European Parliament
2024-2029

Committee on the Environment, Public Health and Food Safety

2024/2835(RSP)

8.10.2024

DRAFT MOTION FOR A RESOLUTION

pursuant to Rule 115(2) and (3) of the Rules of Procedure

on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified cotton COT102 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council
(D098499/04 – 2024/2835(RSP))

Committee on the Environment, Public Health and Food Safety

Members responsible: Martin Häusling, Biljana Borzan, Anja Hazekamp

B10-0000/2024

European Parliament resolution on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified cotton COT102 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council
(D098499/04 – 2024/2835(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 cotton COT102 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D098499/04),

– 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 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 8 July 2024, at which no opinion was delivered, and the vote of the Appeal Committee on 3 September 2024, at which again 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 10 May 2023, and published on 26 June 2023[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 31 March 2017, Syngenta Crop Protection NV/SA, based in Belgium, submitted, on behalf of Syngenta Crop Protection AG, based in Switzerland, an

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1 OJ L 268, 18.10.2003, p. 1.
2 OJ L 55, 28.2.2011, p. 13.
3 EFSA Panel on Genetically Modified Organisms scientific opinion on the assessment of genetically modified cotton COT102 for food and feed uses under Regulation (EC) No 1829/2003 (application EFSA-GMO-DE-2017-141), EFSA Journal 2023;21(6):8031, https://doi.org/10.2903/j.efsa.2023.8031.
4 In its eighth term, Parliament adopted 36 resolutions and, in its ninth term, Parliament adopted 38 resolutions objecting to the authorisation of GMOs.

application to the national competent authority of Germany for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from genetically modified cotton COT102 (the 'GM cotton'), in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 ('the application'); whereas the application also covered the placing on the market of products containing or consisting of the GM cotton for uses other than food and feed, with the exception of cultivation;

B. whereas, on 10 May 2023, EFSA adopted a favourable opinion, which was published on 10 May 2023 , concluding that the GM cotton is as safe as its non-GM comparator and the tested non-GM cotton varieties with respect to potential effects on human and animal health and the environment;

C. whereas the GM cotton contains genes producing insecticidal proteins ('Bt toxins') and an antibiotic resistance marker gene;

D. whereas cottonseed oil may be used in the production of a wide variety of food products such as dressings, mayonnaise, fine bakery wares, chocolate spreads and chips; whereas consumption of cottonseed flour is the most likely way in which humans could be exposed to the two proteins resulting from the genetic modification; whereas cotton is commonly used in animal feed in the form of undelinted seeds and meal;

Outstanding questions concerning Bt toxins

E. whereas the toxicity of the Bt toxins was assessed on the basis of feeding studies using only isolated Bt proteins produced by bacteria; 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 which showed that even the presence of extremely low levels of PI enhanced the toxicity of Bt toxins up to 20-fold[5];

F. whereas this enhanced toxicity is not taken into account in EFSA risk assessments, even though it is relevant for all Bt plants approved for import or cultivation in 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, therefore, be ruled out;

G. 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[6], meaning that they can increase the allergenicity of other proteins

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5 MacIntosh, S.C., Kishore, G.M., Perlak, F.J., Marrone, P.G., Stone, T.B., Sims, S.R., Fuchs, R.L., 'Potentiation of *Bacillus thuringiensis* insecticidal activity by serine protease inhibitors', Journal of Agricultural and Food Chemistry, 1990, 38, pp. 1145-1152, https://pubs.acs.org/doi/abs/10.1021/jf00094a051.

6 For a review, see Rubio-Infante, N., Moreno-Fierros, L., 'An overview of the safety and biological effects of *Bacillus thuringiensis* Cry toxins in mammals', Journal of Applied Toxicology, May 2016,

with which they come into contact;

Bt crops: effects on non-target organisms

H. whereas, unlike the use of insecticides, where exposure is at the time of spraying and for a limited time afterwards, the use of Bt GM crops leads to continuous exposure of the target and non-target organisms to Bt toxins;

I. whereas the assumption that Bt toxins exhibit a single target-specific mode-of-action can no longer be considered correct and effects on non-target organisms cannot be excluded[7];

J. whereas an increasing number of non-target organisms are reported to be affected in many ways; whereas 39 peer-reviewed publications that report significant adverse effects of Bt toxins on many 'out-of-range' species are mentioned in a recent overview[8];

Reducing dependency on imported feed

K. 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-delegate Christophe Hansen, Commission President Ursula von der Leyen asks him to look at ways to reduce imports of critical commodities;

Inclusion of antibiotic resistance marker gene

L. whereas the GM cotton produces the APH4 protein, which is used as an antibiotic resistance marker gene ('ARMG') and which deactivates the activity of the antibiotic hygromycin B;

M. whereas Article 4(2) of Directive 2001/18/EC of the European Parliament and of the Council[9] requires that 'GMOs which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment are taken into particular consideration when carrying out an environmental risk assessment, with a view to identifying and phasing out antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment' and sets a deadline of 2004, beyond which they should not be placed on the Union market;

36(5), pp. 630 648, https://onlinelibrary.wiley.com/doi/full/10.1002/jat.3252.

