European Parliament
2019-2024

Committee on the Environment, Public Health and Food Safety

2019/2859(RSP)

29.10.2019

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 × NK603 × DAS-40278-9 and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D062828/04 – 2019/2859(RSP))

Committee on the Environment, Public Health and Food Safety

Members responsible: Tilly Metz

Günther Sidl, Anja Hazekamp, Eleonora Evi, Sirpa Pietikäinen

B9-0000/2019

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 × NK603 × DAS-40278-9 and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council
(D062828/04 – 2019/2859(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 × NK603 × DAS-40278-9 and sub-combinations MON 89034 × NK603 × DAS-40278-9, 1507 × NK603 × DAS-40278-9 and NK603 × DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D062828/04),

– 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[1], 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[2],

– having regard to the opinion adopted by the European Food Safety Authority (EFSA) on 28 November 2018, and published on 16 January 2019[3],

– having regard to its previous resolutions objecting to the authorisation of genetically modified organisms ('GMOs')[4,]

[1] OJ L 268, 18.10.2003, p. 1.
[2] OJ L 55, 28.2.2011, p. 13.
[3] Scientific opinion on the Assessment of genetically modified maize MON 89034 × 1507 × NK603 × 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-2013-112), EFSA Journal 2019; 17(1):5522, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5522
[4] In its eighth term, the European Parliament adopted 36 resolutions objecting to the authorisation of genetically modified organisms. Furthermore, in its ninth term the Parliament has adopted the following resolutions:
- European Parliament resolution of 10 October 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MZHG0JG (SYN-ØØØJG-2), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2019)0028).

– having regard to Rule 112(2) and (3) of its Rules of Procedure,

– having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,

A. whereas, on 11 January 2013, Dow AgroSciences Europe (the 'applicant') submitted, on behalf of Dow AgroSciences LLC, an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified maize MON 89034 × 1507 × NK603 × DAS-40278-9 ('the stacked GM maize') and sub-combinations thereof; 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 seven sub-combinations of the stacked GM maize have already been authorised, or are in the process of being authorised under a separate application; whereas the remaining three sub-combinations (MON 89034 x NK603 x DAS-40278-9, 1507 x NK603 x DAS-40278-9 and NK603 x DAS 40278-9) are covered by the draft Commission implementing decision;

C. whereas the stacked GM maize is derived from crossing four genetically modified ('GM') maize events, and confers tolerance to herbicides containing glufosinate, glyphosate, quizalofop and 2,4-D as well as producing three insecticidal proteins ('Bt' or 'Cry' proteins): Cry1A.105, Cry2Ab2 and Cry1F which are toxic to certain lepidopteran larvae[5];

D. whereas, on 28 November 2018, EFSA adopted a favourable opinion, which was published on 16 January 2019[6];

E. whereas Regulation (EC) No 1829/2003 states that GM food or feed must not have adverse effects on human health, animal health or the environment, and requires the Commission to take into account any relevant provisions of Union law and other legitimate factors relevant to the matter under consideration when drafting its decision;

F. whereas no data were submitted by the applicant to EFSA for the three sub-

---

- European Parliament resolution of 10 October 2019 on the draft Commission implementing decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified soybean A2704-12 (ACS-GMØØ5-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2019)0029).
- European Parliament resolution of 10 October 2019 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 (Texts adopted, P9_TA(2019)0030).

[5] See Table 4 on page 10 of the EFSA opinion. Lepidoptera is an order of insects that includes butterflies and moths.

[6] Scientific opinion on the Assessment of genetically modified maize MON 89034 × 1507 × NK603 × 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-2013-112), EFSA Journal 2019; 17(1):5522, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5522

combinations within the scope of the draft Commission implementing decision[7];

Member State comments and independent study

G. whereas Member States submitted many critical comments to EFSA during the three-month consultation period[8]; whereas those critical comments include the observation that the data provided by the applicant is insufficient to ensure a correct risk assessment, that the risk assessment conducted by EFSA is not sufficient in its present form, having failed to properly assess the overall safety and potential toxicity of the stacked GM maize event for humans, animals and the environment, that EFSA did not take into account recent studies about the potential toxicity of Bt toxins, and that it is impossible to reach conclusions concerning the health risks associated with the stacked GM maize without carrying out chronic feeding studies to properly assess organ and reproductive toxicity, and immune system responses, which take into account realistic residue levels of complementary herbicides and potential combinatorial and cumulative effects;

H. whereas an independent study[9] also concludes that the risk assessment by EFSA is not acceptable in its present form, having failed to properly assess the overall safety and potential toxicity of the stacked GM maize event;

