Why Science Cannot Tame Politics: The New EU Comitology Rules and the Centralised Authorisation Procedure of GMOs

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The centralised authorisation of GMOs in the European Union (EU) has received considerable academic attention in recent years, partly due to the fact that Member States have not been able to agree on authorisation decisions in the comitology committee. As a consequence, these authorisations are given by the European Commission. These decisions are invariably in favour of authorisation despite the fact that Member States had been divided on this issue. Apart from the on-going discussions on a possible reform of the GMO authorisation (allowing for national restrictions or prohibitions), the new comitology rules brought about by the Lisbon Treaty are of equal importance as they might affect the authorisation of GMOs. In this article we discuss some of the changes to comitology and present empirical material on the first authorisation decisions after the entering into force of the new comitology rules. By drawing on delegation theory we will argue that, for the time being, the level of politicisation of GMO authorisation is unlikely to change.

I. Introduction

The regulation of risks in the European Union (EU) has received considerable academic attention in recent years, addressing intricate issues pertaining to risk assessment and risk management, the precautionary principle, science-based policy making but also institutional design and legitimacy of decision making under scientific uncertainty. A key concern in this respect is the regulatory regime concerning Genetically Modified Organisms (GMOs) which has been widely seen as a regulatory failure. This failure is ascribed to different (yet inter-related) aspects. The risk assessment of the European Food Safety Authority (EFSA) is said to be intolerant of the related scientific uncertainty.[1] The diverging stances of Member States on the GMO issue render this uncertainty problematic, because it makes EFSA the de-facto decision maker for an issue which is normatively charged and politically salient. This is particularly visible in the authorisation procedure of the so-called Food and Feed Regulation.[2] Neither the responsible comitology committee nor the Council of Ministers, in both of which the Member States are represented, have been able to form a decisive opinion on whether to grant or reject authorisation.[3] This leaves the responsibility of decision making with the European Commission which by granting authorisation in all cases has exclusively followed the positive assessment of EFSA.As a consequence Member States have begun to invoke safeguard clauses to unilaterally ban GMOs.[4] This puts into question the efficiency and legitimacy of the current GMO regime because it hampers the smooth functioning of the internal market and assigns de facto decision mak-

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1 Marjolein B. A. van Asselt and Ellen Vos, "Wrestling with uncertain risks: EU regulation of GMOs and the uncertainty paradox", 11(1-2) *Journal of Risk Research* (2008), pp. 281–300.

2 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268/1.

3 The referral of a decision to the Council is an extremely rare case, and the vast majority of these cases stem from GMO authorisations in the SCFCAH; see e.g. Report from the Commission on the working of the committees during 2010, COM(2011) 879 final from 12.12.2011.

4 Such a ban is based on Art. 23 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberative release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 106/1.

ing on a salient issue to an unelected, regulatory body.[5]

It is thus little surprising that a reform of the GMO regime is currently a prominent topic in the EU.[6]While these reforms may bear important repercussions, we wish to discuss another aspect of EU decision making which, potentially, may be of similar importance in this respect. Due to the entry into force of the Treaty on the Functioning of the European Union (TFEU) in December 2009, the comitology rules had to be changed.[7] Since the failure of the GMO regime is (at least partly) an institutional failure, the question comes up whether the reform of comitology yields a significant effect. This is an important enquiry because the new comitology rules change the institutional design in which Member States and the Commission are supposed to make GMO-related decisions. This question has therefore already received some scholarly attention. As Weimer argues, these changes might result in de-politicisation of comitology and a strengthening of science-based decision making as regards the centralised GMO authorisation.[8] In contrast, Paskalev assumes that changes will be of negligible significance since the GMO authorisation is characterized by disguised politicisation which remains unaffected by the new comitology rules.[9] In this article we provide the first empirical evidence to show that changes are indeed of little significance. In the context of the GMO authorisation procedure under the Food and Feed Regulation, the Commission keeps granting authorisations based on a positive assessment of EFSA. In line with Paskalev's argument we aim to illustrate that EFSA and comitology are institutional designs derived from different logics of delegation which, in combination, do not facilitate deliberative and legitimate decision making.

