Comitology between Political Decision-Making and Technocratic Governance: Regulating GMOs in the European Union

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The EU's comitology system is generally considered to be an effective mechanism for facilitating efficient policy implementation while at the same time ensuring a degree of Member State control over the process. However, if this assessment is applicable to most areas of routine decision-making, the regulation of GMO authorizations by the European Commission, which also falls under comitology, presents a markedly different picture. The article shows the particular problems that occur in this field, outlining the involvement of a number of different actors (comitology committees, Council, European Commission and the European Food Safety Authority (EFSA) and their interaction in what has become a complex and protracted policy process. The articles identifies a number of key issues – the reliance of the Commission on EFSA's scientific expertise, the weakness of political accountability due to divisions among the Member States, the difficulties of the European Commission to achieve compliance with European and international rules – and discusses the impact that these have on the legitimacy, efficiency and effectiveness of policy-making in this area. The article concludes that, due to the problems arising from the particular arrangement of interests and procedures in this area, the operation of comitology in the regulation of GMOs is highly problematic.

Introduction[1]

Technological advance has led to important changes in many areas, and in the process has created new challenges for the regulatory activity of public bodies. One area that has caused particular controversy has been that of genetic modifications to organisms. Genetically-modified organisms (GMOs) have been introduced in a range of foodstuffs and animal feeds, leading to debates about the balance between the benefits and the risks associated with this technology. Across the world, authorities have had to make choices concerning the regulation of GMOs, be it about permissions for industrial trials, the cultivation of GMO crops, or the authorisation of trade in GMO products.

In Europe, the challenges related to the regulation of GMOs are met within the decision-making process of the EU. A number of legislative acts have established a regulatory framework for the authorisation of cultivation, import, use and sale of GMOs and their placing on the market as food or food ingredients. Within this framework, powers to decide on individual applications from market operators are delegated to the European Commission, which in turn is working with both Member State representatives through comitology committees and scientific experts, especially through the European Food Safety Authority (EFSA).

This article looks at the operation of comitology in the area of GMO authorisations. This area is interesting, given that in the regulation of GMOs comitology constitutes a forum for the deliberation of a highly politicised issue, on which the Member States are often deeply divided. At the same time, it is a highly technical issue, and comitology provides for detailed procedures of administrative and technocratic governance in the European Union. We seek to illustrate the difficult issues arising in this context: in delegating powers concerning the authorisation of GMOs to the European Commission, the EU's legislative institutions have not only passed on technical decisions to the EU's executive and scientific experts. To a large extent, this delegation of powers also implies that de facto it is the European Commission that has the final say on the shape of EU policy regarding GMOs, as Member States are divided among themselves and therefore not able to muster the qualified majority in Council that would be required to block the Commission's proposed authorisations. The Commission, in turn, relies heavily in its decision-making on the scientific opinions provided by the experts in EFSA.

Even such a brief summary of the state of play regarding GMO regulation in the EU highlights two points: first, this is a very complex area of EU regulatory governance in which predictions about policy-outcomes are hazardous; and, second, there is a very peculiar balance between technocratic governance and political decision-making. This article seeks to contribute to a better understanding of the relationship between technical expertise and political decision-making in this particular field, and thereby to illuminate the functioning of comitology in a crucial area of EU regulatory governance.

In order to do so, we first elaborate briefly in the following section the functioning of the comitology system in general, before then discussing the regulatory framework for the authorisation of GMOs and the respective involvement of the European Commission, Member States' representatives and scientific experts in more detail. We illustrate the decision-making process of GMO authorisations by looking at one individual case in more detail. We then analyse this situation by examining a number of key issues arising from the discussion: firstly, the demands concerning risk regulation that the EU decision-making procedure has to address; secondly, the degree of political control that is being exercised over European officials and scientific experts to whom powers have been delegated in the GMO area; and thirdly, the challenges concerning legitimacy and effectiveness of GMO regulatory activity that arise from the this situation. By way of conclusion, we assess the state of play of GMO regulation against the background of the preceding analysis, and look ahead to the future challenges in this area.

