



Plenary sitting

B8-0142/2019

21.2.2019

MOTION FOR A RESOLUTION

pursuant to Rule 106(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 Bt11 × MIR162 × 1507 × GA21 and sub-combinations Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D060244/03 – 2019/2553(RSP))

Committee on the Environment, Public Health and Food Safety

Members responsible: Bart Staes

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

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 Bt11 × MIR162 × 1507 × GA21 and sub-combinations Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D060244/03 – 2019/2553(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 Bt11 × MIR162 × 1507 × GA21 and sub-combinations Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D060244/03),
- 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) 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 14 January 2019, 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 powers²,
- having regard to the opinion adopted by the European Food Safety Authority (EFSA) on 31 May 2018, and published on 11 July 2018³,
- 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 the assessment of genetically modified maize Bt11 x MIR162 x 1507 x GA21 and three subcombinations independently of their origin, for food and feed uses under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2010-86), EFSA Journal 2018;16(7):5309, <https://doi.org/10.2903/j.efsa.2018.5309>

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 (OJ C 399, 24.11.2017, p. 71).

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- 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 (OJ C 35, 31.1.2018, p. 19).
 - 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 (OJ C 35, 31.1.2018, p. 17).
 - 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) (OJ C 35, 31.1.2018, p. 15).
 - 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 maizes combining two or three of those events (OJ C 86, 6.3.2018, p. 108).
 - 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) (OJ C 86, 6.3.2018, p. 111).
 - 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 (OJ C 215, 19.6.2018, p. 76).
 - Resolution of 6 October 2016 on the draft Commission implementing decision authorising the placing on the market of genetically modified maize MON 810 products (OJ C 215, 19.6.2018, p. 80).
 - 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 (OJ C 215, 19.6.2018, p. 70).
 - 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 (OJ C 215, 19.6.2018, p. 73).
 - 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 (OJ C 215, 19.6.2018, p. 83).
 - 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 maizes 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 (OJ C 298, 23.8.2018, p. 34).
 - 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 (OJ C 307, 30.8.2018, p. 71).
 - 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 cotton GHB119 (BCS-GHØØ5-8) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ C 307, 30.8.2018, p. 67).
 - Resolution of 13 September 2017 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 (OJ C 337, 20.9.2018, p. 54).
 - Resolution of 4 October 2017 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean FG72 × A5547-127 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (OJ C 346, 27.9.2018, p. 55).
 - Resolution of 4 October 2017 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-44406-6, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (OJ C 346, 27.9.2018, p. 60).
 - Resolution of 24 October 2017 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 maize 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the

Council on genetically modified food and feed (OJ C 346, 27.9.2018, p. 122).

– Resolution of 24 October 2017 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 × 40-3-2 (DP-305423-1 × MON-04032-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (OJ C 346, 27.9.2018, p. 127).

– Resolution of 24 October 2017 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified oilseed rapes MON 88302 × Ms8 × Rf3 (MON-88302-9 × ACSBN005-8 × ACS-BN003-6), MON 88302 × Ms8 (MON-88302-9 × ACSBN005-8) and MON 88302 × Rf3 (MON-88302-9 × ACS-BN003-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (OJ C 346, 27.9.2018, p. 133).

– Resolution of 1 March 2018 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 maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (Texts adopted, P8_TA(2018)0051).

– Resolution of 1 March 2018 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 × NK603 (MON-87427-7 × MON-89034-3 × MON-00603-6) and genetically modified maize combining two of the events MON 87427, MON 89034 and NK603, and repealing Decision 2010/420/EU (Texts adopted, P8_TA(2018)0052).

– Resolution of 3 May 2018 on the draft Commission implementing decision renewing the authorisation for the placing on the market of food and feed produced from genetically modified sugar beet H7-1 (KM-000H71-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (Texts adopted, P8_TA(2018)0197).

- Resolution of 30 May 2018 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 maize GA21 (MON-00021-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (Texts adopted, P8_TA(2018)0221).

- Resolution of 30 May 2018 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × 59122 × MON 810 × NK603, and genetically modified maize combining two or three of the single events 1507, 59122, MON 810 and NK603, and repealing Decisions 2009/815/EC, 2010/428/EU and 2010/432/EU pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (Texts adopted, P8_TA(2018)0222).

