X MON 810, see Van Asselt & Vos, 'Wrestling with uncertain Risks' supra n. 75 at 283.

⁸⁶ Ibid.

assessment practices.⁸⁷ One case is particularly important in this regard, namely EFSA's series of risk assessments of Pioneer's maize 1507.⁸⁸ This case is particularly controversial, because it represents the first application for cultivation submitted to EFSA since its establishment and under the new 2001-2003 legal framework.⁸⁹

Maize 1507 is an insect-resistant genetically modified maize characterized by the insertion of two genetic constructs: one which produces Cry1F, a protein that makes the maize resistant to certain Lepidoptera (larvae of the European corn borer and of the Mediterranean corn borer), and another which makes the maize tolerant to glufosinate ammonium, an herbicide which use will be phased out in the EU by 2017. Since the initial submission of the application by the company Pioneer in 2001 a total of six scientific opinions have been produced by EFSA throughout the years. Both Member States and independent institutes have raised concerns over potential risks to human health and the environment as well as strong objections as to the quality of EFSA's risk assessment. In its initial risk assessments EFSA remained reluctant to seriously engage with these contesting views on the safety of maize 1507. Likely being aware of the political pressure to provide authoritative scientific advice as the new expert agency EFSA framed its advice in definite terms. It concluded that the cultivation of maize 1507 '*will not have* adverse effects on human health and/or the environment.' (emphasis added)⁹⁰ In its subsequent opinions EFSA held on to this conclusion despite strong criticism and conflicting scientific studies.⁹¹

⁸⁷ See for a similar conclusion with regard to several cases of GMO assessment see Poli, 'Scientific advice' supra n. 75 who, at 130, notes that in the period 2010 and 2012 EFSA started paying closer attention to the interactions between GMO crops and the environment, and made efforts to answer concerns raised by Member States and NGOs.

⁸⁸ The following account is based on a forthcoming empirical study by M. Weimer & G. Pisani (of file with the authors).

⁸⁹ Another similarly controversial case has been the authorization of BASF's 'Amflora' Potato, which for reasons of space cannot be discussed here in detail. For a detailed account see forthcoming publication by M. Weimer & G. Pisani (on file with authors).

⁹⁰ EFSA, 'Opinion of the Scientific Panel on Genetically Modified Organism on a request from the Commission related to the notification (Reference C/ES/01/01) for the placing on the market of insect-tolerant genetically modified maize 1507 for import, feed and industrial processing and cultivation, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/Mycogen Seeds,' Question No EFSA-Q-2004-072, *The EFSA Journal* (2005) 181, 1-33.

⁹¹ See eleven independent scientific studies listed in EFSA (2008), *Scientific Opinion of the Panel on Genetically Modified Organisms on a request from the European Commission to review scientific studies related to the impact on the environment of the cultivation of maize Bt11 and 1507*, *The EFSA Journal* (2008), 851, pp. 6-7.

Moreover, it engaged in boundary work by rejecting to consider the issue of adequacy of the applicant's monitoring plan in relation to potential adverse effects on non-target organisms as beyond outside of the scope of risk assessment.⁹²

Interestingly, however, starting from 2010 EFSA has shown a slight yet meaningful change in its approach by providing a more nuanced answer to the Commission's request, acknowledging the need to improve its methodology, the existence of knowledge gaps as well as potential risks arising from the cultivation of maize 1507. The change followed a Commission request for a new EFSA opinion this time based on scientific questions raised by a new independent study made available to the Commission.⁹³

The study raised a number of objections to the conclusions made by EFSA, from the inadequacy of founding an impact assessment on analogies with other Bt toxins, to the necessity of undertaking further studies on the effects of Cry1F on the environment and biodiversity. Notably, it claimed that maize 1507 produced high concentration of Bt toxin in pollen, and that this evidence would have significantly altered the outcome as to the effects on development of insect resistance and the impact on soil, air and water. The study concluded that, instead of relying on partial information and overlooking the existent uncertainties, EFSA should have requested further data to the applicant in order for its final assessment to be reliable.

At the plenary meeting of October 2010, the GMO Panel for the first time acknowledged the need for improving the methodology used in order to produce a more accurate assessment on non-target organisms. On 18 November 2011 EFSA published a new opinion, which was further updated in February 2012, giving a more nuanced answer to the request of the Commission and acknowledging some potential risks.⁹⁴ Firstly, it estimated that, in spite of what was stated in its previous opinions, the concentration of Cry1F in pollen of maize 1507 was about 350 times the concentration of Cry1Ab in other GMOs, and acknowledged potential risks in the

⁹² EFSA (2006), Annex to the opinions of the Scientific Panel on Genetically Modified Organisms on the insect resistant genetically modified Bt11 and 1507 maize.

⁹³ The study at issue is A. Bauer-Panskus & C. Then, (2010) Testbiotech opinion on the application for market approval of genetically modified maize 1507 (DAS-Ø15Ø7-1), available at www.testbiotech.org/en/node/365 (last accessed 27 January 2014). EFSA makes explicit reference to it in: EFSA (2010), Minutes of the 61st plenary meeting of the scientific panel on genetically modified organisms held on 20 -21 October 2010 in Parma, Italy (p.7).

⁹⁴ EFSA (2012), 'Scientific Opinion updating the evaluation of the environmental risk assessment and risk management recommendations on insect resistant genetically modified maize 1507 for cultivation', EFSA Journal 2011; 9 (11): 2429.

absence of appropriate mitigation measures. However, the Panel did not collect and analyze further data on the concentration of the Bt toxin on other parts of the plant, which would have been relevant, for instance, to the assessment of the impact on soil and water. Then, it identified potential risks in relation to the evolution of resistance to Cry1F in target pests and the toxicity of the protein to sensitive non-target lepidopteran, such as European butterflies. The Panel acknowledged the need for further studies to fill the knowledge gap. Ultimately, however, EFSA still concluded that the risks identified can be minimized or managed through appropriate monitoring and mitigation measures. Therefore, it found maize 1507 ‘*unlikely to raise safety concerns for the environment.*’ (emphasis added)⁹⁵

In two further supplementing opinions, published in October and November 2012,⁹⁶ EFSA reiterated the potential risks in the absence of adequate monitoring and mitigation measures, suggested precautionary measures to protect particular ecosystems and geographical areas, and called Pioneer to amend its post-market environmental monitoring plan accordingly. Importantly, the Panel also acknowledged that existent studies on resistance evolution based on other geographical and factual circumstances might be misleading for a reliable assessment of the impact of Cry1F and that, therefore, further studies would be needed to evaluate the response of the European and Mediterranean corn borer.

