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COMMISSION STAFF WORKING DOCUMENT

**Considerations on legal issues on genetically modified food and feed raised in the
opinion of the Legal Service of the Council of the European Union of 21 December 2015**

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CONSIDERATIONS ON LEGAL ISSUES ON GENETICALLY MODIFIED FOOD AND FEED RAISED IN THE OPINION OF THE LEGAL SERVICE OF THE COUNCIL OF THE EUROPEAN UNION OF 21 DECEMBER 2015

1. INTRODUCTION

1. The Commission adopted on 22 April 2015 a Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory¹. It is proposed to insert a new Article 34a which would provide the Member States a legal basis to adopt, if they so wish, measures restricting or prohibiting the use of products authorised under that Regulation, subject to certain conditions:

"1. Member States may adopt measures restricting or prohibiting the use of products referred to in Article 3(1) and 15(1) authorised pursuant to this Regulation provided that such measures are:

(a) reasoned and based on compelling grounds in accordance with Union law which shall, in no case, conflict with the risk assessment carried out pursuant this Regulation;

(b) proportional and non-discriminatory.

2. Where a Member State intends to adopt measures as provided for in paragraph 1, it shall first submit to the Commission a draft of those measures, and the corresponding justification. The Commission shall immediately notify to the other Member States the draft measures and the corresponding justification. The Member State may submit the draft measures and such information before the authorisation procedure provided for in Articles 7 and 19 has been completed.

During a period of 3 months from the date of submission to the Commission of the draft measures and information in accordance with the first subparagraph:

(a) the Member State shall refrain from adopting and implementing those measures;

(b) the Commission and the Member States may make any comments they consider appropriate to the Member State which has submitted the draft measures.

3. Measures adopted in accordance with paragraph 1 of this Article shall provide for a reasonable period of time during which existing stocks of the products referred to in Article 3(1) and 15(1) concerned by such measures, which could legally be used before the date of adoption of the measures, may be used up.

¹ COM(2015) 177 final; interinstitutional reference 2015/0093 (COD).

4. Measures adopted in accordance with paragraph 1 of this Article shall not affect the use, in the Member State concerned, of food and feed containing an adventitious or technically unavoidable presence of genetically modified material which, by application of the thresholds set out in Articles 12 and 24, are not required to be labelled in accordance with this Regulation.

5. Paragraph 1 to 4 of this Article shall not apply to GMOs for cultivation.”

2. The rationale of the proposal is explained in particular by the following recitals in the proposed Regulation:

"(4) The use of genetic engineering in plants and in food and feed is a subject which divides opinion in the Member States and this is reflected in the decision-making process leading to the authorisation of GMOs and GM food and feed. Since the date of application of Regulation (EC) No 1829/2003, the results of the voting in the committees or in Council show that there has never been a qualified majority either in favour of or against the authorisation of those products. Therefore, authorisations have been adopted by the Commission at the end of the procedure, in accordance with applicable legislation, without the support of the Member States' committee opinion.

(5) Once a GMO or a GM food and feed is authorised in accordance with Directive 2001/18/EC or Regulation (EC) No 1829/2003, the Member States may not prohibit, restrict or impede the free circulation of that product within their territory, except in accordance with strict conditions which are laid down by Union law –and require to provide evidence of a severe risk to health or to the environment. Some Member States have had recourse to the safeguard clauses and the emergency measures provided for respectively in Articles 23 of Directive 2001/18/EC and Article 34 of Regulation (EC) No 1829/2003. Other Member States have made use of the notification procedure provided for in Article 114(5) and (6) of TFUE which also is required to be based on new scientific evidence relating to the protection of the environment or the working environment. Other Member States have adopted unilateral prohibitions. Some of these measures have been challenged before national jurisdictions or the Court of justice.

(6) That situation was changed recently as regards GMOs for cultivation due to the adoption, on 13 March 2015, of Directive (EU) 2015/412 which amended Directive 2001/18/EC to allow Member States to restrict or prohibit the cultivation of GMOs in their territory. The new provisions are primarily aimed at enabling Member States to decide whether or not they wish to permit the cultivation of GMO crops on their territory, without affecting the risk assessment provided in the system of Union authorisations of GMOs. They were intended to provide more predictability to operators and limit the recourse by the Member States to the safeguard clauses provided for in Article 23 of Directive 2001/18/EC and 34 of Regulation (EC) No 1829/2003. It was also expected that those amendments would have a positive impact on the decision-making process for the authorisation of GMOs for cultivation.

