European Parliament

2019-2024

TEXTS ADOPTED

P9_TA(2021)0333

Genetically modified soybean DAS-81419-2

European Parliament resolution of 7 July 2021 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean DAS-81419-2 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D073421/01 – 2021/2759(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-81419-2 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D073421/01),

– 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 17 May 2021, at which no opinion was delivered,


– having regard to the opinion adopted by the European Food Safety Authority (EFSA) on 26 October 2016, and published on 5 December 2016\(^3\),


– having regard to its previous resolutions objecting to the authorisation of genetically modified organisms (‘GMOs’),

1 In its eighth term, Parliament adopted 36 resolutions objecting to the authorisation of GMOs. Furthermore, in its ninth term Parliament has adopted the following resolutions:
– European Parliament resolution of 14 May 2020 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 × A5547-127,
having regard to Rule 112(2) and (3) of its Rules of Procedure,


– European Parliament resolution of 11 November 2020 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 87460 × MON 89034 × MIR162 × NK603 and genetically modified maize combining two, three or four of the single events MON 87427, MON 87460, MON 89034, MIR162 and NK603, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2020)0293).


– European Parliament resolution of 17 December 2020 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87427 × MON 89034 × MIR162 × MON 87411 and genetically modified maize combining two or three of the single events MON 87427, MON 89034, MIR162 and MON 87411 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P9_TA(2020)0366).


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

A. whereas, on 9 February 2012, Dow Agro Sciences Ltd submitted an application to the national competent authority of the Netherlands for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified soybean DAS-81419-2 (‘the GM soybean’), in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 (‘the application’); whereas the application also concerned the placing on the market of products containing or consisting of the GM soybean for uses other than food and feed, with the exception of cultivation;

B. whereas, on 26 October 2016, EFSA adopted a favourable opinion, which was published on 5 December 2016, in relation to that application;

C. whereas the GM soybean has been developed to produce two synthetically derived Bt toxins, Cry1F and Cry1Ac, which confer resistance to certain lepidopteran species, and to be resistant to the herbicide glufosinate¹;

Lack of assessment of herbicide residues, metabolites and cocktail effects

D. whereas a number of studies show that herbicide-tolerant GM crops result in a higher use of ‘complementary’ herbicides, in large part because of the emergence of herbicide-tolerant weeds²; whereas, as a consequence, it has to be expected that the GM soybean will be exposed to both higher and repeated doses of glufosinate, and that therefore a higher quantity of residues may be present in the harvest;

E. whereas glufosinate is classified as toxic to reproduction 1B and therefore meets the ‘cut-off criteria’ set out in Regulation (EC) No 1107/2009 of the European Parliament and of

¹ EFSA opinion, page 1.
the Council\textsuperscript{1}; whereas the approval of glufosinate for use in the Union expired on 31 July 2018\textsuperscript{2};

F. whereas assessment of herbicide residues and their break-down products found on GM plants is considered outside the remit of the EFSA Panel on Genetically Modified Organisms (‘EFSA GMO Panel’) and is therefore not undertaken as part of the authorisation process for GMOs;

G. whereas, due to specific agricultural practices in the cultivation of herbicide-tolerant GM plants, there are specific patterns of applications, exposure, occurrence of specific metabolites and emergence of combinatorial effects that require special attention; whereas those were not considered by EFSA;

\textit{Outstanding questions concerning Bt toxins}

H. whereas toxicological tests for GM authorisations are carried out with isolated Bt toxins; whereas little significance can be attributed to toxicological tests conducted with proteins in isolation due to the fact that Bt toxins in GM crops, such as maize, cotton and soybeans, are inherently more toxic than isolated Bt toxins; whereas this is because protease inhibitors (PI), present in the plant tissue, can increase the toxicity of the Bt toxins by delaying their degradation; whereas this phenomenon has been demonstrated in a number of scientific studies, including one conducted for Monsanto 30 years ago which showed that even the presence of extremely low levels of PI enhanced the toxicity of Bt toxins up to 20-fold\textsuperscript{3};

I. whereas those effects have never been taken into account in EFSA risk assessments, even though they are relevant for all Bt plants approved for import or cultivation in the Union; whereas risks, arising from this enhanced toxicity due to the interaction between PI and Bt toxins, to humans and animals consuming food and feed containing Bt toxins cannot be ruled out;

J. whereas a number of studies show that side effects have been observed that may affect the immune system following exposure to Bt toxins and that some Bt toxins may have adjuvant properties\textsuperscript{4}, meaning that they can increase the allergenicity of other proteins with which they come into contact;

K. whereas assessment of the potential interaction of herbicide residues and their metabolites with Bt toxins is considered outside the remit of the EFSA GMO Panel and is therefore

\footnotesize
\begin{itemize}
\item[2] https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/active-substances/?event=as.details&amp;as_id=79
\end{itemize}
not undertaken as part of the risk assessment; whereas this is problematic since residues from spraying with glufosinate are known to disturb the microbiome which, for example, may enhance immune reactions in combination with Bt toxins¹;

**Comments from Member State competent authorities**

L. whereas Member State competent authorities submitted comments to EFSA during the three-month consultation period²; whereas critical comments include the feedback that the submitted data concerning pest and disease pressure are insufficient for a detailed analysis of ecological interaction of the GM soybean with the environment, that the applicant only refers to substantial unintended losses of the GM soybean during loading and unloading as a route for environmental exposure and that other routes of exposure of the environment by waste materials from processing or use of the soybean (e.g. manure, faeces from animals fed the GM soybean) were not specifically assessed and that the proposed monitoring plan does not address relevant questions for the general surveillance of human and animal health and cannot be regarded as sufficiently elaborated;