This case shows an interesting development in two respects. Firstly, the pressure exerted by national authorities and independent research studies as well as the recurrent referral back to EFSA by the Commission seems to have forced the agency to engage more seriously with competing views and uncertainty information⁹⁷. It moved from providing a definite answer (‘maize 1507 will not have adverse effects’) to a more nuanced answer (if monitoring and mitigation measures are taken maize 1507 is ‘unlikely to raise safety concerns for the environment’) while indicating knowledge gaps and remaining uncertainties in risk assessment. EFSA did not employ the same type of boundary work as before by adopting a holistic approach, which includes the consideration of monitoring and mitigation measures in the risk assessment. Secondly, however, this ultimately did not alter the substantial outcome of EFSA’s risk assessment, namely the finding of safety.

⁹⁵ Ibid, at 1.

⁹⁶ Published on 25 October 2012, EFSA Journal 2012; 10 (11): 2934 and on 9 November 2012, EFSA Journal 2012; 10 (10): 2933.

⁹⁷ On this term Van Asselt & Vos, ‘Wrestling with uncertain Risks’ supra n. 75.

Potential risks and uncertainties arising from the cultivation of maize 1507 were treated as manageable through post-authorisation measures such as monitoring and mitigation.

2.2. Politicization, deadlock and reversion to hierarchy in *comitology*

EFSA's constructed scientific authority has strong *de-facto* influence on the outcome of authorisation decisions taken by the Commission within *comitology*. In the authorisation practice hitherto the Commission ultimately followed every scientific opinion issued by EFSA, all of which were in favor of authorizing the product. In no case did the Commission exercise its discretion to depart from EFSA's advice for example on the basis of socio-economic concerns or with reference to scientific uncertainty and the need for a precautionary approach.⁹⁸ However, in view of the new Commission practice developed over the last couple of years to delay authorisations while referring opinions back to EFSA for an update, it may no longer be adequate to compare the Commission with a blind driver receiving directions from the passenger in the back seat.⁹⁹ The Commission does not follow EFSA blindly, but so far it did always follow EFSA's advice in the end even if with considerable delay. This indicates that the Commission is often, especially in controversial cases of GMO cultivation, paralyzed between EFSA's scientific opinion and national as well as public opposition to GMO cultivation. Above all, it is not able, or does not see itself as being entitled,¹⁰⁰ to exercise political discretion, and to depart from EFSA's advice even where there are indications of scientific uncertainty or strong socio-economic objections. It should be emphasized that from the Commission's point of view, EFSA's epistemic authority seems to be the only legitimate basis for the authorization decision, which ultimately contributes to the loss of *political* responsibility for GMO authorisations in the EU. Importantly, the *comitology* process, due to its malfunctioning in this field, fails to mitigate this problem.

⁹⁸ See e.g. Mihail Kritikos, 'Traditional Risk Analysis and Releases of GMOs into the European Union: Space for Non-Scientific Factors?', (2009) 34 (3) *European Law Review*, 405.

⁹⁹ This metaphor was originally expressed by a Commission official and cited in E. Vos and F. Wendler (2006), *Food Safety Regulation in Europe: A Comparative Institutional Analysis* (Antwerpen: Intersentia, 2006) at 122.

¹⁰⁰ The problem seems to be one of legal entitlement. The legal grounds for authorization under Regulation 1829/2003 (Article 4 (1) & (5)) are framed in narrower terms than its regulatory objectives, and stand in contrast with Article 7 of the Regulation which requires the Commission to take into account 'other legitimate factors'. See on this J. Scott (2004) *European regulation of GMOs: Thinking about judicial review in the WTO*, 57 *Current Legal Problems* 117, at 118-119.

The failure of deliberative decision-making in Council and comitology committees in the GMO field are well researched.¹⁰¹ Since the restarting of authorisations in 2004, the Commission was able to push through all new applications for GMO authorisations despite the lack of approval on the part of the national representatives. The decision-making process in each case was highly politicised and accompanied by strong opposition on the part of the majority of Member States within the comitology procedure. All the Commission draft decisions were referred to the Council (under the old comitology rules) and could be adopted only because of the Qualified Reversed Majority Voting (QRMV) rule in the regulatory procedure.¹⁰² Shaffer and Pollack describe the nature of decision-making across both *comitology* committees and the Council as ‘a record of persistent conflict, bargaining from fixed positions, formal votes on nearly every proposed decision, substantial numbers of abstentions (representing a refusal to take a position) and ultimate deadlock.’¹⁰³ Recent research indicates that this practice continues also under the new *comitology* rules,¹⁰⁴ since the Commission has maintained the right to adopt decisions by default in case the newly established appeals committee fails to deliver an opinion.¹⁰⁵ The political deadlock in the Council is thus being reproduced in the new forum of the appeals committee.

All this leads to the *de-facto* ineffectiveness of the national input into the authorisation process. Instead of shared authority and co-operation the Commission appears as the most powerful institution in the GMO authorization process.¹⁰⁶ Through the by now common practice of adopting the final decision by default following the reversed majority voting rule – a mechanism that originally was created for exceptional cases – the Commission reinstalls top down unilateral

¹⁰¹ M. Pollack and G. Shaffer, ‘Risk regulation, GMOs, and the limits of deliberation’ in D. Naurin and H. Wallace (eds) *The European Union Council of Ministers* (Palgrave MacMillan, 2008); Lee, *EU regulation of GMOs*, supra n. 14; Kritikos, ‘Traditional Risk Analysis’, supra n. 99; S. Borras, ‘Legitimate governance of risk at EU level? The case of genetically modified organisms’ (2006) 73 *Technological Forecasting & Social Change* at 61.

