



TEXTS ADOPTED

P8_TA(2019)0313

Genetically modified soybean MON 87751 (MON-87751-7)

European Parliament resolution of 27 March 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified soybean MON 87751 (MON-87751-7), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D060916/01 – 2019/2603(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 soybean MON 87751 (MON-87751-7), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (D060916/01),
- 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 of the Standing Committee on the Food Chain and Animal Health referred to in Article 35 of Regulation (EC) No 1829/2003, on 7 March 2019, 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 20 June 2018 and published on 2 August 2018³,
- having regard to the proposal for a regulation of the European Parliament and of the

¹ OJ L 268, 18.10.2003, p. 1.

² OJ L 55, 28.2.2011, p. 13.

³ EFSA GMO Panel (EFSA Panel on genetically Modified Organisms), 2018. Scientific opinion on the assessment of genetically modified soybean MON 87751 for food and feed uses under Regulation (EC) No 1829/2003 (application EFSA-GMO-NL-2014-121). EFSA Journal 2018; 16(8):5346, 32 pp. doi: 10.2903/j.efsa.2018.5346.

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, 2017/0035(COD)),

- having regard to its previous resolutions objecting to the authorisation of genetically modified organisms¹,
 - 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 September 2014, Monsanto Europe S.A./N.V. submitted on behalf of 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) soybean MON 87751 ('the application') to the national competent authority of the Netherlands, and whereas the application also covered the placing on the market of products containing or consisting of GM soybean MON 87751 for uses other than food and feed, with the exception of cultivation;
- B. whereas, on 20 June 2018, EFSA adopted a favourable opinion in relation to the

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

authorisation¹;

- C. whereas GM soybean MON 87751 was developed to confer resistance against certain lepidopteran pests and expresses the Bt proteins Cry1A.105 and Cry2Ab2 for this purpose;

Bt toxins

- D. whereas studies show that Bt toxins may have adjuvant properties which reinforce the allergenic properties of other foodstuffs; whereas soybeans themselves produce many plant allergens, and there is a specific risk that the Bt protein can enhance the immune system response to these compounds at the consumption stage;
- E. whereas a member of the EFSA Panel on Genetically Modified Organisms (EFSA GMO Panel) previously stated that while unintended effects have never been identified in any application where Bt proteins are expressed, they could ‘not be observed by the toxicological studies that are currently recommended and performed for the safety assessment of GM plants at EFSA because they do not include the appropriate tests for this purpose’²;
- F. whereas in relation to the current authorisation, the EFSA GMO Panel itself recognises that there is limited knowledge and experimental evidence available on the potential of the newly expressed proteins to act as adjuvants³;

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

- G. whereas studies stress the need for further research and long-term studies on the adjuvant properties of Bt toxins; whereas, while questions remain in relation to the role of Bt toxins and their adjuvant properties, GM plants containing them should not be authorised for import for food and feed uses;

Toxicity and 90-day feeding studies

- H. whereas two 28-day repeated dose toxicity studies with mice were performed, one with the Cry1a.105 protein and one with the Cry2Ab2 protein;
- I. whereas those toxicity studies were conducted with the isolated proteins, i.e. not with the proteins in combination, which were derived from bacteria and therefore not identical to those produced in the plant; whereas that means that the studies did not emulate exposure under practical conditions;
- J. whereas the two toxicity studies did not fully comply with the relevant OECD requirements in that coagulation examinations were based on a relatively low number of samples and functional observational battery and locomotor activity tests were not performed; whereas it is essential that all such requirements are fulfilled in the authorisation procedure;
- K. whereas multiple statistically significant differences between the control and test group were identified in the 90-day feeding study which, according to comments from a Member State competent authority, should have been examined further¹;

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

- L. whereas the 90-day feeding study with rats contained the following weaknesses: the study did not use two different dosages of test material as required by Commission Implementing Regulation (EU) No 503/2013¹ and none of the test materials were analysed for possible contamination with other genetically modified organisms (GMOs);
- M. whereas, while EFSA identifies soymilk as being the main contributor in human diets with the highest chronic exposure², toasted defatted soybean meal was used as the test material in the feeding study; whereas expression levels of the Bt proteins in the soybean meal were not measured, meaning that it is not possible to link the outcome of the study with specific Bt toxin levels;