Comitology in Practice: The Case of GMOs

Before looking in greater detail at the specific area of GMO authorisation in the EU, we first need to take a brief look at the nature of comitology more generally. The development of this system of implementing committees has been the focus of a growing body of literature[2] which has established the historical trajectory and key issues involved. Comitology was an ad hoc solution in the 1960s to assist with the implementation of the Common Agricultural Policy (CAP). The delegation of powers to the Commission and the supervision of the Commission's use of these powers through committees composed of Member States' representatives was considered a convenient mechanism to satisfy both the search for greater efficiency and the desire by Member States to maintain a degree of control over the process.

Since then, comitology has gone through a number of reforms aimed at making procedures more systematic and transparent, but above all to allow the European Parliament, as co-legislator in most of EU law, a degree of oversight about the way implementing committees work. With the most recent reform of the Comitology Decision in 2006, introducing a new 'regulatory procedure with scrutiny', the Parliament

now has the power to veto implementing acts proposed by the Commission under this procedure.

The comitology system has expanded significantly over time. Iit now encompasses approximately 264 committees[3] and the European Commission is adopting on average more than 2500 implementing acts that have first gone through comitology. Despite the administrative burdens associated with this process, the system appears to function smoothly, with the Commission able to adopt more then 99 per cent of the implementing measures submitted to committees. Given how few cases are being referred to the Council under the management and regulatory procedures, the comitology system appears to satisfy its dual role of providing efficiency and ensuring a degree of Member State control over the process of implementation.[4]

However, while this is the general picture of comitology that is reflected both in the official reports issued annually by the Commission and by the academic literature on the subject, we are interested here in what happens in the fraction of cases where the Commission is at least initially blocked from implementing the proposed measures – which is the area of authorising GMO products. More specifically, we intend to look at the functioning of the system concerning the authorisation of GMOs to be placed on the market under Regulation 1829/2003/EC on genetically modified food and feed.

Rapid technological changes within the field of GMOs require decisions on this issue to be taken swiftly and efficiently, and the comitology system – designed with precisely the intention of speeding up EU decision-making on technical issues – is in theory well suited to deal with this issue. However, what may be observed within this area is that the relevant regulatory committee involved – the Standing Committee on the Food Chain and Animal Health (SCFCAH),[5] Section on 'Genetically Modified Food and Feed and Environmental Risk' – is consistently unable to deliver opinions on the Commission's draft decisions regarding authorisation of GMOs to be placed on the market. As a matter of fact, an examination of the relevant voting records suggests that the committee did not manage to deliver an opinion on any of the fifteen draft decisions for authorisation submitted by the Commission since the establishment of this committee in 2002,[6] either because the required qualified majority could not be achieved or due to a lack of any vote taken before the expiry of the proscribed time period. The reason for this state of affairs is not so much that the Member States as a whole disagree with the Commission on this issue, but rather that there are divisions among the Member States which make it virtually impossible to achieve a qualified majority either in favour or against the authorisation of GMO foods.

Under the regulatory procedure that is being applied in these cases, the absence of an opinion either way means that dossiers regarding the authorisation of GMOs under this Regulation are referred to the Council. This in turn implies a prolongation of a procedure that, as mentioned before, was originally designed to enhance the efficiency of EU decision-making. However, swift decision-making is then compromised further as the divisions on this issue also proliferate within the Council itself.[7] 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. As a result, the Council is not in a position to overrule the European Commission (something that would again require a qualified majority) which means that ultimately the decisional responsibility regarding authorisation reverts back to the Commission. At the end of the day, therefore, it is the European Commission which is finally taking the decision on application authorising GMOs to be placed on the market,[8] even though these are never endorsed by a qualified majority of the Member States.

This state of affairs raises serious questions about the accountability of EU governance; to put it bluntly, it implies that the more controversial implementation in a given area of EU decision-making is, the more likely it is, in the end, that regulatory decisions are taken by the European Commission – an unelected body that actually relies heavily on the advice it receives from a decentralized agency such as EFSA in coming to its own decisions. Before exploring in greater depth the wider implications of this state of affairs, the following section will briefly illustrate the actual process of implementation in the case of one particular application for the authorisation of a new, genetically-modified maize with the official name 'MON863'.