- Resolution of 24 October 2018 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 maize NK603 × MON 810 (MON-00603-6 × MON-00810-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P8_TA(2018)0416).

- Resolution of 24 October 2018 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 × 1507 × MON 88017 × 59122, and genetically modified maize combining two, three or four of the single events MON 87427, MON 89034, 1507, MON 88017 and 59122 and repealing Decision 2011/366/EU (Texts adopted, P8_TA(2018)0417).

- Resolution of 31 January 2019 on the draft Commission implementing decision amending Implementing Decision 2013/327/EU as regards the renewal of the authorisation to place on the market feed containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P8_TA(2019)0057).

- Resolution of 31 January 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize 5307 (SYN-05307-1), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (Texts adopted, P8_TA(2019)0058).

- Resolution of 31 January 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 87403 (MON-87403-1), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P8_TA(2019)0059).

- Resolution of 31 January 2019 on the draft Commission implementing decision authorising the placing on the

- 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 10 August 2010, Syngenta Crop Protection AG submitted, through its affiliated company Syngenta Crop Protection NV/SA, 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 (GM) maize Bt11 × MIR162 × 1507 × GA21 (‘the application’) to the national competent authority of Germany, and the application also covered the placing on the market of products containing or consisting of GM maize Bt11 × MIR162 × 1507 × GA21 for uses other than food and feed, with the exception of cultivation;
- B. whereas the scope of the application, which included all sub-combinations of GM maize Bt11 × MIR162 × 1507 × GA21 at the time of submission, was subsequently limited to include the three sub-combinations Bt11 x MIR162 x 1507, MIR162 x 1507 x GA21 and MIR162 x 1507, independently of their origin, for food and feed uses, import and processing;
- C. whereas the four-event stack maize Bt11 x MIR162 x 1507 x GA21 was produced by conventional crossing to combine four single maize events leading to expression of, *inter alia*, two different Cry proteins (also known as Bt proteins) for protection against certain lepidopteran pests, and expressions of proteins for tolerance against glyphosate and glufosinate;
- D. whereas EFSA adopted a favourable opinion in relation to this application; whereas, however, a minority opinion was expressed by a member of the EFSA Panel on Genetically Modified Organisms (EFSA GMO Panel);

Lack of data on the three sub-combinations

- E. whereas the applicant did not provide data for any of the three sub-combinations, nor did they justify why they do not consider it to be necessary for the risk assessment; whereas EFSA did not request data on the three sub-combinations; whereas it is not known whether those sub-combinations have even been produced yet;

EFSA minority opinion

- F. whereas the minority opinion adopted by a member of the EFSA GMO Panel states that it is unacceptable that ‘assessments’ of GM crops (i.e. the three sub-combinations) for which no data has been provided are given the same weight and reliability as assessments of GM crops for which data has been provided and assessed;

market of products containing, consisting of or produced from genetically modified cotton GHB614 × LLCotton25 × MON 15985 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P8_TA(2019)0060).

- G. whereas, as stated in the minority opinion, studies show that side effects have been observed that may affect the immune system following certain conditions of exposure to Bt proteins and that some Bt proteins may have adjuvant properties, meaning that they can increase the allergenicity of other proteins that they come into contact with;
- H. whereas the minority opinion finds that while unintended effects 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’⁵;
- I. whereas the minority opinion also states that, owing to a lack of data on the three sub-combinations, ‘the risk of increased expression of the newly expressed Bt proteins and of a possible cumulative effect of their combination on the immune system (e.g. resulting in an adjuvant activity) cannot be ruled out’, and that it is not possible to clarify the role of genetically modified organisms (GMOs) in increasing allergenic risk, nor therefore to fully protect consumers who may be at risk;

Lack of assessment and controls of complementary herbicides and their residues

- J. whereas application of the complementary herbicides, in this case glufosinate and glyphosate, is part of regular agricultural practice in the cultivation of herbicide-resistant plants, and it can therefore be expected that they will be exposed to both higher and repeated doses, which will not only lead to a higher burden of residues in the harvest, and therefore in the imported product, but may also influence the composition of the GM plant and its agronomic characteristics;
- K. whereas the use of glufosinate is not permitted in the Union, as it has been classified as toxic to reproduction and thus falls under the cut-off criteria set out in Regulation (EC) No 1107/2009 of the European Parliament and of the Council⁶;
- L. whereas questions remain concerning the carcinogenicity of glyphosate; 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 World Health Organisation’s International Agency for Research on Cancer classified glyphosate as a probable carcinogen for humans;
- M. whereas, in general, according to the EFSA Panel on Plant Protection Products and their Residues, conclusions on the safety of residues from spraying GM crops with glyphosate formations cannot be drawn⁷; whereas additives and their mixtures used in commercial formulations for spraying glyphosate can show a higher toxicity than the

⁵ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5309>, p. 34.