(7) The reasons for the amendments made to Directive 2001/18/EC, by Directive (EU) 2015/412 as regards GMOs for cultivation are also relevant for other GMOs and GM food and feed covered by Regulation (EC) No 1829/2003. Indeed, the results of the vote on the implementing decision for the authorisation of products covered by

Regulation (EC) No 1829/2003 which are not intended for cultivation in the relevant committee, or in the Council, is always "no opinion" (no qualified majority either in favour of or against the authorisation) and there are also Member States in which the use of these products is prohibited. Taking those matters into account, it is appropriate to amend Regulation (EC) No 1829/2003 in order to provide the possibility for the Member States to restrict or prohibit the use of GMOs and GM food and feed in all or part of their territory, on the basis of compelling grounds compatible with Union law - not related to risks to human and animal health and to the environment, as those are already assessed at Union level, pursuant to Regulation (EC) No 1829/2003. This possibility should not apply to GMOs for cultivation which are already covered by the amendments made to Directive 2001/18/EC, by Directive (EU) 2015/412."

3. The proposal does not amend other provisions of Regulation (EC) No 1829/2003.
4. On 21 December 2015, the Legal Service of the Council of the European Union issued an opinion² concerning the choice of the legal basis for the proposal and its compatibility with internal market and World Trade Organisation (WTO) rules. The conclusions of this opinion read as follows:
 - *"the Commission proposal in its current wording could not be based on Article 114 TFEU, since no evidence is provided that it would result in an improved functioning of the authorisation and safeguard mechanisms provided for in that Regulation;"*
 - *"there would be serious doubts about the compatibility with internal market and WTO rules of any restricting or prohibiting measures that Member States could adopt on the basis of the new Article 34a to be inserted in Regulation 1829/2003."*

2. LEGAL BASIS OF THE PROPOSAL

2.1 The Council Legal Service's main arguments

5. The Council Legal Service argues that the Commission proposal does not provide evidence that, firstly, the existing situation regarding the use of GM food and feed does not allow the smooth functioning of the internal market and, secondly, that the proposed Regulation is intended to remedy such a situation (see point 20 of the opinion).
6. The Council Legal Service reaches this conclusion on the basis of arguments concerning mainly the notion of "use" of GM food and feed and its links with the notion of "placing on the market":
 - The Council Legal Service points out that *"according to the established case-law of the Court of Justice, national measures restricting or prohibiting the "use" of a product on the territory of a Member State have a considerable influence on the behaviour of consumers, which, in its turn, affects the access of that product to the market of that Member State."*

² Document 15529/15.

- The Council Legal Service also contends that the presence in the proposal of a transitional measure concerning the exhaustion of stocks "*shows that the national restricting or prohibiting measures provided for in the Commission proposal, even if formally limited to the use of GM food and feed, have actually a direct effect also on the placing on the market of the products concerned*";

2.2 The position of the Commission services

7. The Commission proposal is based on Article 114 TFEU on the approximation of the provisions laid down by laws, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market. Article 114 TFEU was, alongside Articles 43 and 168(4)(b) TFEU³, the legal basis of Regulation (EC) No 1829/2003.
8. Firstly, the legal basis of this proposal cannot be considered in isolation from the Regulation it proposes to amend, which is also based on Article 114 TFEU. Indeed, the proposal introduces limited changes, consisting of a single operational article, a new Article 34a, in the framework already established by Regulation (EC) No 1829/2003.
9. The existing harmonised rules set out in this Regulation will not be affected by this proposal. Notably, the Commission will remain empowered to decide on the authorisation of GM food and feed, based on a risk assessment and, if relevant, on other legitimate factors under the substantial and procedural conditions set out in the Regulation.
10. The proposal would supplement the rights that the Member States derive from Article 34 of the Regulation⁴, under which they may adopt emergency measures in case of a serious risk to human health, animal health or the environment. The newly inserted provision would allow Member States to use other relevant legitimate factors at their level, to decide on the use of authorised GM food and feed on their territory, taking into account their particular national circumstances.
11. The case-law of the Court has already recognised that the EU legislature retains the right, in domains which it has already harmonised for the purpose of the establishment and functioning of the internal market, to adjust that harmonisation, in order to safeguard the general interests recognised by the Treaty and to take account of any

³ Ex-Articles 37 and 152(4)(b) EC.

