European Parliament
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Plenary sitting

B9-0346/2020

04.11.2020

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 87427 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and NK603, and repealing Commission Implementing Decision (EU) 2018/1111 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council
(D068777/01 – 2020/2836(RSP))

Committee on the Environment, Public Health and Food Safety

Members responsible: Tilly Metz

Günther Sidl, Anja Hazekamp, Eleonora Evi, Sirpa Pietikäinen

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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 maize MON 87427 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and NK603, and repealing Commission Implementing Decision (EU) 2018/1111 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council
(D068777/01 – 2020/2836(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 87427 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and NK603, and repealing Commission Implementing Decision (EU) 2018/1111 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D068777/01),

– 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 15 September 2020, at which 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 22 May 2019, and published on 8 July 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 of the EFSA Panel on Genetically Modified Organisms on the assessment of genetically modified maize MON 87427 × MON 89034 × MIR162 × NK603 and subcombinations, for food and feed uses, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2016-131), EFSA Journal 2019;17(7):5734, https://doi.org/10.2903/j.efsa.2019.5734
[4] In its eighth term, Parliament adopted 36 resolutions objecting to the authorisation of GMOs. Furthermore, in its ninth term 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

– 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 15 February 2016, Monsanto Europe S.A/N.V. submitted, on behalf of Monsanto company, United States, 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 87427 × MON 89034 × MIR162 × NK603 ('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; whereas, in addition, the application covered the placing on the market of products containing, consisting of or produced from 10 sub-combinations of the single transformation events constituting the stacked GM maize;

B. whereas the stacked GM maize is derived from crossing four genetically modified ('GM') maize events (MON 87427, MON 89034, MIR162 and NK603), confers tolerance to glyphosate-containing herbicides and produces three insecticidal proteins (Cry1A.105, Cry2Ab2 and Vip3Aa20 known as 'Bt' or 'Cry' proteins) which are toxic to certain lepidopteran (butterfly and moth) larvae[5];

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).
- 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).
- European Parliament resolution of 14 November 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 cotton LLCotton25 (ACS-GHØØ1-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2019)0054).
- European Parliament resolution of 14 November 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 MON 89788 (MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2019)0055).
- European Parliament resolution of 14 November 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 × 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 (Texts adopted, P9_TA(2019)0056).
- European Parliament resolution of 14 November 2019 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 × 1507 × 5307 × GA21 and genetically modified maize combining two, three, four or five of the single events Bt11, MIR162, MIR604, 1507, 5307 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2019)0057).
- European Parliament resolution of 14 May 2020 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 × A5547-127, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2020)0069).

C. whereas previous assessments of the four single events and four of the sub-combinations of the stacked GM maize, which have already been authorised, were used as a basis for the assessment of the four-event stacked GM maize and the remaining six sub-combinations[6];

D. whereas, on 22 May 2019, EFSA adopted a favourable opinion, which was published on 8 July 2019, in relation to that application;

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;

Member State comments and additional points

F. whereas Member States submitted many critical comments to EFSA during the three-month consultation period[7]; whereas those critical comments include concerns that no analysis has been done regarding glyphosate residues or glyphosate metabolites on the stacked GM maize, that there has been no testing of the possible synergistic or antagonistic effects of the Cry proteins and the Vip protein and of herbicide residues, that questions on the safety of GM maize and derived food and feed remain unanswered, that the potential long-term reproductive or developmental effects of the food or feed have not been assessed and that, due to missing information, the safety of the stacked GM maize cannot be fully assessed;

G. whereas an independent scientific analysis has found that, inter alia, no final conclusion can be drawn regarding the safety of the stacked GM maize, that the toxicological assessment and the environmental risk assessment are unacceptable and that the risk assessment does not fulfil requirements for assessing risks to the immune system[8];

H. whereas no experimental data was provided by the applicant for the currently unauthorised six sub-combinations of the stacked GM maize;

Lack of assessment of herbicide residues, metabolites and cocktail effects

I. whereas a number of studies show that herbicide-tolerant GM crops result in a higher use of 'complementary' herbicides, due in large part to the emergence of herbicide-tolerant weeds[9]; whereas, as a consequence, it has to be expected that the stacked GM

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[5] EFSA opinion, p. 11.
[6] Idem, p. 3.
[7] Member State comments: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2016-00148
[8] Testbiotech comment on EFSA's assessment of genetically engineered maize MON 87427 × MON 89034 × MIR162 × NK603 and subcombinations, August 2019, https://www.testbiotech.org/en/content/testbiotech-comment-efsa-assessment-genetically-engineered-maize-mon87427xmon89034xMIR162xNK603
[9] See, for example, Bonny, S., 'Genetically Modified Herbicide-Tolerant Crops, Weeds, and Herbicides: Overview and Impact', Environmental Management, January 2016, 57(1), pp. 31-48, https://www.ncbi.nlm.nih.gov/pubmed/26296738 and Benbrook, C.M., 'Impacts of genetically engineered crops on pesticide use in the U.S. - the first sixteen years', Environmental Sciences Europe 24, 24 (2012), https://enveurope.springeropen.com/articles/10.1186/2190-4715-24-24, and Schütte, G., Eckerstorfer, M., Rastelli, V. et al., 'Herbicide resistance and biodiversity: agronomic and environmental aspects of genetically

maize will be exposed to both higher and repeated doses of glyphosate, and that therefore a higher quantity of residues may be present in the harvest; whereas the stacked GM maize expresses three glyphosate-tolerant proteins, making it even more tolerant to higher dosages and repeated spraying;

