



**2019/2829(RSP)**

18.9.2019

# **DRAFT MOTION FOR A RESOLUTION**

pursuant to Rule 112(2) and (3) of the Rules of Procedure

on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D062827/02 – 2019/2829(RSP))

**Committee on the Environment, Public Health and Food Safety**

Members responsible: Tilly Metz

Günther Sidl, Anja Hazekamp, Eleonora Evi, Sirpa Pietikäinen, Nicolae Ștefănuță

**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 MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D062827/02 – 2019/2829(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 MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D062827/02),
- 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 feed<sup>1</sup>, and in particular Articles 7(3) and 19(3) 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 July 2019, at which no opinion was delivered, and to the vote of the Appeal Committee on 16 September 2019, at which again 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 powers<sup>2</sup>,
- having regard to the opinion adopted by the European Food Safety Authority (EFSA) on 28 November 2018, and published on 14 January 2019<sup>3</sup>,
- having regard to its previous resolutions objecting to the authorisation of genetically modified organisms ('GMOs')<sup>4</sup>,
- having regard to the motion for a resolution of the Committee on the Environment,

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<sup>1</sup> OJ L 268, 18.10.2003, p. 1.

<sup>2</sup> OJ L 55, 28.2.2011, p. 13.

<sup>3</sup> Scientific opinion on the Assessment of genetically modified maize MON 89034 x 1507 x MON 88017 x 59122 x DAS-40278-9 and subcombinations independently of their origin for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2013-113), EFSA Journal 2019;17(1):5521, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5521>

<sup>4</sup> In its 8th term, the European Parliament adopted 36 resolutions objecting to the authorisation of genetically modified organisms.

Public Health and Food Safety,

- having regard to Rule 112(2) and (3) of its Rules of Procedure,
- A. whereas, on 6 February 2013, Dow AgroSciences Europe submitted, on behalf of Dow AgroSciences LLC, an application to the national competent authority of the Netherlands ('the application') for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 ( 'the stacked GM maize'), in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003; whereas the application also covered the placing on the market of products containing or consisting of the stacked GM maize for uses other than food and feed, with the exception of cultivation;
- B. whereas the application covered the placing on the market of products containing, consisting of or produced from twenty-five subcombinations of the single transformation events constituting the stacked GM maize; whereas eleven of those subcombinations have already been authorised<sup>5</sup>; whereas the remaining fourteen subcombinations are, in addition to the stacked GM maize, covered by the draft Commission implementing decision;
- C. whereas, on 28 November 2018, EFSA adopted a favourable opinion, in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003, which was published on 14 January 2019<sup>6</sup>;
- D. whereas the stacked GM maize is derived from crossing five genetically modified ('GM') maize events and confers resistance to herbicides containing glufosinate, glyphosate and 2,4-D as well as producing six insecticidal proteins ('Bt' or 'Cry' proteins): Cry1A.105, Cry2Ab2, Cry1F and CryBb1 which are toxic to certain lepidopteran larvae and Cry34Ab1 and Cry25Ab1 which are toxic to certain coleopteran larvae<sup>7</sup>;

### Member State comments

- E. whereas Member States submitted many critical comments to EFSA during the three-month consultation period<sup>8</sup>, including that no final conclusion (especially in relation to foodstuffs) is possible with reference to the long-term reproductive or developmental effects of the food and/or feed in question that further information is required before the risk assessment can be finalised, that the compositional analysis

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<sup>5</sup> 1507 x 59122, authorised by Commission Implementing Decision (EU) 2018/1110 ; MON 89034 × MON 88017, authorised by Commission Implementing Decision (EU) 2018/2046; and MON 89034 × 1507 × MON 88017 × 59122, MON 89034 × 1507 × MON 88017, MON 89034 × 1507 × 59122, MON 89034 × MON 88017 × 59122, 1507 × MON 88017 × 59122, MON 89034 × 1507, MON 89034 × 59122, 1507 × MON 88017, MON 88017 × 59122, authorised by Commission Implementing Decision 2013/650/EU

<sup>6</sup> Scientific opinion on the Assessment of genetically modified maize MON 89034 x 1507 x MON 88017 x 59122 x DAS-40278-9 and subcombinations independently of their origin for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2013-113), EFSA Journal 2019;17(1):5521, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5521>

<sup>7</sup> See EFSA opinion, p. 10-11.