II. Delegation theory and GMO regulation in the EU

In order to underpin this case theoretically we will draw on delegation theory.[10] This theoretical perspective sheds light on the institutional design in which decisions are made, and which may restrict actors' preferences in this respect. Such a perspective is of particular value for the analysis of a policy issue in which Member States' preferences are fiercely divided, yet this is not reflected in the decision output as authorization decisions are unequivocally positive on granting authorisation. It is thus essential to analyse delegation of tasks by the Member States to the key players in the GMO regulatory regime, namely EFSA and the European Commission.

1. Different logics of delegation, comitology and the creation of EU agencies

Following Majone we can distinguish between two logics of delegation.[11] According to the first logic, Member States delegate tasks in order to reduce decision making costs for instance by drawing on the expertise of a supranational institution. The logic of reduced decision making costs acknowledges the functional need of delegation, but the delegating authority (i.e. the Member States) may devise institutional structures and procedures to retain control as much as possible.[12] The comitology system, emerging in the 1960s, is a case in point. In order to cope with the technicalities of agricultural policy the Commission was endowed with the task to prepare specific market interventions. In order to oversee the Commission, comitology committees were established in which the Member States were represented. This institutional design which has expanded beyond agricultural policy over the years was also owed to the so-called Meroni doctrine.[13] In essence, the

5 Thomas Christiansen and Josine Polak, "Comitology between Political Decision-Making and Technocratic Governance: Regulating GMOs in the European Union," *EIPASCOPE*, (2009).
6 See Sara Poli, "The Commission's New Approach to the Cultivation of Genetically Modified Organisms", 1(4) *European Journal of Risk Regulation* (2010), pp. 339–344.
7 Art. 290 and 291 TFEU.
8 Maria Weimer, "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", 1(4) *European Journal of Risk Regulation* (2010), pp. 345–352.
9 Vesco Paskalev, "Can Science Tame Politics: The Collapse of the New GMO Regime in the EU", 3(2) *European Journal of Risk Regulation* (2012), pp. 190–201.
10 Jonas Tallberg, "Delegation to Supranational Institutions: Why, How, and with What Consequences?",25(1)*West European Politics* (2002), pp. 23–46.
11 See GiandomenicoMajone, "Two Logics of Delegation. Agency and Fiduciary Relations in EU Governance", 2(1) *European Union Politics* (2001), pp. 103–122.
12 See Mathew D. McCubbins, Roger G. Noll and Barry R. Weingast, "Administrative Procedures as Instruments of Political Control", 3(2) *Journal of Law, Economics and Organization* (1987), pp. 243–277; Terry Moe, "The positive theory of public bureaucracy", in Dennis C. Mueller (ed.) *Perspectives on public choice. A handbook* (Cambridge: Cambridge University Press, 1997).
13 Case 9/56, *Meroni & Co., Industrie Metallurgische S.p.A. v. High Authority*, (1958) ECR-133.

Meroni doctrine restricts the delegation of tasks with recourse to the institutional design of the EU and its enshrined balance of power. The system of comitology is thus in line with the Meroni doctrine.[14]

The Meroni doctrine received renewed interest in the wake of "agencification" in the EU.[15] Since the early 1990s, starting with the European Medicines Agency (EMA) a number of agencies dealing with risk has been created. Similar to comitology, and owing to Meroni, most EU agencies have only limited mandates or decision making authority in very limited technical areas. There are elaborated control mechanisms in place allowing Member States and the Commission to oversee the agencies.[16] While agencies dealing with the regulation of risk play an important role in risk assessment, the decision whether or not to grant market access – i.e. risk management – is ultimately taken by the Commission and the Member States via comitology.[17] The respective logic of delegation based on which most EU agencies operate is thus one of reduced decision making costs. While it is generally conceded that agencies may provide valuable expertise, the mandate of most agencies runs short of de jure decision making power. This logic is present in the creation of EMA for instance which should rectify the deficiencies associated with mutual recognition of Member States' risk assessments and national pharmaceuticals authorisation.[18]

