MOTION FOR A RESOLUTION

pursuant to Rule 106(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 GHB614 × LLCotton25 × MON 15985 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D059692/02 – 2019/2524(RSP))

Committee on the Environment, Public Health and Food Safety

Member responsible: Bart Staes

Guillaume Balas, Lynn Boylan, Eleonora Evi, Sirpa Pietikäinen, Valentinas Mazuronis
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 GHB614 × LL Cotton 25 × MON 15985 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D059692/02 – 2019/2524(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 GHB614 × LL Cotton 25 × MON 15985 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D059692/02),

– 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 feed1, and in particular Articles 7(3) and 19(3) thereof,

– having regard to the vote on 3 December 2018 of the Standing Committee on the Food Chain and Animal Health referred to in Article 35 of Regulation (EC) No 1829/2003, at which no opinion was delivered,


– having regard to the opinion adopted by the European Food Safety Authority (EFSA) on 7 March 2018 and published on 20 April 20183,


– having regard to its previous resolutions objecting to the authorisation of genetically modified organisms4,


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– Resolution of 16 December 2015 on Commission implementing decision (EU) 2015/2279 of 4 December 2015 authorising the placing on the market of products containing, consisting of, or produced from genetically


- Resolution of 8 June 2016 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 × GA21, and genetically modified maizes combining two or three of those events (OJ C 86, 6.3.2018, p. 108).

- Resolution of 8 June 2016 on the draft Commission implementing decision as regards the placing on the market of a genetically modified carnation (Dianthus caryophyllus L., line SHD-27531-4) (OJ C 86, 6.3.2018, p. 111).


- Resolution of 5 April 2017 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21, and genetically modified maizes combining two, three or four of the events Bt11, 59122, MIR604, 1507 and GA21 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (OJ C 298, 23.8.2018, p. 34).


- Resolution of 24 October 2017 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 maize 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the
– having regard to the motion for a resolution of the Committee on the Environment, Public Health and Food Safety,

– having regard to Rule 106(2) and (3) of its Rules of Procedure,

A. whereas, on 11 February 2011, Bayer CropScience AG submitted an application, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, for the placing on the market of foods, food ingredients and feed containing, consisting of or produced from cotton GHB614 × LLcotton25 × MON 15985 and the subcombination LLcotton25 × MON 15985 (‘the application’) to the national competent authority of the Netherlands; whereas the application also covered the placing on the market of

– Resolution of 1 March 2018 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 × NK603 (MON-87427-7 × MON-89034-3 × MON-00603-6) and genetically modified maize combining two of the events MON 87427, MON 89034 and NK603, and repealing Decision 2010/420/EU (Texts adopted, P8_TA(2018)0052).
– Resolution of 24 October 2018 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 maize MON 87427 × MON 89034 × 1507 × MON 88017 × 59122, and genetically modified maize combining two, three or four of the single events MON 87427, MON 89034, 1507, MON 88017 and 59122 and repealing Decision 2011/366/EU (Texts adopted, P8_TA(2018)0416).
genetically modified (GM) cotton GHB614 × LLCotton25 × MON 15985 and the
subcombination LLCotton25 × MON 15985 in products containing it or consisting of it
for uses other than food and feed, with the exception of cultivation;

B. whereas, on 7 March 2018, EFSA adopted a favourable opinion in relation to the
application;

C. whereas GM cotton GHB614 × LLCotton25 × MON 15985 expresses the 2mEPSPS
protein, which confers tolerance to glyphosate-containing herbicides, the PAT protein,
which confers tolerance to glufosinate-ammonium-based herbicides and the Cry1Ac and
Cry1Ab2 proteins, which confer protection against certain lepidopteran pests; whereas,
in addition, the plant produces proteins (NPTII and AAD) that confer resistance to
antibiotics;

D. whereas, while the human consumption of cottonseed oil may be relatively limited in
Europe, it can be found in a wide variety of food products, including dressings,
mayonnaise, fine bakery wares, chocolate spreads and chips1;

E. whereas cotton is fed to animals mainly in the form of cottonseed cake/meal or as full
fat cottonseeds2;

Residues and components of the complementary herbicides

F. whereas application of the complementary herbicides, in this case glyphosate and
glufosinate, is part of regular agricultural practice in the cultivation of herbicide-
resistant plants and it can therefore be expected that they will be exposed to both higher
and repeated doses, which will not only lead to a higher burden of residues in the
harvest, and therefore in the imported product, but may also influence the composition
of the GM plant and its agronomic characteristics;