⁴ "Where it is evident that products authorised by or in accordance with this Regulation are likely to constitute a serious risk to human health, animal health or the environment, or where, in the light of an opinion of the Authority issued under Article 10 or Article 22, the need to suspend or modify urgently an authorisation arises, measures shall be taken under the procedures provided for in Articles 53 and 54 of Regulation (EC) No 178/2002."

change in perceptions or circumstances⁵. The purpose of the proposal is precisely to proceed to such an adjustment.

12. Secondly, unlike the Council's Legal Service, the Commission services consider that the aim of the proposed Regulation is genuinely to ensure the smooth functioning of the internal market and that this is sufficiently demonstrated in its recitals.
13. Recitals 4 and 5 of the proposed Regulation highlight problems affecting the functioning of the internal market in this specific sector, in particular difficulties in the decision-making process for authorisations of GM food and feed, the recourse of Member States to safeguard measures, as well as unilateral prohibitions of GM food and feed⁶.
14. It is clear especially from recitals 4 to 7 that the purpose of this proposal is to remedy these problems. The proposed Regulation is expected to facilitate the decision-making process for the authorisation of GM food and feed, give more predictability to operators and limit the recourse by the Member States to safeguard clauses/emergency measures, thereby ensuring a smoother functioning of the internal market.
15. Moreover, the problems identified by the Commission are also explained in detail in the explanatory memorandum to the Commission proposal and in the Communication "Reviewing the decision-making process on genetically modified organisms" adopted by the Commission on the same day as its proposal for a Regulation.
16. Thirdly, the arguments of the Council Legal Service mainly seek to show the link between the notions of "use" and of "placing on the market" of a product. However, in the view of the Commission services, these arguments fail to establish, how this link would be such as to question the use of Article 114 TFEU as a legal basis.
17. Notably, the Council Legal Service refers to case-law pointing out the influence of restrictions or prohibitions on the use of a product on the behaviour of consumers. However, firstly, the Commission services do not deny that restrictions or prohibitions on the use of a product may have effects on the placing on the market of that product. Secondly, it is a fact that many measures adopted for the purpose of the establishment and the functioning of the internal market, such as labelling requirements or conditions of use, do have a similar impact while being rightfully based on Article 114 TFEU. Significantly, this is also the case of safeguard clauses introduced in EU legislation allowing Member States to adopt emergency measures, such as Article 34 of Regulation (EC) No 1829/2003.
18. It is also worth reminding that this proposal is inspired to a large extent by Directive (EU) 2015/412 of the European Parliament and of the Council, which is also based on Article 114 TFEU. This Directive introduced the possibility for a Member State, to

⁵ Case C-491/01, *British American Tobacco*, 10 December 2002, paragraphs 77 and 78; Case C-58/08, *Vodafone*, 8 June 2010, paragraph 34.

⁶ One of these measures was examined by the Court in Case C-313/11, *Commission vs Poland*, 18 July 2013. The national legislation concerned remains in force.

demand that the geographical scope of an authorisation for cultivation be adjusted to the effect that all or part of the territory of that Member State be excluded from cultivation. The Council endorsed the choice of Article 114 TFEU as the legal basis of this Directive, which, just as the present proposal, refers only to possible bans or restrictions on the "use" of GMOs (the cultivation).

19. Finally, the Commission services do not see how the proposed provision (Article 34a, paragraph 3) on the exhaustion of stocks could be considered as contradictory with the use of Article 114 TFEU as a legal basis. Indeed, as the Council Legal Service acknowledges it, this is a typical provision in legislation based on Article 114 TFEU. This type of provision is intended to give economic operators some time to adapt to changes in the rules regulating the functioning of the internal market in a given sector.
20. In the light of the above, the Commission services are of the opinion that the proposal, as it stands, can lawfully be based on Article 114 TFEU. However, there is always the possibility to consider clarifications to the recitals if this would improve the understanding of Article 114 TFEU as a legal basis.

3. POSSIBLE NATIONAL MEASURES: INTERNAL MARKET

3.1 The Council Legal Service's main arguments

21. The Council's Legal Service argues that it would be very difficult, if not impossible, to identify, in practice, the type of national measures that could lawfully be adopted by the Member States on the basis of this new provision (see point 26 of the opinion).
22. According to the Council Legal Service, while the protection of public morality could theoretically be invoked, national restricting or prohibiting measures based on these grounds would be unlikely to be accepted by the Court.

