



2017/0000(RSP)

19.4.2017

DRAFT MOTION FOR A RESOLUTION

pursuant to Rule 106(2) and (3) of the Rules of Procedure

draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize DAS-40278-9, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed(2017/0000(RSP))

Committee on the Environment, Public Health and Food Safety

Members responsible: Bart Staes

Lynn Boylan, Guillaume Balas, Eleonora Evi, Valentinas Mazuronis, Sirpa Pietikäinen

European Parliament resolution on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize DAS-40278-9, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (D050183– 2017/0000 (RSP))

The European Parliament,

- having regard to the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize DAS-40278-9, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (D050183),
- having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed¹, and in particular Articles 7(3), 9(2) and 19(3) and 21(2) thereof,
- having regard to the vote of the Standing Committee on the Food Chain and Animal Health referred to in Article 35 of Regulation (EC) No 1829/2003, on 27 March 2017, where no opinion was delivered,
- having regard to Articles 11 and 13 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers²,
- having regard to the opinion adopted by the European Food Safety Authority (EFSA) on 26 October 2016, and published on 5 December 2016³;
- having regard to the proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (COM(2017)0085, COD(2017)0035),
- having regard to its previous resolutions objecting to the authorisation of genetically modified organisms⁴,

¹ OJ L 268, 18.10.2003, p. 1.

² OJ L 55, 28.2.2011, p. 13.

³ Scientific Opinion on an application by DOW AgroSciences LLC (EFSA-GMO-NL-2010-89) for placing on the market the genetically modified herbicide-tolerant maize DAS-40278-9 for food and feed uses, import and processing under Regulation (EC) No 1829/2003; doi: 10.2903/j.efsa.2016.4633; EFSA Journal 2016;14(12):4633 [25 pp.].

⁴ - Resolution of 16 January 2014 on the proposal for a Council decision concerning the placing on the market for cultivation, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line 1507)

- having regard to the motion for a resolution of the Committee on the Environment,

genetically modified for resistance to certain lepidopteran pests (OJ C 482, 23.12.2016, p. 110)),

- Resolution of 16 December 2015 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize NK603 × T25 (P8_TA(2015)0456),

- Resolution of 3 February 2016 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87705 × MON 89788 (P8_TA(2016)0040),

- Resolution of 3 February 2016 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87708 × MON 89788 (P8_TA(2016)0039),

- Resolution of 3 February 2016 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean FG72 (MST-FGØ72-2) (P8_TA(2016)0038),

- Resolution of 8 June 2016 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21, and genetically modified maize combining two or three of those events (P8_TA(2016)0271),

- Resolution of 8 June 2016 on the draft Commission implementing decision as regards the placing on the market of a genetically modified carnation (*Dianthus caryophyllus* L., line SHD-27531-4) (P8_TA(2016)0272),

- Resolution of 6 October 2016 on the draft Commission implementing decision renewing the authorisation for the placing on the market for cultivation of genetically modified maize MON 810 seeds (P8_TA(2016)0388),

- Resolution of 6 October 2016 on the draft Commission implementing decision authorising the placing on the market of genetically modified maize MON 810 products (P8_TA(2016)0389),

- Resolution of 6 October 2016 on the draft Commission implementing decision concerning the placing on the market for cultivation of genetically modified maize Bt11 seeds (P8_TA(2016)0386),

- Resolution of 6 October 2016 on the draft Commission implementing decision concerning the placing on the market for cultivation of genetically modified maize 1507 seeds (P8_TA(2016)0387),

- Resolution of 6 October 2016 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913 (P8_TA(2016)0390),

- Resolution of 5 April 2017 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21, and genetically modified maize combining two, three or four of the events Bt11, 59122, MIR604, 1507 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European parliament and of the Council on genetically modified food and feed (P8_TA-PROV(2017)0123).

- having regard to Rule 106(2) and (3) of its Rules of Procedure,
- A. whereas on 11 November 2010, Dow AgroSciences Europe submitted an application for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from DAS-40278-9 maize to the national competent authority of the Netherlands in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003; whereas that application also covered the placing on the market of genetically modified maize DAS-40278-9 in products consisting of it or containing it for uses other than food and feed as any other maize, with the exception of cultivation;
- B. whereas on 26 October 2016, the European Food Safety Authority (EFSA) adopted a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003, which was published on 5 December 2016⁵;
- C. whereas the DAS-40278-9 maize expresses the AAD-1 protein which confers tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and aryloxyphenoxypropionate (AOPP) herbicides;
- D. whereas independent research raises concerns about the risks of the active ingredient of 2,4-D as regards embryo development, birth defects and endocrine disruption; whereas it is not clear if, and to what extent, 2,4-D products contain impurities of highly toxic dioxins and furans, which are human carcinogens and endocrine disruptors and which persist in the environment and accumulate in the food chain⁶;
- E. whereas the approval of the active substance 2,4-D was renewed in 2015; whereas the presence of impurities such as dioxins and furans has been acknowledged below certain levels; whereas information by the applicant as regards the potential endocrine properties of the substance still has to be submitted⁷;
- F. whereas authorising the import of DAS-40278-9 maize into the Union will undoubtedly lead to an increase in its cultivation elsewhere, such as in the US, Brazil and Argentina, and to a corresponding increase in the use of 2,4-D and AOPP herbicides; whereas independent research raises also concerns about major gaps in the comparative assessment, serious gaps as regards the toxicology assessment (e.g. the fact that no testing of the whole plant in a feeding study was requested, no long-term or accumulated effects were considered, the impact on reproductive systems was not discussed, as well as methodological flaws within the animal studies), and an

