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Genetically modified soybean MON 89788 (MON-89788-1)

European Parliament resolution of 14 November 2019 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 soybean MON 89788 (MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D061871/04 – 2019/2857(RSP))

The European Parliament,

– having regard to the draft Commission implementing decision renewing the authorisation for the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 89788 (MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D061871/04),

– 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 11(3) and 23(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 30 April 2019, at which no opinion was delivered, and to the vote of the Appeal Committee on 5 June 2019, at which again 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 2 July 2008, and published on 11 July 2008[3],

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1 OJ L 268, 18.10.2003, p. 1.
2 OJ L 55, 28.2.2011, p. 13.
3 Opinion of the Scientific Panel on Genetically Modified Organisms on application (reference EFSA-GMO-NL-2006-36) for the placing on the market of the glyphosate tolerant genetically modified soybean MON89788, for food and feed uses, import and

– having regard to the opinion in relation to renewal adopted by the European Food Safety Authority on 17 October 2018, and published on 16 November 2018[1],

– having regard to its previous resolutions objecting to the authorisation of genetically modified organisms ('GMOs')[2],

– having regard to Rule 112(2) and (3) of its Rules of Procedure,

– having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety;

A. whereas, Commission Decision 2008/933/EC[3] authorised the placing on the market of food and feed containing, consisting of or produced from genetically modified soybean MON 89788 ('soybean MON 89788');

B. whereas, on 20 November 2017, the authorisation holder, Monsanto Europe S.A./N.V., on behalf of Monsanto Company, submitted to the Commission an application, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for the renewal of that authorisation;

C. whereas, on 17 October 2018, the European Food Safety Authority (EFSA) adopted a

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processing under Regulation (EC) No 1829/2003 from Monsanto, The EFSA Journal (2008) 758, 1-23, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2008.758

[1] Scientific opinion on the Assessment of genetically modified soybean MON 89788 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-011), EFSA Journal 2018;16(11):5468, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5468

[2] In its eighth term, the European Parliament adopted 36 resolutions objecting to the authorisation of GMOs. Furthermore, in its ninth term the Parliament has adopted the following resolutions:
- European Parliament resolution of 10 October 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MZHG0JG (SYN-ØØØJG-2), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2019)0028).
- European Parliament resolution of 10 October 2019 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 soybean A2704-12 (ACS-GMØØ5-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2019)0029).
- European Parliament resolution of 10 October 2019 on the draft Commission implementing decision authorising the placing on the market of products containing,

favourable opinion[1], which was published on 16 November 2018, in relation to the renewal of that authorisation;

D. whereas Regulation (EC) No 1829/2003 states that genetically modified (GM) 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;

E. whereas soybean MON 89788 has been made tolerant to glyphosate-based herbicides; whereas soybean MON 89788 has been developed to provide tolerance to glyphosate by expressing the CP4 EPSPS protein[2];

Lack of assessment of glyphosate residues and metabolites

F. whereas a number of studies show that herbicide-tolerant GM crops result in a higher use of those herbicides, in large part because of the emergence of herbicide-tolerant weeds[3]; whereas, as a consequence, it has to be expected that crops of soybean MON 89788 will be exposed to both higher and repeated doses of glyphosate which will potentially lead to a higher quantity of residues in the harvest;

G. whereas questions concerning the carcinogenicity of glyphosate remain; whereas EFSA concluded in November 2015 that glyphosate was 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 International Agency for Research on Cancer (IARC), the specialised cancer agency of the World Health Organization, classified glyphosate as a probable carcinogen for humans; whereas a number of recent scientific peer-reviewed studies confirm the carcinogenic potential of

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consisting of or produced from genetically modified maize MON 89034 × 1507 × MON 88017 × 59122 × DAS-40278-9 and genetically modified maize combining two, three or four of the single events MON 89034, 1507, MON 88017, 59122 and DAS-40278-9 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2019)0030).