However, the creation of EU agencies has often been the immediate response to external events with little consideration of a common institutional design.[19] The importance of such events also helps to explain important institutional features of EFSA and the regulation of GMOs. In contrast to other agencies, the assessment of risk is not conducted by experts representing Member States' competent authorities. The respective committee in EFSA, the GMO Panel, is composed of experts being independent from the Member States. As a result, the input of Member States to the assessment of risk is limited and we can submit that EFSA is an example of the second logic of delegation. According to this logic, Member States delegate in order to enhance the credibility of their policy commitment by giving away political power to independent agencies (or the European Central Bank and the EU Courts for instance). In contrast to the first logic, credible commitment aims to overcome the political myopia enshrined in democratic political systems assuming short-term interests of policy makers.[20]

The logic of credible commitment is thus present in the creation of EFSA which served the explicit purpose to reinforce public trust in the EU food safety regime after the BSE crisis had revealed the high level of politicisation in the various scientific committees.[21] Accordingly, the agency enjoys a higher level of independence as can be seen by the composition of EFSA's GMO Panel. However, the credibility commitment by the Member States is undermined by the legal constraints of the Meroni doctrine which limits the role of EFSA to risk assessment while Commission and Council are responsible for risk management.[22] As it seems, EFSA is not the sole holder of the 'property rights' of GMO authorisation; a right which is essential for a logic of delegation aiming for credible commitment.[23]

14 Jørgen Grønnegaard Christensen and Vibeke Lehmann Nielsen, "Administrative capacity, structural choice and the creation of EU agencies", 17(2) *Journal of European Public Policy* (2010), pp. 176–204; Steve Peers and Marios Costa, "Accountability for Delegated and Implementing Acts after the Treaty of Lisbon", 18(3) *European Law Journal* (2012), pp. 427–460.

15 Stefan Griller and Andreas Orator,04/D40 "Meroni Revisited – Empowering European Agencies between Efficiency and Legitimacy", *NEWGOV New Modes of Governance Project* (2007); Merijn Chamon, "EU agencies between Meroni and Romano or the devil and the deep blue sea", 48*Common Market Law Review* (2011), 1055–1075.

16 In most agencies the steering board (often called Management Board) is composed of by Member States' representatives, the Commission and increasingly the European Parliament (EP).

17 The very existence of comitology is in fact an expression of Member States' concern to retain control in risk regulation. See Ernesto Previdi, "The Organisationof Public and Private responsibilities in European Risk Regulation", in Christian Joerges, Karl-Heinz Ladeur and Ellen Vos (eds) *Integrating Scientific Expertise into Regulatory Decision Making* (Baden-Baden: Nomos Verlagsgesellschaft, 1997).

18 See John S. Gardner, "The European Agency for the Evaluation of Medicines and European Regulation of Pharmaceuticals", 2(1) *European Law Journal* (1996), pp. 48–82. Sebastian Krapohl, "Credible Commitment in Non-Independent Regulatory Agencies: A Comparative Analysis of the European Agencies for Pharmaceuticals and Foodstuffs", 10(5) *European Law Journal* (2010), pp. 518–538.

19 For instance, the European Maritime Safety Agency (EMSA) was established in the aftermath of the *Erika* (1999) and *Prestige* (2002) oil tanker accidents, and the European Centre for Disease Prevention and Control (ECDC), was created in order to respond faster to health threats such as SARS. In June 2012 Council, EP and Commission agreed on a common approach towards a more streamlined governance arrangement of EU agencies. To what extent these arrangements affect the functioning of EU agencies remains to be seen in the future.

20 See Giandomenico Majone, "The regulatory state and its legitimacy problems", 22(1) *West European Politics* (1999), pp. 1–24.

21 See Grace Skogstad, "Legitimacy and/or policy effectiveness?: network governance and GMO regulation in the European Union", 10(3) *Journal of European Public Policy* (2003), pp. 329 *et sqq*.

