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Plenary sitting

B8-0569/2017

20.10.2017

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 oilseed rapes MON 88302 x Ms8 x Rf3 (MON-883Ø2-9 × ACSBNØØ5-8 × ACS-BNØØ3-6), MON 88302 x Ms8 (MON-883Ø2-9 × ACSBNØØ5-8) and MON 88302 x 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
(D052753 – 2017/2907(RSP))

Committee on the Environment, Public Health and Food Safety

Member responsible: Bart Staes

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

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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 oilseed rapes MON 88302 x Ms8 x Rf3 (MON-883Ø2-9 × ACSBNØØ5-8 × ACS-BNØØ3-6), MON 88302 x Ms8 (MON-883Ø2-9 × ACSBNØØ5-8) and MON 88302 x 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
(D052753 – 2017/2907(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 oilseed rapes MON 88302 x Ms8 x Rf3 (MON-883Ø2-9 × ACSBNØØ5-8 × ACS-BNØØ3-6), MON 88302 x Ms8 (MON-883Ø2-9 × ACSBNØØ5-8) and MON 88302 x 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 (D052753),

– 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 September 2017, 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 (EFSA) on 1 March 2017, and published on 10 April 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),

– 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] https://www.efsa.europa.eu/en/efsajournal/pub/4767
[4] - Resolution of 16 January 2014 on the proposal for a Council decision concerning the placing on the market

– 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 3 December 2013 Monsanto Europe S.A. and Bayer CropScience N.V.

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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 (Texts adopted, P8_TA(2015)0456).
- 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 (Texts adopted, P8_TA(2016)0040).
- 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 (Texts adopted, P8_TA(2016)0039).
- 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) (Texts adopted, P8_TA(2016)0038).
- 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 (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

submitted an application for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from genetically modified oilseed rape MON 88302 x Ms8 x Rf3 to the national competent authority of the Netherlands, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003; whereas that application also covered the placing on the market of genetically modified oilseed rape MON 88302 x Ms8 x Rf3 in products consisting of it or containing it for uses other than food and feed as any other oilseed rape, with the exception of cultivation; whereas the application covered, for those uses, all sub-combinations of the single genetic modification events constituting oilseed rape MON 88302 x Ms8 x Rf3;

B. whereas on 1 March 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 10 April 2017;

C. whereas Regulation (EU) No 1829/2003 states that genetically modified 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;

D. whereas the three-event stack oilseed rape (OSR) was produced by conventional crossing to combine three single OSR events: MON 88302, expressing the 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein for tolerance to glyphosate-containing herbicide, MS8, expressing Barnase and phosphinothricin acetyltransferase (PAT) proteins, and RF3, expressing Barstar and PAT proteins, for tolerance to glufosinate-ammonium-containing herbicides and for obtaining heterosis (hybrid vigour);

E. whereas many critical comments were submitted by Member States during the three-month consultation period; whereas the most critical general comments include the observation that ‘the presented data do not support a comprehensive and robust assessment of potential interactions between the single events incorporated into the GM OSR MON 88302 x Ms8 x Rf3, which is required according to EFSA guidance’, that ‘given the study batteries and designs, no final evidence is possible with reference to long-term (especially in regards to foodstuffs), reproductive or developmental effects’, that ‘information (data and data analyses) provided on phenotypic evaluation, composition and toxicology is insufficient’ and that ‘further studies should be carried out to prove the safety of OSR MON 88302 x Ms8 x Rf3’[1];

F. whereas key specific areas of concern relate to the lack of a 90-day feeding study on rats, the lack of assessment of the residues of the complementary herbicides on

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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).

[1] Annex G - Member States’ comments and GMO Panel responses
http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-01002

imported food and feed, the possible negative health consequences thereof and the inadequacy of the environmental monitoring plan;

G. whereas, on the basis of the lack of a 90-day sub-chronic toxicity report on rats, the French Agency for Food, Environmental and Occupational Health and Safety duly rejected the application to place OSR MON 88302 x Ms8 x Rf3 on the market[1];

H. whereas an independent study concludes that the opinion of EFSA should be rejected on account of major flaws and substantial gaps and, hence, the import of viable kernels of the stacked event MON 88302 x MS8 x RF3 into the Union should not be authorised[2];

I. whereas the application of the complementary herbicides is part of regular agricultural practice in the cultivation of herbicide-resistant plants, and it can therefore be expected that residues from spraying will always be present in the harvest and are inevitable constituents; whereas it has been shown that herbicide-tolerant genetically modified crops result in higher use of complementary herbicides than their conventional counterparts[3];

J. whereas glyphosate's current authorisation expires on 31 December 2017 at the latest; whereas questions on the carcinogenicity of glyphosate remain; whereas EFSA concluded in November 2015 that glyphosate is 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 WHO's International Agency for Research on Cancer (IARC) classified glyphosate as a probable carcinogen for humans;

K. 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[4]; whereas additives and their mixtures used in commercial formulations for spraying glyphosate can show a higher toxicity than the active ingredient alone[5]; whereas a number of studies show that glyphosate formulations can act as endocrine disruptors[6];

