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*Plenary sitting*

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**B8-0075/2019**

23.1.2019

## **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 maize MON 87403 (MON-874Ø3-1), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D059691/02 – 2019/2523(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 maize MON 87403 (MON-874Ø3-1), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D059691/02 – 2019/2523(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 maize MON 87403 (MON-874Ø3-1), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D059691/02),
- 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<sup>1</sup>, 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 Articles 11 and 13 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<sup>2</sup>,
- having regard to the opinion adopted by the European Food Safety Authority (EFSA) on 8 March 2018 and published on 28 March 2018<sup>3</sup>,
- having regard to the proposal for a regulation of the European Parliament and of the Council amending Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (COM(2017)0085, COD(2017)0035),
- having regard to its previous resolutions objecting to the authorisation of genetically modified organisms<sup>4</sup>,

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<sup>1</sup> OJ L 268, 18.10.2003, p. 1.

<sup>2</sup> OJ L 55, 28.2.2011, p. 13.

<sup>3</sup> Assessment of genetically modified maize MON 87403 for food and feed uses, import and processing, under Regulation (EC) No 1829/2003 (application EFSA- GMO- BE- 2015- 125), <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5225>

<sup>4</sup> – Resolution of 16 January 2014 on the proposal for a Council decision concerning the placing on the market for cultivation, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line 1507) genetically modified for resistance to certain lepidopteran pests (OJ C 482, 23.12.2016, p. 110).

– 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

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- modified maize NK603 × T25 (OJ C 399, 24.11.2017, p. 71).
- Resolution of 3 February 2016 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87705 × MON 89788 (OJ C 35, 31.1.2018, p. 19).
  - Resolution of 3 February 2016 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 (OJ C 35, 31.1.2018, p. 17).
  - Resolution of 3 February 2016 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean FG72 (MST-FGØ72-2) (OJ C 35, 31.1.2018, p. 15).
  - 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 maize 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 6 October 2016 on the draft Commission implementing decision renewing the authorisation for the placing on the market for cultivation of genetically modified maize MON 810 seeds (OJ C 215, 19.6.2018, p. 76).
  - Resolution of 6 October 2016 on the draft Commission implementing decision authorising the placing on the market of genetically modified maize MON 810 products (OJ C 215, 19.6.2018, p. 80).
  - Resolution of 6 October 2016 on the draft Commission implementing decision concerning the placing on the market for cultivation of genetically modified maize Bt11 seeds (OJ C 215, 19.6.2018, p. 70).
  - Resolution of 6 October 2016 on the draft Commission implementing decision concerning the placing on the market for cultivation of genetically modified maize 1507 seeds (OJ C 215, 19.6.2018, p. 73).
  - Resolution of 6 October 2016 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913 (OJ C 215, 19.6.2018, p. 83).
  - 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 maize 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 17 May 2017 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize DAS-40278-9, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (OJ C 307, 30.8.2018, p. 71).
  - Resolution of 17 May 2017 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB119 (BCS-GHØØ5-8) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ C 307, 30.8.2018, p. 67).
  - Resolution of 13 September 2017 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-68416-4, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (OJ C 337, 20.9.2018, p. 54).
  - Resolution of 4 October 2017 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean FG72 × A5547-127 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (OJ C 346, 27.9.2018, p. 55).
  - Resolution of 4 October 2017 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-44406-6, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (OJ C 346, 27.9.2018, p. 60).
  - 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 26 June 2015, Monsanto Europe SA/NV submitted, on behalf of the Monsanto company, United States, 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 genetically modified (GM) maize MON 87403 ('the application') to the national competent authority of Belgium, and whereas the application also covered the placing on the market of

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Council on genetically modified food and feed (OJ C 346, 27.9.2018, p. 122).

- Resolution of 24 October 2017 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 × 40-3-2 (DP-305423-1 × MON-04032-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (OJ C 346, 27.9.2018, p. 127).
- Resolution of 24 October 2017 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified oilseed rapes MON 88302 × Ms8 × Rf3 (MON-88302-9 × ACSBN005-8 × ACS-BN003-6), MON 88302 × Ms8 (MON-88302-9 × ACSBN005-8) and MON 88302 × Rf3 (MON-88302-9 × ACS-BN003-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (OJ C 346, 27.9.2018, p. 133).
- Resolution of 1 March 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 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (Texts adopted, P8\_TA(2018)0051).
- 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 3 May 2018 on the draft Commission implementing decision renewing the authorisation for the placing on the market of food and feed produced from genetically modified sugar beet H7-1 (KM-0000H71-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (Texts adopted, P8\_TA(2018)0197).
- Resolution of 30 May 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 GA21 (MON-00021-9) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (Texts adopted, P8\_TA(2018)0221).
- Resolution of 30 May 2018 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × 59122 × MON 810 × NK603, and genetically modified maize combining two or three of the single events 1507, 59122, MON 810 and NK603, and repealing Decisions 2009/815/EC, 2010/428/EU and 2010/432/EU pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (Texts adopted, P8\_TA(2018)0222).
- 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 NK603 × MON 810 (MON-00603-6 × MON-00810-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P8\_TA(2018)0416).
- Resolution of 24 October 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 × 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)0417).

products containing or consisting of GM maize MON 87403 for uses other than food and feed, with the exception of cultivation;