22 Giandomenico Majone, "Foundations of Risk Regulation: Science, Decision-Making, Policy Learning and Institutional Reform", 1(1) *European Journal of Risk Regulation* (2010), pp. 5–19.

23 See Giandomenico Majone, "Two Logics of Delegation", *supra* note 11.

2. The practice of GMO authorisation

From a theoretical perspective, this constraint entails considerable problems with regard to EFSA and the Commission, to both of which Member States have delegated tasks in GMO authorisation.

1. First, it can be said that issues of high scientific uncertainty defy a neat separation between risk assessment and risk management because such separation enables authoritative claims made by EFSA about the relevance of scientific and non-scientific arguments regarding the assessment.[24] At the time of writing EFSA has issued 39 opinions on applications for GMO authorisations under the Food and Feed Regulation.[25] All of these opinions have been positive, i.e. GM feed or food was seen either as safe as the non-GMO equivalent or unlikely to cause any adverse effects. Thus, the role of EFSA as a forum in which competing scientific arguments are deliberated is hardly fulfilled.[26] The assessment by the GMO Panel relies on a particular notion of scientific authority which deceives subjectivity and uncertainty in the assessment process; alternative scientific opinions, input by non-experts and lay knowledge play virtually no role in the assessment process.[27]
2. Second, while EFSA has unequivocally concluded that all applications can be considered safe, the Member States have been deeply divided on this issue already since the late 1990s.[28] Due to the high salience of the GMO issue the comitology committee has not been able to form a decisive opinion on whether to grant or reject authorisations.[29] As Christiansen and Polak point out, "opinions on the matter of GMOs are not only fairly evenly divided among the Member States, but are also politically charged, with most actors set in rather entrenched positions on this matter".[30] Since 2005 when EFSA delivered the first scientific opinion under the Food and Feed Regulation, more than 30 decisions on GMO authorisation have been referred to the Council. The Member States' representatives have a clear mandate and vote strictly based on the instructions from their national ministries.[31] The comitology committee can thus be seen as a 'Mini-Council of hard-nosed bargaining among Member States' rather than a forum of deliberation among policy experts.[32] Likewise the GMO Panel, the promise of comitology as a forum in which competing scientific arguments are deliberated seems unfulfilled.
3. Third, due to the inability of the Member States to form a decisive opinion in the comitology committee, the responsibility of making decisions on GMO authorisation rests with the Commission. While the Member States have been deeply divided on the issue of GMO authorisation, every EFSA opinion has been endorsed by the Commission, thus granting an authorisation. The fact that the Commission is pursuing the authorisation of GMOs despite the division of Member States has been regarded as being politically provocative.[33] It might be difficult for the Commission to deviate from EFSA's opinion due to the so-called Pfizer doctrine which requires that reasons to deviate "must be of scientific level at least commensurate with that of the opinion in question.[34] However, as Paskalev convincingly shows, the risk assessment of EFSA itself does not always live up to such a requirement.[35] The manifest as-

24 Marjolein B. A. van Asselt and Ellen Vos, "Wrestling with uncertain risks", *supra* note 1.

25 This number is derived from EFSA's Register of Questions (see http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=NDA&foodsectorarea=26) by searching for 'Output'. The search was restricted to opinions by a scientific panel, using '1829/2003' in the title to single out those opinions which are related to respective applications, renewal of applications and requests to evaluate national safeguard measures.

26 Damian Chalmers, "'Food for Thought': Reconciling European Risks and Traditional Ways of Life", 66(4) *The Modern Law Review* (2003), pp. 532–562.

27 Mihail Kritikos, "Traditional risk analysis and releases of GMOs into the European Union: space for non-scientific factors?", 34(3)*European Law Review* (2009), pp. 405–432.

28 Yves Tiberghien, "Competitive Governance and the Quest for Legitimacy in the EU: the Battle over the Regulation of GMOs since the mid-1990s", 31(3) *Journal of European Integration* (2009), pp. 389–407.

