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Genetically modified maize MON 94804

European Parliament resolution of 26 November 2024 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 94804 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D099729/02 – 2024/2841(RSP))

(C/2025/1804)

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 maize MON 94804 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D099729/02),

— 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 Article 7(3) and Article 19(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 17 September 2024, at which no opinion was delivered,

— having regard to Article 11 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 13 March 2024, and published on 26 April 2024 ([3]),

— having regard to its previous resolutions objecting to the authorisation of genetically modified organisms ('GMOs') ([4]),

— having regard to Rule 115(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 on 14 February 2023, Bayer Agriculture BV, based in Belgium, submitted on behalf of Bayer CropScience LP, based in the United States, 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 maize MON 94804 (the 'GM maize'), in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 ('the application');

B. whereas the application also covered the placing on the market of products containing or consisting of the GM maize for uses other than food and feed, with the exception of cultivation;

C. whereas, on 13 March 2024, EFSA adopted a favourable opinion, which was published on 26 April 2024, concluding that the GM maize is as safe as its conventional counterpart and the tested non-GM maize varieties with respect to potential effects on human and animal health and the environment;

([1]) OJ L 268, 18.10.2003, p. 1, ELI: http://data.europa.eu/eli/reg/2003/1829/oj.
([2]) OJ L 55, 28.2.2011, p. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj.
([3]) EFSA Panel on Genetically Modified Organisms scientific opinion on assessment of genetically modified maize MON 94804 for food and feed uses, under Regulation (EC) No 1829/2003 (application GMFF-2022-10651), EFSA Journal, 2024;22(4):8714, https://doi.org/10.2903/j.efsa.2024.8714.
([4]) In its eighth term, Parliament adopted 36 resolutions and, in its ninth term, Parliament adopted 38 resolutions objecting to the authorisation of GMOs.

D. whereas the GM maize was genetically engineered to produce an artificial miRNA intended to selectively suppress two genes within a larger gene family involved in the biosynthetic pathway of gibberellic acid (GA), thus reducing the plant's height;

Outstanding questions concerning the effects of artificial miRNA

E. whereas, the introduction of the artificial miRNA not only interferes with the targeted genes, but also involves other regulatory functions; whereas miRNA undergoes further processing in the plant, and thereby interacts with specific plant enzymes; whereas its effects in many cases are not restricted to the target gene, but often involve metabolic cascades of several hundred other gene functions;

F. whereas the applicant presents insufficient and incomplete data on interactions between the artificial miRNA, the products emerging from further processes in the cells, the persistence of these molecules in the cells and their interference in other regulatory networks;

G. whereas to conclude miRNAs do not present a risk of toxicity for humans and animals, EFSA assumes that the artificial miRNA would be rapidly degraded; whereas however, several studies, including the one they quote to support that assertion ([5]), report that, supported by specific mechanisms, miRNA can be taken from the gut;

Outstanding questions concerning the effects of reduced gibberellins level

H. whereas, as highlighted by the experts from Member States ([6]), gibberellins are major regulators of various physiological processes in plants;

I. whereas apart from plant stature, gibberellins also regulate germination and flowering, play a role in the regulation of stress tolerance and are part of complex regulatory crosstalk with other plant hormones in various signalling pathways, e. g. physiological processes affecting plant composition; whereas gibberellins are also involved in the immune response of plants to pathogens;

J. whereas most impacts on these different processes have not been explored by the applicant, apart from the potential effects on germination, flowering and grain weight;

K. whereas gene expression and its impact on bioactive gibberellins production and metabolic impact was only investigated in field conditions with no particular stress factors, while GA is known to be involved in many biotic and abiotic stress responses;

Reducing dependency on imported feed

L. whereas one of the lessons from the COVID-19 crisis and the still ongoing war in Ukraine is the need for the Union to end the dependencies on some critical materials; whereas in the mission letter to Commissioner-designate Christophe Hansen, Commission President Ursula von der Leyen asks him to look at ways to reduce imports of critical commodities ([7]);

Member State competent authority and stakeholder comments

M. whereas Member States submitted many critical comments to EFSA during the three-month consultation period ([8]) including that gibberellins are major regulators of various physiological processes in plants, in particular related to biotic and abiotic stressors, and that the data provided by the applicant are incomplete in assessing the potential impact of reduced gibberellins levels on all these processes, and that the variety in field trials is insufficient; whereas

([5]) Dávalos, A., Henriques, R., Latasa, M. J., Laparra, M., & Coca, M. (2019). Literature review of baseline information on non-coding RNA (ncRNA) to support the risk assessment of ncRNA-based genetically modified plants for food and feed. EFSA Supporting Publications, 16(8), EN-1688. https://doi.org/10.2903/sp.efsa.2019.EN-1688.

([6]) Annex 8 of EFSA Panel on Genetically Modified Organisms scientific opinion on assessment of genetically modified maize MON 94804 for food and feed uses, under Regulation (EC) No 1829/2003 (application GMFF-2022-10651), EFSA Journal, 2024;22(4):8714, https://doi.org/10.2903/j.efsa.2024.8714.

([7]) https://commission.europa.eu/document/2c64e540-c07a-4376-a1da-368d289f4afe_en.

([8]) https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903/j.efsa.2024.8714&file=efs28714-sup-0008-Annex8.pdf.

Member States also criticised the lack of data on the risks posed by a possible long term stability of the artificial miRNA in the plant, or by the fact that a non-negligible part of the modified DNA is susceptible to be taken from the gut of animals or human beings as well as the fact that the data provided do not prove that gene transfer from plant to bacteria is unlikely;

N. whereas Regulation (EC) No 1829/2003 states 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;

Undemocratic decision-making

O. 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 adopted 38 objections to the placing GMOs on the market;

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;

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 ([9]);

R. whereas the vote on 17 September 2024 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;

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 ([10]), 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. 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 ([11]); expresses its deep disappointment, however, that, since then the Commission has continued to authorise GMOs for import into the Union, despite ongoing objections by Parliament and a majority of Member States voting against;

5. Urges the Commission, again, to take into account the Union's obligations under international agreements, such as the Paris Climate Agreement, the United Nations Convention on Biological Diversity and the United Nations Sustainable Development Goals; reiterates its call for draft implementing acts to be accompanied by an explanatory memorandum explaining how they uphold the principle of 'do no harm' ([12]);

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

([9]) 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 Article 6(3) of Regulation (EU) No 182/2011.

([10]) 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, ELI: http://data.europa.eu/eli/reg/2002/178/oj).

([11]) https://tillymetz.lu/wp-content/uploads/2020/09/Co-signed-letter-MEP-Metz.pdf.

([12]) European Parliament resolution of 15 January 2020 on the European Green Deal (OJ C 270, 7.7.2021, p. 2), paragraph 102.