¹⁰² Under QRMV the Commission can adopt the final decision, if there is no qualified majority in the comitology committee or the Council against such decision.

¹⁰³ Pollack & Shaffer ‘Risk regulation’ supra n. 102 at 17.

¹⁰⁴ Regulation (EU) 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission’s exercise of implementing powers, OJ (2011) L 55/13.

¹⁰⁵ See recent empirical study by C. Klika, J. Kim & E. Versluis, ‘Why science cannot tame politics: The new EU comitology rules and centralised authorisation procedure of GMOs’, (3/2013) *European Journal of Risk Regulation*.

¹⁰⁶ This power is of course very contingent as the Commission is not able to enforce compliance with its decisions post-authorisation in several of the Member States.

decision-making vis-à-vis the Member States in this process. The weakness of national representation in comitology is even more precarious as *comitology* networks are not able to effectively mitigate the strong influence of EFSA on the Commission. This, in turn, reinforces the scientification of the authorisation process.

The authorization process for the Pioneer maize 1507 epitomizes these problems. Interestingly, this was the only known case, in which the Commission has attempted to depart from EFSA's opinion, and to reject authorization. In 2007, former Commissioner Dimas presented a draft decision proposing not to approve maize 1507 for cultivation in the EU on the basis of the high degree of scientific uncertainty and the lack of scientific knowledge over significant traits of that GMO. The draft proposal stressed the need for a cautious approach based on the precautionary principle, and indicated that the degree of uncertainty was so high that it was 'not possible to establish appropriate management measures which would effectively mitigate the potential damage on the environment'.¹⁰⁷

However, instead of submitting the proposal to the Regulatory Committee, the Commission again turned to EFSA. As described in the previous section it asked EFSA to review its previous risk assessment in the light of eleven scientific publications. EFSA reaffirmed its previous findings stating that these publications did not provide new information that would change previous environmental risk assessments of maize 1507.¹⁰⁸ Following that the Commission made a U-turn in its position. It drafted a new proposal this time in favour of authorizing maize 1507. The Commission now relied on EFSA's statement that there is no evidence of the adverse effects of maize 1507 on human health and the environment taking over EFSA's suggestion for risk management strategies to minimise potential risks.

¹⁰⁷ The document reported a number of objections raised by MSs concerning the impact on soil organisms and arthropods, the long-term effects of the Bt toxin on the environment, and it also pointed out that, *ex lege*, environmental risk assessments need to consider potential effects on non-target organisms and cumulative long-term effects which, at that time, were not adequately evaluated. Importantly, the Commission seemed to question the reliability of a meta-review of the applicant's assessment, marking the lack of crucial data such as the concentration of Bt toxin, and contesting the methodology used by EFSA in its assessment. See EU Commission (2007), Draft Commission Decision of [...] concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line 1507) genetically modified for resistance to certain lepidopteran pests and for tolerance to the herbicide glufosinate-ammonium. ENV/07/.

¹⁰⁸ EFSA (2008), Scientific Opinion of the Panel on Genetically Modified Organisms on a request from the European Commission to review scientific studies related to the impact on the environment of the cultivation of maize Bt11 and 1507, *The EFSA Journal* (2008), 851, at 21.

The previous doubts and concerns with regard to existent knowledge gaps did no longer appear in the new draft.

The following process of authorization of maize 1507 has been marked by delay, inaction, and ultimately a ruling of the EU General Court in 2013.¹⁰⁹ As usual, in 2009 the *comitology* committee failed to reach a qualified majority either in favour or against the Commission draft proposal. However, the Commission did not continue the procedure by submitting its draft to the Council until November 2013, when it was forced to do so by the finding of the EU General Court that the Commission has breached its procedural obligations, and has failed to act in the sense of Article 265 TFEU.¹¹⁰ In its latest draft the Commission proposed to authorize maize 1507 subject to the implementation of certain post-market surveillance measures, case specific monitoring and instructions to farmers. It justified its proposal on the basis that EFSA did not identify new scientific publications that would have invalidated its previous opinions on the safety of maize 1507.¹¹¹ Most striking about this proposal is the absence of any references¹¹² to the potential risks and uncertainties identified by EFSA in its latest more nuanced opinions (see above). In other words, EFSA's shift towards a more uncertainty tolerant approach was not followed by the Commission, but was instead met with a strikingly uncertainty intolerant response. This contradicts previous findings that the Commission inherits its uncertainty intolerance from EFSA.¹¹³

At the time of writing, the Council decision on maize 1507 was still pending. However, for the first time the European Parliament has actively intervened in the *comitology* procedure.¹¹⁴ In a parliamentary resolution from January 2014, the Parliament calls on the Council to reject the Commission proposal; considers that the Commission proposal exceeds the implementing powers of the Commission

¹⁰⁹ EU General Court, Case T-164/10, Pioneer Hi-Bred International v European Commission, 26 September 2013.

¹¹⁰ Treaty on the Functioning of the European Union. See General Court *ibid.*.

¹¹¹ Commission proposal for a Council decision concerning the placing on the market for cultivation, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line 1507) genetically modified for resistance to certain lepidopteran pests, COM(2013) 758 Final, 6 November 2013

¹¹² With the exception of the potential Bt toxin resistance in corn borers, for which the Commission refers to an EFSA opinion from 2005.

¹¹³ As suggested by Van Asselt & Vos, 'Wrestling with uncertain Risks' *supra* n. 75.

¹¹⁴ Pursuant to Article 8 (1) of Council Decision 1999/468/EC ('old *comitology* rules'). These rules remain applicable to the authorization procedure of maize 1507 because it is a pending procedure in the sense of Article 14 of Regulation 182/2011.

conferred to it under Directive 2001/18; and calls on the Commission not to authorise any new GMO variety and not to renew old ones until the risk assessment methods have been significantly improved.¹¹⁵ The Parliament strongly criticizes the Commission for, *inter alia*, not having considered EFSA's indications of potential risks,¹¹⁶ and for having modified its initial proposal without again consulting the comitology committee. And, it stresses that the General Court's ruling 'does not prevent the Commission from reconsidering its position and presenting a new proposal to the standing committee, (...), recommending that maize 1507 not be authorized.' It follows, therefore, that the European Parliament has emerged as a new political actor in the *comitology* procedure filling the political vacuum created by disagreement and the failure of deliberation in both the *comitology* committee and the Council.

