



2017/0000(RSP)

28.6.2017

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 soybean DAS- 68416-4, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (D051451 – 2017/0000(RSP))

Committee on the Environment, Public Health and Food Safety

Member responsible: Bart Staes

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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 soybean DAS- 68416-4, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (D051451 – 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 soybean DAS-68416-4, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (D051451),
- 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 12 June 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 January 2017, and published on 16 March 2017³,
- 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 <https://www.efsa.europa.eu/en/efsajournal/pub/4719>.

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

- Resolution of 16 December 2015 on Commission implementing decision (EU)

2015/2279 of 4 December 2015 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(2017)0123).

- Resolution of 17 May 2017 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 (P8_TA(2017)0215).

- Resolution of 17 May 2017 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from

- having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,
 - having regard to Rule 106(2) and (3) of its Rules of Procedure,
- A. whereas on 25 January 2011, Dow AgroSciences Europe submitted an application for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from genetically modified DAS-68416-4 soybean 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 soybean DAS-68416-4 in products consisting of it or containing it for uses other than food and feed as any other soybean, with the exception of cultivation;
 - B. whereas on 26 January 2017, 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 16 March 2017⁵;
 - C. whereas Regulation (EU) No 1829/2003 specifies that genetically modified food or feed must not have adverse effects on human health, animal health or the environment and that the Commission shall take into account any relevant provisions of Union law and other legitimate factors relevant to the matter under consideration when drafting its decision;
 - D. whereas many critical comments were submitted by Member States during the three-month consultation period⁶; whereas the most worrying assessments find that, for example, ‘the current application and the presented risk assessment data do not provide sufficient information to exclude adverse effects in animal and human unambiguously’, that ‘the data so far provided by the applicant are not sufficient to complete the evaluation of the application’ and ‘limited studies make it challenging to perform a complete risk assessment’;
 - E. whereas Member States criticise, inter alia, the lack of studies on the effect of genetically modified soybean on human and animal health meaning that the environmental risk assessment cannot be finalised, the choice and location of the field sites for the comparative assessment, the fact that the toxicological risk assessment cannot be completed because there was no appropriate toxicity text with plant material from DAS-68416-4 soybean, the lack of information on the complementary herbicides which may be used on the genetically modified crop and their metabolites, that the nutritional assessment is supported by an industry study from which no scientific conclusions can be drawn, and the fact that the applicant’s proposal for an environmental monitoring plan do not meet the objectives defined in Annex VII to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001

genetically modified cotton GHB119 (BCS-GHØØ5-8) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (P8_TA(2017)0214).

⁵ <https://www.efsa.europa.eu/en/efsajournal/pub/4719>

⁶ Annex G - Member States’ comments and GMO Panel responses
<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2011-00052>

on the deliberate release into the environment of genetically modified organisms⁷;

- F. whereas the DAS-68416-4 soybean expresses the aryloxyalkanoate dioxygenase-12 (AAD-12) protein which confers tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and other related phenoxy herbicides; whereas it also expresses the phosphinothricin acetyltransferase (PAT) protein, conferring tolerance to glufosinate ammonium-based herbicides;
- G. whereas independent research raises concerns about the risks of the active ingredient of 2,4-D as regards embryo development, birth defects and endocrine disruption⁸; whereas although the approval of the active substance 2,4-D was renewed in 2015, information from the applicant as regards the potential endocrine properties is still outstanding⁹;
- H. whereas glufosinate is classified as toxic to reproduction and thus falls under the exclusion criteria set out in Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market¹⁰; whereas the approval of glufosinate expires on 31 July 2018¹¹;
- I. whereas a number of experts have voiced concerns about a breakdown product of 2,4-D, 2,4-Dichlorophenol, which may be present on imported DAS-68416-4 soybeans; whereas 2,4-Dichlorophenol is a known endocrine disruptor with reproductive toxicity;
- J. whereas due to the fact that it is highly soluble in fats and oils, 2,4-Dichlorophenol is expected to accumulate in soy oil during the processing of soybeans; whereas the major soy product used by humans is soy oil which is incorporated into, among many other products, some infant formulas¹²;
- K. whereas the amount of 2,4-Dichlorophenol in a product may be higher than the amount of 2,4-D residue; whereas a Union maximum residue level (MRL) does not exist for 2,4-Dichlorophenol;
- L. whereas a recent UN report shows that pesticides are responsible for an estimated 200 000 acute poisoning deaths per year, 99 % of which occur in developing countries¹³;