3 Commission Decision 2008/933/EC of 4 December 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON89788 (MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (*OJ L 333, 11.12.2008, p. 7).*

1 Scientific opinion on the Assessment of genetically modified soybean MON 89788 for renewal of authorisation under Regulation (EC) No 1829/2003 (application EFSA-GMO-RX-011), EFSA Journal 2018;16(11):5468, https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5468

2 Initial EFSA opinion, p. 1.

3 See, for example, Bonny, S., 'Genetically Modified Herbicide-Tolerant Crops, Weeds, and Herbicides: Overview and Impact', Environmental Management, January 2016, 57(1), pp. 31-48, https://www.ncbi.nlm.nih.gov/pubmed/26296738 and Benbrook, C.M., 'Impacts of genetically engineered crops on pesticide use in the U.S. – the first sixteen years', Environmental Sciences Europe, 28 September 2012, Vol. 24(1), https://enveurope.springeropen.com/articles/10.1186/2190-4715-24-24

glyphosate[1];

H. whereas in GM plants, the way that complementary herbicides are broken down by the plant, and the composition and thus toxicity of the break-down products ('metabolites'), may be driven by the genetic modification itself[2]; whereas, according to EFSA, toxicological data allowing a consumer risk assessment to be performed for several break-down products of glyphosate relevant for GM glyphosate-tolerant crops are missing[3];

Lack of maximum residue levels and related controls

I. whereas, under Regulation (EC) No 396/2005 of the European Parliament and of the Council[4], which aims to ensure a high level of consumer protection, specific maximum residue levels (MRLs) should be set for food and feed produced in third countries, when the use of pesticides results in levels of residues different from those resulting from agricultural practice within the Union[5]; whereas this is indeed the case for imported herbicide-tolerant GM crops because of the increased volumes of herbicides used vis-à-vis non-GM crops;

J. whereas, however, according to a 2018 EFSA review of the existing MRLs for glyphosate, available data were insufficient to derive MRLs and risk assessment values for glyphosate in relation to a number of GM crops, including for soybeans with an EPSPS modification[6];

K. whereas assessment of herbicide residues and their metabolites on GM plants is considered outside the remit of the EFSA Panel on Genetically Modified Organisms and is therefore not undertaken as part of the authorisation process for GMOs;

L. whereas the lack of analysis of herbicide residues on the GM crops and associated health risks was raised by many Member State competent authorities as a concern in

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1 See, for example, https://www.sciencedirect.com/science/article/pii/S1383574218300887, https://academic.oup.com/ije/advance-article/doi/10.1093/ije/dyz017/5382278, https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0219610, and https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6612199/

2 This is indeed the case for glyphosate, as stated in EFSA Review of the existing maximum residue levels for glyphosate according to Article 12 of Regulation (EC) No 396/2005, EFSA Journal 2018;16(5):5263, p. 12, https://www.efsa.europa.eu/fr/efsajournal/pub/5263

3 EFSA conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate, EFSA Journal 2015;13(11):4302, p. 3, https://www.efsa.europa.eu/en/efsajournal/pub/4302

4 Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

5 See recital 26 of Regulation (EC) No 396/2005.

6 Reasoned Opinion on the review of the existing maximum residue levels for glyphosate according to Article 12 of Regulation (EC) No 396/2005, EFSA Journal 2018; 16(5):5263, p. 4. https://doi.org/10.2903/j.efsa.2018.5263

their comments on EFSA's risk assessment[1];

Other remarks

M. whereas many Member States expressed concern over the quality of the post-market environmental monitoring (PMEM) plan, stating, inter alia, that it does not fully meet the objectives set out in Annex VII to Directive 2001/18/EC of the European Parliament and of the Council[2]or the relevant supplementary guidance notes; Member States also commented generally that the monitoring of soybean MON 89788 is inadequate, that it does not provide any sound data to support the conclusion that there has been no adverse health or environmental effects with the import and use of soybean MON 89788 and that it does not provide lessons pertinent to the safety of its use for animal or human consumption[3];

N. whereas EFSA, in response to Member State comments, has repeatedly stated that it considers that further discussion between applicants and the Commission as risk manager is needed on the practical implementation of the PMEM for GM plants for import and processing;

O. whereas the Biotechnology working group of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) states that, because the literature review conducted by the applicant of scientific studies published since soybean MON 89788 was first authorised has been too restrictive, it cannot come to a conclusion as to the safety of soybean MON 89788;

P. whereas GM soybean, when it is cultivated in countries such as Brazil and Argentina, is a key driver of large-scale deforestation; whereas this aspect, in addition to the Union's obligations under the UN Sustainable Development Goals, the Paris Climate Agreement and other international biodiversity targets, has not been considered in the authorisation process;