L. whereas imported genetically modified (GM) soybean 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[7];

M. whereas glufosinate is classified as toxic to reproduction and thus falls under the so-called 'cut-off' criteria set out in Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant

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[1] Idem.
[2] https://www.testbiotech.org/sites/default/files/TBT%20comment%20MON80332%20x%20MS8%20x%20RF3_v2.pdf
[3] https://link.springer.com/article/10.1007%2Fs00267-015-0589-7
[4] 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
[5] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3955666
[6] https://www.testbiotech.org/sites/default/files/TBT%20Background%20Soybean%20305423%20x%2040-3-2.pdf
[7] https://www.omicsonline.org/open-access/detection-of-glyphosate-in-malformed-piglets-2161-0525.1000230.php?aid=27562

protection products on the market[1]; whereas the approval of glufosinate expires on 31 July 2018[2];

N. whereas one Member State competent authority has highlighted the inconsistency of authorising the import of this glufosinate-tolerant GM OSR given that it is unlikely that the authorisation for the use of glufosinate in the Union will be renewed due to its reproductive toxicity[3] ;

O. whereas the residues from spraying with the complementary herbicides were not assessed; whereas it cannot therefore be concluded that this genetically engineered OSR sprayed with glyphosate and glufosinate is safe for use in food and feed;

P. whereas, in addition, many Member State competent authorities have raised concerns about the potential of this GM OSR to establish itself as a feral crop population in the Union, particularly along import transport routes, and have pointed out the insufficiency of the monitoring plan in this regard;

Q. whereas one Member State commented that 'Glyphosate is commonly used for weed control along railways and roadsides in the Union. The high glyphosate tolerance of MON88302 x Ms8 x Rf3 may lead to selective advantage under such circumstances. The effects of this selective advantage on the persistence and invasiveness should be taken into account on assessing the likelihood of the line to form permanent populations in Europe, especially considering the ability of oilseed rape to survive in the seed bank';

R. whereas, according to a 2011 Austrian study, 'Several international studies identify seed spillage during transport activities as a major component for the establishment of feral OSR populations in roadside habitats', that 'it is a well-known problem that feral OSR populations are ubiquitous in countries where OSR is grown but also in countries where OSR seeds are just imported and subsequently transported to oil processing plants' and that 'moreover, importing different types of herbicide tolerant (HT) OSR lines can result in multiple-resistant feral populations ('gene stacking') causing or exacerbating herbicide management problems of road side habitats'[4];

S. whereas the development of GM 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 GM crops; whereas more than 20 different varieties of glyphosate-resistant weeds have been documented in scientific publications[5]; whereas glufosinate-resistant weeds have been observed since 2009;

T. 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 14 September 2017 delivered no opinion; whereas 14 Member States voted against the draft implementing act, only nine Member States, representing only 36.48 % of the Union population voted

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[1] OJ L 309, 24.11.2009, p. 1.
[2] http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32015R0404&from=EN
[3] Annex G - Member States' comments and GMO Panel responses http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-01002
[4] https://www.bmgf.gv.at/cms/home/attachments/3/0/9/CH1060/CMS1215778250501/osrimportban_gt73,ms8xrf3_2011_(nicht_zu_versenden_).pdf, p. 4.
[5] https://link.springer.com/chapter/10.1007/978-94-007-7796-5_12

in favour, and five Member States abstained;

U. whereas on several occasions the Commission has deplored the fact that, since the entry into force of Regulation (EC) No 1829/2003, it has adopted authorisation decisions 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[1];

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

W. whereas recital 14 of Regulation (EU) No 182/2011 states that the Commission will, 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;

X. whereas the Commission's proposal to amend Regulation (EU) No 182/2011 is not sufficient in terms of addressing the lack of democracy in the GMO authorisation process;

Y. whereas democratic legitimacy can only be ensured by providing, at the very least, that when no opinion is delivered by the Food Chain and Animal Health Standing Committee, the Commission proposal is withdrawn; whereas this procedure already exists for some other standing committees;

1. Considers that the draft Commission implementing decision exceeds the implementing powers provided for in Regulation (EC) No 1829/2003;

2. Considers that the 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[2], to provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, the environment, 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 to suspend any implementing decision regarding applications for authorisation of genetically modified organisms until the authorisation procedure has been revised in such a way so as to address the shortcomings of the current

[1] 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).
[2] OJ L 31, 1.2.2002, p. 1.

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) made resistant to a combination of herbicides, as is the case with oilseed rape MON 88302 x Ms8 x Rf3, without a full assessment of the specific cumulative effects of the residues from spraying with the combination of the complementary herbicides and its commercial formulations as applied in the countries of cultivation;

7. Calls on the Commission to request much more detailed testing to determine health risks relating to stacked events such as oilseed rape MON 88302 x Ms8 x Rf3;

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 the complementary herbicides and their residues into the risk assessment of HT GMP, regardless of whether the genetically modified 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, the Commission and the governments and parliaments of the Member States.