29 Mark A. Pollack and Gregory C. Shaffer, *When cooperation fails: The International Law and Politics of Genetically Modified Foods* (Oxford: Oxford University Press, 2009). Michelle Everson and Ellen Vos, "The scientification of politics and the politicisation of science", in Michelle Everson and Ellen Vos (eds), *Uncertain Risks Regulated* (Abingdon et al.: Routledge, 2009).

30 Thomas Christiansen and Josine Polak, "Comitology between Political Decision-Making and Technocratic Governance", *supra* note 5.

31 Ellen Vos and Frank Wendler, "Food Safety Regulation at the EU level", in Ellen Vos and Frank Wendler (eds) *Food Safety Regulation in Europe: A comparative institutional analysis*", (Antwerpen: Intersentia, 2006).

32 Jens Blom-Hansen and GijsJan Brandsma, "The EU Comitology System: Intergovernmental Bargaining *and* Deliberative Supranationalism?", 47(4) *Journal of Common Market Studies* (2009), pp. 719–740.

33 Maria Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology* (Cheltenham and Northampton: Edward Elgar, 2008), at p. 102.

34 See Case T-13/99 *Pfizer Animal Health SA v Council of the European Union* (2002) ECR II-03305

35 Vesco Paskalev, "Can Science Tame Politics", *supra* note 9.

sessment errors in the authorisation of the Amflora potato for instance would justify the annulment of the authorisation, in line with the Pfizer doctrine, due to the contradictory evidence regarding the risk involved. Yet, the risk assessment EFSA came to the conclusion that the use would be safe despite such contradictions and dissenting views in the GMO Panel. The Commission subsequently authorised Amflora after the comitology committee and the Council had failed to form a decisive opinion.

The peculiarity of GMO authorisation stems from the incompatibility of the logic of delegation enshrined in EFSA (to provide for credible commitment) and the decision making procedures of comitology (to provide reduced decision making costs). While the former is intrinsically related to scientific legitimacy by way of sound, yet inclusive risk assessment, the latter is related to political legitimacy in that Member States deliberate on risk management options in comitology. However, no such deliberation takes place in the comitology committee, and as a result, the GMO authorization procedure is characterized by the predominance of (questionable) scientific legitimacy.[36]

III. GMO authorisation and the new comitology rules

As Weimer argues, the biggest gap between a legitimate system of GMO authorization and the actual practice of authorization can be observed in comitology, due to the reasons mentioned above. The question whether the reform of comitology yields a significant effect on the authorization is thus an important enquiry because new rules alter the institutional design in which decisions on GMO authorization are taken. The new comitology rules after the TFEU are the latest in a series of decisions by the Council to provide a legal framework for the system of comitology.[37] The reform of the comitology system is based on a twofold rationale. First, the reform builds upon past experience and aims to clarify responsibilities and simplify the decision making process.[38] Second, with the coming into force of the TFEU, new comitology rules were legally required.[39]

1. The new comitology rules

Although the comitology reform is a legal necessity, fleshing out the ins-and-outs of the comitology system is politically important given the general balance of power within the EU.[40] In this section we concentrate on those aspects which are relevant to GMO authorisations. In this context Article 291 TFEU on so-called implementing decisions is crucial because GMO authorisations are adopted via implementing decisions. The provisions of Article 291 TFEU have been specified, for the first time, in a regulation by the European Parliament and the Council.[41]

The first step in the decision making process does not differ from the old comitology rules, i.e. the Commission, based on EFSA's risk assessment, prepares a draft decision and the comitology committee delivers an opinion. However, the innovation is where the committee rejects the Commission proposal or cannot form an opinion. While the old rules provided for the referral of the decision to the Council, the new rules refer the decision to a so-called appeal committee, composed of Member State representatives.[42] In the first proposal for the new rules, the Commission envisaged to abandon such referral completely given that Article 291 refers to Member State control regarding implementing decisions, and not Council control.[43] Both the EP and the Council objected this

36 Maria Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology*, *supra* note 33; Maria Weimer, "Legitimacy through Precaution in European Regulation of GMOs? From the Standpoint of Governance as Analytical Perspective", in Christian Joerges and Poul F. Kjaer (eds), *Transnational Standards of Social Protection Contrasting European and International Governance*, vol 5 (ARENA Report No 5/08, RECON Report No 4 2008), p. 195.