2.3. Soft harmonisation of co-existence rules

A further example where a top-down approach to GMO regulation is being re-introduced through the backdoor, so-to-speak, is the management of co-existence between GM crops and other agricultural crops. As shown above, the exclusion of co-existence from the scope of harmonisation together with the use of a "soft law" instrument and multi-level expert networks under the auspices of the Commission suggest that co-existence was supposed to be managed in a de-centralised way.

However, in the institutional practice of managing co-existence the ideal of multi-level governance did not quite realise. Critical appraisals¹¹⁷ of Commission's activities in this area suggest that its commitment to diversity and national autonomy may be a lip service.

¹¹⁵ European Parliament resolution of 16 January 2014 on the proposal for a Council decision concerning the placing on the market for cultivation, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line 1507) genetically modified for resistance to certain lepidopteran pests (2013/2974 (RSP)).

¹¹⁶ In particular the resolution mentions the risks associated with that GMO's tolerance to the toxic herbicide glufocinate, which is supposed to be phased out in the EU by 2017.

¹¹⁷ See Lee, 'Multi-level governance' supra n. 69; T. Etty, "Regulating Coexistence in the EU: Moving beyond 'Subsidiarity vs Harmonisation' towards Synergetic Governance"; idem "Co-existence - The missing Link in the EU Legislative Framework: Subsidiarity vs Harmonisation on the Final Frontier of the EU Regulatory Regime for Agricultural Biotechnology," (3rd International Conference on GMO free regions, Biodiversity and rural Development, European Parliament, Brussels 2007).

Instead of enabling diversity and mutual learning the Commission has in fact tried, through the backdoor of its “soft” approach to co-existence, to implement its own narrow understanding of appropriate co-existence measures, and in this way to control national policies in this area.

The main problems in this regard are related to the way the Commission frames co-existence in its Co-existence Recommendation.¹¹⁸ It has been observed that this “soft law” instrument is used to define the goals, scope and proportionality of national co-existence measures in a top-down and authoritative way. The Commission advocates a specific approach to co-existence management (namely a farm-level, crop-by-crop approach),¹¹⁹ and outlines measures that it considers as appropriate. Most importantly, it defines co-existence in very narrow terms, namely as a purely economic issue. According to the Commission, since all environmental and health issues are dealt with in the authorization process, and only authorised GMOs can be cultivated in the EU, co-existence only covers the economic aspects associated with the admixture of GM and non-GM crops.¹²⁰ However, such a narrow framing of co-existence is highly contested.¹²¹ It is being argued that especially ecological concerns, but also health and other socio-economic concerns continue to be relevant after authorisation.

Despite of its “soft” nature the Co-existence Recommendation seems to be highly influential in shaping national strategies, also because it is being used in a legal context strongly shaped by the constraints of EU internal market law; and by an institution, which plays a vital role in guarding the compliance with these legal obligations.¹²² A further disciplining effect of the Recommendation results from the relevance of co-existence measures in the framework of the so-called Technical Regulations Information System (TRIS) established under Directive 98/34/EC.¹²³ Co-

¹¹⁸ See Commission Recommendation on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops, OJ 2010 C 200/1.

¹¹⁹ The new Co-existence Recommendation did not significantly change this, although it grants more flexibility in creating GMO-free regions. See for a detailed analysis J. Varela, “The New Strategy on Coexistence in the 2010 European Commission Recommendation,” *European Journal of Risk Regulation* 1, no. 4 (2010): 353-358.

¹²⁰ See Commission Recommendation on Co-existence, supra n. 129, Annex 1.2..

¹²¹ See Lee, ‘Multi-level governance’ supra n. 69; Ety, ‘Regulating Coexistence’, supra n. 119.

¹²² See Ety, *ibid.*

¹²³ Of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services, OJ (1998), L24/37.

existence measures are technical regulations concerning products in the sense of this Directive, and thus have the potential to distort the internal market. Consequently, they need to be notified in draft form to the Commission and the other Member States before being adopted into national law. Measures that have not been duly notified cannot be enforced or invoked before the national courts. When assessing national co-existence measures in the TRIS framework the Commission refers to its own understanding of the proportionality and legality of national co-existence measures as defined in the Co-existence Recommendation. An example in this regard is the Commission's practice to object to national draft measures that apply purity standards for non-GM products stricter than the legal labelling threshold for GMOs (namely 0,9 %). As Thijs Etty observes, by doing so the Commission achieves a re-interpretation of the labelling threshold for GMOs, which is supposed to be a maximum tolerable adventitious impurity standard, as a minimum threshold for national regulatory intervention on co-existence.¹²⁴

The unilateral top-down definition of the goals and principles of co-existence in the Commission Recommendation, and the authoritative use of this instrument in the co-existence networks as well as within the TRIS framework demonstrate the trend toward top-down regulation in the management of co-existence. The Commission practice makes the Recommendation a type of "steering soft law," which has a strong normative, and even comes close to a binding effect. Maria Lee describes the governance arrangements of co-existence in the following terms:

'At the time of the moratorium, the European Commission had resisted legislating on coexistence, preventing harmonization. But now, paradoxically, it seems to be busy 're-Europeanizing' the whole area, asserting its own authority in a heavy-handed manner. The indirect control that the European Commission exercises now, however, is more autonomous than anything that it might have achieved through legislation. Unfortunately, it has left us with a framework that is obscure, both in its forum and in its technical, highly legalistic approach to a complex and subtle area. More generally, the role of the internal market tends to centralize authority on GMOs after authorization.'¹²⁵

¹²⁴ See Etty *supra* n. 119.

¹²⁵ Lee, 'Multi-level governance' *supra* n. 69 at 120-121.

