European Parliament
2014-2019

TEXTS ADOPTED

P8_TA(2017)0123

Genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21

European Parliament 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 (D049280 – 2017/2624(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 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 (D049280),

– 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 7(3), 9(2) and 21(2) 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 27 January 2017, where no opinion was delivered, and to the vote of the Appeal Committee on 27 March 2017, where again 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[2],

– having regard to the opinion adopted by the European Food Safety Authority (EFSA) on

1 OJ L 268, 18.10.2003, p. 1.
2 OJ L 55, 28.2.2011, p. 13.

15 July 2016[1], which includes a minority opinion, and EFSA's previous opinions on maize containing the single events, Bt11 (expressing Cry1Ab and PAT proteins), 59122 (expressing Cry34Ab1, Cry35Ab1 and PAT proteins), MIR604 (expressing mCry3A and PMI proteins), 1507 (producing Cry1F and PAT proteins) and GA21 (expressing mEPSPS protein),

– 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[2],

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1 EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2016. Scientific Opinion on an application by Syngenta (EFSA-GMO-DE-2011-99) for the placing on the market of maize Bt11 × 59122 × MIR604 × 1507 × GA21 and twenty sub-combinations, which have not been authorised previously independently of their origin, for food and feed uses, import and processing under Regulation (EC) No 1829/2003; EFSA Journal 2016;14(8):4567 [31 pp.]; doi:10.2903/j.efsa.2016.4567

2 - 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 the 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 (P8_TA(2015)0456),
- 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 (P8_TA(2016)0040),
- 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 (P8_TA(2016)0039),
- 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) (P8_TA(2016)0038),
- 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 (P8_TA(2016)0271),
- 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) (P8_TA(2016)0272),
- 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 (P8_TA(2016)0388),

– 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,

The application

A. whereas on 1 July 2011 Syngenta submitted an application for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from Bt11 × 59122 × MIR604 × 1507 × GA21 maize to the national competent authority of Germany in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003; whereas that application also covered the placing on the market of genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21 in products consisting of it or containing it for uses other than food and feed as any other maize, with the exception of cultivation;

B. whereas on 21 February 2014 Syngenta extended the scope of the application to all sub-combinations of the single genetic modification events constituting Bt11 × 59122 × MIR604 × 1507 × GA21 maize, except the sub-combination 1507 × 59122, which was already authorised by Commission Decision 2010/432/EU[1];

C. whereas on 31 March 2016 Syngenta updated the scope of the application by excluding the following four sub-combinations, which were in the scope of another application: Bt11 × GA21 maize, MIR604 × GA21 maize, Bt11 × MIR604 maize, and Bt11 × MIR604 × GA21[2];

D. whereas no specific data regarding any of the 20 sub-combinations have been submitted

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- resolution of 6 October 2016 on the draft Commission implementing decision authorising the placing on the market of genetically modified maize MON 810 products (P8_TA(2016)0389),
- 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 (P8_TA(2016)0386),
- 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 (P8_TA(2016)0387),
- 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 (P8_TA(2016)0390).

[1] Commission Decision 2010/432/EU of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507x59122 (DAS-Ø15Ø7-1xDAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 202, 4.8.2010, p. 11).

[2] Commission Implementing Decision (EU) 2016/1685 of 16 September 2016 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 the events Bt11, MIR162, MIR604 and GA21, and repealing Decisions 2010/426/EU, 2011/892/EU, 2011/893/EU and 2011/894/EU (OJ L 254, 20.9.2016, p. 22).

by the applicant[1];

E. whereas the intended uses of the five-event stack are to control lepidopteran and coleopteran maize pests and provide tolerance to herbicides containing glufosinate ammonium or glyphosate[2]; whereas the intended uses of the different sub-combinations are similar, depending on the combinations;

The EFSA opinion

F. whereas on 26 August 2016, the European Food Safety Authority (EFSA) gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 with regard to the GM-maize Bt11 × 59122 × MIR604 × 1507 × GA21 and all of the sub-combinations covered by the scope of the application; whereas the EFSA opinion included a minority opinion;

G. whereas EFSA acknowledges that no specific data have been submitted for all 20 sub-combinations, that many of them have not even been created yet, and that no scientific information regarding them could be retrieved in a literature search, but nevertheless concludes that all 20 sub-combinations are 'expected to be as safe as the five-event stack maize';

H. whereas EFSA does not consider any post-market monitoring for the GM-events concerned to be necessary; whereas EFSA merely states that the requirement for monitoring should be considered on the basis of the new protein expression data provided, if these sub-combinations were to be created via targeted breeding approaches and imported into the Union;

Concerns

I. whereas hundreds of critical comments have been submitted by Member States during the three-month consultation period[3]; whereas those comments refer to, *inter alia*:

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1 As confirmed in the EFSA opinion referred to above (EFSA Journal 2016;14(8):4567 [31 pp.]).

2 SYN-BTØ11-1 maize expresses the Cry1Ab protein which confers protection against certain lepidopteran pests and a PAT protein which confers tolerance to glufosinate-ammonium herbicides.
DAS-59122-7 maize expresses the Cry34Ab1 and Cry35Ab1 proteins which confer protection against certain coleopteran pests and a PAT protein which confers tolerance to glufosinate-ammonium herbicides.
SYN-IR6Ø4-5 maize expresses the modified Cry3A protein which provides protection against certain coleopteran pests and PMI protein which was used as a selectable marker.
DAS-Ø15Ø7-1 maize expresses the Cry1F protein which confers protection against certain lepidopteran pests and the PAT protein, used as a selectable marker, which confers tolerance to the glufosinate-ammonium herbicide.
MON-ØØØ21-9 maize expresses the mEPSPS protein which confers tolerance to glyphosate herbicides.

