Thursday 1 March 2018

P8_TA(2018)0052

Genetically modified maize MON 87427 × MON 89034 × NK603

European Parliament 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 (D054771-02 — 2018/2569(RSP))

(2019/C 129/02)

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 × 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 (D054771-02),

— having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([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 16 January 2018, where 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 on 28 June 2017, and published on 1 August 2017 ([3]),

— having regard to the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (COM(2017)0085, COD(2017)0035),

([1]) OJ L 268, 18.10.2003, p. 1.
([2]) OJ L 55, 28.2.2011, p. 13.
([3]) https://www.efsa.europa.eu/en/efsajournal/pub/4922

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— having regard to its previous resolutions objecting to the authorisation of genetically modified organisms ([1]),

— 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,

([1]) — 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 maizes combining two or three of those events (Texts adopted, P8_TA(2016)0271).
— 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) (Texts adopted, P8_TA(2016)0272).
— 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 (Texts adopted, P8_TA(2016)0388).
— Resolution of 6 October 2016 on the draft Commission implementing decision authorising the placing on the market of genetically modified maize MON 810 products (Texts adopted, P8_TA(2016)0389).
— 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 (Texts adopted, P8_TA(2016)0386).
— 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 (Texts adopted, P8_TA(2016)0387).
— 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 (Texts adopted, P8_TA(2016)0390).
— 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 (Texts adopted, P8_TA(2017)0123).
— 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 (Texts adopted, P8_TA(2017)0215).
— 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 (Texts adopted, P8_TA(2017)0214).
— 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 (Texts adopted, P8_TA(2017)0341).
— 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 (Texts adopted, P8_TA(2017)0377).
— 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 (Texts adopted, P8_TA(2017)0378).
— 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 (Texts adopted, P8_TA(2017)0396).
— 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 (Texts adopted, P8_TA(2017)0397).
— 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-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 (Texts adopted, P8_TA(2017)0398).

A. whereas, on 13 September 2013, Monsanto Europe S.A. submitted an application for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from genetically modified (GM) maize MON 87427 × MON 89034 × NK603 to the national competent authority of Belgium in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003; whereas that application also covered the placing on the market of products consisting of or containing genetically modified maize MON 87427 × MON 89034 × NK603 for uses other than food and feed as any other maize, with the exception of cultivation;

B. whereas the application covered, for those uses, all three sub-combinations of GM maize MON 87427 × MON 89034 × NK603;

C. whereas GM maize MON 87427 × MON 89034 × NK603 contains two genes for glyphosate resistance and produces Cry1A.105 and Cry2Ab2 proteins which confer resistance to specific lepidopteran pests;

D. whereas on 28 June 2017 the European Food Safety Authority (EFSA) adopted a favourable opinion, in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003, which was published on 1 August 2017 ([1]);

E. whereas Regulation (EC) No 1829/2003 states that genetically modified food or feed must not have adverse effects on human health, animal health or the environment and that the Commission shall 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 many critical comments were submitted by Member States during the three-month consultation period ([2]); whereas the most critical comments include the fact that the compositional analysis does not cover residues of the complementary herbicides nor its metabolites; that, due to concerns over, inter alia, studies showing an increase in the incidence of bladder stones in mice fed on MON 89034, a conclusion about the risks associated with the use of this GM organism ('GMO') in human or animal food cannot be drawn; that further information is required before the risk assessment can be finalised, and that no conclusions are possible with regard to sub-chronic (no 90-day study was performed), long-term, reproductive or developmental effects of the whole food and/or feed;

G. whereas the competent authority of one Member State has drawn attention to the fact that, for the GM maize MON 87427 × MON 89034 × NK603 (treated with glyphosate) statistically significant differences with the non-GM comparator were identified for 16 grain endpoints ([3]) and 2 forage endpoints ([4]), that even more statistically different grain endpoints (42) were identified in a comparison between the GM maize not treated with glyphosate and its non-GM comparator, and that a significant decrease in the vitamin and mineral content of crops is a major concern for human and animal health given that Type B malnutrition is a global problem;

H. whereas an independent study ([5]) has found that, given those statistical differences, it can be assumed that the GM maize is essentially different from its comparator with regard to many compositional and biological characteristics and that, while the changes taken as isolated data might not raise safety concerns, the overall number of effects and their strong significance should have been taken as a starting point for more detailed investigations; whereas EFSA did not undertake further studies;

I. whereas no experimental data were provided by the applicant for the sub-combinations MON 87427 × MON 89034 and MON 87427 × NK603; whereas, while the EFSA GMO panel expects, following extrapolation of experimental data provided for the other sub-combination and single events, the two sub-combinations to be as safe as the assessed single maize events, MON 89034 × NK603 and MON 87427 × MON 89034 × NK603, no evaluation of the uncertainty relating to the extrapolation was performed; whereas this weakness may invalidate the general conclusion of the EFSA

([1]) https://www.efsa.europa.eu/en/efsajournal/pub/4922

([2]) Annex G — Member States' comments and GMO Panel responses: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00765

([3]) ADF, ash, calcium, magnesium, phosphorus, zinc, arginine, glycine, stearic acid, niacin, α-tocopherol, ferulic acid and p-coumaric acid. See page 94 of Annex G — Member States' comments and GMO Panel responses (http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00765) and page 13 of the EFSA opinion (https://www.efsa.europa.eu/en/efsajournal/pub/4922).

([4]) Moisture and calcium.

