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Committee on the Environment, Public Health and Food Safety

2017/0000(RSP)

21.9.2017

DRAFT 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 soybean FG72 x A5547-127 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed
(D051972– 2017/0000(RSP))

Committee on the Environment, Public Health and Food Safety

Members responsible: Bart Staes, Guillaume Balas, Lynn Boylan, Eleonora Evi, Sirpa Pietikäinen, Valentinas Mazuronis

B8-0000/2017

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 soybean FG72 x A5547-127, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (D051972– 2017/0000(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 soybean FG72 x A5547-127, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (D051972),

– 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), 9(2) and 19(3) and 21(2) 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 17 July 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 6 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],

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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/4744

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 (P8_TA(2015)0456).
- Resolution of 3 February 2016 on the draft Commission implementing decision

– 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 December 2013, Bayer Crop Science LP and M.S. Technologies LLC submitted an application for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from genetically modified soybean FG72 x A5547-127 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 soybean FG72 x A5547-127 in products consisting of it or containing it for uses other than food and feed in the same

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authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87705 × MON 89788 (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 (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) (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 (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)) (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 (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 (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 (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 (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 (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

way as any other soybean, with the exception of cultivation;

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 6 April 2017[1];

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 soybean FG72 × A5547-127 was developed to confer tolerance to isoxaflutole- (5-cyclopropylisoxazol-4-yl 2-mesyl-4-trifluoromethylphenyl ketone), glyphosate- (*N*-(phosphonomethyl) glycine) and glufosinate (l-phosphinothricin) ammonium-based herbicides; whereas Tolerance to those herbicides is achieved by expression of the HPPD W336 (4-hydroxyl phenyl-pyruvate-dioxygenase), 2mEPSPS (5-enolpyruvylshikimate-3-phosphate synthase) and PAT (phosphinothricin acetyl-transferase) proteins, respectively;

E. whereas many critical comments were submitted by Member States during the three-month consultation period[2]; whereas the most critical comments include the observation that in the absence of a 90 day sub-chronic toxicity test, no conclusion on the risks relating to the use of this GMO in human and animal feed can be drawn, that information provided on composition, phenotypic evaluation and toxicology is insufficient and conclusions reached on equivalence between the GMO and the conventional soybean, and on food and feed safety, based on this information are premature, and that this GMO soybean has not been tested with the scientific vigour needed to establish its safety;

F. whereas an independent study concludes that the risk assessment by EFSA is not acceptable in its present form since it does not identify knowledge gaps and uncertainties and fails to assess toxicity, or impact on the immune system and the reproductive system[3];

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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 (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 (P8_TA(2017)0214).
- European Parliament 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 (D051451 – 2017/2780(RSP))

1 https://www.efsa.europa.eu/en/efsajournal/pub/4744

2 Annex G - Member States' comments and GMO Panel responses http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-01032

3 http://www.testbiotech.org/en/node/1975

G. 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;

H. whereas glufosinate is 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 Council of 21 October 2009 concerning the placing of plant protection products on the market[1]; whereas the approval of glufosinate expires on 31 July 2018[2];

I. whereas isoxaflutole is likely to be carcinogenic to humans[3], is toxic to some aquatic organisms and to non-target plants, and it and its degradation products and metabolites contaminate water easily; whereas such concerns have resulted in restrictions on its use[4];

J. 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[5];

K. whereas the residues from spraying with the complementary herbicides were not assessed by EFSA; whereas it, therefore, cannot be concluded that genetically engineered soybeans sprayed with isoxaflutole, glyphosate and glufosinate are safe for use in food and feed;

L. whereas the development of genetically modified crops that are 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; whereas more than 20 different varieties of glyphosate resistant weeds have been documented in scientific publications[6]; whereas glufosinate resistant weeds have been observed since 2009;

M. 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 17 July 2017 delivered a 'no opinion'; whereas 15 Member States voted against, only 10 Member States, representing only 38,43% of the Union population, voted in favour, and three Member States abstained;

N. whereas the vote of the Appeal committee on 14 Sept 2017 delivered a 'no opinion';

1 OJ L 309, 24.11.2009, p. 1.
2 http://eur-lex.europa.eu/legalcontent/EN/TXT/HTML/?uri=CELEX:32015R0404&from=EN
3 https://a816-healthpsi.nyc.gov/ll37/pdf/carcclassJuly2004_1.pdf
4 Annex G - Member States' comments and GMO Panel responses,p27 http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2013-01032
5 https://link.springer.com/article/10.1007%2Fs00267-015-0589-7
6 https://link.springer.com/chapter/10.1007/978-94-007-7796-5_12

whereas 15 Member States voted against, only 11 Member States, representing 38,69 % of the Union population, voted in favour, and two Member States abstained;

O. 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[1];

P. whereas the European 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;

Q. 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;

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, 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 genetically modified organisms until the authorisation procedure has been revised in such a way as to address the shortcomings of the current procedure, which has proven inadequate;

5. 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 with their commercial formulations as applied in the countries of cultivation;

6. Calls on the Commission not to authorise any HT GMP made resistant to a combination of herbicides, as is the case with soybean FG72 × A5547-127, without 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

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.

countries of cultivation;

7. Calls on the Commission to request much more detailed testing of the health risks relating to stacked events such as soybean FG72 × A5547-127;

8. Calls on the Commission to develop strategies for health risk assessment and toxicology, as well as 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 GMPs, 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 and the Commission, and to the governments and parliaments of the Member States.