The MON863 'story' started in July 2002, when Monsanto Europe S.A. filed an application with the relevant authority in Germany requesting authorisation to place on the market its genetically modified maize line MON863. The respective German authority then conducted an assessment study on its safety[9] and presented an initial assessment report – indicating that additional assessment was needed – to the Commission's Directorate-General of Health and Consumer Protection (DG SANCO) in April 2003.[10] The Commission subsequently circulated the report amongst the relevant competent authorities of all Member States, following which they communicated their comments on this report to the Commission.

As a matter of fact, several Member States raised objections regarding a potential authorisation in this case. The subsequent informal conciliation phase resulted in deadlock as several Member States maintained objections, and the Commission consequently requested a risk assessment opinion from EFSA. Following the conclusion of this risk assessment study, EFSA's GMO Panel came in April 2004 to the conclusion that MON863 was safe.[11] However, the subsequent circulation by the German authority of an evaluation report questioning some aspects of a study carried out by Monsanto for the authorisation of MON863[12] compelled the Commission to refer the case to the EFSA again so that it could conduct a retrospective evaluation of the data derived from the study. This evaluation resulted in a re-confirmation that "the placing on the market of MON 863 maize is unlikely to have an adverse effect on human and animal health or the environment in the context of its proposed use".[13] Based on these consecutive positive scientific

opinions from EFSA, the Commission then submitted in May 2005 its draft decision to authorise the placing on the market of MON863 to the SCFCAH for discussion and voting.[14]

However, as suggested above, the vote in the SCFCAH did not deliver a qualified majority either in favour or against the draft[15] and the matter was now referred to the Environment Council. The subsequent lack of a qualified majority either for or against the authorisation in Council in October 2005 meant that the matter now returned to the Commission, allowing it to adopt its original proposal after all. In January 2006, despite a further critical report on the safety of MON863,[17] written parliamentary questions regarding the alleged shortcomings of the Monsanto study referred to earlier,[18] a simple majority of Member States in the Environment Council being against authorisation,[19] and a negative public attitude towards GMOs in general,[20] the Commission nevertheless went on to adopt Decision 2006/68/EC authorising the placing on the market of foods and food ingredients derived from MON863.[21]

GMO Authorisation: The Challenge for Comitology

The way in which the authorisation process unfolded in this case stirred up a broader debate that focused on the virtues of science-based regulation as well as on the merits of the comitology regulatory procedure within the specific area of GMO regulation. It demonstrated that, while the comitology procedures seem to work extremely well for routine decision-making, there might be problems in those rare cases like GMO authorisation where the issue is politicised and Member States' positions are divided. The following section examines more closely the key issues at stake: the challenges to risk regulation under conditions of relative uncertainty; the degree of political control that is being exercised over technocrats and scientific experts; the relationship between the European Commission and a scientific advisory body such as EFSA; and more generally the legitimacy and effectiveness of regulatory mechanisms in an area such as this.

The Role of Experts regarding the Regulation of 'Uncertain Risks'

One of the focal points in this context concerns the high degree of reliance on scientific expertise within this particular area of risk regulation. The significant role of such expertise derives not only from the nature of the subject-matter, but also from the legislative framework itself. EU legislation stipulates that Commission decisions regarding authorisation "have to be based on risk assessment"[22] and has clearly defined the subject of GMO regulation as "an expert scientific issue... kept separate from socio-ethical issues".[23]

However, the reliance of those charged with the responsibility for risk management, the European Commission, on those responsible for risk assessment, the scientific GMO Panel at the EFSA, is further magnified: although the Commission is formally only expected to "[take] into account the opinion of the [EFSA]",[24] it has turned out in practice to be virtually impossible for it to deviate from this opinion. The justifications for diverging from such an opinion "must be of a scientific level at least commensurate with that of the opinion in question",[25] and the Commission simply does not command the resources to provide the strong scientific basis for an objection that would be legally required. Thus, it comes as no surprise that in every single case where a GMO authorisation was at stake, the Commission proposed to approve the placing on the market of the GMO product in line with the EFSA's opinion. As a matter of fact, this state of affairs serves as an apt illustration of the de facto centre-stage position that EFSA has in this regulatory process.

