

Wednesday 13 March 2019

P8_TA(2019)0197

Genetically modified maize MON 87411 (MON-87411-9)

European Parliament resolution of 13 March 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 87411 (MON-87411-9), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D060243/03 — 2019/2552(RSP))

(2021/C 23/07)

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 87411 (MON-87411-9), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D060243/03,
- 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 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 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 powers ⁽²⁾,
- having regard to the opinion adopted by the European Food Safety Authority (EFSA) on 31 May 2018, and published on 28 June 2018 ⁽³⁾,
- having regard to its previous resolutions objecting to the authorisation of genetically modified organisms ⁽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 87411 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2015-124), EFSA Journal 2018; 16(6):5310, p. 29, <https://doi.org/10.2903/j.efsa.2018.5310>

⁽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).
 — 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 maize combining two or three of those events (OJ C 86, 6.3.2018, p. 108).

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- 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 maize combining two, three or four of the events Bt11, 59122, MIR604, 1507 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (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-3Ø5423-1 × MON-Ø4Ø32-6) 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 rapeseeds MON 88302 × Ms8 × Rf3 (MON-883Ø2-9 × ACSBNØØ5-8 × ACS-BNØØ3-6), MON 88302 × Ms8 (MON-883Ø2-9 × ACSBNØØ5-8) and MON 88302 × Rf3 (MON-883Ø2-9 × ACS-BNØØ3-6) 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-89Ø34-3 × MON-ØØ6Ø3-6) 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-ØØØH71-4) 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).

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- 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 5 February 2015, Monsanto Europe N.V. submitted, on behalf of the Monsanto Company, United States, 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 maize MON 87411 ('the application') to the national competent authority of the Netherlands, and the application also covered the placing on the market of products consisting of genetically modified (GM) maize MON 87411 for uses other than food and feed as with any other maize, with the exception of cultivation;
- B. whereas, on 31 May 2018, EFSA adopted a favourable opinion in relation to this application;
- C. whereas GM maize MON 87411 was developed to confer resistance to corn rootworms by the expression of a modified version of the Bt Cry3Bb1 gene and a DvSnf7 dsRNA expression cassette, and tolerance to glyphosate-containing herbicides;
- D. whereas, owing to the resistance of corn rootworms to Bt proteins including Cry3Bb1 in some growing regions of the United States, GM maize MON 87411 has been engineered to also produce an insecticidal double-stranded RNA, dsRNA;
- E. whereas the intended effect of the dsRNA is that it is taken up in the gut of the target organism, in this case larvae of the corn rootworm, interfering with gene regulation of essential biological processes, thereby killing the rootworm;

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- 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-ØØØ21-9) 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-ØØ6Ø3-6 × MON-ØØ81Ø-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-Ø53Ø7-1), 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-874Ø3-1), 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 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).

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- F. whereas Commission Implementing Regulation (EU) No 503/2013 ⁽¹⁾ stipulates that when silencing approaches with RNAi are used in genetically engineered plants, a bioinformatics analysis is required in order to identify potential 'off target' genes; whereas, in this context, a thorough analysis requires the structure of the dsRNA to be compared with genomic regions in organisms that might come into contact with the molecules, including non-target organisms;
- G. whereas, however, EFSA restricted its considerations and risk assessment to potential off-target effects in plants, without looking at effects in humans and livestock and their gut microbiomes that are exposed to maize via the food and feed chain; whereas an assessment of the EFSA opinion by an independent institute describes this as a perfect example of a 'don't look, don't find' strategy, incompatible with existing regulation ⁽²⁾;
- H. whereas the assessment concludes that for, *inter alia*, the reason mentioned above, EFSA's risk assessment of molecular characteristics is not conclusive and is not sufficient to show food and feed safety;
- I. whereas the 90-day toxicity study submitted by the applicant showed statistically significant weight depression of rats fed with GM maize MON 87411; whereas while this finding was dismissed by EFSA because it was not accompanied by test diet-related clinical signs and histopathological changes in the digestive tract, it is plausible that the dsRNA produced in GM maize MON 87411 can interact with the gut microbiome directly without direct uptake from the gut, and that this could explain the findings from animal feeding studies showing weight differences without pathological effects; whereas this should have been further investigated by EFSA;

Lack of assessment and controls of complementary herbicides and their residues

- J. whereas application of the complementary herbicides, in this case 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 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;
- L. 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 drawn ⁽³⁾; whereas additives and their mixtures used in commercial formulations for spraying glyphosate can show a higher toxicity than the active ingredient alone ⁽⁴⁾;
- M. 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, Brazil, Canada and the United States);

⁽¹⁾ Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (OJ L 157, 8.6.2013, p. 1).

⁽²⁾ [https://www.testbiotech.org/sites/default/files/Testbiotech_Comment_Maize%20 Mon87411.pdf](https://www.testbiotech.org/sites/default/files/Testbiotech_Comment_Maize%20Mon87411.pdf)

⁽³⁾ 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>

⁽⁴⁾ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3955666>

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- N. 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 Panel on Genetically Modified Organisms; whereas the impact of spraying GM maize MON 87411 with herbicides has not been assessed;
- O. whereas, as part of the coordinated multiannual control programme of the Union for 2019, 2020 and 2021, Member States are not obliged to measure glyphosate residues on any maize imports in order to check compliance with maximum residue levels (MRLs) ⁽¹⁾; whereas it cannot be guaranteed that glyphosate residues on GM maize MON 87411 will comply with Union MRLs;

Lack of democratic legitimacy

- P. 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;
- Q. 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 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 democratic ⁽²⁾;
- R. whereas, on 28 October 2015, Parliament rejected at first reading ⁽³⁾ 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 Council ⁽⁴⁾, 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 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;
 5. 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;
 6. 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;

⁽¹⁾ OJ L 92, 10.4.2018, p. 6.

⁽²⁾ 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).

⁽³⁾ OJ C 355, 20.10.2017, p. 165.

⁽⁴⁾ OJ L 31, 1.2.2002, p. 1.

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7. Calls on the Commission to suspend any implementing decision regarding applications for authorisation of genetically modified organisms (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;
 8. 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;
 9. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.
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