37 See 87/373/EEC: Council Decision of 13 July 1987 laying down the procedures for the exercise of implementing powers conferred on the Commission. OJ L 197/33; Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission. OJ 1999, L 184/23; Council Decision 2006/512/EC of 17 July 2006amending Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission, OJ 2006, L 200/11.

38 See Proposal for a Regulation of the European Parliament and of the Council laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers, COM (2010) 83 final from 9.3.2010.

39 See Art. 290 and 291 TFEU.

40 Gijs Jan Brandsma and Jens Blom-Hansen, "Negotiating the Post-Lisbon Comitology System: Institutional Battles over Delegated Decision-Making", 50(6) *Journal of Common Market Studies* (2012), pp. 939–957.

41 Regulation (EU) 182/2011 of the European Parliament and of the Council 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.

42 Rules of procedure for the appeal committee (Regulation (EU) No 182/2011). Adopted by the appeal committee on 29 March 2011, OJ 2011, C 183/13.

43 Paul Craig, "Delegated acts, implementing acts and the new Comitology Regulation", 36(5) *European Law Review* (2011), pp. 671 *et sqq*.

Table 1: GMOs discussed in the appeal committee

GM Product	Date	Result	Number of votes		
			In favour	Against	Abstentions
40-3-2 soybean	17-01-2012	No opinion	181	80	84
A5547-127 soybean	17-01-2012	No opinion	181	113	51
MON87701 maize	17-01-2012	No opinion	181	96	68
356043 soybean	17-01-2012	No opinion	181	94	70
MON87701xMON89788 soybean	13-06-2012	No opinion	149	87	109
MIR 162 maize	27-09-2012	No opinion	152	96	97

and the idea of a kind of 'super committee' gathered support during the inter-institutional negotiations.[44] This 'super committee' then became the appeal committee.[45]

The rules of procedure of the appeal committee lay down that each Member State "shall decide on the composition of its delegation", yet, "with a view to achieving a level of representation as homogenous as possible".[46] It is important to emphasize that the appeal committee is not an additional permanent body, but rather a procedural tool which can be seen as a "virtual entity".[47] The appeal committee is thus a kind of comitology committee with a higher level of representation; it is supposed to provide "the opportunity to reconsider the draft implementing act or to make changes if need be".[48]

Another important change applies when the appeal committee is unable to reach a decision by qualified majority. Under the old comitology rules it was stipulated that the decision proposal *shall* be adopted by the Commission in case no decisive opinion could be found in the Council; hence, the Commission had basically no choice other than adopting the proposal.[49] Under the new rules, the Commission *may* adopt the proposal in case the appeal committee cannot find a decisive opinion.[50]

2. GMO authorisation under the new comitology rules

The new comitology rules beg two important questions. First, how does the appeal committee decide in case the comitology committee cannot find a decisive opinion on GMO authorisation? Since the new comitology rules entered into force on 1 March 2011, six decisions on the authorisation of GMOs under the Food and Feed Regulation have been referred to the appeal committee; these referrals stem from Commission decision proposals for which the comitology committee could not form an opinion between November 2011 and September 2012. These six cases do not stand for a large *n* but they provide first empirical evidence whether or not the new rules affect GMO authorisation.

On 17 January 2012 the appeal committee – Appeal committee on genetically modified food and feed and environmental risk –met for the first time in order to discuss four draft decisions. In line with the old regime, no qualified majority could be found either for or against authorisation. The same holds for the subsequent two cases in which the vote of the appeal committee was indecisive, and thus yielded the same result as the previous Council discussions (see Table 1). This is little surprising given that coordination among the ministerial level and the representatives in appeal committee is likely to take place

44 Gijs Jan Brandsma and Jens Blom-Hansen, "Negotiating the Post-Lisbon Comitology System", *supra* note 40.
45 See Regulation (EU) 182/2011, *supra* note 41, Art. 5.
46 Rules of procedure for the appeal committee, *supra* note 42, Art. 5.
47 See Summary Record, Plenary Meeting of the Advisory Group on the Food Chain and Animal and Plant Health, SANCO.03/VK D(2011), 14 March 2011.
48 See Commission website Comitology Register; <http://ec.europa.eu/transparency/regcomitology/index.cfm?do=FAQ.FAQ> (last accessed on 5 August 2013).
49 See Council Decision 1999/468/EC, *supra* note 37.
50 See Regulation (EU) 182/2011 *supra* note 41, Art. 6(3).