⁵ Available at: <https://www.efsa.europa.eu/en/efsajournal/pub/4633>

⁶ <http://www.pan-europe.info/sites/pan-europe.info/files/public/resources/reports/pane-2014-risks-of-herbicide-2-4-d.pdf>

⁷ Commission Implementing Regulation (EU) 2015/2033 of 13 November 2015 renewing the approval of the active substance 2,4-D in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 298, 14.11.2015, p. 8).

inconclusive assessment of the possible impact on the immune system⁸;

- G. whereas many critical comments were submitted by Member States during the three-month consultation period; whereas those comments refer to, inter alia: missing or insufficient data, missing explanations, contradictory statements in the application, poor test design, missing tests, e.g. as regards allergenicity, questionable results of the safety assessment studies, the lack of any 90-day subchronic toxicity study with the whole food, which makes it impossible to assess the potential risk of consuming food products made with the maize, and the choice and design of the studies taken into consideration for the risk assessment⁹;
- H. whereas, in spite of all these concerns, EFSA did not consider any post-market monitoring of food/feed derived from maize DAS-40278-9 to be necessary;
- I. whereas the vote of the Standing Committee on the Food Chain and Animal Health referred to in Article 35 of Regulation (EC) No 1829/2003, on 27 March 2017 delivered no opinion; whereas 16 Member States voted against, while only 9 Member States, representing only 36,22 % of the Union population voted in favour, and 3 Member States abstained;
- J. whereas, in both the explanatory memorandum of its legislative proposal presented on 22 April 2015 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 territory and in the explanatory memorandum of the legislative proposal presented on 14 February 2017 amending Regulation (EU) No 182/2011, the Commission deplored the fact that, since the entry into force of Regulation (EC) No 1829/2003, authorisation decisions have been adopted by the Commission without the support of the Member States' committee opinion and that the return of the dossier to the Commission for final decision, which is very much the exception for the procedure as a whole, has become the norm for decision-making on genetically modified food and feed authorisations; whereas that practice has, on several occasions, been deplored by Commission President Juncker as not being democratic¹⁰;
- K. whereas the European Parliament rejected the legislative proposal of 22 April 2015 amending Regulation (EC) No 1829/2003 on 28 October 2015 at first reading and called on the Commission to withdraw it and submit a new one;
- L. whereas Recital 14 of Regulation (EU) No 182/2011 of the European Parliament and of

⁸ Bauer-Panskus/ Then: Testbiotech comment on EFSA Scientific Opinion on an application by DOW AgroSciences LLC (EFSA-GMO-NL-2010-89) for placing on the market the genetically modified herbicide-tolerant maize DAS-40278- 9 available at: <https://www.testbiotech.org/node/1862>

⁹ See EFSA Register of Questions, Annex G to Question Number EFSA-Q-2010-01326, available online at: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2010-01326>

¹⁰ E.g. in the Opening Statement at the European Parliament plenary session included in the political guidelines for the next European Commission (Strasbourg, 15 July 2014) or in the State of the Union Address 2016 (Strasbourg, 14 September 2016).

the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers clearly states that: 'When considering the adoption of other draft implementing acts concerning particularly sensitive sectors, notably taxation, consumer health, food safety and protection of the environment, the Commission, in order to find a balanced solution, will, as far as possible, act in such a way as to avoid going against any predominant position which might emerge within the appeal committee against the appropriateness of an implementing act.'¹¹;

1. Considers that the draft Commission implementing decision exceeds the implementing powers provided for in Regulation (EC) No 1829/2003;
2. Considers that the Commission implementing decision is not consistent with Union law, in that it is not compatible with the aim of Regulation (EC) No 1829/2003, which is, in accordance with the general principles, laid down in Regulation (EC) No 178/2002¹², to provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market;
3. Calls on the Commission to withdraw its draft implementing decision;
4. Calls on the Commission to suspend any implementing decision regarding applications for authorisation of genetically modified organisms until the authorisation procedure has been revised in such a way so as to address the shortcomings of the current procedure, which has proven inadequate;
5. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.

¹¹ OJ L 55, 28.2.2011, p. 13.

¹² OJ L 31, 1.2.2002, p. 1.