2023/2810(RSP)

20.9.2023

DRAFT MOTION FOR A RESOLUTION

pursuant to Rule 112(2) and (3) of the Rules of Procedure

on the draft Commission implementing decision renewing the authorisation for placing on the market of products containing, consisting of or produced from genetically modified maize MIR162 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Implementing Decisions (EU) 2016/1685, 2019/1305 and 2019/2087 as regards the reference material (D090639/01 – 2023/2810(RSP))

Committee on the Environment, Public Health and Food Safety

Members responsible: Martin Häusling, Anja Hazekamp, Sirpa Pietikäinen, Günther Sidl

The European Parliament,

– having regard to Commission implementing decision renewing the authorisation for placing on the market of products containing, consisting of or produced from genetically modified maize MIR162 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Implementing Decisions (EU) 2016/1685, 2019/1305 and 2019/2087 as regards the reference material (D090639/01),

– having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council, and in particular Article 9(2), Article 11(3), Article 21(2) and Article 23(3) thereof,

– having regard to the vote of the Standing Committee on Plants, Animals, Food and Feed referred to in Article 35 of Regulation (EC) No 1829/2003, on 3 July 2023, at which no opinion was delivered, and the vote of the Appeal Committee on 8 September 2023, at which again no opinion was delivered,


– having regard to the opinion adopted by the European Food Safety Authority (EFSA) on 1 September 2022, and published on 22 September 2022,3

– having regard to its previous resolutions objecting to the authorisation of genetically modified organisms (‘GMOs’),4

4 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 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 MZH0JGJ (SYN-ØØØJG-2),
having regard to Rule 112(2) and (3) of its Rules of Procedure,


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 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 (OJ C 202, 28.5.2021, p. 20).


European Parliament resolution of 14 November 2019 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 × 1507 × 5307 × GA21 and genetically modified maize combining two, three, four or five of the single events Bt11, MIR162, MIR604, 1507, 5307 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ C 208, 1.6.2021, p. 18).


European Parliament resolution of 11 November 2020 on the draft Commission implementing decision authorising the placing on the market of products containing,
– having regard to the motion for a resolution by the Committee on the Environment,

– 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 (OJ C 415, 13.10.2021, p. 15).


– European Parliament resolution of 7 July 2021 on the draft Commission implementing
Public Health and Food Safety,


– 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 maize 1507 × MIR162 × MON810 × NK603 and genetically modified maize combining two or three of the single events 1507, MIR162, MON810 and NK603, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ C 99, 1.3.2022, p. 59).


– European Parliament resolution of 23 June 2022 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize DP4114 × MON 810 × MIR604 × NK603 and genetically modified maize combining two or three of the single events DP4114, MON 810, MIR604 and NK603, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ C 32, 27.1.2023, p. 6).

A. whereas Commission Implementing Decision 2012/651/EU\(^5\) authorised the placing on the market of food and feed containing, consisting of or produced from genetically modified maize MIR162 (‘the GM maize’); whereas the scope of that authorisation also covered the placing on the market of products other than food and feed containing or consisting of the GM maize, for the same uses as any other maize, with the exception of cultivation;

B. whereas on 12 February 2021, Syngenta Crop Protection NV/SA, based in Belgium, submitted, on behalf of Syngenta Crop Protection AG, based in Switzerland, an application to the Commission, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for renewal of the authorisation;

C. whereas, on 31 May 2012, EFSA adopted a favourable opinion, which was published on 21 June 2012, in relation to the initial authorisation application\(^6\);

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D. whereas on 1 September 2022, EFSA adopted a favourable opinion in relation to the renewal of the authorisation of the GM maize, which was published on 22 September 2022;

E. whereas the GM maize has been engineered to produce the protein VIP3a20 (a ‘Bt toxin’), which is toxic to certain lepidopteran pests;

**Outstanding questions concerning Bt toxins**

F. whereas the toxicity of the Bt toxin was assessed on the basis of feeding studies, using only the isolated Bt protein produced by bacteria\(^7\); 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 Bt toxins by delaying their degradation; whereas this phenomenon has been demonstrated in a number of scientific studies, including one conducted for Monsanto thirty years ago which showed that even the presence of extremely low levels of PI enhanced the toxicity of Bt toxins up to 20-fold\(^8\);