3 See EFSA Register of Questions, Annex G to Question Number EFSA-Q-2011-00894, available online at: http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2011-00894 (last point).

missing information and data, poorly performed studies, missing studies, missing evidence to exclude certain routes of exposure, an insufficient data basis, e.g. as regards digestibility, missing consideration of the combined effects of the different Bt toxin proteins when judging the potential for allergenicity and toxicity, shortcomings as regards the experimental design of the field trials and the statistical analysis, missing reports on the results of the monitoring, failure to demonstrate that the product does not have any adverse effects on the environment, failure to further assess detected statistically significant differences, e.g. in nutritional composition, and failure to conduct immunological tests with regard to a potentially higher allergenic potential;

J. whereas a minority opinion was expressed by Jean-Michel Wal, Member of the EFSA GMO Panel[1], stating that: 'no specific data regarding any of those 20 sub-combinations have been provided by the Applicant, who also did not give a satisfactory rationale explaining the reasons why those data are missing and/or why he would consider that they are not necessary for the risk assessment. This is a most important reason for expression of this minority opinion, considering that there cannot be two kinds of risk assessment, a comprehensive one based on a complete set of data and another one for which no specific data at all are available and which is based on assumptions and indirect considerations deduced by the Panel by the so called "weight of evidence approach" and extrapolation of data obtained for the single events, the five-event stack and other stacks that were submitted and assessed in other applications. In addition to this matter of principle, in the present case, this may result in uncontrolled risk for the health of human consumers in certain segments of the population.';

K. whereas, more specifically, the minority opinion questions why the kind of extrapolation made to assess potential adverse effects is not precisely defined: 'The criteria, procedure and the level of confidence that should be required for this extrapolation are not given and there is no critical appraisal of its limitations. No evaluation of the resulting uncertainty has been performed, e.g. using a probabilistic analysis, as recommended by the Draft Guidance on Uncertainty in EFSA Scientific Assessment (Revised for Internal Testing) of the EFSA Scientific Committee. These weaknesses may invalidate the general conclusion.';

L. whereas the EFSA minority opinion also points to several shortcomings and contradictory arguments with regard to the application, e.g. the fact that the applicant on the one hand alludes to the fact that all sub-combinations had been produced, and its protein expression level had been analysed[2], but on the other hand does not provide any data on any of the sub-combinations;

M. whereas the genetically modified maize varieties SYN-BTØ11-1, DAS-59122-7 and DAS-Ø15Ø7-1 involved express a PAT-protein which confers tolerance to the glufosinate-ammonium herbicide; whereas glufosinate is classified as toxic to reproduction and thus falls under the exclusion criteria set out in Regulation (EC) No

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1 See Appendix A of the EFSA opinion.

2 The application states that 'the Bt11 × 59122 × MIR604 × 1507 × GA21 maize and all of its sub-combinations independently of their origin have been produced by conventional breeding crosses (...) (point ii)', and 'the analysis of the protein expression level confirms that the crossing of the GM maize single events (...) results in no interaction between them in Bt11 × 59122 × MIR604 × 1507 × GA21 maize or the sub-combinations of fewer of these events independently of their origin. (point x)'.

1107/2009; whereas the approval of glufosinate expires on 31 July 2018[1];

N. whereas the genetically modified MON-ØØØ21-9 maize, as described in the application, expresses the mEPSPS protein which confers tolerance to glyphosate herbicides; whereas the International Agency for Research on Cancer – the specialised cancer agency of the World Health Organisation – classified glyphosate as probably carcinogenic to humans on 20 March 2015[2];

The procedure

O. whereas 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 27 January 2017 delivered no opinion; whereas only 10 Member States, representing only 38,43°% of the Union population voted in favour, while 13 Member States voted against, with four Member States abstaining,; whereas the vote of the Appeal Committee on 27 March 2017 again delivered no opinion;

P. whereas, in both 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 Member States' committee opinion 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 this practice has, on several occasions, been deplored by Commission President Juncker as not being democratic[3];

Q. whereas the legislative proposal of 22 April 2015 amending Regulation (EC) No 1829/2003 was rejected by Parliament on 28 October 2015 on the grounds that, while cultivation necessarily takes place on a Member State's territory, GMO trade crosses borders, which means that a national 'sales and use' ban proposed by the Commission could be impossible to enforce without reintroducing border checks on imports; whereas the Parliament not only rejected the legislative proposal, but also called on the Commission to withdraw its proposal and submit a new one;

R. whereas it is already the case that Recital 14 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 clearly rules that: 'When considering

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1 http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.detail&language=EN&selectedID=1436

2 IARC Monographs Volume 112: evaluation of five organophosphate insecticides and herbicides, 20 March 2015 (http://monographs.iarc.fr/ENG/Monographs/vol112/mono112.pdf).

3 E.g. 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).

the adoption of other draft implementing acts concerning particularly sensitive sectors, notably taxation, consumer health, food safety and protection of the environment, the Commission, in order to find a balanced solution, will, 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.'[1];

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

2. Considers that the 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[2], to provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market;

3. Considers, more specifically, that it runs contrary to the principles of the general food law, as laid down in Regulation (EC) No 178/2002, to approve varieties for which no safety data have been provided, which have not even been tested, or which have not even been created yet;

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

5. 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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1 OJ L 55, 28.2.2011, p. 13.
2 OJ L 31, 1.2.2002, p. 1.