III. Seeking escape routes – the Commission proposal on national ‘opt-outs’ for GMO cultivation

In response to the protracted problems of GMO regulation described above, especially to the national resistance to EU authorizations, in July 2010 the European Commission presented a reform proposal for the GMO legal framework. It adopted a legislative proposal¹²⁶ to amend Directive 2001/18 on the deliberate release of GMOs into the environment in order to grant member states more freedom to restrict or ban the cultivation of GMOs on their territory. The new “recipe” of the Commission is flexibility and subsidiarity,¹²⁷ and it represents a substantial policy turn as compared to Commission policy towards national restrictions of GMO cultivation up until today.

The proposal aims at introducing a new Article 26b¹²⁸ of the Directive containing an ‘opt-out’ clause, which under certain conditions would allow a member state to restrict or prohibit the cultivation of GMOs previously authorized for cultivation at EU level in all or part of its territory. The aim of this proposal according to the Commission is to grant member states more flexibility to decide on GMO cultivation after it has been authorized at EU level, and, thereby, “to address specific national or local aspects raised by the cultivation of GMOs.”¹²⁹ In return, the Commission hopes for a facilitation of and more clarity in decision-making in future authorisation procedures at EU level.

¹²⁶ See Proposal for a Regulation of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, COM (2010) 375 final from 13.7.2010, The proposal is currently awaiting the 1st reading in the Council as part of the ordinary legislative procedure (former co-decision) according to Art. 294 TFEU; see for comments ‘Symposium on the EU’s GMO Reform’ in (4/2010) *European Journal of Risk Regulation*, 339.

¹²⁷ See Commission proposal, *ibid.*, p. 3, 8, 11.

¹²⁸ It states: ‘Member States may adopt measures restricting or prohibiting the cultivation of all or particular GMOs authorised in accordance with Part C of this Directive or Regulation (EC) No 1829/2003, and consisting of genetically modified varieties placed on the market in accordance with relevant EU legislation on the marketing of seed and plant propagating material, in all or part of their territory, provided that:

(a) those measures are based on grounds other than those related to the assessment of the adverse effect on health and environment which might arise from the deliberate release or the placing on the market of GMOs; and,

(b) that they are in conformity with the Treaties.

By way of derogation to Directive 98/34/EC, Member States that intend to adopt reasoned measures under this Article shall communicate them to the other Member States and to the Commission, one month prior to their adoption for information purposes.”

¹²⁹ Commission proposal, *supra* n. 128 at 3 and 6.

The Commission based this legislative amendment on the internal market competence of Article 114 TFEU.¹³⁰ In the explanatory memorandum the Commission also refers to Article 2 TFEU – a new provision introduced by the Lisbon Treaty – concerning the categories and areas of Union competence.¹³¹ Article 2 (2), third sentence, provides that in the case of a shared competence between the Union and the member states, the latter “*shall again exercise their competence to the extent that the Union has decided to cease exercising its competence.*” In its proposal the Commission explicitly states to be acting in accordance with Article 2 (2) TFEU, and especially sentence three thereof,¹³² which indicates that the Commission considers the amendment as a retreat from a competence area previously occupied by the Union, and therefore a roll back of EU harmonization with regard to GMO cultivation.¹³³

Article 26b stipulates mainly two substantial conditions¹³⁴ for the lawful adoption of restrictive “opt-out” measures by a member state.¹³⁵ Firstly, the national measure must be based on grounds other than those covered by the environmental and health risk assessment carried out in the EU authorisation process. This is likely to refer to the socio-economic aspects of GMO cultivation.¹³⁶ It also indicates that the

¹³⁰ This might seem unusual seeing that the measure does not aim at approximating national provisions on GMO cultivation, but rather at granting more freedom to the Member States to opt out from a harmonised framework for EU authorisations on GMO cultivation. See critical discussion in S. Poli, ‘The Member States’ long and winding road to partial regulatory autonomy in cultivating genetically modified crops in the EU’ (2/2013) *European Journal of Risk Regulation*, 143.

¹³¹ Commission proposal, *supra* n. 128 at 11.

¹³² *ibid* at 8 and 11.

¹³³ For an explanation of why the Commission decided to make that proposal see paper refereed for JCMS...

¹³⁴ A further procedural requirement for the application of this “opt-out” clause would be the notification of the planned national measure to the other member states and the Commission one month prior to its adoption. In addition, the formulation “reasoned measures” in the last paragraph of the clause indicates a reason-giving requirement for the member state.

¹³⁵ Note that this provision does not as such provide the freedom to regulate GMO cultivation at national rather than at EU level. The EU authorisation procedures as set out in the Deliberate Release Directive as regards cultivation of GM crops and in the Regulation 1829/2003 as regards cultivation of GMOs to be marketed in or as food are, at least formally, not affected by this amendment. Another implied condition for recourse to Article 26b, therefore, would be that the GMO in question has already been authorized at EU level in accordance with the Deliberate Release Directive or Regulation 1829/2003. Otherwise, of course, the free circulation of the GMO on the EU market would be unlawful as such due to the general prior-authorisation requirement for all GMOs to be marketed in the EU.

¹³⁶ See European, Commission, Report from the Commission to the European Parliament and the Council on socio-economic implications of GMO cultivation on the basis of member

purpose of creating Article 26b in addition to the already existent provision concerning the right of the Member States to adopt co-existence measures is to provide for a further, more extensive option for member states to deviate from EU authorisations on GMO cultivation on non-scientific grounds. Secondly, the national measure must be in conformity with the general law of the EU Treaties.¹³⁷

The Commission proposal is arguably the first genuine attempt to accommodate the diversity of national preferences towards GMOs in the Union. It is certainly a compromise ultimately aiming to remedy the impasse in *comitology*, thereby saving the EU authorization procedure including EFSA's central position within it. Rolling back EU harmonization has never happened before in the history of EU integration, and it was, of course, not the Commission's idea alone.¹³⁸ This makes it an astonishing process, while at the same time demonstrating the weakness of the Commission's political authority to decide on GMO cultivation for the Union as a whole. The proposal seems to acknowledge that a EU authorisation regime, which is enforced against the opposition of a majority of Member States, is not sustainable in the long term.