G. whereas this enhanced toxicity is not taken into account in EFSA risk assessments, even though it is relevant for Bt plants approved for import into the Union; whereas risks to humans and animals that consume food and feed containing Bt toxins and which arise from this enhanced toxicity due to the interaction between PI and Bt toxins cannot be ruled out;

H. 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\(^9\), meaning that they can increase the allergenicity of other proteins with which they come into contact;

I. whereas in a patent recently issued by the European Patent Office\(^10\), the patent holder, Syngenta, claims that maize containing vip3 proteins tend to show decreased fertility; whereas the patent states: ‘Vip3 has been observed to cause decreased male fertility in certain inbred maize plants under normal growing conditions (...) The degree to which male fertility is decreased is also affected by environmental factors, such as water availability and temperature. In Vip3-induced reductions in male fertility, drought and high temperature conditions exacerbate the reduction in male fertility’;

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J. whereas, since the observed fertility reduction seems to be more pronounced under drought and high temperatures, it is a plausible hypothesis that climate change has to be considered a relevant factor in the risk assessments of GM plants containing vip3 genes, including the GM Maize, requiring studies to be carried out under a broad range of environmental conditions;

K. whereas the information on reduced fertility raises a number of other questions which should have also been thoroughly investigated as part of the assessment carried out by EFSA, including to what extent the genetic background of the GM maize is impacted by the reduced fertility and which other traits of the GM maize may be impacted;

L. whereas Syngenta failed, however, to disclose this information on decreased fertility to EFSA as part of the process for renewal of the authorisation of the GM maize;

M. whereas, during the consultation period in relation to the initial authorisation application, Member States submitted many critical comments to EFSA’s draft opinion\(^1\); whereas those critical comments include that the toxicological assessment lacks information regarding long-term, reproductive or developmental effects, that there was a lack of in-depth analysis on the observed significant differences in the agronomic and comparative assessments, that the data provided by the applicant are not sufficient to complete the environmental risk assessment and that the extensive labelling of basic biosafety data related to the biology of the GM maize as ‘confidential business information’ is unacceptable;

N. whereas, during the consultation period in relation to the renewal application, Member States again submitted comments to EFSA’s draft opinion\(^2\); whereas a Member State authority commenting on the renewal found that the risk assessment cannot be finalised because important information was missing, especially on the specificity and toxicity of the insecticidal protein Vip3Aa20 and for all exposure pathways, apart from for loss and spillage, and that the monitoring plan and the monitoring reports from 2013 to 2020 have many deficiencies and are neither in line with Directive 2001/18/EC of the European Parliament and of the Council\(^3\) and the corresponding guidelines nor with 2011 EFSA guidance on the post-market environmental monitoring of genetically modified plants;

O. whereas the use of Bt GM crops leads to continuous exposure of both target and non-target organisms to Bt toxins; whereas effects on non-target organisms cannot be excluded; whereas the wide use of Bt GM crops is leading to increased resistance of the targeted pests;

Undemocratic decision-making

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\(^1\) Member State comments, accessible via the OpenEFSA portal: [https://open.efsa.europa.eu/](https://open.efsa.europa.eu/)

\(^2\) Member State comments, accessible via the OpenEFSA portal: [https://open.efsa.europa.eu/](https://open.efsa.europa.eu/)

P. whereas the vote on 3 July 2023 of the Standing Committee on Plants, Animals, Food and Feed 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 8 September 2023 of the Appeal Committee again delivered no opinion:

Q. 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;

R. whereas, in its eighth term, 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, Parliament has already adopted 34 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;

S. 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 imports of GMO crops for food and feed;

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 and to submit a new draft to the committee;

4. Calls on EFSA to investigate the substantial differences between native Bt toxins and those expressed by synthetic transgenes in GM crop plants, and to widen its risk assessment in order to fully take into account all interactions and combinatorial effects between Bt-toxins, GM plants and their constituents, the environment as well as impacts on health and food safety;

5. Calls on EFSA to no longer accept toxicity studies based on isolated proteins which are likely to be different in structure and biological effects compared to those produced by the plant itself, and to require that all tests are carried out with tissue from the GM plant;

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