Member State competent authority comments

- N. whereas Member State authorities submitted many critical comments during the three-month consultation period³, inter alia that many questions regarding the safety and possible toxicity of GM soybeans remain unresolved, that the combinatory effects of both proteins have not been analysed, that further information should be considered before the risk assessment can be finalised, that the environmental monitoring plan does not meet the objectives set out in Annex VII to Directive 2001/18/EC of the European Parliament and of the Council⁴ and that it should be amended before consent is given, and that there is no reason to presume that consumption of Cry proteins is safe and does not represent a danger to humans, animals or the environment;

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

- O. whereas the Union is party to the UN Convention on Biological Diversity, which places on its parties the responsibility to ensure that activities within their jurisdictions do not cause damage to the environment of other States¹; whereas the decision on whether or not to authorise the GM soybean is within the Union's jurisdiction;
- P. whereas, in line with a request from one Member State, existing data on the impact of the cultivation of GM soybean MON 87751 on producing and exporting countries should be considered in the application; whereas the same Member State recommends a study to assess how imports of certain products influence crop choices in Europe and therefore the biodiversity resulting from such agrosystem choices²;
- Q. whereas the competent authorities of several Member States have criticised the lack of robustness of the post-market monitoring plan;

Lack of democratic legitimacy

- R. whereas the vote on 7 March 2019 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 there was not a qualified majority in favour of authorisation;
- S. whereas on several occasions³ the Commission has deplored the fact that, since the entry into force of Regulation (EC) No 1829/2003, it has adopted authorisation decisions without the support of the Standing Committee on the Food Chain and Animal Health and that the return of the dossier to the Commission for a final decision, which is very much the exception for the procedure as a whole, has become the norm for

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-000H71-4) 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).

decision-making on GM food and feed authorisations; whereas that practice has also been deplored by President Juncker as undemocratic¹;

- T. whereas, on 28 October 2015, Parliament rejected at first reading² 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;
- U. whereas recital 14 of Regulation (EU) No 182/2011 states that the Commission should, as far as possible, act in such a way as to avoid going against any predominant position which might emerge within the appeal committee against the appropriateness of an implementing act, especially on sensitive issues such as consumer health, food safety and the environment;
- V. 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 that the Commission must take into account any relevant provisions of Union law and other legitimate factors relevant to the matter under consideration when drafting its decision to renew the authorisation;
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 Council³, to provide the basis for

– 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).

– Resolution of 31 January 2019 on the draft Commission implementing decision amending Implementing Decision 2013/327/EU as regards the renewal of the authorisation to place on the market feed containing or consisting of genetically modified oilseed rapes Ms8, Rf3 and Ms8 × Rf3 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P8_TA(2019)0057).

– Resolution of 31 January 2019 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 (Texts adopted, P8_TA(2019)0058).

– Resolution of 31 January 2019 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 (Texts adopted, P8_TA(2019)0059).

– Resolution of 31 January 2019 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

ensuring a high level of protection of human life and health, animal health and welfare,

Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P8_TA(2019)0060).

– European Parliament resolution of 13 March 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize 4114 (DP-ØØ4114-3), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P8_TA(2019)0196).

– European Parliament resolution of 13 March 2019 on the draft Commission implementing decision authorising the placing on the market of products containing, consisting of or produced from genetically modified maize MON 87411 (MON-87411-9), pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P8_TA(2019)0197).

– European Parliament resolution of 13 March 2019 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 × 1507 × GA21 and sub-combinations Bt11 × MIR162 × 1507, MIR162 × 1507 × GA21 and MIR162 × 1507 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (Texts adopted, P8_TA(2019)0198).

1 <https://www.efsa.europa.eu/en/efsajournal/pub/5346>

2 <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2018.5309> p34

3 EFSA response to Member States comments, p109, Annex G:

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00719>

1 Annex G, Member States comments, pp. 27-33,

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00719>

1 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).

2 EFSA opinion, p. 22, <https://www.efsa.europa.eu/en/efsajournal/pub/5346>

3 Annex G, Member State comments,

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00719>

4 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).

1 United Nations Convention on Biological Diversity, 1992, Article 3,

<https://www.cbd.int/convention/articles/default.shtml?a=cbd-03>

2 Annex G, Member States comments, pp. 67-68,

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2014-00719>

3 See, for example, 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.

1 For example. in 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).

2 OJ C 355, 20.10.2017, p. 165.

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;
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.

³ 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 on food safety (OJ L 31, 1.2.2002, p. 1.).