And yet, all hopes that the Commission proposal will be adopted as legislation are about to fade away. While the European Parliament adopted the draft with some amendments,¹³⁹ the passing of legislation has been blocked in the Council.¹⁴⁰ The latest attempt to reach political agreement took place under the Danish presidency in 2012. The latter prepared a compromise text,¹⁴¹ which was able to obtain the approval of a large majority of the national representatives in the

States contributions, as requested by the Conclusions of the Environmental Council of December 2008, COM (2011) final, 15.04.2011; see also K. Zurek, Karolina, 'Indicating Reasons for National GM "Opt-Outs"' (2/2011) at 241.

¹³⁷ See for a more detailed analysis Weimer 'What price flexibility' supra n. 12.

¹³⁸ See Environmental Council conclusions supra n. 85; see refereed paper for JCMS...

¹³⁹ Interestingly, the amendments introduced by the Parliament are emphasizing the importance of procedural requirements for the adoption of national opt-outs. The Member States shall carry out an independent cost-benefit analysis taking into account alternatives and a prior public consultation. See European Parliament legislative resolution of 5 July 2011, 2010/0208(COD) available at <http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P7-TA-2011-314> (last accessed on 14.03.2012).

¹⁴⁰ In its first reading. Reference is made to the situation as of February 2014.

¹⁴¹ It introduced a two-step approach. As a first step Member States would be able to restrict the cultivation of a GMO authorized at EU level on their territory on the basis of a voluntary agreements with the GMO producer. If that would not be possible, Member States would be entitled to ban the crop on their territory unilaterally.

Council.¹⁴² However, a blocking minority of France, Germany, Belgium and the United Kingdom prevented the compromise from being adopted.¹⁴³ France and Germany both maintain so-called national safeguard measures banning GMOs, which the Commission has attacked as unlawful. Over the last years France became one of the leaders of the GMO opposition among the Member States. It contested EFSA's scientific authority with new scientific studies indicating potential environmental and health risks several times. Moreover, both France and Belgium have supported the Dutch initiative¹⁴⁴ calling on the Commission to amend Directive 2001/18.¹⁴⁵ British opposition is in line with its previous commitment to agricultural biotechnology. It is not, however, in line with the UK's otherwise clamorous demand for the re-nationalisation of EU powers.¹⁴⁶

What lies behind this latest instance of deadlock in the Council? Why do several Member States prefer the *status-quo* of a deadlocked EU authorization process and legal uncertainty and even illegality of national bans post-authorization over a reform that seems to give them what they wanted: more autonomy? Why, when it comes to GMOs, do Member States fail to do the very least, namely to agree to disagree? The situation escapes a straightforward answer. Each Member State has their own distinct set of reasons to either support or reject the Commission proposal. The progress report of the Danish presidency, however, indicates two sets of reasons, which were explicitly invoked by the blocking Council members. On the one hand, legal arguments of a potential incompatibility of national 'opt-outs' on GMOs with the EU internal market and WTO law were invoked.¹⁴⁷ On the other hand, some Member States saw the Commission proposal as being in conflict with the Council

¹⁴² See Council of the European Union, Interinstitutional File 2010/0208 (COD) of 6 June 2012, Progress Report on the Proposal for a Regulation of the European Parliament and the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory.

¹⁴³ The progress report of the Danish presidency, *ibid*, concludes: "Despite the fact that significant progress has been made, the Presidency, taking into account the outcome of the informal consultations and Member States views at the COREPER meeting on 31 May 2012, is concluding that a political agreement on the GMO dossier is not possible."

¹⁴⁴ Council of the European Union, 'Note from the Netherlands delegation on "GMOs: approval and cultivation"' Council Agriculture and Fisheries, 7581/09, 23 March.

¹⁴⁵ 'Draft minute, 2934th meeting of the Council of the European Union' Council Agriculture and Fisheries, 7296/09, 23 March.

¹⁴⁶ As evidences by the currently on-going review of the balance of competences between the UK and the EU.

¹⁴⁷ See for an exploration of the legal arguments Poli, 'The Member States' long and winding road' *supra* n. 132.

Conclusions on GMOs adopted in 2008.¹⁴⁸ The latter called for an improvement of the implementation of the EU framework by, among others, strengthening the environmental assessment of GMOs and improving the use of expertise. Member States, such as France, who are concerned about the environmental impact of GMOs, were therefore anxious that the reform would divert attention from the problems of the environmental risk assessment by EFSA, as well as from the need to reform the EU authorization procedure. Excluding environmental reasons as grounds for justifying national 'opt-outs' would contradict their overall approach towards GMOs.¹⁴⁹ Overall, the proposal has raised fears that the Commission wants to use the reform to get more GMOs authorized at EU level. The reform seems indeed somewhat half-hearted because of its exclusive focus on socio-economic objections to GMO cultivation. Such focus does not address the problems of scientification and over-reliance on epistemic legitimacy as described above in this chapter. After all, opposition to GMOs is not only based on socio-economic interests and conflicts, but also on conflicting views on how to deal with the scientific uncertainty surrounding the long-term impact of GMOs on public health and the environment. It is worth mentioning that the EPEC external evaluation report of the GMO framework has stressed that 'consideration of these more fundamental reforms should not delay or substitute for efforts to improve the authorisation system as it exists today.'¹⁵⁰

There is, however, potentially another less explicit reason why several Member States might prefer the *status-quo*. The Commission, in its explanatory memorandum of the reform proposal offers a clue. It states 'Given the more national or regional approach towards GMO cultivation, it is also expected that the level of public involvement in the national and regional decision making will increase and Member States will allocate more resources and time to involve their public with regard to their decisions.'¹⁵¹ In other words, allowing the Member States to decide on national GMO 'opt-outs' would *de-jure* assign responsibility where it *de-facto* already resides: the national governments and their societies. This could arguably also bring about more political and democratic accountability for GMO decisions in the EU as national governments would no longer be able to shift the blame for unpopular authorizations to the Commission and EFSA. Yet, more public

¹⁴⁸ See Environmental Council conclusions supra n. 85.

¹⁴⁹ See personal interview with a Danish representative on 9 May 2013.

¹⁵⁰ See EPEC report supra n. 70 at 74.