⁶ 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).

⁷ EFSA conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate. EFSA Journal 2015;13(11):4302, <http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4302/epdf>

active ingredient alone⁸;

- N. whereas the Union has already removed a glyphosate additive known as POE-tallowamine from the market owing to concerns over its toxicity; whereas problematic additives and mixtures may, however, still be permitted in the countries where this GM maize is cultivated (currently Argentina, Canada and Japan);
- O. whereas information on residue levels of herbicides and their metabolites is essential for a thorough risk assessment of herbicide-tolerant GM plants; whereas residues from spraying with herbicides are considered outside the remit of the EFSA GMO Panel; whereas the residues from spraying GM maize Bt11 × MIR162 × 1507 × GA21 or the three sub-combinations with herbicides have not been assessed;
- P. whereas, furthermore, metabolites of complementary herbicides occurring on stacked plants may differ from those on the parental plant, which EFSA did not consider in its assessment;
- Q. whereas, according to an independent study⁹, EFSA should have requested that the applicant submit data from field trials with the highest dosage of herbicides that can be tolerated by the plants; whereas material from those plants should have been assessed with regard to organ toxicity, immune system reactions and reproductive toxicity, also taking into account combinatorial effects with other plant compounds and Bt toxins;
- R. whereas, as part of the coordinated multiannual control programme of the Union for 2019, 2020 and 2021, Member States are not obliged to measure glufosinate or glyphosate residues on any maize imports in order to check compliance with maximum residue levels (MRLs)¹⁰; whereas it cannot be guaranteed that glyphosate and glufosinate residues on GM maize Bt11 × MIR162 × 1507 × GA21 or the three sub-combinations will comply with Union MRLs;

Lack of democratic legitimacy

- S. whereas the vote on 14 January 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;
- 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 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

⁸ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3955666>

⁹ https://www.testbiotech.org/sites/default/files/Testbiotech_Comment_Maize%20Bt11xMIR162x1507xGA21_fin.pdf, p. 6.

¹⁰ Commission Implementing Regulation (EU) 2018/555 of 9 April 2018 (OJ L 92, 10.4.2018, p. 6).

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 genetically modified food and feed authorisations; whereas that practice has, on several occasions, been deplored by President Juncker as not being democratic¹¹;

- U. whereas, on 28 October 2015, Parliament rejected at first reading¹² the legislative proposal of 22 April 2015 amending Regulation (EC) No 1829/2003 and called on the Commission to withdraw it and submit a new one;
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 Council¹³, 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 genetically modified food and feed, while ensuring the effective functioning of the internal market;
 3. Calls on the Commission to withdraw its draft implementing decision;
 4. Calls on the Commission not to authorise the import, for food or feed uses, of any GM plants which have been made tolerant to a herbicide that is not authorised for use in the Union, in this case glufosinate;
 5. Calls on the Commission not to authorise any herbicide-tolerant GM plants without a full assessment of the residues from spraying with complementary herbicides, metabolites and commercial formulations as applied in the countries of cultivation;
 6. 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;
 7. Calls on the Commission not to authorise any sub-combinations of stacked events unless they have been thoroughly evaluated by EFSA on the basis of complete data submitted by the applicant;
 8. Calls on EFSA to further develop and systematically use methods that permit the identification of unintended effects of stacked GM events which are known and expected, such as in relation to the adjuvant properties of Bt toxins;

¹¹ 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 the 2016 State of the Union Address (Strasbourg, 14 September 2016).

¹² OJ C 355, 20.10.2017, p. 165.

¹³ OJ L 31, 1.2.2002, p. 1.

9. 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;
10. 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;
11. 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;
12. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.