Undemocratic decision-making

Q. whereas the vote on 30 April 2019 of the Standing Committee on the Food Chain and Animal Health referred to in Article 35 of Regulation (EC) No 1829/2003 delivered no opinion, meaning that the authorisation was not supported by a qualified majority of Member States; whereas, the vote on 5 June 2019 of the Appeal Committee also delivered no opinion;

R. whereas the Commission recognises that the fact that GMO authorisation decisions continue to be adopted by the Commission without a qualified majority of Member States in favour, which is very much the exception for product authorisations as a whole but has become the norm for decision-making on GM food and feed authorisations, is

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1 Member State comments on soybean MON 89788 can be accessed via EFSA's register of questions: http://registerofquestions.efsa.europa.eu/roqFrontend/login?

2 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

3 Member State comments on the soybean MON 89788 can be accessed via EFSA's register of questions: http://registerofquestions.efsa.europa.eu/roqFrontend/login?

problematic[1]; whereas that practice has, on several occasions, been deplored by the Commission President as not being democratic[2];

S. whereas, in its eighth term, the European Parliament adopted a total of 36 resolutions objecting to the placing on the market of GMOs for food and feed (33 resolutions) and to the cultivation of GMOs in the Union (three resolutions); whereas there was not a qualified majority of Member States in favour of authorising any of those GMOs; whereas despite its own acknowledgement of the democratic shortcomings, the lack of support from Member States and the objections of Parliament, the Commission continues to authorise GMOs;

T. whereas no change of law is required for the Commission to be able not to authorise GMOs when there is no qualified majority of Member States in favour in the Appeal Committee[3];

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[4], to provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, and environmental and consumer interests, in relation to GM food and feed, while ensuring the effective functioning of the internal market;

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

4. Reiterates its commitment to advancing work on the Commission proposal amending Regulation (EU) No 182/2011; calls on the Council to move forward with its work in relation to that Commission proposal as a matter of urgency;

5. Calls on the Commission, in the meantime, to stop authorising GMOs when no opinion is delivered by Member States in the Appeal Committee, whether for cultivation or for

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1 See, for example, the explanatory memorandum of the Commission's legislative proposal presented on 22 April 2015 amending Regulation (EC) No 1829/2003 as regards the possibility for the Member States to restrict or prohibit the use of GM food and feed on their territory and the explanatory memorandum of the Commission's legislative proposal presented on 14 February 2017 amending Regulation (EU) No 182/2011.

2 See, for example, 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).

3 The Commission 'may, and not 'shall', go ahead with authorisation if there is no qualified majority of Member States in favour at the Appeal Committee, according to Regulation (EU) No 182/2011 (Article 6(3)).

4 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

food and feed uses, in accordance with Article 6(3) of Regulation (EU) No 182/2011;

6. Calls on the Commission not to authorise herbicide-tolerant GM crops until the health risks associated with the residues have been comprehensively investigated on a case-by-case basis, which requires a full assessment of the residues from spraying the GM crops with complementary herbicides, their metabolites and any combinatorial effects;

7. Calls on the Commission to fully integrate the risk assessment of the application of complementary herbicides and their residues into the risk assessment of herbicide-tolerant GM plants, regardless of whether the GM plant concerned is to be cultivated in the Union or is for import into the Union for food and feed uses;

8. Reiterates its alarm that the Union's high dependence on imports of animal feed in the form of soybeans causes deforestation in third countries and recalls that the UN Sustainable Development Goals can only be achieved if supply chains become sustainable and synergies are created between policies[1];

9. Calls on the Commission not to authorise the import of GM soybeans unless it can be clearly demonstrated that their cultivation did not contribute, directly or indirectly, to deforestation;

10. Urges the Commission to treat the Union's obligations under international agreements, such as the Paris Climate Agreement, the UN Convention on Biological Diversity and the UN Sustainable Development Goals, as 'relevant provisions of Union law' and/or 'legitimate factors' under Regulation (EC) No 1829/2003, and to give them the weight they deserve, as well as communicating on how they have been taken into account in the decision-making process;

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

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1 European Parliament resolution of 11 September 2018 on transparent and accountable management of natural resources in developing countries: the case of forests (Texts adopted, P8_TA(2018)0333), paragraph 67.