¹⁵¹ See Commission proposal supra n. 128 at 6.

involvement at national level could turn out to be a double-edged sword, at least for those national governments that either support GMO cultivation, or are not generally against it (e.g. the UK, Germany, Spain, and The Netherlands). Once citizens realize that it is their national governments that decide on GMO cultivation, public pressure from anti-GM groups is likely to rise.¹⁵² It seems, therefore, that it is politically not convenient to transfer competences in this field back to the national level.

IV. Final remarks: The promise of deliberation in European risk governance

What does the present analysis of the ‘GMO conundrum’ teach us about deliberative theories of EU law and governance? It is sometimes suggested that EU regulation of GMOs is a unique, exceptional case, which makes generalization difficult. The extent to which the GMO case is unique stands in fact in direct negative proportion to the extent to which insights gained from the GMO case can be generalized. In other words, the more uniqueness we see the less generalization is possible.

There is arguably something exceptional about the regulatory conundrum in the field of EU regulation of GMOs. This exceptionality, however, is not intrinsic to the subject of agricultural biotechnology as such. Instead, the exceptional nature of EU regulation in this field refers to the high degree of institutional path-dependence,¹⁵³ as well as to how deeply entrenched and irreconcilable positions towards GMOs in the EU have become overtime. Agricultural biotechnology as a policy field shares several features with other areas of risk and technology regulation. Such features are, for example, the unavailability of conclusive scientific evidence of absence of harm, scientific uncertainty, potential for long term impact on the environment and public health, high media visibility, strong economic incentives and market pressure, and the relevance of consumer risk perceptions and other non-

¹⁵² This analysis is confirmed by two interviews with Brussels insiders; a personal interview of 9 May 2013 with a Danish COREPER representative who participated in the negotiation of a compromise during the 2012 Danish presidency and an e-mail interview with a Commission Official from DG Sanco of October 2013; According to the DG SANCO official, Spain is an example of a country which cultivates GMOs on a large scale, but where virtually no public debate on GMOs currently takes place. According to the official this is likely to change if competences are transferred back to Madrid.

¹⁵³ See Pollack & Shaffer ‘When cooperation fails’ supra n. 35; See also D. Vogel, *The politics of precaution. Regulating health, safety, and environmental risks in Europe and the United States* (Princeton: Princeton University Press, 2012) 77.

risk related ethical and socio-economic concerns. In the risk governance literature GMO risks have been characterized as so-called uncertain risks.¹⁵⁴ Regulating such risks is especially challenging, but it is not exceptional. Other examples of policy fields, which are highly controversial or have the potential to become a case of regulatory controversy, can easily be found, such as animal cloning for food, nanotechnology, and bisphenol A.¹⁵⁵ In other words, the problems of regulating GMOs in Europe are problems inherent to risk regulation, as well as to the broader task of integrating technological innovations into society in a democratic and socially sustainable way. If that is true, then the experience of regulating GMOs in the EU is an extremely important source for learning about risk governance in general, and the potential of deliberation to contribute to its legitimacy, in particular.

Firstly, the GMO case challenges the sociological basis of both the 2nd dimension of CLC and its predecessor theory of deliberative supranationalism, namely that the EU comes closest to the ideal of transnational deliberation in networks as the basis for legitimate transnational governance¹⁵⁶. While the EU legal structures of GMO regulation embody the idea of proceduralized cooperation and the balancing of different risk and non-risk concerns, rule implementation in practice failed to manage the political dimension of GMOs. In both deliberative *fora* of the authorization procedure, EFSA and comitology, de-centralised multi-level governance reverted to *de-facto* assertion of authority and top-down regulation overriding national concerns. Ultimately, the failure of cooperation and deliberation within these *fora* strengthened the Commission's reliance on scientific experts within the regime. As a result, in practice EU authorisation of GMOs, although not foreseen as such, reverts to a purely technocratic process.

It may well be that learning is easier to achieve in theory than in practice. In response to the GMO and other case studies of EU governance, especially in the field of Europe's economic crisis management, Joerges has recently suggested the need to

¹⁵⁴ Van O. Renn & M. Van Asselt 'Risk Governance', (2011) 14 (4) *Journal of Risk Research*, 431; E. Vos & M. Everson (eds.), *Uncertain Risks Regulated* (Abingdon, Oxon; New York, NY: Routledge-Cavendish, 2009).

¹⁵⁵ See for an overview M. Van Asslet, E. Vos and E. Versluis (eds), *Balancing between Trade and Risk* (London: Routledge Taylor& Francis, 2013); for different fields in a comparative US perspective, Vogel, *The politics of precaution* supra n. 155 and J. Wiener et al, *The reality of precaution. Comparing risk regulation in the United States and Europe* (Washington: RFF Press, 2011).

¹⁵⁶ See Joerges 'Law, science' supra n. 4.

reconceive CLC as a critical rather than re-constructive theory.¹⁵⁷ Moreover, the 2nd dimension of CLC has to a certain extent evolved beyond the plea for deliberate supranationalism in transnational governance by developing an additional normative requirement. Regulatory outcomes of transnational governance must remain revisable by, for example, providing for the possibility of national opt-outs for those Member States whose legitimate regulatory concerns demand a deviation from the common European solution.¹⁵⁸ It seems therefore adequate to complement the 'trivial insight'¹⁵⁹ of deliberative supranationalism, namely that 'crises which can no longer be managed at the national level require transnational responses' with a similarly trivial insight that where transnational responses fail to produce legitimate solutions for the whole of the Union, a differentiated approach allowing for national derogations should be adopted. Seen in this light, the Commission reform proposal on national 'opt-outs' for GMO cultivation is a normatively desirable development even given its legal and political difficulties. Equally, the current impasse of the reform process in the Council of Ministers raises further legitimacy concerns.