Table 2: Comparison of votes in comitology and the appeal committee

GM Product	Number of votes in comitology (appeal committee)		
	In favour	Against	Abstentions
40-3-2 soybean	190 (181)	80 (80)	75 (84)
A5547-127 soybean	190 (181)	113 (113)	42 (51)
MON87701 maize	181 (181)	84 (96)	80 (68)
356043 soybean	181 (181)	94 (94)	70 (70)
MON87701xMON89788 soybean	149 (149)	87 (87)	109 (109)
MIR 162 maize	152 (152)	96 (96)	97 (97)

when it comes to politically salient issues.[51] Indeed, based on the meeting records, we see that generally two members of each Member State's permanent representation, and in some cases members of the national ministry, participated in the meetings. Given the fact that the Council had delivered only 'no opinion' on GMOs authorisations prior to the establishment of the appeal committee, it is unlikely that the appeal committee would have come to a different outcome.

Thus, the Commission's interest in de-coupling the representation of Member States' interest in comitology from the Council seems unrealistic, even more so as the weighted votes are the same in comitology, the Council and the new appeal committee.[52] The distribution of votes is very similar in comitology and the appeal committee respectively, and the voting results not only reveal that the diverging opinions are divided among Member States. As can be seen in Table 2, the national positions are also firmly established when it comes to the GMO issue. Although some Member States have altered their position, a comparison of votes shows that national positions are entrenched and that the appeal committee does not provide for a deliberative forum in which national positions are substantially changing. Similar to the comitology committee it is a kind of 'Mini-Council' in which hard-nosed bargaining, if at all, is prevalent.

The second question then is how the Commission decides after a decision proposal has been referred back to it, and whether GMO authorisations are granted by default as they were before. As mentioned above, under the old comitology rules it was stipulated that the decision proposal *shall* be adopted by the Commission, while the new rules stipulate that the Commission *may* adopt the proposal. Hence, the Commission has the legal leeway to take into account the deeply divided preferences of Member States and the political salience of the GMO issue. As Kritikos argues, part of the failure of the regulatory GMO regime is the inability of the Commission to facilitate a regulatory process in which scientific and political legitimacy are present, and which generates broad public support.[53] However, the new comitology rules have not led to a different pattern of Commission decision making as all six GMOs have been authorised by the Commission.[54] This is noteworthy given that the Commission (in a declaration under the old comitology regime) has stated "to avoid going against any predominant position which might emerge within the Council against the appropriateness of an implementing measure".[55] Admittedly, the authorisation procedure is characterized by the absence of any 'predominant position'; however, it is certainly a "particularly sensitive" sector for which the Commission has pledged "to find a balanced solution".[56]

51 Paul Craig, "Delegated acts", *supra* note 43.
52 *Ibid*.
53 Mihail Kritikos, "Traditional risk analysis and releases of GMOs", *supra* note 27.
54 The respective Commission decisions can be found in the Eur-lex database. A search has been conducted restricting results to decisions under the 1829/2003 Regulation with a time span between February 2012 and November 2012 yielding the six GMO authorisations under consideration here. (The last previous Commission decisions from December 2011 are based on comitology no-votes from February 2011, thus before the new comitology regime entered into force in March the same year.)
55 Declarations on Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, OJ 1999, C 203/1.
56 *Ibid*.

