



Plenary sitting

B8-0074/2019

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 5307 (SYN-Ø53Ø7-1), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed
(D059689/02 – 2019/2522(RSP))

Committee on the Environment, Public Health and Food Safety

Member responsible: Bart Staes

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 5307 (SYN-Ø53Ø7-1), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (D059689/02 – 2019/2522(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 5307 (SYN-Ø53Ø7-1), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (D059689/02),
- 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 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 powers²,
- having regard to the opinion adopted by the European Food Safety Authority (EFSA) on 16 April 2015 and published on 5 May 2015³, and to the Statement complementing the EFSA Scientific Opinion on application (EFSA-GMO-DE-2011-95) for the placing on the market of genetically modified maize 5307 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Crop Protection AG taking into consideration an additional toxicological study, adopted by EFSA on 7 March 2018 and published on 11 April 2018⁴,
- having regard to the proposal for a regulation of the European Parliament and of the Council of 14 February 2017 amending Regulation (EU) No 182/2011 laying down the

¹ OJ L 268, 18.10.2003, p. 1.

² OJ L 55, 28.2.2011, p. 13.

³ Scientific Opinion on application (EFSA-GMO-DE-2011-95) for the placing on the market of genetically modified maize 5307 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Crop Protection AG, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4083>

⁴ Statement complementing the EFSA Scientific Opinion on application (EFSA-GMO-DE-2011-95) for the placing on the market of genetically modified maize 5307 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Crop Protection AG taking into consideration an additional toxicological study, <https://www.efsa.europa.eu/en/efsajournal/pub/5233>

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 organisms¹,

¹ – 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 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 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 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 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 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 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-3Ø5423-1 × MON-Ø4Ø32-6) 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-883Ø2-9 × ACSBNØØ5-8 × ACS-BNØØ3-6), MON 88302 × Ms8 (MON-883Ø2-9 × ACSBNØØ5-8) and MON 88302 × Rf3 (MON-883Ø2-9 × ACS-BNØØ3-6) 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-89Ø34-3 × MON-ØØ6Ø3-6) 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-ØØØH71-4) 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-ØØØ21-9) 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-ØØ6Ø3-6 × MON-ØØ81Ø-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).

- 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 7 April 2011, Syngenta Crop Protection AG submitted an application, through its affiliated company Syngenta Crop Protection NV/SA, 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 5307 ('the application') to the national competent authority of Germany; whereas the application also covered the placing on the market of products containing or consisting of GM maize 5307 for uses other than food and feed, with the exception of cultivation;
 - B. whereas GM maize 5307 produces a new insecticidal protein, eCry3.1Ab, which is toxic to certain beetles and weevils and which is derived from a fusion and rearrangement of toxins that naturally occur in soil bacteria known as *Bacillus thuringiensis* (Bt); whereas GM maize 5307 also expresses the protein phosphomannose isomerase (PMI), which is used as a selection marker;
 - C. whereas EFSA concluded in its 2015 opinion that it was unable to complete its food/feed risk assessment owing to inadequacies in the 28-day toxicity study provided by the applicant, in particular because the datasets were from two separate experiments and because an insufficient number of animals were used¹;
 - D. whereas the applicant later provided a new 28-day toxicity study; whereas, however, the second study did not meet all the requirements of the Organisation for Economic Cooperation and Development (OECD) guidelines on repeated dose 28-day oral toxicity studies in rodents², as requested by EFSA;
 - E. whereas, in its 2018 statement, EFSA adopted a favourable opinion in relation to this application;
 - F. whereas although Cry proteins (Bt toxins) have been recognised as having adjuvant properties, meaning that they may reinforce the allergenic properties of other foodstuffs, this was not analysed by EFSA; whereas that is problematic, because Bt toxins may be mixed with allergens in food and feed such as soybeans;
 - G. whereas in the 28-day toxicity study accepted by EFSA, only the isolated protein was tested; whereas, however, it has been shown that the toxicity of Bt toxins can be enhanced through interactions with other compounds such as plant enzymes, other Bt toxins and residues from spraying with herbicides; whereas testing the Bt toxin alone and in isolated form does not allow, therefore, for any conclusions to be drawn on its health impact after consumption³;
 - H. whereas EFSA noted that the 'applicant identified relevant similarities between the

¹ EFSA opinion, 2015, p. 15, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4083>

² EFSA statement, 2018, p. 4, <https://www.efsa.europa.eu/en/efsajournal/pub/5233>

³ See analysis from the Institute for Independent Impact Assessment in Biotechnology, TESTBIOTECH, p. 3 for further details: https://www.testbiotech.org/sites/default/files/Testbiotech_Comment_Maize%205307.pdf

amino acid sequence of eCry3.1Ab and parasporins, which might act as cytotoxic proteins on mammalian cells¹; whereas EFSA did not investigate that further;

- I. whereas many critical comments were submitted by Member State competent authorities during the three-month consultation period²;
- J. whereas, according to one competent authority³, expression levels of eCry3.1Ab in GM maize 5307 kernels exceed the default maximum residue level permitted, which is 0,01 mg/kg as set out in Regulation (EC) No 396/2005 of the European Parliament and of the Council⁴;
- 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, been deplored by President Juncker as not being democratic⁵;
- M. whereas, on 28 October 2015, Parliament rejected at first reading⁶ 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

¹ EFSA opinion, 2015, p. 9, <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2015.4083>

² cf. Annex G, Member State comments,

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2011-00310>

³ Member State comments, p. 95.

⁴ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

⁵ 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).

⁶ OJ C 355, 20.10.2017, p. 165.

178/2002¹, 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, the Commission, and the governments and parliaments of the Member States.

¹ OJ L 31, 1.2.2002, p. 1.