EUROPEAN UNION

Committee of the Regions

NAT-VI/003

5th commission meeting – 21 September 2015

DRAFT OPINION
of the
Commission for Natural Resources
on
The decision-making process on genetically modified food and feed

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This document will be discussed at the meeting of the **Commission for Natural Resources** to be held **from 11 a.m. to 6 p.m. on 21 September 2015**. To allow time for translation, any amendments must be submitted through the online tool for tabling amendments (available through the Members' Portal: http://cor.europa.eu/members) **by no later than 3 p.m. (Brussels time) on Friday 8 September 2015**. A user guide is available at http://toad.cor.europa.eu/CORHelp.aspx.

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Reference documents

Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) 1829/2003 as regards the possibility for Member States to restrict or prohibit the use of genetically modified food and feed on their territory – COM(2015) 177 final

Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Reviewing the decision-making process on genetically modified organisms (GMOs) – COM(2015) 176 final

Draft opinion of the Commission for Natural Resources on the decision-making process on genetically modified food and feed

I. POLICY RECOMMENDATIONS

THE EUROPEAN COMMITTEE OF THE REGIONS

1. broadly welcomes the intention underlying the Commission's proposal to give a greater say to the regions and extend their decision-making powers;

2. seriously questions the appropriateness of the measure in this particular case, however;

3. points to the widespread mistrust and lack of acceptance among the general population with respect to genetically modified organisms. This mistrust and lack of acceptance should be addressed, for instance by ensuring a more transparent authorisation process for genetically modified food and feed;

4. reiterates the call for clearer labelling rules so that consumers can make informed purchasing choices. Transparent labelling must also clearly show the use of genetically modified feed in the production of animal food products;

5. refers here to the Committee of the Regions opinion on *Freedom for Member States to decide on the cultivation of genetically modified crops in their territory* (CdR 338/2010 fin) (adopted at the 88th plenary session on 27 and 28 January 2011) and its *Resolution on the priorities for the 2016 work programme of the European Commission* (adopted at the 113th plenary session on 9 July 2015).

Authorisation procedure for genetically modified food and feed

6. notes that the European Union has a very comprehensive legal framework governing the authorisation, traceability and labelling of genetically modified organisms (GMOs) and genetically modified (GM) food and feed, based on: Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC; Regulation (EC) No 1829/2003 of 22 September 2003 on genetically modified food and feed; and Directive (EC) No 1830/2003 of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC;

7. observes that the proposed regulatory framework provides that no GMO or genetically modified food or feed may be placed on the market without prior authorisation having being granted under the relevant legal framework;

8. notes that the authorisation procedure for genetically modified food and feed provides for a concluding scientific assessment of the application documents by the European Food Safety Authority (EFSA);

9. notes further that after receiving the EFSA assessment, the Commission presents the Member States, represented in the Standing Committee on Plants, Animals, Food and Feed, with a draft decision as to whether the authorisation should be granted or refused;

10. observes that if the result of voting is inconclusive both in the Standing Committee for Plants, Animals, Food and Feed and in the Appeal Committee, the Commission is obliged under the GMO legal framework and the Charter of Fundamental Rights to take a decision on any application for authorisation;

Review of the authorisation procedure for genetically modified food and feed

11. points out that in its work programme for 2015 the Commission announced its intention to review the process for approving genetically modified organisms in order to address the concerns of the general public and of Member States about the Commission's current legal obligation to grant authorisation of GMOs even in cases where no qualified majority of the Member States is in favour of such authorisation;

12. is surprised that the promise of a review has yielded only a proposal on the use of genetically modified food and feed, as opposed to a radical revision of the authorisation procedure as had been indicated;

13. draws attention to the voting behaviour of the individual Member States under the current authorisation procedure pursuant to Regulation (EC) No 1829/2003 on GM food and feed;

14. laments the fact that voting on genetically modified food and feed in the Standing Committee and the Appeal Committee regularly fails to produce a qualified majority for or against the draft decision;

15. remarks that a Member States may be motivated to abstain or to vote against authorisation because of concerns relating not only to the scientific assessment but also to issues outside the scope of the EFSA risk assessment;

16. notes that under current legislation, the Commission must take a decision on authorisation applications;

17. regrets in particular that the Commission therefore always in practice takes the decision without the endorsement of the Member States' vote, with Commission decisions in the case of a positive EFSA opinion generally being to grant authorisation;

18. deplores the consequence of this, namely that concerns – e.g. relating to social considerations – of one or more Member States expressed during the authorisation process tend not to be taken into account in the decision to grant authorisation;

19. stresses for this reason that authorisation based solely on the EFSA's risk assessment is increasingly being criticised;

Proposals for improving the current authorisation procedure

20. shares the Member States' view that since authorisation or non-authorisation of GMOs is a matter of great public interest, it is imperative that there be a way of taking concerns, including non-scientific concerns, into account in the decision-making process;

21. regrets that this is not in practice the case at the moment: under the current procedure the EFSA's risk assessment is ultimately the main basis for a decision taken by the Commission, since opinions of the Member States diverge and there are not enough votes to achieve a qualified majority;

22. advocates a system whereby, subject to legal examination and notwithstanding observations about the current proposal for a regulation, it should only ever be possible in future for the Commission to take a positive decision on an application if the Standing Committee or the Appeal Committee also votes in favour by at least a qualified majority;

23. believes that this would allow any continuing reservations on the part of the Member States to be better accommodated and would strengthen their sense of responsibility for the way they vote;

24. does not share the Commission's view that the existing legal framework must be preserved and that voting rules are immutable solely on the basis that they apply in other policy areas;