The need for scientific expertise in the regulation of GMO authorisations therefore clearly leaves the European authorities with a dilemma: on the one hand, the Commission cannot but rely on the expertise of EFSA, but doing so does raise questions about the legitimacy of decisions which ultimately have to be taken by institutions that are politically accountable. A critical issue therefore is the relationship between political decision-makers and scientific experts.

The European Commission and EFSA in the Regulatory Process

In the EU, the use of scientific expertise in the regulation of GMOs depends on the direction which Commission and Member States' representatives have given to decision-making in this policy-area. As pointed out previously, however, both the comitology committee (SCFCAH) and the Council have consistently been unable to achieve a qualified majority regarding draft decisions for GMO authorisation. This has meant that decisional responsibility has always reverted back to the European Commission. In effect, neither the re-presentatives in the comitology committee nor the Ministers in the Council have been able to indicate the direction that member states wish to take in this process. Even if written parliamentary questions regarding the authorisation of MON863 triggered a debate on risk assessment standards and the role of the EFSA with the responsible Commissioner Kyprianou,[26] the perception must be that Member States are actually too internally divided to provide political leadership on this issue. De facto, decisions have been made by 'unelected bureaucrats', following advice from independent scientists. Not only risk assessment, but also risk management, has been conducted outside the political arena..

The resulting 'political deficit' regarding GMO authorisations may be considered problematic for two reasons. Firstly, the effect of it is that the Commission has de facto been endowed with the responsibility for adopting decisions that, without exception, approve the placing on the market of GMOs notwithstanding the political disagreements among the Member States in the Council and even the resistance to such authorisations by a (simple) majority of the national delegations in some cases (e.g. MON863). Although the Commission has declared that it would refrain from going against a "predominant position" in the Council on matters of sensitivity,[27] the obligation in the Comitology Decision that "the proposed implementing act shall be adopted by the Commission"[28] makes it quite difficult, if not legally impossible, for the Commission to abandon its draft proposals to authorise. However, given the political nature of

this uncertain and highly-sensitive area of governance, the limited degree to which the Member States are able to lend direction to the process and, in contrast to that, the influence exerted by technocrats and scientists – even if legally justified – may certainly be considered contentious.

The limited effectiveness of political control is also problematic because of the Commission's performance as a risk manager vis-à-vis EFSA. The establishment of EFSA as a non-majoritarian agency was very much driven by the recognition of the widely accepted need to separate risk

assessment and risk management; something which was done by explicitly denying the EFSA any regulatory powers. Indeed, the Commission strongly emphasised that "risk management must be left to an institutional framework with full political accountability" and insisted that "the drafting and making of legislation will remain the responsibility of the Commission, the Parliament and the Council".

However, in practice the Commission's decisions have largely confirmed the opinions given by the EFSA.[29] This suggests that not the Commission, but rather EFSA itself may in a sense be seen as the de facto risk manager. In the context of the regulation of uncertain risks,[30] where risk assessment standards are subject to debate, the limited influence of those political institutions that are ultimately in charge of decision-making, may be seen as detrimental to the legitimacy of EU policy in this area.

Member State Responses to EU-Level Implementing Decisions

Taken together, these observations may lead to the consideration that there may well be a need to re-examine the legitimacy potential of the existing procedure for the regulation of GMOs: in a situation where sensitive, value-laden choices about the authorisation of GMOs are not only based on scientific advice, but where final decisions are indirectly made by an unelected body, concerns regarding the extent to which the current procedure makes it possible to hold decision-makers to account may be considered very well justified.