3.2 The position of the Commission services

23. The Commission services note that the Council's Legal Service does not question the compatibility of the Commission proposal as such with internal market rules.
24. The Commission services agree with the Council's Legal Service that any national measure based on the proposed Regulation should be substantiated to withstand the Court scrutiny and not be contradictory, and that substantive, persuasive and unequivocal evidence would be required.
25. As regards the Member State measures that may be adopted under the proposal, assessing their compatibility with internal market rules is inherently speculative because neither the text nor the surrounding factual circumstances exist as yet, both of which would be necessary parts of any such assessment. However, the Commission services do not share the scepticism of the Council's Legal service about the actual possibility for the Member States to lawfully adopt such national measures.

26. Notably, a national measure which is genuinely based and substantiated on public morality or ethical considerations, one of the grounds listed in Article 36 TFEU on the basis of which national measures derogating from Article 34 TFEU may be justified, could in practice stand the scrutiny of the Court. In case C-165/08, *Commission vs Poland*, the Court already dealt with ethical considerations in relation to GMOs. In that specific case, the Court held in points 57 and 59 of its judgement that the reasons why it could not accept that Member State's defence was the mixed nature of the justifications invoked by that Member State and the lack of substantiation that such ethical considerations were indeed at the origin of the national measures. However, importantly, this ruling did not put into question the established case-law of the Court recognising that Member States enjoy a degree of discretion when defining their own conception of public morals⁷.
27. In that respect, it should be reminded that Regulation (EC) 1829/2003 acknowledges the overall relevance of ethical considerations in relation to GM food and feed, since Article 33 thereof refers to the possibility to consult the European Group on Ethics in Science and New Technologies, or any other appropriate body it might establish, on ethical issues.
28. Moreover, in accordance with established case-law of the CJEU, the grounds listed in Article 36 TFEU are not the only grounds on the basis of which national measures derogating from Article 34 TFEU may be justified. Indistinctly applicable measures may also be justified on the basis of overriding reasons of public interest⁸ that have been developed in the case-law of the CJEU. The Council's Legal Service considers that it does not seem possible, in this case, to rely on such grounds (cf footnote 16 of its legal opinion). The Commission services see no reasons to set aside these grounds, especially since there is no closed list of such grounds and that new grounds may be recognised by case-law.
29. It is also worth reminding that the possibility offered to the Member States in this proposal is in essence not different from the possibility offered to the Member States in Directive (EU) 2015/412 concerning the cultivation of GMOs.
30. Another possibility is that the measures adopted on the basis of the proposed Regulation consist of regional or local measures, which, by reasons of their limited scale, could in certain cases not be considered as equivalent to an obstacle to free circulation of goods as defined by Article 34 TFEU. This argument had been developed by the Council's Legal Service itself in a previous opinion, dated 5 November 2010⁹, in the context of the negotiation of Directive (EU) 2015/412.

⁷ Case C-34/79, *Henn and Darby*, 14 December 1979.

⁸ Case 120/78, *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein* (known as the "Cassis de Dijon" case), 20 February 1979, and the subsequent case-law.

⁹ Document 15696/10, paragraph 35.

31. Finally, the compatibility with EU law of the national measures that could be adopted on the basis of the proposed Regulation is also protected by the substantial and procedural conditions included in the proposal to that effect. Measures adopted by Member States will have to be based on compelling grounds, respect the proportionality principle and be non-discriminatory (cf paragraph 1 of the proposed Article 34a). The Commission and the other Member States will be consulted on the draft measures prepared by a Member State and will have an opportunity to make comments (cf paragraph 3 of the proposed Article 34a).

4. POSSIBLE NATIONAL MEASURES: WTO (GATT 1994)

4.1 The Council Legal Service's main arguments

32. As far as WTO rules are concerned, the Council Legal Service considers that Article III.4 of the GATT, which provides that imported products must be treated in a way no less favourable than the way "like products" of national origin are treated, is likely to be the provision at stake.
33. The Council Legal Service considers that, on the one hand, GM food and feed, and, on the other hand, non-GM food and feed would be probably not considered "like products" under that provision.
34. It nevertheless looks into possible justifications under Article XX of the GATT, would GM food and feed and non-GM food and feed be considered like products in a "worst-case scenario". The Council Legal Service refers to Article XX(a) concerning measures "necessary to protect public morals", but considers that it would be very difficult in practice to rely on it.