⁷ [OJ L 106, 17.4.2001, p. 1.](#)

⁸ <http://www.pan-europe.info/sites/pan-europe.info/files/public/resources/reports/pane-2014-risks-of-herbicide-2-4-d.pdf>

⁹ 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).

¹⁰ OJ L 309, 24.11.2009, p. 1.

¹¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32015R0404&from=EN>

¹² Member State consultation document, pages 31 and 32.

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2011-00052>

¹³ <https://documents-dds-ny.un.org/doc/UNDOC/GEN/G17/017/85/PDF/G1701785.pdf?OpenElement>

whereas the Union has signed up to the sustainable development goals (SDGs) which include a commitment to substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination by 2030 (SDG 3, target 3.9), one of the indicators for which is the mortality rate attributed to unintentional poisoning¹⁴; whereas it has been shown that herbicide tolerant genetically modified crops result in higher use of these herbicides than their conventional counterparts¹⁵;

- M. whereas the Union is committed to Policy Coherence for Development which aims at minimising contradictions and building synergies between different Union policies, including in the areas of trade, environment and agriculture¹⁶, to benefit developing countries and increase the effectiveness of development cooperation¹⁷;
- N. whereas authorising the import of DAS-68416-4 soybean into the Union will undoubtedly lead to an increase in its cultivation in third countries, including in developing countries, and to a corresponding increase in the use of 2,4-D and glufosinate herbicides;
- O. whereas the development of genetically modified crops tolerant to several selective herbicides is mainly due to the rapid evolution of weed resistance to glyphosate in countries that have relied heavily on genetically modified crops;
- P. 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 12 June 2017 delivered a no opinion; whereas 15 Member States voted against, while only 11 Member States, representing only 36,57 % of the Union population voted in favour, and two Member States abstained;
- Q. whereas on several occasions the Commission has 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 Standing Committee on the Food Chain and Animal Health 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 also been deplored by Commission President Juncker as not being democratic¹⁸;
- R. 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;

¹⁴ <https://sustainabledevelopment.un.org/sdg3>

¹⁵ <https://link.springer.com/article/10.1007%2Fs00267-015-0589-7>

¹⁶ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52005DC0134&from=EN>

¹⁷ https://ec.europa.eu/europeaid/policies/policy-coherence-development_en

¹⁸ For example, 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).

- S. whereas, pursuant to recital 14 of Regulation (EU) No 182/2011, the Commission should, 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, especially on sensitive issues such as consumer health, food safety and the environment;
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 178/2002¹⁹, 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. Calls on the Commission not to authorise any herbicide tolerant genetically modified plants (HT GMP) without full assessment of the residues from spraying with the complementary herbicides and their commercial formulations as applied in the countries of cultivation;
 6. Calls on the Commission not to authorise any HT GMP made resistant to a combination of herbicides, as is the case with soybean DAS- 68416-4, without full assessment of the specific cumulative effects of the residues from spraying with the combination of the complementary herbicides and its commercial formulations as applied in the countries of cultivation;
 7. Calls on the Commission to request much more detailed testing of health risks relating to stacked events such as DAS- 68416-4;
 8. Calls on the Commission to develop strategies for health risk assessment and toxicology as well as post market monitoring that target the whole food and feed and its mixtures as being present in the food and feed chain under practical conditions;
 9. Calls on the Commission to fully integrate the risk assessment of the application of the complementary herbicides and their residues into the risk assessment of HT GMP, regardless of whether the genetically modified plant is for cultivation in the Union or for import for food and feed;
 10. Calls on the Commission to fulfil its obligation of Policy Coherence for Development

¹⁹ OJ L 31, 1.2.2002, p. 1.

stemming from Article 208 of Treaty on the Functioning of the European Union;

11. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.