J. 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 concluded in March 2017 that no classification was warranted; whereas, on the contrary, in 2015, the International Agency for Research on Cancer, the specialised cancer agency of the World Health Organization, classified glyphosate as a probable carcinogen for humans;

K. whereas in its scientific opinion of 22 May 2019, the EFSA Panel on Genetically Modified Organisms (EFSA GMO Panel) states that 'the assessment of herbicide residues in maize herbicide-tolerant crops relevant for this application has been investigated by the EFSA Pesticides Unit'[10]; whereas, according to an opinion by the EFSA Pesticides Unit however, data on glyphosate residues on GM maize with EPSPS modifications[11] are insufficient to derive maximum residue levels and risk assessment values[12];

L. whereas, again according to the EFSA Pesticides Unit, 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[13];

M. whereas assessment of herbicide residues, and herbicide break-down products, found on GM plants, along with their potential interaction with Bt proteins, is considered outside the remit of the 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[14];

Bt proteins

N. 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

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modified herbicide-resistant plants', Environmental Sciences Europe 29, 5 (2017), https://link.springer.com/article/10.1186/s12302-016-0100-y

[10] EFSA opinion, p. 9.

[11] The stacked GM maize contains an EPSPS modification.

[12] EFSA Review of the existing maximum residue levels for glyphosate according to Article 12 of Regulation (EC) No 396/2005 – revised version to take into account omitted data, EFSA Journal 2019;17(10):5862, p. 4, https://www.efsa.europa.eu/en/efsajournal/pub/5862

[13] 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

[14] 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, EFSA Journal 2018;16(5):5263, p. 12, https://www.efsa.europa.eu/fr/efsajournal/pub/5263

have adjuvant properties[15], meaning that they can increase the allergenicity of other proteins that they come into contact with;

O. 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 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'[16];

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

Q. whereas a recent study has shown that a rapid rise in the use of neonicotinoid seed treatments in the United States is associated with increased planting of GM Bt maize[17]; whereas the Union has banned the outdoor use of three neonicotinoids, including as seed coatings, because of their impact on honeybees and other pollinators[18];

Undemocratic decision-making

R. whereas the vote on 15 September 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;

S. 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 which has become the norm for decision-making on GM food and feed authorisations, is problematic;

T. whereas, in its eighth term, 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, to date, Parliament has adopted eight objections in its ninth term; whereas there was not a qualified majority of Member States in favour of authorising any of those GMOs; whereas despite its own

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

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

[17] Douglas, M.R., Tooker, J.F., 'Large-Scale Deployment of Seed Treatments Has Driven Rapid Increase in Use of Neonicotinoid Insecticides and Preemptive Pest Management in U.S. Field Crops', Environmental Science and Technology 2015, 49, 8, 5088-5097, https://pubs.acs.org/doi/10.1021/es506141g

[18] Neonicotinoids, https://ec.europa.eu/food/plant/pesticides/approval_active_substances/approval_renewal/neonicotinoids_en

acknowledgement of the democratic shortcomings, the lack of support from Member States and the objections of Parliament, the Commission continues to authorise GMOs;

U. whereas, under Regulation (EU) No 182/2011, the Commission may decide not to authorise a GMO when there is no qualified majority of Member States in favour in the Appeal Committee[19]; whereas no change of law is required in this respect;

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[20], 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. Welcomes the fact that the Commission finally recognised, in a letter of 11 September 2020 to Members, the need to take sustainability into account when it comes to authorisation decisions on GMOs[21]; expresses its strong disappointment, however, that, on 28 September 2020, the Commission authorised another GM soybean for import[22] despite objections by Parliament and a majority of Member States;

5. Calls on the Commission to move forward with the utmost urgency concerning the development of sustainability criteria, with full involvement of Parliament; calls on the Commission to provide information on how this process will be undertaken and in what timeframe;

6. Urges the Commission, again, to take into account 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;

7. Reiterates it call on the Commission to stop authorising GMOs, whether for cultivation or for food and feed uses, when no opinion is delivered by Member States in the Appeal Committee, in accordance with Article 6(3) of Regulation (EU) No 182/2011;

8. Reiterates its call 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

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[19] The Commission 'may', and not 'shall', go ahead with authorisation if there is no qualified majority of Member States in favour at the Appeal Committee according to Article 6(3) of Regulation (EU) No 182/2011.
[20] 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).
[21] https://tillymetz.lu/wp-content/uploads/2020/09/Co-signed-letter-MEP-Metz.pdf
[22] MON 87708 × MON 89788 × A5547-127, https://webgate.ec.europa.eu/dyna/gm_register/gm_register_auth.cfm?pr_id=100

such GM crops with complementary herbicides, an assessment of the herbicide break-down products and any combinatorial effects;

9. Reiterates its call 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;

10. Reiterates its call 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;

11. Considers, more specifically, that to approve varieties for which no safety data have been provided, which have not been tested, or which have not even been created yet, runs contrary to the principles of general food law, as laid down in Regulation (EC) No 178/2002;

12. Reiterates its call 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;

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