25. therefore calls on the Commission to consider whether it would be possible to change the authorisation requirements for GMOs at risk management level in a way that is compatible with European law;

26. like the Commission, is in favour of a single risk assessment system;

27. calls for closer cooperation between the European Commission and national or regional authorities responsible for GMO cultivation;

28. points out that this could improve acceptance of the risk assessment by the Member States as well as improving the quality of the assessment;

29. would advocate a better examination of the environmental concerns raised about genetically modified plants, as well as GM food and feed, during the authorisation procedure;

30. sees a pressing need to include the reinforced guidelines of the EFSA for the environmental impact assessment of genetically modified plants in the annexes of the directive on deliberate release of GMOs (2001/18/EC), so as to give these binding legal force;

Appraisal of the proposal for a Regulation

31. observes that in its Communication COM(2015) 176 the Commission discusses in detail the way the authorisation procedure works, which it too regards as unsatisfactory, and proposes a change in the regulation on genetically modified food and feed, along the same lines as provided for in Directive (EU) 2015/412 (opt-out rules for GMO cultivation);

32. believes that the Commission's objective of better addressing the concerns of individual Member States would be better achieved by a revision of the environmental risk assessment part of the authorisation process in the very near future – as has just been provided for in Article 3 of Directive (EU) 2015/412 – than by the proposal for a Directive that is now on the table;

33. notes that the point of the proposal is not to change the uniform level of safety that has been established through the EU-wide risk assessment by the EFSA. The EU legal framework already has provisions allowing the Member States to ban a product pending re-evaluation at EU level in cases where new findings indicate that a genetically modified food or feed could pose a serious risk to health or the environment;

34. notes that Member States should be granted the right to adopt decisions at national level to restrict or to ban the use of GMOs in food and feed that are authorised at EU level (opt-out measures with respect to the use of GMOs);

35. points out that the Member States must nevertheless ensure in such cases that their measures comply with EU law in respect of the proportionality principle and the requirement not to discriminate between national and non-national products, and with the EU's international commitments in the WTO;

36. notes that as well as being consistent with WTO global-level provisions, measures must be compatible with the principle of free circulation of goods in the internal market as laid down in Article 34 of the Treaty on the Functioning of the European Union (TFEU), which proscribes any measures that would have an equivalent effect to quantitative restrictions on free movement of goods;

37. observes that Member States wanting to use the prohibition option must justify their measures on the basis of Article 36 TFEU and with compelling reasons of general interest in accordance with European Court of Justice case law; in addition, the reasons invoked by the Member State for banning a product may not conflict with the assessment carried out by the EFSA for risks to human and animal health and to the environment;

38. considers it unsatisfactory that, as current experience indicates, a prohibition option entails unreasonably high hurdles for a Member State to overcome before it can exercise this option at national level and impose a ban;

39. in that regard, regrets the failure to provide a list of examples of legally watertight grounds on which a national prohibition could be justified. Such a list, which has proved helpful in providing legal certainty, is contained for example in Directive (EU) 2015/412 amending

Directive 2001/18/EC in relation to the option accorded the Member States of restricting or banning the cultivation of genetically modified organisms (GMOs) on their sovereign territory;

40. thus explicitly laments the failure to attach an impact assessment to the proposal;

41. in short, criticises the Commission's proposal for giving Member States the option of restricting or banning the use of GMOs in food and feed products authorised by the EU yet giving no indication of how countries can implement such a decision with legal certainty at national level;

42. believes that it is therefore very difficult to predict at the moment to what extent the prohibition option could be used at all in practice given the multitude of conditions to be met;

43. notes with dissatisfaction that current experience suggests it is impossible to cost-effectively monitor a national ban in view of the free circulation of goods in the internal market and of global goods flows, not to mention the multiple links in the process chains of industrial food and feed production;

44. believes it would be preferable to take more account of Member States' concerns by changing the weighting of votes in the two committees referred to above, rather than having a national prohibition system. Such systems can only be introduced after clearing many hurdles and are moreover virtually impossible to monitor;

45. does not therefore agree with the Commission's conclusions that led to this proposal for a Regulation;

46. would consequently recommend that the proposal for a regulation be rejected.

Brussels, …

II. PROCEDURE

Title	Decision-making process for genetically modified food and feed
Reference documents	COM(2015) 177 final and COM(2015) 176 final
Legal basis	Article 307(4) TFEU
Procedural basis	Own-initiative opinion
Date of Council/EP referral/Date of Commission letter	–
Date of Bureau/President's decision	12 May 2015
Commission responsible	Commission for Natural Resources
Rapporteur	Mark Weinmeister (DE/EPP), CoR member, Secretary of State for European Affairs, *Land* of Hesse
Analysis	July 2015
Discussed in commission	Scheduled for 21 September 2015
Date adopted by commission	Scheduled for 21 September 2015
Result of the vote in commission (majority, unanimity)	
Date of adoption in plenary	Provisionally 12-14 October 2015
Previous Committee opinions	• CdR 33/2002 – Opinion on the *Proposals for Regulations on genetically modified food and feed, on their traceability and labelling, and on their transboundary movement*[1] • CdR 149/2006 – Opinion on the *Report on the implementation of national measures on the coexistence of genetically modified crops with conventional and organic farming*[2] • CdR 338/2010 – Opinion on *Freedom for Member States to decide on the cultivation of genetically modified crops in their territory*[3]
Date of subsidiarity monitoring consultation	–

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1 OJ C 278, 14.11.2002, p. 31.

2 OJ C 57, 10.3.2007, p. 11.

3 OJ C 104, 2.4.2011, p. 62.