On top of this, as already mentioned, the Commission's decisions granting authorisation have to confront often substantial opposition not only from a majority of Member States, but indeed also large sections of the wider public in Europe. A number of Member States have invoked safeguard clauses seeking to ban the placing on the market of certain GMOs for which EU authorisation was granted, a development that may be considered as an indication that the current practice of dealing with GMO regulations may not be the most effective mechanism to make policy in the face of divided opinions from Member States

EU legislation stipulates that for a national safeguard measure to be justified, it must be based on "new or additional evidence" which was not taken into account for the original risk assessment for the respective GMO product, and which would necessitate a review of the original scientific opinion of the EFSA.[31] The validity of the evidence submitted by the Member State is, upon request by the Commission, assessed by the EFSA, which has without exception concluded that the information produced would not challenge its own prior risk assessment. Following up on such opinions, the Commission then submitted proposals requesting the respective Member States to repeal their provisional safeguard measures. However, it has been difficult to actually enforce the lifting of such national bans: the SCFCAH comitology committee has been unable to deliver an opinion on such proposals and the Council has - in the large majority of cases - indicated its opposition to the forced lifting of national bans.[32]

The repeated rejections by the Council of the proposed Commission measures has created difficulties: firstly, as political disagreements in the Council prevent the Commission from adopting proposals that are required by both EU legislation and by international law, the EU is in constant violation of both. Secondly, this also puts the Commission in an impossible position: as the EFSA has consistently re-confirmed the safety of GMOs, the Commission could only act by re-submitting time and again the same (or slightly amended) proposal requesting a Member State to lift its ban, only to see it subsequently being rejected by the Ministers in the Council.

The protracted nature of this process and its outcomes is perhaps most aptly illustrated by the Commission's attempts to force Austria, one the staunchest opponent of the authorisation of genetically modified crops, to open its market for the genetically modified maize line MON810. The first Commission proposal requesting Austria to repeal its national safeguard measures regarding this GMO product was submitted to SCFCAH in November 2004. However, as the committee could not give an opinion on this proposal, the

draft decision was referred to the Council, which, acting by qualified majority, in its turn rejected the proposal. Following a re-confirmation by the EFSA of the safety of MON810, the Commission submitted a second draft decision to the Council requesting Austria to repeal its safeguard measures. Upon the rejection of this proposal by the Ministers in December 2006 and another reconfirmation of the EFSA that the GMO was "unlikely to have adverse effects on human and animal health in the context of its proposed uses", the Commission again re-submitted its draft decision to the Council. However, at the Council meeting in March 2009 over twenty Member States voted against the Commission's proposal, and thereby defeated the Commission's attempt to lift Austria's ban for the third time, after a process that has already lasted for more than four years at the moment of writing.[33]

At the same Council meeting in March, the majority of Ministers backed another national ban introduced by Austria, and a safeguard measure notified by Hungary which the Commission had sought to get lifted for the second time. Proposals lifting national bans imposed by Greece and France have – given the absence of an Opinion in the SCFCAH – also been referred to the Council this spring. In case of further negative votes in the Council, the Commission might feel that it has no choice but to take the 'recalcitrant' Member States to the ECJ in order to find a solution to a very protracted issue. The Commission has done so once in the past, when the Court of First Instance, and then the European Court of Justice, upheld the Commission's decision requesting Austria to lift its general ban on genetic engineering.[34]

However, if anything could be derived from this discussion, it is that the Member States' preparedness to accept each others' explicit will on this sensitive issue prevails against their legal obligation to ensure the smooth functioning of the internal market and their compliance with international trade rules. Clearly, this broadly shared opposition amongst Member States to the enforced lifting of national bans puts in question the workability of the comitology system. This is an interesting addition to the earlier observation regarding the problems arising from the divergence of Member States' positions regarding the authorisation of GMOs. In any case, in the light of this problem one may conclude that the effectiveness of the comitology system falls somewhat short of the expectations that one may have in it, both based on theoretical notions of its functioning and on the empirical record of its performance in any other area than GMOs.

Comitology and the Regulation of GMOs: Not a Good Match?