I. whereas that independent study finds that EFSA should have taken the results of the comparative analysis as a starting point for more detailed investigations, since the analysis revealed many significant differences between the stacked GM maize and its conventional counterpart, especially when the stacked GM maize was treated with complementary herbicides;

J. whereas the independent study further concludes that in light of those significant differences, chronic feeding studies and/or multigenerational studies should have been requested by EFSA, in order to be able to properly assess organ and reproductive toxicity and immune system responses, while taking into account the high amount of Bt toxins and realistic residue levels of complementary herbicides and potential combinatorial and cumulative effects;

Lack of assessment of herbicide residues, metabolites and cocktail effects

K. whereas a number of studies show that herbicide-tolerant GM crops result in a higher use of 'complementary' herbicides, in large part because of the emergence of herbicide-tolerant weeds[10]; 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, quizalofop and 2,4-D, and that therefore a higher quantity of residues may be present in

[7] EFSA opinion, p. 20.

[8] Member State comments on the stacked GM maize can be accessed via EFSA's register of questions: http://registerofquestions.efsa.europa.eu/roqFrontend/login?3

[9] https://www.testbiotech.org/sites/default/files/Testbiotech_Comment_MON%2089034%20x%201507%20x%20NK603%20x%20DAS40278-9.pdf

[10] 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

the harvest;

L. whereas questions concerning the carcinogenicity of glyphosate remain; whereas EFSA concluded in November 2015 that glyphosate was unlikely to be carcinogenic and the European Chemicals Agency (ECHA) concluded in March 2017 that no classification was warranted; whereas, on the contrary, in 2015, the International Agency for Research on Cancer (IARC), the specialised cancer agency of the World Health Organization, classified glyphosate as a probable carcinogen for humans;

M. 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[11];

N. whereas glufosinate is classified as toxic to reproduction 1B and therefore meets the 'cut-off criteria' set out in Regulation (EC) No 1107/2009 of the European Parliament and of the Council[12]; whereas the approval of glufosinate for use in the Union expired on 31 July 2018[13];

O. 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 cytotoxic breakdown products[14];

P. whereas assessment of herbicide residues and their break-down products found on GM plants is considered outside the remit of the EFSA Panel on Genetically Modified Organisms (EFSA GMO Panel) and is therefore not undertaken as part of the authorisation process for GMOs; whereas this is problematic since the way in which complementary herbicides are broken down by the GM plant concerned and the composition, and thus toxicity, of the break-down products ('metabolites'), can be driven by the genetic modification itself[15];

Q. whereas, due to specific agricultural practices in the cultivation of herbicide-tolerant GM plants, there are also specific patterns of herbicide application and therefore plant exposure, as well as the emergence of combinatorial effects between the different herbicide residues and their metabolites, that require special attention; whereas these were not considered by EFSA;

R. whereas it therefore cannot be concluded that consumption of the stacked GM maize or its sub-combinations is safe for human and animal health;

---

[11] EFSA conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, EFSA journal 2015; 13(11):4302, p. 3, https://www.efsa.europa.eu/en/efsajournal/pub/4302

[12] 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).

[13] https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=1436

[14] 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

[15] This is indeed the case for glyphosate, as stated in EFSA Review of the existing maximum residue levels for glyphosate according to Article 12 of Regulation (EC) No 396/2005, 2018, p. 12, https://www.efsa.europa.eu/fr/efsajournal/pub/5263

Lack of maximum residue levels and related controls

S. whereas, under Regulation (EC) No 396/2005 of the European Parliament and of the Council [16] , which aims to ensure a high level of consumer protection, specific maximum residue levels (MRLs) should be set for food and feed produced in third countries, when the use of pesticides results in levels of residues different from those resulting from agricultural practice within the Union; whereas this is indeed the case for imported herbicide-tolerant GM crops because of the increased volumes of herbicides used vis-à-vis non-GM crops;

T. whereas, however, according to a 2018 EFSA review of the existing MRLs for glyphosate, available data were insufficient to derive MRLs and risk assessment values for glyphosate in relation to GM maize with an EPSPS modification[17]; whereas the stacked GM maize has the EPSPS modification[18];

U. whereas, again, under Regulation (EC) No 396/2005 the residues on imported crops for food and feed of active substances which are not authorised for use in the Union, such as glufosinate, should be carefully controlled and monitored[19];