<sup>8</sup> Annex G - Member States comments

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00210>

indicates a lack of equivalence between the stacked GM maize and its conventional counterpart and that, therefore, safety cannot be guaranteed, that the post-market environmental monitoring plan is inadequate, and that more research is needed on the biological role and activities of Cry proteins with regard to mammals before they can be deemed safe;

- F. whereas no experimental data were provided by the applicant for the fourteen currently unauthorised subcombinations of the stacked GM maize<sup>9</sup>; whereas stacked events should not be authorised without a thorough assessment of experimental data relating to each subcombination;

### **Complementary herbicides**

- G. whereas a number of studies show that herbicide-tolerant GM crops result in a higher use of those herbicides<sup>10</sup>; whereas, as a consequence, it has to be expected that the stacked GM maize will be exposed to both higher and repeated doses of glufosinate, glyphosate and 2,4-D, and therefore a higher quantity of residues may be present in the harvest;
- H. whereas, under the coordinated multiannual control programme of the Union for 2020, 2021 and 2022, Member States are not obliged to measure glyphosate, glufosinate or 2,4-D residues on imports of maize<sup>11</sup>; whereas it cannot be excluded that the stacked GM maize or products derived from it for food or feed will exceed Union Maximum Residue Levels (MRLs), which have been put in place for the purpose of protecting consumer health;
- I. whereas questions concerning the carcinogenicity of glyphosate remain; whereas EFSA concluded in November 2015 that glyphosate was unlikely to be carcinogenic; whereas, on the contrary, in 2015 the World Health Organisation's International Agency for Research on Cancer classified glyphosate as a probable carcinogen for humans;
- J. whereas, according to EFSA, toxicological data allowing a consumer risk assessment to be performed for several break-down products of glyphosate relevant for GM glyphosate-tolerant crops are missing<sup>12</sup>;
- K. whereas in GM plants, the way that complementary herbicides are broken down by the plant, and the composition and thus toxicity of the break-down products ('metabolites') may be driven by the genetic modification itself; whereas, according to

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<sup>9</sup> See EFSA opinion, p.4

<sup>10</sup> See, for example, Bonny S, Genetically Modified Herbicide-Tolerant Crops, Weeds, and Herbicides: Overview and Impact, *Environ Manage.* 2016 Jan;57(1):31-48 <https://www.ncbi.nlm.nih.gov/pubmed/26296738> and Impacts of genetically engineered crops on pesticide use in the U.S. -- the first sixteen years, Charles M Benbrook, *Environmental Sciences Europe*; volume 24, Article number: 24 (2012), <https://enveurope.springeropen.com/articles/10.1186/2190-4715-24-24>

<sup>11</sup> Commission Implementing Regulation (EU) 2019/533 of 28 March 2019 concerning a coordinated multiannual control programme of the Union for 2020, 2021 and 2022 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin (OJ L 88, 29.3.2019, p. 28).

<sup>12</sup> EFSA conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, EFSA journal 2015; 13(11):4302, p3 <https://www.efsa.europa.eu/en/efsajournal/pub/4302>

EFSA, this is indeed the case when the complementary herbicide is glyphosate<sup>13</sup>;

- L. whereas glufosinate is classified as toxic to reproduction 1B and therefore meets the ‘cut-off criteria’ criteria set out in Regulation (EC) No 1107/2009 of the European Parliament and of the Council<sup>14</sup>; whereas the approval of glufosinate for use in the Union expired on 31 July 2018<sup>15</sup>;
- M. 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;
- N. whereas a recent article by an expert involved in developing GM plants questions the safety of GM crops tolerant to 2,4-D because of its degradation into the cytotoxic breakdown product 2,4-dichlorophenol (2,4-DCP)<sup>16</sup>;

### **Bt proteins**

- O. whereas a number of studies show that side effects have been observed that may affect the immune system following exposure to Bt proteins and that some Bt proteins may have adjuvant properties<sup>17</sup>, meaning that they can increase the allergenicity of other proteins that they come into contact with;
- P. whereas a minority opinion adopted by a member of the EFSA Panel on GMOs in the process of assessing a similar but different stacked GM maize and its subcombinations found that while unintended effects on the immune system have never been identified in any application where Bt proteins are expressed, they could ‘not be observed by the toxicological studies [...] currently recommended and performed for the safety assessment of GM plants at EFSA because they do not include the appropriate tests for this purpose’<sup>18</sup>;
- Q. whereas a recent study shows that a rapid rise in the use of neonicotinoid seed treatments in the United States coincides with increased planting of GM Bt maize<sup>19</sup>; whereas the Union has banned the outdoor use of three neonicotinoids, including as

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<sup>13</sup> EFSA Review of the existing maximum residue levels for glyphosate according to Article 12 of Regulation (EC) No 396/2005, 2018, p12 <https://www.efsa.europa.eu/fr/efsajournal/pub/5263>

<sup>14</sup> 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 market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

<sup>15</sup> <https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=1436>

<sup>16</sup> Lurquin, P.F. (2016) Production of a toxic metabolite in 2, 4-D-resistant GM crop plants. 3 Biotech, 6(1): 1-4. <https://link.springer.com/article/10.1007/s13205-016-0387-9#CR25>

<sup>17</sup> For a review, see Rubio Infante, N., & Moreno-Fierros, L. (2016) An overview of the safety and biological effects of Bacillus thuringiensis Cry toxins in mammals. Journal of Applied Toxicology, 36(5): 630-648. <http://onlinelibrary.wiley.com/doi/10.1002/jat.3252/full>

<sup>18</sup> Application EFSA-GMO-DE-2010-86 (Bt11 3 MIR162 3 1507 3 GA21 maize and three sub combinations independently of their origin) Minority Opinion J.M. Wal, Member of the EFSA GMO Panel, May 2018 <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5309> p. 34.