IV. Conclusions and outlook

Notwithstanding the Commission pledge to find balanced solutions, some question whether the Commission really should be the forum in which such conflicts are to be mediated.[57] As Majone suggests, the answer to the failure of the GMO regime would be to create an agency which is responsible for both assessment and management of risk, and would thus be a sign of credible commitment.[58] However, a truly independent EU agency seems to be no option due to the constraints of the Meroni doctrine. As Weimer suggests, the authorisation of GMOs should be based on a more deliberative approach in which a broad range of interests and concerns are included in the management of risks at the EU level.[59] However, it is doubtful whether a more inclusive interpretation of the GMO authorisation procedure would garner the necessary support to ensure both scientific and political legitimacy. The recourse to more deliberation in regulatory regimes often neglects the pathologies of deliberation.[60] Given the diverse and highly salient views in and among Member States, it may well be that in case of the GMO issue there is no correct answer to which inclusive deliberation will lead all actors involved in the decision making process, as the issue itself might not allow such answers.[61] In a similar vein, Chalmers argues that the potential of EFSA to institutionalize the deliberative logic is limited, and that instead the diversity of views and opinions should be embraced.[62]

In this respect, the debate about the re-nationalisation of parts of the GMO regime is noteworthy. In December 2008 the Council concluded that "Member States should have the opportunity to provide their views on the additional information gathered during the risk assessment period (...) in order to keep EFSA informed of their opinion (...); and their concerns should be duly taken into account".[63] After the Council had rejected a Commission proposal to repeal national safeguard measures on the cultivation of GMOs, some Member States requested the Commission to come up with a proposal to allow national restrictions on cultivation. The freedom to restrict the cultivation of GMOs is also relevant for the centralised authorisation procedure under the Food and Feed Regulation as cultivated GMOs maybe intended as source material for subsequent food and feed production.[64] The re-nationalization of competences in this respect may thus lead to the facilitation of decision making in the centralised authorisation procedure as Member States may be less willing to oppose authorisation, if they are given the freedom to adopt restrictions on cultivation on their territories.[65] In this case, the authorisation procedure may generate a higher level of scientific legitimacy, while political legitimacy is derived from multifaceted deliberation at the Member State level based on national public opinion and interest mediation.

In addition, the GMO issue remains a subject of deliberation at the EU level since the first Citizens' Initiative regarding a moratorium on GM crop production has to be dealt with by the EU institutions.[66] Indeed, one of the most relevant deliberative implications may arise in cases in which such initiatives contradict facets of regulatory regimes in the EU (e.g. the notion of sound science as basis for risk assessment), or highlight the competing values regarding salient political issues.[67] The GMO issue seems to qualify in both respects. However, it is hard to foresee when the regulation on national restrictions will be adopted as the Council has not yet found an agreement on key issues.[68] For the time being, therefore, the current deadlock of the GMO authorisation procedure under the Food and Feed Regulation will persist with a pivotal role for the Commission.

57 Damian Chalmers, "Food for Thought", *supra* note 26.
58 Giandomenico Majone, "Foundations of Risk Regulation", *supra* note 22.
59 Maria Weimer, "Legitimacy through Precaution in European Regulation of GMOs?", *supra* note 36.
60 Jürgen Neyer, 13(5) "The deliberative turn in integration theory," *Journal of European Public Policy* (2006).
61 Loren A. King, 16(1) "Deliberation, Legitimacy, and Multilateral Democracy," *Governance: An International Journal of Policy, Administration, and Institutions* (2003).
62 Damian Chalmers, "Food for Thought", *supra* note 26.
63 Council conclusions, Genetically Modified Organisms (GMOs) (16882/08), Brussels, 5 December 2008.
64 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.
65 See Sara Poli, "The Commission's New Approach", *supra* note 6.
66 See Euractiv, "First 'Citizens' Initiative to call for GM crop freeze", 6 October 2010, available on the internet at http://www.euractiv.com/cap/citizens-initiative-call-gm-crop-news-498524 (last accessed (3 September 2012).
67 Michael Dougan, 48 "What are we to make of the Citizens' Initiative?," *Common Market Law Review* (2011).
68 See Press release 3152nd Council meeting Environment (7478/12), Brussels, 9 March 2012.