This analysis of the (mal)functioning of comitology procedures has focused on the particular area of GMO authorisations. As we indicated at the outset, this is not a typical case – in fact, it is an entirely exceptional field in which the 'normal' assumptions about comitology do not seem to apply. In any other arena, the relation between Commission and Member States representatives in comitology committees works very smoothly, with practically no referrals to the Council and a cooperative, problem solving attitude dominating the proceedings. Authors have characterised the nature of this relationship as 'deliberative supranationalism' and have even gone as far as seeing the evidence here for the 'fusion' of national and European administrative systems.

When it comes to GMO authorisations, however, we have seen how this cooperative relationship breaks down, leaving decision-making to be dominated by EU-level scientific experts and technocrats in EFSA and Commission. This means that through the comitology procedure the Commission regularly takes decisions which go against a large number of Member State positions (and against a good share of public opinion). Individual Member States then impose unilateral bans in response to Commission authorisations, and the Commission's desire to get such bans lifted then results in protracted procedural delays and ultimately a situation of an uneven application of policy in the Union.

Given that comitology was initially designed as a mechanism to achieve an efficient implementation of policies, and that it has helped, on the whole, to engender a close and cooperative working relationship between national administrations and Member States, the way in which comitology has (not) worked in the area of GMO authorisation points to the failure of delegation in this field. The comitology procedure in this particular area can be seen to suffer both from a legitimacy deficit (due to the weak political accountability of decision-making) and an efficiency deficit (due to the inability of the Commission to overcome non-compliance by the Member States).

At the heart of the problem is the fact that Member States have delegated to the Commission (and de facto to EFSA) a power to take decisions which a number of them are unwilling to accept. The delegation of such implementing decisions to the European Commission, and the reliance on independent scientific expertise, appears to be highly problematic in an area of regulating uncertain risks such as GMO authorisation where Member States have been unable to take a clear decision either in favour or against the authorisation of GMOs in the basic acts of EU legislation.

NOTES

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1 The authors are grateful for research assistance and valuable comments received from Johanna Miriam Oettel. The usual disclaimer applies.

2 See e.g. R. Pedler and G. Schaefer (eds) Shaping European Law and Policy: The Role of Committees and Comitology in the Political Process (Maastricht: EIPA, 1996); T. Christiansen, J. Oettel and B. Vaccari (eds) 21st Century Comitology: Implementing Committees in the Enlarged European Union (Maastricht: EIPA, 2009); T. Christiansen & T. Larsson The Role of Committees in the EU Policy-Process (Cheltenham: Edward Elgar, 2007); H. Hofmann and A. Türk, EU Administrative Governance (Cheltenham, Edward Elgar, 2006).

3 European Commission (February 2008) List of Comitology Committees, online on http://ec.europa.eu/transparency regcomitology/docs/comitology_committees_en.pdf.

4 European Commission (2005/2006/2007/2008) Report from the Commission on the Working of Committees during 2004/ 2005/2006/2007 (Brussels: Commission of the European Communities).

5 The SCFCAH was established by Art. 30 of Directive 2001/18 EC on the deliberate release into the environment of geneticall modified organisms.

6 Figure is derived from the Comitology Register of the European Commission, online on http://ec.europa.eu transparency regcomitology/recherche.cfm?CL=en (for data until 1 April 2008) and http://ec.europa.eu/transparency regcomitology index_en.htm (for documents after 1 April 2008). The SCFCAH did deliver favourable opinions in eleven cases, but these did not concern authorisation Decisions.

7 Conclusion based on information provided on EurLex.

8 Conclusion based on data retrieved from EurLex. Since the establishment of the SCFCAH, the Commission has authorised the placing on the market of a number of genetically modified products. Authorisation via a Commission Decision occurred following either a negative opinion of the SCFCAH and the subsequent lack of a Council opinion, or no opinion being delivered by both the SCFCAH and the Council.