Secondly, the GMO case also challenges related accounts of GMO regulation as an experimentalist governance regime. Also here, while the regulatory design can be characterized as building in elements of experimentalism, namely through its procedural structure of cooperation and bottom-up input of various actors, the account of implementation failure in this paper suggests a less optimistic view on the governance practice in this field.¹⁶⁰ As explained above, the input of lower-level units from the national level is *de-facto* precluded in both EFSA and the comitology procedure, and hindered in the management of co-existence post-authorization. This also stands in the way of mutual learning. The latter presupposes an open mind-set of all the actors, in the sense of their willingness to revise both their knowledge about and their attitudes towards GMOs in the light of contributions and experience made by other actors. This, however, is difficult to perceive in the current institutional

¹⁵⁷ See C. Joerges & M. Weimer, 'A Crisis of Executive Managerialism in the European Union – No Alternative?' in J. Scott, G. De Búrca & C. Kilpatrick (eds), *Critical Legal Perspectives on Global Governance. Liber Amicorum for David Trubek* (Hart Publishing).

¹⁵⁸ See C. Joerges, P. Kjaer & T. Ralli "A New Type of Conflicts Law as Constitutional Form in the Postnational Constellation," (2011) 2 (2) *Transnational Legal Theory*, 153.

¹⁵⁹ According to Joerges 'Law, science' supra n. 4.

¹⁶⁰ It may well be possible that in the external dimension of EU GMO governance, notably in the transatlantic relations on GMO policy, more optimism is warranted. See P. Dabrowska-Klosinska, 'The EU and transnational regulation of GMO risks' GR:EEN Working Paper (2013) No. 36.

deadlock, in which positions are both entrenched and politicized. It can, of course, not be excluded that institutional learning on a larger scale will eventually occur. The currently attempted reform of the GMO framework is certainly the result of a long and painful process of institutional failure and learning in this field. An essential condition of experimentalist governance is, however, that actors are able to agree on a common policy objective as a broad framework goal. Yet the political and societal divide on GMOs is so strong in the EU at the moment that neither Member States nor societal groups are able to agree on whether to allow or to prohibit the use of this technology in food and agriculture. They are not even able to agree to disagree, as the reform impasse illustrates.

All this indicates, however, that a response to the failure of deliberation and cooperation at EU level cannot be a return to top-down regulation with ‘behind closed doors’ technocratic deliberation.¹⁶¹ It also contradicts the assumption that deliberation is fostered by technocratic ‘behind close door’ decision-making. In the GMO case the top-down imposition of epistemic authority has only increased politicization. Arguably, in cases of high political contestation and disagreement, especially in multi-level systems, deliberation remains the only way forward because it manages to keep decisions open, where no legitimate final authority is available. EU’s authority as a legal and political system is based on an ongoing contestation and resettlement of legal and political authority,¹⁶² of which the GMO case serves as a vivid example. As one experimentalist scholar has aptly noted, such cases call for the ‘no-final-decider principle’¹⁶³ according to which the EU might well not be the appropriate locus of authority to decide on GMO cultivation at present, but dialogue must go on.

What this chapter has shown, however, is that blaming politicization for the failure of deliberation in GMO regulation does not consider the full regulatory complexity in this field, and in particular the problematic effects of scientification, i.e. an over-reliance on regulatory science and epistemic legitimacy as the basis for GMO authorisations. The two trends of politicization and scientification are not only conflicting. They are actually to some extent mutually accelerative. On the one hand,

¹⁶¹ Nor is the ‘stark normative trade-off between transparency and openness, on the one hand, and deliberative decision-making on the other’ as suggested by Pollack and Shaffer (see quote *supra* in section I.) unavoidable.

¹⁶² See Joerges & Weimer, ‘A crisis’ *supra* n. 159.

¹⁶³ Charles Sabel in the workshop on Workshop on “Experimentalism in Transnational Governance” at the University of Amsterdam, 1-2 November 2013, The Netherlands.

instances of uncertainty intolerance on the part of EFSA and the Commission are contributing to distrust and ever more fierce responses of the anti-GM movement, and therefore to the resistance of several of the Member States. On the other hand, this in turn infuriates GMO proponents who call for science-based decisions. The conclusions of the EPEC external evaluation report of the GMO framework are insightful in this regard:

‘Despite the best effort of many hard-working individuals and ongoing efforts to improve it, the system is not working as envisaged and is not, in aggregate, meeting its objectives. As the analysis in this report and earlier outputs from this evaluation have suggested, the ‘dysfunction’ arises as a consequence of a complex set of factors, both external and internal to the authorisation process.’¹⁶⁴

The report further notes that frustrations with the legislative framework among the consulted parties concentrate on the risk management phase. However, it continues stating that ‘many of the causal factors behind the blockages in decision-making lie “upstream” in the risk assessment process.’¹⁶⁵

This complex intertwinement or co-production between scientification of risk management and politicization of comitology as analyzed in this chapter is, in fact, a major challenge to EU regulation of GMOs, and potentially to other controversial cases of EU risk regulation. The unfortunate results of this are entrenched positions, polarization and a breakdown of dialog. Importantly, the analysis confirms the insight that calling upon scientific experts to resolve political conflicts can ultimately back fire. Overreliance on expert advice leads to the politicization of science, and the consequent de-legitimation of political institutions. As noted by Stuart Shapiro and David Guston in the context of the US public administration,

‘Just as judicial oversight of regulatory affairs has encouraged the politicization of the courts, regulatory peer review [by scientific experts] will likely result in the increased politicization of science. Rather than providing more certainty and leading to closure, the addition of more knowledge can lead to more conflict (Sarewitz 2004). Regulatory peer review [by scientific experts] may thus perversely contribute to the de-legitimation of political institutions by politicizing the science that such institutions are supposed to rely on for conflict resolution.’

¹⁶⁴ EPEC report supra n. 70 at 73.

¹⁶⁵ Ibid at 76; see also at 14-32: ‘the effective functioning of the institutional decision-making phase of the legislative process critically depends on confidence in the risk assessment.’

In the case of EU GMO regulation we are facing the problem of de-legitimation of the EU public administration. Overreliance on EFSA to produce authoritative scientific advice, the Commission's dependency on epistemic legitimacy as the sole basis for risk management together with the failure of the comitology system to exercise political responsibility increasingly contributes to the sense that the EU institutions involved have disqualified themselves as legitimate decision-makers in this field. A successful reform is challenging as it must be able to mitigate the negative effects of both processes, namely of politicization and of scientification.