4.2 The position of the Commission services

35. The Commission services note that this discussion is similar to the one that took place in the context of the negotiation of Directive (EU) 2015/412 on the cultivation of GMOs, on the basis, in particular, of the opinions issued by the Council Legal Service on 5 November 2010 (points 37 to 43) and 12 April 2011¹⁰ (points 20 to 31).
36. In this respect, the Commission services refer to the views they expressed in this context in the Commission Staff Working Document dated 19 November 2010¹¹ (points 48 to 64). These views are applicable *mutatis mutandis* to possible national measures prohibiting or restricting the use of GM food and feed.
37. In particular, the Commission services would like to make the following points.
38. Firstly, the proposal is consistent with WTO law, as it neither mandates WTO inconsistent action nor precludes WTO consistent action. It merely provides that,

¹⁰ Document 8994/11.

¹¹ Document SEC(2010) 1454 final.

within the EU, certain decisions may be taken at Member State level. As regards the Member State measures that may be adopted under the proposal, assessing the WTO consistency or inconsistency of such measures is inherently speculative because neither the text nor the surrounding factual circumstances exist as yet, both of which would be necessary parts of any such assessment.

39. Secondly, the Commission services take note of the opinion of the Council Legal Service to the effect that one of the provisions that could be relevant is Article III:4 of the GATT. The Commission services agree that, depending on the facts of the case, Article III:4 of the GATT could be one of the provisions that comes into play.
40. Thirdly, the Commission services take note of the observation of the Council Legal Service that, under the terms of the proposal, any measures adopted by Member States must be non-discriminatory. This precludes in particular measures that would discriminate against goods on the grounds of origin, *de jure* (that is, explicitly). However, it does not necessarily preclude origin neutral measures, the assessment of which under Article III:4 of the GATT 1994 would depend on all the surrounding factual circumstances.
41. Fourthly, the Commission services also take note of the opinion of the Council Legal Service that, in this respect, "the critical issue" would be whether or not the GM food and feed and non-GM food and feed are like products, and that this would probably not be the case. The Commission services take the view that it is not possible to answer this question with certainty in general and abstract terms, because it depends on the particular food or feed that would be concerned by the measure to be adopted by the Member State. However, the Commission services agree with the Council Legal Service that this would certainly be one way in which to defend an origin neutral measure and one that would probably be successful in certain factual scenarios.
42. Fifthly, the Commission services also take note of the opinion of the Council Legal Service to the effect that an origin neutral measure is "likely" to give rise to less favourable treatment, and take the view that it is not possible to answer this question with certainty in general and abstract terms, because it depends on the particular food or feed that would be concerned by the measure to be adopted by the Member State. In this respect, the Commission services do not believe that it is possible to say in abstract and general terms that such a conclusion is "likely". Rather a complainant would have to demonstrate that the origin neutral measure has an impact on competitive opportunities, as opposed to there being a situation in which the origin of the complaint rather reflects private commercial decisions.
43. Sixthly, the Commission services take note of the opinion of the Council Legal Service to the effect that it is necessary to consider all of the relevant general exceptions provided for in Article XX of the GATT 1994. Whether or not any of these general exceptions would be available would depend on the measure to be adopted by the Member State and all the surrounding circumstances, which are not known at this time.

44. Finally, the Council Legal Service conclusions do not appear to take into account the possible role of the WTO TBT Agreement. In this respect, the Commission services consider that it is quite possible or even likely that measures to be adopted by the Member States would be technical regulations that fall within the scope of the TBT Agreement. This could be the case, for example, if they would be mandatory and would lay down product characteristics. Under the TBT Agreement, unlike the GATT, the list of potentially legitimate regulatory objectives is open. Furthermore, under WTO law, in the event of a conflict between a provision of the GATT and a provision of the TBT Agreement, the provision of the TBT Agreement prevails to the extent of the conflict. Thus, whilst the Commission services cannot speculate with respect to measures not yet adopted, and their factual context, it cannot be ruled out that the open list of legitimate regulatory objectives in the TBT Agreement will still have role to play in the overall legal analysis.
45. For all of these reasons, the Commission services would not concur with the conclusion of the Council Legal Service to the effect that it is possible to state today that there should be "serious doubts" about the compatibility of the envisaged measures with WTO law.