**Undemocratic decision-making**

M. whereas the vote on 17 May 2021 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;

N. 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 problematic;

O. 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, in its ninth term, the European Parliament has already adopted 18 objections to placing GMOs on the market; whereas there was not a qualified majority of Member States in favour of authorising any of those GMOs; whereas the reasons for Member States not supporting authorisations include lack of respect for the precautionary principle in the authorisation process and scientific concerns relating to the risk assessment;

P. 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;

---


² Member State comments on the GM soybean can be accessed via EFSA’s register of questions, [https://open.efsa.europa.eu/](https://open.efsa.europa.eu/)
Q. 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;

_Upholding the Union’s international obligations_

R. whereas Regulation (EC) No 1829/2003 provides that 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; whereas such legitimate factors should include the Union’s obligations under the United Nations (UN) Sustainable Development Goals (‘SDGs’), the Paris Climate Agreement and the UN Convention on Biological Diversity (CBD);

S. whereas a 2017 report by the UN’s Special Rapporteur on the right to food found that, particularly in developing countries, hazardous pesticides have catastrophic impacts on health; whereas UN SDG Target 3.9 aims by 2030 to substantially reduce the number of deaths and illnesses from hazardous chemicals and air, water and soil pollution and contamination; whereas authorising the import of the GM soybean would increase demand for this crop treated with a herbicide that is toxic to reproduction and that is no longer authorised for use in the Union, thereby increasing the exposure of workers in third countries; whereas the risk of increased worker exposure is of particular concern in relation to herbicide-tolerant GM crops, given the higher volumes of herbicides used;

T. whereas deforestation is a major cause of biodiversity decline; whereas emissions from land-use and land-use change, mostly due to deforestation, are the second biggest cause of climate change after burning fossil fuels; whereas the Paris Climate Agreement and the Strategic Plan for Biodiversity 2011-2020 adopted under the UN CBD and the Aichi Biodiversity Targets promote sustainable forest management, protection and restoration efforts; whereas UN SDG 15 includes the target of halting deforestation by 2020; whereas forests play a multifunctional role that support the achievement of most UN SDGs;

U. whereas soya production is a key driver of deforestation in the Amazon, Cerrado and Gran Chaco forests in South America; whereas 97 % and 100 % of soya cultivated respectively in Brazil and Argentina is GM soya; whereas the vast majority of GM soybeans

---

1 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)).
2 https://www.ohchr.org/EN/Issues/Food/Pages/Pesticides.aspx
3 https://www.un.org/sustainabledevelopment/health/
5 Idem, p. 2.
6 See target 15.2: https://www.un.org/sustainabledevelopment/biodiversity/
authorised for cultivation in Brazil and Argentina are also authorised for import into the Union; whereas the GM soybean is already authorised for cultivation in Argentina and Brazil;

V. whereas a recent peer-reviewed scientific study found that the Union is the region with the largest carbon footprint in the world associated with soya imports from Brazil, 13.8% larger than that of China, the largest soya importer, due to a larger share of emissions from embodied deforestation; whereas another recent study found that approximately a fifth of the soya exported to the Union from Brazil’s Amazon and Cerrado regions, mostly for animal feed, may be ‘contaminated with illegal deforestation’;

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, 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. Welcomes the fact that the Commission finally recognised, in a letter of 11 September 2020 to Members, the need to take sustainability into account when it comes to authorisation decisions on GMOs; expresses its deep disappointment, however, that the Commission continues to authorise GM soybeans for import despite objections by Parliament and a majority of Member States;

5. Calls on the Commission to move forward with the utmost urgency concerning the development of sustainability criteria, with full involvement of Parliament; calls on the Commission to provide information on how this process will be undertaken and in what timeframe;

---

6. Urges the Commission, again, to take into account the Union’s obligations under international agreements, such as the Paris Climate Agreement, the UN CBD and the UN SDGs; reiterates its call for draft implementing acts to be accompanied by an explanatory memorandum explaining how they uphold the principle of ‘do no harm’\(^1\);

7. Highlights that the amendments adopted by the European Parliament on 17 December 2020 on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) No 182/2011\(^2\), which were adopted in Parliament as a basis for negotiations with the Council, state that the Commission shall not authorise GMOs when there is not a qualified majority of Member States in favour; insists that the Commission respect this position and calls on the Council to proceed with its work and adopt a general approach on this file as a matter of urgency;

8. Reiterates its 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 such GM crops with complementary herbicides, an assessment of the herbicide break-down products and any combinatorial effects;

9. Reiterates its call 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;

10. Reiterates its call on the Commission not to authorise the import for food or feed uses of any GM plant which has been made tolerant to a herbicide-active substance that is not authorised for use in the Union;

11. Welcomes the announcement of a legislative proposal from the Commission on ‘Measures to avoid or minimise the placing of products associated with deforestation or forest degradation on the EU market’; in the meantime, given the urgency of tackling deforestation in the Amazon, Cerrado and Gran Chaco forests and the fact that Union demand for GM soybeans contributes to deforestation in that region, calls on the Commission to immediately suspend the import of GM soybeans cultivated in Brazil and Argentina, using Article 53 of Regulation (EC) No 178/2002 if necessary, until effective legally binding mechanisms have been put in place to prevent the placing on the Union market of products associated with deforestation and related human rights violations;

12. Reiterates its call for the implementation of a European vegetable protein production and supply strategy\(^3\), which would enable the Union to become less dependent on GM soybean imports and to create shorter food chains and regional markets;

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

---

\(^1\) Texts adopted, P9_TA(2020)0005, paragraph 102.
\(^3\) Texts adopted, P9_TA(2020)0005, paragraph 64.