([5]) https://www.testbiotech.org/sites/default/files/Testbiotech_Comment_Maize%20MON%2087427%20%C3%97%20MON%2089034%20%C3%97%20NK603%20.pdf

opinion and may also be in breach of EFSA's 'Guidance on Uncertainty Analysis in Scientific Assessment' published in January 2018 ([1]); whereas authorisation should not be considered without a thorough assessment of experimental data for each sub combination of a stacked event;

J. whereas the GMO panel of EFSA observed that the post-market environmental monitoring plan submitted by the applicant for the three-event stack maize does not include any provisions for the two sub-combinations MON 87427 × MON 89034 and MON 87427 × NK603, and therefore recommended that the applicant revise the plan accordingly; whereas, according to the monitoring plan submitted by the applicant, this recommendation has not been taken up ([2]);

K. whereas one of the key purposes of the stacked event is to increase the plant's tolerance to glyphosate (both NK603 and MON 87427 express EPSPS enzymes which confer tolerance to glyphosate); whereas, in consequence, it has to be expected that the plant will be exposed to higher and also repeated dosages of glyphosate which will not only lead to a higher burden of residues in the harvest but may also influence the composition of the plants and their agronomic characteristics; whereas this aspect was not covered in the risk assessment; whereas the residues from spraying with glyphosate were also not assessed in the EFSA opinion;

L. whereas questions concerning the carcinogenicity of glyphosate remain; whereas EFSA concluded in November 2015 that glyphosate is 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 WHO's International Agency for Research on Cancer classified glyphosate as a probable carcinogen for humans; whereas the Parliament has established a special committee on the Union's authorisation procedure for pesticides, which will help to establish if there was undue industry influence over the Union agencies' conclusions on glyphosate's carcinogenicity;

M. whereas, according to the EFSA pesticide panel, on the basis of data provided so far, conclusions on the safety of residues from spraying genetically modified 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]); whereas the Union has already removed an additive known as POE tallowamine from the market due to concerns over its toxicity; whereas however, problematic additives and mixtures may still be permitted in the countries where this GM maize is cultivated;

N. whereas imported GM maize is widely used for animal feed in the Union; whereas a peer-reviewed scientific study has found a possible correlation between glyphosate in feed given to pregnant sows, and an increase in the incidence of severe congenital anomalies in their piglets ([5]);

O. whereas the development of genetically modified crops tolerant to several selective herbicides is mainly due to the rapid evolution of weed resistance to glyphosate in countries that have relied heavily on genetically modified crops;

P. whereas insect resistant traits of the stacked event are due to MON 89034 which expresses Bt proteins (Cry1A.105 and Cry2Ab2) conferring resistance to specific lepidopteran pests (e.g. the European corn borer (Ostrinia nubilalis)); whereas, according to an independent study, in the context of EFSA's risk assessment, the residues from glyphosate should have also been considered to be a potent co-stressor since the impact on cells and organisms exposed to several

([1]) https://www.efsa.europa.eu/en/press/news/180124-0
([2]) Annex F — Post-market environmental monitoring plan: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-00765
([3]) EFSA conclusion of 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
([5]) https://www.omicsonline.org/open-access/detection-of-glyphosate-in-malformed-piglets-2161-0525.1000230.php?aid=27562

stressors in parallel can be of great importance for the efficacy of Bt toxins ([1]); whereas a 2017 scientific study on the possible health impacts of Bt toxins and residues from spraying with complementary herbicides concludes that specific attention should be paid to the herbicide residues and their interaction with Bt toxins ([2]); whereas this was not investigated by EFSA;

Q. whereas 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 16 January 2018 delivered no opinion; whereas 14 Member States voted against, while only 11 Member States, representing only 38,75 % of the Union population voted in favour, and three Member States abstained;

R. whereas on several occasions the Commission has 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 Standing Committee on the Food Chain and Animal Health 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 also been deplored by Commission President Juncker as not being democratic ([3]);

S. whereas Parliament rejected the legislative proposal of 22 April 2015 amending Regulation (EC) No 1829/2003 on 28 October 2015 at first reading ([4]) and called on the Commission to withdraw it and submit a new one;

T. whereas recital 14 of Regulation (EU) No 182/2011 states that the Commission should, as far as possible, act in such a way as to avoid going against any predominant position which might emerge within the appeal committee against the appropriateness of an implementing act, especially on sensitive issues such as consumer health, food safety and the environment;

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, to provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market;

3. Calls on the Commission to withdraw its draft implementing decision;

4. 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 so as to address the shortcomings of the current procedure, which has proven inadequate;

5. Calls on the legislators responsible to advance work on the Commission proposal amending Regulation (EU) No 182/2011 as a matter of urgency and to ensure that, inter alia, if no opinion is delivered by the Food Chain and Animal Health Standing Committee with respect to GMOs approvals, either for cultivation or for food and feed, the Commission will withdraw the proposal;

6. Calls on the Commission not to authorise any herbicide-tolerant genetically modified plants (HT GMP) without full assessment of the residues from spraying with the complementary herbicides and their commercial formulations as applied in the countries of cultivation;

7. Calls on the Commission to request much more detailed testing of health risks relating to stacked events such as genetically modified maize MON 87427 × MON 89034 × NK603;

([1]) https://www.testbiotech.org/sites/default/files/Testbiotech_Comment_Maize%20MON%2087427%20%C3%97%20MON%2089034%20%C3%97%20NK603%20.pdf

([2]) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5236067/

([3]) For example, in 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).

([4]) OJ C 355, 20.10.2017, p. 165.

8. Calls on the Commission to develop strategies for health risk assessment, toxicology and post-market monitoring that target the whole food and feed chain;

9. Calls on the Commission to fully integrate the risk assessment of the application of complementary herbicides and their residues into the risk assessment of HT GMP, regardless of whether the GM plant is for cultivation in the Union or for import for food and feed;

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