G. whereas the use of glufosinate is no longer permitted in the Union since 1 August 2018,
as it has been classified as toxic to reproduction and thus falls under the cut-off criteria
set out in Regulation (EC) No 1107/2009 of the European Parliament and of the
Council3;

H. whereas questions remain concerning the carcinogenicity of glyphosate; 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 World Health Organisation’s
International Agency for Research on Cancer classified glyphosate as a probable
carcinogen for humans;

I. whereas, in general, according to the EFSA Panel on Plant Protection Products and their
Residues, conclusions on the safety of residues from spraying GM crops with

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concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC
glyphosate formations cannot be drawn\(^1\); whereas additives and their mixtures used in commercial formulations for spraying glyphosate can show a higher toxicity than the active ingredient alone\(^2\);

J. whereas the Union has already removed a glyphosate additive known as POE tallowamine from the market owing to concerns over its toxicity; whereas problematic additives and mixtures may, however, still be permitted in the countries where this GM cotton is cultivated (currently Japan);

K. whereas information on residue levels of herbicides and their metabolites is essential for a thorough risk assessment of herbicide-tolerant GM plants; whereas residues from spraying with herbicides are considered outside the remit of the EFSA Panel on Genetically Modified Organisms (EFSO GMO panel); whereas the impact of spraying GM cotton with herbicides has not been assessed, nor has the cumulative effect of spraying with both glyphosate and glufosinate;

L. whereas Member States are not legally required to measure glyphosate or glufosinate residues on cotton imports in order to ensure compliance with maximum residue levels as part of the coordinated multiannual control programme of the Union for 2019, 2020 and 2021\(^3\); whereas in the latest European Union report on pesticide residues in food, compiled by EFSA and based on the results of the coordinated multiannual programme as well as the individual programmes of Member States, there is no information on compliance of cotton with maximum residue levels for any pesticides\(^4\); whereas, according to the latest data, it is therefore not known whether glyphosate or glufosinate residues on GM cotton GHB614 × LLcotton25 × MON 15985 comply with Union maximum residue limits;

**Presence of toxic substance gossypol**

M. whereas gossypol is a naturally occurring toxic constituent of cotton; whereas the presence of the EPSPS protein may lead to higher levels of gossypol in GM plants containing this protein\(^5\); whereas the EFSA GMO panel noted that the free gossypol in raw cottonseeds of GM cotton GHB614 × LLcotton25 × MON15985 were higher than in its non-GM comparator (7,200 mg/kg and 6,000 mg/kg respectively)\(^6\), both of which were higher than the legal limit of 5,000 set in Directive 2002/32/EC of the European Parliament and of the Council for animal feed\(^7\);

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\(^2\) [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3955666](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3955666)

\(^3\) Commission Implementing Regulation (EU) 2018/555 of 9 April 2018 concerning a coordinated multiannual control programme of the Union for 2019, 2020 and 2021

\(^4\) The 2016 European Union report on pesticide residues in food


\(^5\) [https://www.testbiotech.org/node/2209](https://www.testbiotech.org/node/2209) p. 2.


\(^7\) Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10) sets a maximum level on gossypol in cottonseed (as a feed material) of 5,000 mg/kg
N. whereas, according to a 2014 study on ‘Gossypol Toxicity from Cottonseed Products’ the most common toxic effect in animals is the impairment of male and female reproduction, causing serious economic losses to the livestock industry, as well as its interference with immune function, reducing an animal’s resistance to infections and impairing the efficiency of vaccines; whereas the EFSA Panel on Contaminants in the Food Chain has described gossypol as an undesirable substance in animal feed;

O. whereas the EFSA GMO panel states that the higher content of gossypol in cottonseed from GM cotton GHB614 x LLcotton25 x MON15985 compared to the non-GM comparator ‘is of no safety concern for animals and humans in practice because (i) the maximum content of free gossypol is regulated by European legislation, and (ii) bleached and refined cottonseed oil as well as flour produced from cottonseed, which may be directly consumed by humans, are essentially free from gossypol; whereas EFSA did not evaluate cotton oil (for human consumption) nor cotton meal (for animal feed) as recommended by the current OECD Consensus document on compositional considerations for new varieties of cotton; whereas the statement that gossypol is subject to legal limits under Union legislation does not provide sufficient assurances that GM cotton GHB614 x LLcotton25 x MON15985 is safe for consumption;

