European Parliament
2014-2019

TEXTS ADOPTED
Provisional edition

P8_TA-PROV(2017)0378

Genetically modified soybean DAS-44406-6

European Parliament 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 (D051971 – 2017/2878(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 DAS-44406-6, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (D051971),

– 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), 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, of 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 17 February 2017, and published on 21 March 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

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/4738

exercise of implementing powers (COM(2017)0085, COD(2017)0035),

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

---

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 (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).

– 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 16 February 2012 Dow Agrosciences LLC and MS 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 DAS-44406-6 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 DAS-44406-6 in products consisting of it or containing it for uses other than food and feed in the same way as any other soybean, with the exception of cultivation;

B. whereas on 17 February 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 21 March 2017[1];

C. 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 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 many critical comments were submitted by Member States during the three-

---

– 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).

[1] https://www.efsa.europa.eu/en/efsajournal/pub/4738

month consultation period[1]; whereas the most critical comments include the observation that 'the current application and the presented risk assessment data do not provide sufficient information to exclude adverse effects on humans and animals unambiguously'[2], 'information on phenotypic evaluation, composition and toxicology is insufficient'[3] and the competent authority 'considers necessary further analysis to evaluate the concentration of glyphosate, 2,4-D, glufosinate and their degradation products in seeds and forage intended for food and feed purposes in order to exclude any potential adverse effect on human and animal health'[4];

E. 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, impact on immune system and the reproductive system'; whereas the same study finds that 'the monitoring plan should be rejected because it will not make essential data available'[5];

F. whereas soybean DAS-44406-6 expresses 5-enolpyruvyl-shikimate-3-phosphate synthase (2mEPSPS), conferring tolerance to glyphosate-based herbicides, aryloxyalkanoate dioxygenase (AAD-12), conferring tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and other related phenoxy herbicides, and phosphinothricin acetyl transferase (PAT), conferring tolerance to glufosinate ammonium-based herbicides;

G. whereas glyphosate's current authorisation expires on 31 December 2017 at the latest; whereas doubts 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 independent research raises concerns about the risks of the active ingredient of 2,4-D as regards embryo development, birth defects and endocrine disruption[6]; whereas although the approval of the active substance 2,4-D was renewed in 2015, information from the applicant as regards the potential endocrine properties is still outstanding[7];

I. 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

---

1 Annex G – Member States' comments and GMO Panel responses: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2012-00368

2 Annex G – Member States' comments and GMO Panel responses, p. 1.

3 Annex G – Member States' comments and GMO Panel responses, p. 52.

4 Annex G – Member States' comments and GMO Panel responses, p. 87.

5 http://www.testbiotech.org/node/1946

6 http://www.pan-europe.info/sites/pan-europe.info/files/public/resources/reports/pane-2014-risks-of-herbicide-2-4-d.pdf

7 Commission Implementing Regulation (EU) 2015/2033 of 13 November 2015 renewing the approval of the active substance 2,4-D in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 298, 14.11.2015, p. 8).

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

J. whereas a number of experts have voiced concerns about a breakdown product of 2,4-D, 2,4-Dichlorophenol, which may be present on imported soybean DAS-44406-6; whereas 2,4-Dichlorophenol is a known endocrine disruptor with reproductive toxicity;

K. whereas toxicity of 2,4-Dichlorophenol, a direct metabolite of 2,4-D, may be higher than the herbicide itself; whereas 2,4-Dichlorophenol is classified as an IARC carcinogen type 2B and is included in the list of chemicals developed for review within the EU-strategy for endocrine disruptors[3];

L. whereas, due to the fact that it is highly soluble in fats and oils, 2,4-Dichlorophenol is expected to accumulate in soy oil during the processing of soybeans; whereas the major soy product used by humans is soy oil, which is incorporated into, among many other products, some infant formulas[4];

M. whereas the amount of 2,4-Dichlorophenol in a product may be higher than the amount of 2,4-D residue; whereas a Union maximum residue level (MRL) does not exist for 2,4-Dichlorophenol;

N. whereas the residues from spraying with the complementary herbicides were not assessed; whereas it, therefore, cannot be concluded that genetically engineered soybeans sprayed with 2,4-D, glyphosate and glufosinate are safe for use in food and feed;

O. 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 twenty different varieties of glyphosate-resistant weeds have been documented in scientific publications[5]; whereas glufosinate-resistant weeds have been observed since 2009;

P. whereas authorising the import of soybean DAS-44406-6 into the Union will undoubtedly lead to an increase in its cultivation in third countries and to a corresponding increase in the use of glyphosate, 2,4-D and glufosinate herbicides; whereas soybean DAS-44406-6 is currently cultivated in Argentina, Brazil, the USA

---

1 OJ L 309, 24.11.2009, p. 1.

2 Commission Implementing Regulation (EU) 2015/404 of 11 March 2015 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances beflubutamid, captan, dimethoate, dimethomorph, ethoprophos, fipronil, folpet, formetanate, glufosinate, methiocarb, metribuzin, phosmet, pirimiphos-methyl and propamocarb (OJ L 67, 12.3.2015, p. 6).

3 Annex G – Member States' comments and GMO Panel responses, p. 5. http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2012-00368

4 Member States' comments and GMO Panel responses in relation to authorisation request for GM soybean DAS-68416-4, p. 31. http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2011-00052

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

and Canada;

Q. whereas the Union has signed up to the sustainable development goals (SDGs), which include a commitment to substantially reduce 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 it has been shown that herbicide-tolerant genetically modified crops result in higher use of these herbicides than their conventional counterparts[2];

R. 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[3], to benefit developing countries and increase the effectiveness of development cooperation[4];

S. 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;

T. whereas the vote of the appeal committee on 14 September 2017 delivered a 'no opinion'; whereas 14 Member States voted against, only 12 Member States, representing 38,78 % of the Union population, voted in favour, and two 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, 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[5];

V. whereas Parliament rejected the legislative proposal of 22 April 2015 amending Regulation (EC) No 1829/2003 on 28 October 2015 at first reading[6] 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

---

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

2 https://link.springer.com/article/10.1007%2Fs00267-015-0589-7

3 Commission communication of 12 April 2005 entitled 'Policy Coherence for Development – Accelerating progress towards attaining the Millennium Development Goals' (COM(2005)0134).

4 https://ec.europa.eu/europeaid/policies/policy-coherence-development_en

5 For example, in the opening statement at Parliament's plenary session included in the political guidelines for the next Commission (Strasbourg, 15 July 2014) or in the 2016 State of the Union address (Strasbourg, 14 September 2016).

6 Texts adopted, P8_TA(2015)0379.

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 and 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[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 as to address the shortcomings of the current procedure, which has proven to be 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 DAS-44406-6, 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 countries of cultivation;

7. 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;

8. 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;

9. Calls on the Commission to fulfil its obligation of policy coherence for development stemming from Article 208 of the Treaty on the Functioning of the European Union;

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

---

1 OJ L 31, 1.2.2002, p. 1.