- B. whereas maize MON 87403 is genetically modified to increase the biomass and yield of the ears (which become the corn cob for harvest) through insertion of a truncated gene sequence derived from another plant species (*Arabidopsis thaliana*); whereas this leads to the expression of a protein (AtHB17Δ113) which is intended to act in competition with a similar natural protein that controls gene regulation and growth of the plants;
- C. whereas many critical comments were submitted by competent authorities during the three-month consultation period<sup>1</sup>; whereas the remarks included, inter alia, the observations that experimental data did not support the claim of increased yield for GM maize MON 87403, that it is not possible to conclude on the safety of the long-term reproductive or developmental effects of the whole food and/or feed, that the applicant's proposal for an environmental monitoring plan does not meet the objectives defined in Annex VII to Directive 2001/18/EC of the European Parliament and of the Council<sup>2</sup> and, crucially, that the evidence provided was not considered sufficient to reassure consumers of the safety of GM maize MON 87403;
- D. whereas despite EFSA giving the green light as regards the safety of GM maize MON 87403, an independent analysis of EFSA's evaluation shows that the exact molecular mechanisms involved in the expression of AtHB17Δ113, as well as how this results in the supposed intended effects and any possible side effects, remain poorly understood and require further research<sup>3</sup>; whereas without comprehensive understanding of the genetic modification it is not possible to fully evaluate the associated risks;
- E. whereas the outcome of field trials performed by the applicant shows that the observed effects of the intended trait, i.e. increased biomass and yield of the ears, were not only very small but also inconsistent; whereas the EFSA Panel on Genetically Modified Organisms (EFSA GMO Panel) acknowledged that 'the change due to the intended trait is known to be of limited amplitude...which suggests that the manifestation of the trait may depend on environmental conditions in the field trials'<sup>4</sup>;
- F. whereas the field trials were only performed in the United States; whereas if authorised for import into the Union, GM maize MON 87403 may be cultivated in a wide range of maize-producing countries, with vastly differing climatic and agronomic conditions and additional stressors such as water limitation or drought; whereas the impact of these stressors and conditions, which the EFSA GMO Panel acknowledges may impact the manifestation of the trait (and therefore also any unintended effects), has therefore not

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<sup>1</sup> Member States' comments:

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2018-00222>

<sup>2</sup> 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).

<sup>3</sup> Testbiotech comment on EFSA GMO Panel, 2018, Scientific opinion on the assessment of genetically engineered maize MON 87403 for food and feed uses, import and processing, from Monsanto: <https://www.testbiotech.org/node/2210>

<sup>4</sup> EFSA opinion, p. 3: <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5225>

been adequately addressed;

- G. whereas, paradoxically, while the EFSA GMO Panel concluded that the compositional analysis (comparison of the composition of GM maize MON 87403 with a non-GM comparator based on field trial results) ‘did not identify issues requiring further assessment regarding food and feed safety and its environmental impact’, the panel also questioned ‘whether the compositional data obtained from the field trials would allow a thorough risk assessment’;
- H. whereas the potential risks posed by this GM maize to human and animal health and the environment have not been adequately examined by the EFSA GMO Panel; whereas it is unacceptable that the Commission proposes to authorise this GM maize on the basis of the EFSA opinion;
- I. whereas one of the studies referenced in the EFSA opinion was a study co-authored by an EFSA GMO Panel member and a scientist working for Syngenta<sup>1</sup>; whereas it has been noted that references to this study were later removed from the EFSA opinion, while EFSA noted that their removal ‘does not materially affect the content or outcome’<sup>2</sup>;
- J. whereas Parliament welcomes the fact that EFSA’s Executive Director has committed to ensuring that, in the future, EFSA staff members will no longer co-author scientific publications with industry-affiliated scientists, in order to avoid perceptions of inappropriate proximity to industry and in the interests of increasing consumer confidence in the Union food safety system<sup>3</sup>; whereas it is of the utmost importance that all studies used by EFSA in its work are clearly referenced;
- K. 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;
- L. 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 States’ 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,

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<sup>1</sup> For details, see Testbiotech comment on EFSA GMO Panel, 2018, Scientific opinion on the assessment of genetically engineered maize MON 87403 for food and feed uses, import and processing, from Monsanto: <https://www.testbiotech.org/node/2210>

<sup>2</sup> See EFSA opinion, p. 2: <https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2018.5225>

<sup>3</sup> July 2018 letter from EFSA to Testbiotech:

[http://www.testbiotech.org/sites/default/files/EFSA\\_letter\\_Testbiotech\\_July\\_2018%20.pdf](http://www.testbiotech.org/sites/default/files/EFSA_letter_Testbiotech_July_2018%20.pdf)

been deplored by President Juncker as not being democratic<sup>1</sup>;

- M. whereas on 28 October 2015, Parliament rejected at first reading<sup>2</sup> 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. 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<sup>3</sup>, 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 genetically modified food and feed, while ensuring the effective functioning of the internal market;
  3. Calls on the Commission to withdraw its draft implementing decision;
  4. 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;
  5. 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;
  6. 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;
  7. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.

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<sup>1</sup> See, 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).

<sup>2</sup> OJ C 355, 20.10.2017, p. 165.

<sup>3</sup> OJ L 31, 1.2.2002, p. 1.