9 Commission Decision 2006/68/EC of 13th January 2006 on the placing on the market of foods and food ingredients derived from genetically modified maize line MON 863 as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council, online on http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2006/ l_034/l_03420060207en00260028.pdf. The application was made under Regulation (EC) 258/97 concerning novel food and food ingredients, the precursor of Regulation (EC) 1829/2003 on genetically modified food and feed. Under the 'old' Regulation, an applicant had to file its application with the national competent authority of the Member State where the GMO was to be placed on the market in the first instance.

10 Ibid.

11 Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the safety of foods and food ingredients derived from insect-protected genetically modified maize MON 863 and MON 853 x MON 810, The EFSA Journal (2004) 50, 1-25, online on http:// www.efsa.europa.eu/en/science/gmo/gmo_opinions/383.html.

12 J. Lemen, B. Hammond, S. Riordan, C. Jiang & M. Nemeth, 2002) Sponsor Summary of CV-2002-260: 13-Week Dietary Subchronic Comparison Study with MON 863 Corn in Rats Preceded by a 1-Week Baseline Food Consumption Determiniation (Monsanto).

13 Statement on an evaluation of the 13-week rat feeding study on MON 863 maize, accessed on http://www.efsa.europa.eu/ EFSA/efsa_locale-1178620753812_1178620775579.htm.

14 European Commission (23 May 2005) Voting Result Fiche, online on http://ec.europa.eu/transparency/regcomitology repository_prod/9999/2005/EN/9999-2005-1639-EN-.Doc.

15 With 175 votes in favour, 81 votes against and 61 abstentions, no qualified majority was reached either way (ibid.).

16 Council of the European Union (11 January 2006) Draft Minutes 2685th Meeting of the Council of the European Union (Brussels: Council of the European Union).

17 Séralini, G. (June 2005) Report on MON 863 Maize Produced by Monsanto CIE (Paris: Comité de Recherche et d'Information Indépendantes sur la Génie Génétique)

18 Written Question by Hiltrud Breyer (VERTS/ALE) to the Commission on the approval of MON 863 genetically modified maize – shortcomings identified in expert reports (P- 4154/05), online on http://www.europarl.europa.eu/sides/ getDoc.do?pubRef=-//EP//TEXT+WQ+P-2005-4154+0+DOC+ XML+V0//EN&language=EN.

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21 Commission Decision 2006/68/EC of 13th January 2006 on the placing on the market of foods and food ingredients derived from genetically modified maize line MON 863 as novel foods or novel food ingredients under Regulation (EC) No 258/97 of the European Parliament and of the Council, online on http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/ oj/2006/l_034/l_03420060207en00260028.pdf.

22 Commissioner Markos Kyprianou in European Parliament (2007) MON 863 – Risk management (debate) (Brussels: European Parliament).

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24 Regulation 1829/2003, Art. 7(1).

25 Case T-13/99 Pfizer Animal Health SA v Council of the European Union, Judgement of the Court of First Instance, 11 September 200 [2002] ECR II-03305.

26 European Parliament (9 July 2007) Debate on MON 863 – Risk Management.

27 Council, Declarations on Council Decision 1999/458/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, OJ C203, 17.07.1999.

28 Council Decision 1999/458/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission, Art. 5(6) (emphasis added).

29 Supra note 23.

30 Van Asselt, M. & Vos, E. (2008) 'Wrestling with Uncertain Risks: EU Regulation of GMOs and the Uncertainty Paradox', *Journal of Risk Research, 11, 218-300.*

31 Directive 2001/18/EC, Article 23(1).

32 In nine out of eleven cases, a qualified majority was opposed to a forced lifting of bans.

33 European Commission (10 February 2009) Proposal for a Council Decision concerning the provisional prohibition of the use and sale in Austria of genetically modified maize (Zea mays L. Line MON810) pursuant to Directive 2001/18/EC of the European Parliament and of the Council (COM(2009) 56 final).

34 Joined Cases T-366/03 and T-235/04 Land Oberösterreich and Republic of Austria v Commission of the European Communities (Rec.2005, p.II-4005); Joined Cases C-439/05 P and C-454/ 05 P Land Oberösterreich and Republic of Austria v Commission of the European Communities (Rec.2007, p.I-7141).