European Parliament
2014-2019

Plenary sitting

B8-0570/2017

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 soybean 305423 x 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
(D052752 – 2017/2906(RSP))

Committee on the Environment, Public Health and Food Safety

Members responsible: Bart Staes

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

B8-0570/2017

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 305423 x 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
(D052752 – 2017/2906(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 305423 x 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 (D052752),

– 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) and 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 14 July 2016, and published on 18 August 2016[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/4566
[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

– 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 20 September 2007 Pioneer Overseas Corporation submitted an application for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from genetically modified soybean 305423 x 40-3-2 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 305423 x 40-3-2 in products consisting of it or containing it for uses other than food and feed as any other soybean, with the exception of cultivation;

B. whereas on 14 July 2016 the European Food Safety Authority (EFSA) adopted a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No

---

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 (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

1829/2003, which was published on 18 August 2016;

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 one of the parental plants, soybean 305423, was genetically engineered with the intention of changing the oil composition in plants and to be resistant to acetolactate synthase (ALS)-inhibiting herbicides, which include herbicides of the imidazolinone, sulfonylurea, triazolopyrimidine, pyrimidinyl(thio)benzoate and sulfonylaminocarbonyltriazolinone chemical families; whereas the other parental plant, soybean 40-3-2, incorporates the EPSPS gene to make it resistant to glyphosate-based herbicides; whereas these genetically modified soybeans were combined to create a so-called stacked event which is resistant to two herbicides and altered in oil composition;

E. whereas many critical comments were submitted by Member States during the three-month consultation period[1]; whereas the most critical comments relate to observations that it is not possible to give a favourable verdict, from the perspective of human or animal nutrition, on the safety profile of products derived from soya varieties carrying transformation events 305423 and 40-3-2, that it is not possible to draw conclusions on the allergenicity of this stacked soybean, that 'sufficient data and appropriate comparators are missing for assessing potential interactions between the parental lines and for detecting unintended effects in the stacked events compared to the parental lines' and that 'the risk assessment of soybean 305423 x 40-3-2 cannot be finalised on the basis of the data provided';

F. whereas the applicant provided a 90-day toxicological feeding study which was rejected by EFSA due to its insufficient quality; whereas, as a result, the risk assessment contains no such study, a fact which was criticised by a number of Member State competent authorities; whereas this data gap is unacceptable, especially given that 2006

---

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).

[1] Annex G – Member States' comments and GMO Panel responses
http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2007-175

EFSA guidelines require such a study[1];

G. whereas, on the basis of a number of data gaps (including the lack of assessment of unintended effects resulting from the genetic modification in question, the lack of assessment of toxic effects and the lack of assessment of residues from spraying with complementary herbicides), an independent study concludes that the risk assessment cannot be concluded and that the application should therefore be rejected[2];

H. 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];

I. 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;

J. whereas, according to the EFSA pesticide panel, conclusions on the safety of residues from spraying genetically modified crops with glyphosate formations cannot be drawn on the basis of the data provided so far[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];

K. whereas imported genetically modified 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];

L. whereas there is no comprehensive risk assessment of residues from spraying ALS inhibitors as complementary herbicides on genetically modified soybeans; whereas, on the contrary, major data gaps were identified by the EFSA pesticide panel in the case of thifensulfuron, which is one of the active ingredients that acts as an ALS inhibitor[8];

---

[1] Idem.

[2] https://www.testbiotech.org/sites/default/files/TBT%20Background%20Soybean%20305423%20x%2040-3-2.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

[8] 'the potential endocrine disruption of thifensufron-methyl was identified as an issue that could not be finalised

M. whereas the residues from spraying with the complementary herbicides were not assessed; whereas it cannot therefore be concluded that genetically engineered soybean 305423 x 40-3-2 sprayed with glyphosate and ALS inhibitor herbicides is safe for use in food and feed;

N. whereas authorising the import of soybean 305423 x 40-3-2 into the Union will undoubtedly lead to an increase in its cultivation in third countries and to a corresponding increase in the use of the complementary herbicides;

O. whereas soybean 305423 x 40-3-2 is cultivated in Argentina, Canada and Japan; whereas the devastating impact of the use of glyphosate on health in Argentina has been widely documented;

P. whereas the Union has signed up to the UN's sustainable development goals (SDGs), which include a commitment to substantially reducing the number of deaths and illnesses from hazardous chemicals, and air, water and soil pollution and contamination, by 2030 (SDG 3, target 3.9)[1]; whereas the Union is committed to policy coherence for development (PCD), which aims at minimising contradictions and building synergies between different Union policies, including in the areas of trade, environment and agriculture, to benefit developing countries and increase the effectiveness of development cooperation;

Q. 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; whereas more than 20 different varieties of glyphosate-resistant weeds have been documented in scientific publications[2];

R. 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, only 10 Member States, representing only 38.43 % of the Union population voted in favour, and four Member States abstained;

S. 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];

---

and a critical area of concern'. Conclusion on the peer review of the active substance thifensulfuron-methyl. EFSA journal 13(7):4201, p. 2 http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2015.4201/epdf

[1] https://sustainabledevelopment.un.org/sdg3

[2] https://link.springer.com/chapter/10.1007/978-94-007-7796-5_12

[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).

T. 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;

U. 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;

V. whereas the Commission's proposal to amend Regulation 182/2011 is not sufficient in terms of addressing the lack of democracy in the GMO authorisation process;

W. 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 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[1], 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 procedure, which has proven inadequate;

5. Calls on the legislators responsible to advance work on the Commission proposal amending Regulation (EU) 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 specific cumulative effects of the residues from spraying with the combination of 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 to determine health

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

risks relating to stacked events such as soybean 305423 x 40-3-2;

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 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 and the Commission, and to the governments and parliaments of the Member States.