V. whereas, under the latest coordinated multiannual control programme of the Union (for 2020, 2021 and 2022), Member States are not obliged to measure glufosinate (nor any other herbicide) on maize (GM or otherwise)[20]; whereas it cannot be excluded that the stacked GM maize, its subcombinations or products derived from it for food and feed will exceed MRLs, which should be put in place and monitored to ensure a high level of consumer protection;

Bt proteins

W. 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[21], meaning that they can increase the allergenicity of other proteins that they come into contact with;

X. whereas a minority opinion adopted by a member of the EFSA GMO Panel in the process of assessing another stacked GM maize and its sub-combinations 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

[16] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1). See recital 26.
[17] Reasoned Opinion on the review of the existing maximum residue levels for glyphosate according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018; 16(5):5263, p4. https://doi.org/10.2903/j.efsa.2018.5263
[18] See Table 4 on page 10 of the EFSA opinion.
[19] See recital 8 of Regulation (EC) No 396/2005
[20] 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.
[21] 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

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'[22];

Y. 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[23]; whereas the Union has banned the outdoor use of three neonicotinoids, including as seed coatings, because of their impact on honeybees and other pollinators[24];

Z. whereas assessment of the potential interaction of herbicide residues and their metabolites with Bt proteins is considered outside the remit of the EFSA GMO Panel and is therefore not undertaken as part of the risk assessment;

Undemocratic decision-making

AA. whereas the vote on 12 July 2019 of the Standing Committee on the Food Chain and Animal Health referred to in Article 35 of Regulation (EC) No 1829/2003 delivered no opinion, meaning that the authorisation was not supported by a qualified majority of Member States; whereas, the vote of 16 September 2019 of the Appeal Committee also delivered no opinion;

AB. whereas the Commission recognises that the fact that GMO authorisation decisions continue to be adopted by the Commission without a qualified majority of Member States in favour, which is very much the exception for product authorisations as a whole but has become the norm for decision-making on GM food and feed authorisations, is problematic[25]; whereas that practice has, on several occasions, been deplored by the Commission President as not being democratic[26];

AC. whereas, in its eighth term, the European Parliament adopted a total of 36 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 (three 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;

AD. whereas no change of law is required for the Commission to be able not to authorise

---

[22] Application EFSA-GMO-DE-2010-86 (Bt11 x MIR162 x 1507 x GA21 maize and three sub combinations independently of their origin) Minority Opinion J.M. Wal, Member of the EFSA GMO Panel, EFSA Journal 2018;16(7):5309, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5309, p. 34.

[23] '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

[24] https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en

[25] See, for example, the explanatory memorandum of the Commission's 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 the explanatory memorandum of the Commission's legislative proposal presented on 14 February 2017 amending Regulation (EU) No 182/2011.

[26] 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).

GMOs when there is no qualified majority of Member States in favour in the Appeal Committee[27];

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[28], 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 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, in the meantime, to stop authorising GMOs when no opinion is delivered by Member States in the Appeal Committee, whether for cultivation or for food and feed uses, in accordance with Article 6(3) of Regulation (EU) No 182/2011;

6. Calls on the Commission not to authorise herbicide-tolerant GM crops until the health risks associated with the residues have been comprehensively investigated on a case-by-case basis, which requires a full assessment of the residues from spraying the GM crops with complementary herbicides, their metabolites and any combinatorial effects;

7. 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;

8. Calls on the Commission not to authorise the import plant for food or feed uses of any GM plant which has been made tolerant to a herbicide-active substance that is not authorised for use in the Union;

9. Calls on the Commission not to authorise any sub-combinations of stacked GM events unless they have been thoroughly evaluated by EFSA on the basis of complete data submitted by the applicant;

10. Considers, more specifically, that to approve varieties for which no safety data have been provided, which have not even been tested, or which have not even been created yet, runs contrary to the principles of the general food law, as laid down in Regulation

[27] The Commission 'may, and not 'shall', go ahead with authorisation if there is no qualified majority of Member States in favour at the Appeals Committee, according to Regulation (EU) 182/2011 (Article 6(3)).

[28] 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).

(EC) No 178/2002;

11. Calls on EFSA to further develop and systematically use methods that permit the identification of unintended effects of stacked GM events, such as in relation to the adjuvant properties of Bt toxins;

12. Urges the Commission to treat the Union's obligations under international agreements, such as the Paris Climate Agreement, the UN Convention on Biological Diversity and the UN Sustainable Development Goals, as 'relevant provisions of Union law' and/or 'legitimate factors' under Regulation (EC) No 1829/2003, and to give them the weight they deserve, as well as communicating on how they have been taken into account in the decision-making process;

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