<sup>19</sup> ‘Large-Scale Deployment of Seed Treatments Has Driven Rapid Increase in Use of Neonicotinoid Insecticides and Preemptive Pest Management in U.S. Field Crops’ Margaret R. Douglas and John F. Tooker, Environ. Sci. Technol.20154985088-5097, Publication Date (Web):March 20, 2015 <https://pubs.acs.org/doi/10.1021/es506141g>

seed coatings, because of their impact on honeybees and other pollinators<sup>20</sup>;

- R. whereas assessment of herbicide residues and their metabolites on GM plants, as well as their potential interaction with Bt proteins, is considered outside the remit of the EFSA Panel on GMOs;

### **Undemocratic process**

- S. whereas both the Standing Committee on the Food Chain and Animal Health referred to in Article 35 of Regulation (EC) No 1829/2003 (vote on 12 July 2019) and the Appeal Committee (vote on 16 September 2019) delivered no opinion, meaning that the authorisation is not supported by a qualified majority of Member States;
- T. whereas, both in 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 GM 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 opinion of the Member States' committee 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 GM food and feed authorisations; whereas that practice has, on several occasions, been deplored by the Commission President as not being democratic<sup>21</sup>;
- U. whereas, in its 8th term, the European Parliament adopted resolutions objecting to the placing on the market of GMOs for food and feed (33 resolutions) and to the cultivation of GMOs in the Union (3 resolutions); whereas there was not a qualified majority of Member States in favour of authorising any of those GMOs; whereas despite its own acknowledgement of the democratic shortcomings, the lack of support from Member States and the objections of Parliament, the Commission continues to authorise GMOs even though it is under no legal obligation to do so;
1. Considers that the draft Commission implementing decision exceeds the implementing powers provided for in Regulation (EC) No 1829/2003;
  2. Considers that the draft 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 178/2002 of the European Parliament and of the Council<sup>22</sup>, to provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, and environmental and consumer interests, in relation to

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<sup>20</sup> [https://ec.europa.eu/food/plant/pesticides/approval\\_active\\_substances/approval\\_renewal/neonicotinoids\\_en](https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en)

<sup>21</sup> See, for example, 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).

<sup>22</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

- GM food and feed, while ensuring the effective functioning of the internal market;
3. Calls on the Commission to withdraw its draft implementing decision;
  4. Reiterates its commitment to advancing work on the Commission proposal amending Regulation (EU) No 182/2011; calls on the Council to move forward with its work in relation to that Commission proposal as a matter of urgency;
  5. Calls on the Commission to suspend any implementing decision regarding applications for authorisation of GMOs until the authorisation procedure has been revised in such a way as to address the shortcomings of the current procedure which has proven inadequate;
  6. Calls on the Commission to withdraw proposals for GMO authorisations if no opinion is delivered by the Standing Committee on the Food Chain and Animal Health, whether for cultivation or for food and feed uses;
  7. Calls on the Commission not to authorise any herbicide-tolerant GM plants without a full assessment of the residues from spraying with complementary herbicides, their metabolites and commercial formulations as applied in the countries of cultivation;
  8. Calls on the Commission to fully integrate the risk assessment of the application of complementary herbicides and their residues into the risk assessment of herbicide-tolerant GM plants, regardless of whether the GM plant concerned is to be cultivated in the Union or is for import into the Union for food and feed uses;
  9. Calls on the Commission not to authorise the import of any GM plant for food or feed uses which has been made tolerant to a herbicide which is not authorised for use in the Union, in this case glufosinate;
  10. Calls on the Commission not to authorise any subcombinations of stacked events unless they have been thoroughly evaluated by EFSA on the basis of data submitted by the applicant that are complete;
  11. Considers, more specifically, that to approve sub-combinations for which no safety data have been provided, and which have not even been tested or created yet, runs contrary to the principles of general food law, as laid down in Regulation (EC) No 178/2002;
  12. Calls on EFSA to further develop and systematically use methods that permit the identification of unintended effects of stacked GM events, including in relation to the adjuvant properties of Bt toxins;
  13. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.