Cry proteins and link to allergic reactions

P. whereas GHB614 x LLcotton25 x MON15985 expresses two Bt toxins (the Cry1Ac and Cry1Ab2 proteins) which confer protection against certain lepidopteran pests; whereas although Cry1 proteins have been recognised as having adjuvant properties, meaning that they can possibly reinforce the allergenic properties of other foodstuffs, this was not analysed by EFSA;

Q. whereas a 2017 scientific study on the possible health impacts of Bt toxins and residues from spraying with complementary herbicides concludes that specific attention should be paid to the herbicide residues and their interaction with Bt toxins; whereas this was not investigated by EFSA;

Antibiotic resistance

R. whereas GHB614 x LLcotton25 x MON15985 produces proteins (NPTII and AAD) that confer resistance to antibiotics; whereas NPT11 confers resistance to neomycin and kanamycin; whereas AAD confers resistance to streptomycin; whereas all of these antimicrobials are classified as ‘critically important’ by the WHO;

S. whereas Article 4(2) of Directive 2001/18/EC of the European Parliament and of the Council requires that genetically modified organisms (GMOs) which contain genes

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1 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4033412/
4 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5236067/
5 p21 http://apps.who.int/iris/bitstream/handle/10665/255027/9789241512220-eng.pdf?sequence=1
expressing resistance to antibiotics in use for medical or veterinary treatment are taken into particular consideration when carrying out an environmental risk assessment and that the overall aim is to identify and phase out in GMOs antibiotic resistance marker genes (ARMGs) which may have adverse effects on human health or on environmental safety;

T. whereas the EFSA GMO panel examined, in a 2004 opinion, the use of ARMGs in the selection of transgenic events in plants due to concerns that the use of such marker genes could potentially lead to increased resistance to antibiotics in humans and animals as a result of gene transfer from GM plants to bacteria;

U. whereas, according to this 2004 opinion, the AAD gene belongs to group II of antibiotic resistance genes which ‘should be restricted to field trial purposes and should not be present in GM plants to be placed on the market’¹;

Comments from Member State competent authorities

V. whereas many critical comments were submitted by competent authorities during the three-month consultation period, including, but not restricted to, the issues outlined above²;

Lack of democracy in the decision-making process

W. whereas the vote on 3 December 2018 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;

X. whereas, both in the explanatory memorandum of its 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 genetically modified food and feed on their territory and in the explanatory memorandum of the legislative proposal presented on 14 February 2017 amending Regulation (EU) No 182/2011, the Commission deplored the fact that, since the entry into force of Regulation (EC) No 1829/2003, authorisation decisions have been adopted by the Commission without the support of the opinion of the Member State Committee and that the return of the dossier to the Commission for final decision, which is very much the exception for the procedure as a whole, has become the norm for decision-making on genetically modified food and feed authorisations; whereas that practice has, on several occasions, been deplored by President Juncker as not being democratic³;

²cf. Annex G, Member States comments
³See, 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).
Y. whereas, on 28 October 2015, Parliament rejected at first reading\(^1\) the legislative proposal of 22 April 2015 amending Regulation (EC) No 1829/2003 and called on the Commission to withdraw it and submit a new one;

1. Considers that the draft Commission implementing decision exceeds the implementing powers provided for in Regulation (EC) No 1829/2003;

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

3. Calls on the Commission not to authorise the import, for food or feed uses, of any genetically modified plant which has been made tolerant to a herbicide which is not authorised for use in the Union, in this case glufosinate;

4. Calls on the Commission not to authorise any herbicide-tolerant GM plants without full assessment of the residues from spraying with complementary herbicides, metabolites and commercial formulations as applied in the countries of cultivation;

5. 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;

6. Calls on the Commission not to authorise any GM plants which contain antimicrobial resistant genes;

7. 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;

8. Calls on the Commission to suspend any implementing decision regarding applications for authorisation of GMOs until the authorisation procedure has been revised in such a way as to address the shortcomings of the current procedure, which has proven inadequate;

9. Calls on the Commission to withdraw proposals for GMO authorisations if no opinion is delivered by the Standing Committee on the Food Chain and Animal Health, whether for cultivation or for food and feed uses;

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