7 See, for example, Hilbeck, A., Otto, M., 'Specificity and combinatorial effects of Bacillus thuringiensis Cry toxins in the context of GMO environmental risk assessment', Frontiers in Environmental Science 2015, 3:71, https://doi.org/10.3389/fenvs.2015.00071

8 Hilbeck, A., Defarge, N., Lebrecht, T., Bøhn, T., 'Insecticidal Bt crops. EFSA's risk assessment approach for GM Bt plants fails by design', RAGES 2020, p. 4, https://www.testbiotech.org/wp-content/uploads/2023/12/RAGES_report-Insecticidal-Bt-plants.pdf

9 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).

N. whereas Commission Implementing Regulation (EU) No 503/2013[10] states that it is now possible to develop GMOs without the use of ARMGs [...] the applicant should therefore aim to develop GMOs without the use of ARMGs;

O. whereas several Member States raised critical comments regarding the use of ARMGs, including that, in the face of the current crisis concerning antibiotic resistance, it would be wise to implement the precautionary principle, especially in the present case where the application of the ARMG is completely unnecessary and the removal of the ARMG from the plant genome possible; whereas one Member State's competent authority gave the authorisation an unfavourable opinion based on the presence of the ARMG in the genome of the GM cotton;

P. whereas the European Medical Agency has confirmed there are no products containing hygromycin B authorised for therapeutic, prophylactic or any other medical uses in humans or animals in the Member States and there are no central authorisations for human or veterinary use for medicinal products that contain hygromycin B11; whereas the EFSA opinion states that 'the GMO Panel considers that the risk assessment may need to be updated in case products containing hygromycin B or other substrates of the APH4 enzyme obtain future market approval in the EU.'; whereas, however, hygromycin B is used in veterinary products which are sold outside the Union;

Q. whereas the Parliament has, on at least one previous occasion, objected to the import of GM crops which contained ARMGs[11];

R. whereas antimicrobial resistance poses a threat to global health, food security, and achieving the 2030 Sustainable Development Goals, and drug-resistant infections know no borders[12];

Member State competent authority and stakeholder comments

S. whereas Member States submitted many critical comments to EFSA during the three-month consultation period[13] including that cultivation of the GM cotton on agricultural fields is to be considered as deliberate contamination of natural environments with antibiotic resistance genes, as well as that the information provided on molecular characterisation, composition and toxicology is insufficient and therefore EFSA's conclusions of equivalence of the GM cotton with conventional cotton in terms of

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10 Commission Implementing Regulation (EU) No 503/2013 of 3 April 2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003 of the European Parliament and of the Council and amending Commission Regulations (EC) No 641/2004 and (EC) No 1981/2006 (OJ L 157, 8.6.2013, p. 1).

11 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).

12 https://www.who.int/campaigns/world-amr-awareness-week/2024/amr-is-invisible-i-am-not#:~:text=Similar%20to%20COVID%2D19%2C%20drug,meet%20AMR%20national%20action%20plans.

13 https://efsa.onlinelibrary.wiley.com/action/downloadSupplement?doi=10.2903%2Fj.efsa.2023.8031&file=efs28031-sup-0008-Annex8.pdf

food and feed safety is premature;

T. 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; whereas such legitimate factors should include the Union's commitments to tackle antimicrobial resistance;

Undemocratic decision-making

U. 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;

V. 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;

W. 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[14];

X. whereas the vote on 8 July 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; whereas the vote on 3 September 2024 of the Appeal Committee again delivered no opinion;

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[15], 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;

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14 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

15 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).

4. Reiterates its call on the Commission not to authorise the placing on the market of any GM plants containing genes which confer antimicrobial resistance; notes that authorisation would be in violation of Article 4(2) of Directive 2001/18/EC which calls for a phase out of ARMGs which may have adverse effects on human health or on the environment;

5. 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[16]; 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;

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'[17];

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

16 https://tillymetz.lu/wp-content/uploads/2020/09/Co-signed-letter-MEP-Metz.pdf

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