Thursday 6 October 2016

P8 TA(2016)0388

Renewing the authorisation for genetically modified maize MON 810 seeds

European Parliament 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 (MON-ØØ81Ø-6) seeds (D046170/00 — 2016/2921(RSP))

(2018/C 215/15)

The	European	Parliament,
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- having regard to the draft Commission implementing decision renewing the authorisation for the placing on the market for cultivation of genetically modified maize MON 810 (MON-ØØ81Ø-6) seeds (D046170/00,
- 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 Article 23(3) thereof,
- 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 scientific opinion updating the risk assessment conclusions and risk management recommendations on the genetically modified insect-resistant maize MON 810, delivered on 6 December 2012 by the European Food Safety Authority (3),
- having regard to the scientific opinion supplementing the conclusions of the environmental risk assessment and risk management recommendations for the cultivation of the genetically modified insect-resistant maize Bt11 and MON 810, adopted on 6 December 2012 by the European Food Safety Authority (4),
- having regard to the opinion updating risk management recommendations to limit exposure of non-target Lepidoptera of conservation concern in protected habitats to Bt-maize pollen, delivered on 28 May 2015 by the European Food Safety Authority (5),
- having regard to the scientific opinion on the annual post-market environmental monitoring (PMEM) report on the cultivation of genetically modified maize MON 810 in 2014 from Monsanto Europe S.A., delivered on 9 March 2016 by the European Food Safety Authority (6),

(2) OJ L 55, 28.2.2011, p. 13.

(3) EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion updating the risk assessment conclusions and risk management recommendations on the genetically modified insect resistant maize MON 810. EFSA Journal 2012; 10(12):3017 [98 pp.], doi:10.2903/j.efsa.2012.3017.

pp.], doi:10.2903/j.efsa.2012.3017.

(4) EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion supplementing the conclusions of the environmental risk assessment and risk management recommendations for the cultivation of the genetically modified insect resistant maize Bt11 and MON 810. EFSA Journal 2012; 10(12):3016 [32 pp.], doi:10.2903/j.efsa.2012.3016.

(5) EFSA Panel on Genetically Modified Organisms (GMO); Scientific Opinion updating risk management recommendations to limit exposure of non-target Lepidoptera of conservation concern in protected habitats to Bt-maize pollen. EFSA Journal 2015; 13 (7):4127 [31 pp.], doi:10.2903/j.efsa.2015.4127.

(6) EFSA Panel on Genetically Modified Organisms (GMO), 2016. Scientific opinion on the annual post-market environmental monitoring (PMEM) report on the cultivation of genetically modified maize MON 810 in 2014 from Monsanto Europe S.A. EFSA Journal 2016; 14(4):4446 [26 pp.], doi:10.2903/j.efsa.2016.4446.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

Thursday 6 October 2016

- having regard to its 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 (1),
- 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 and 18 April 2007, Monsanto Europe S.A. submitted to the Commission three applications, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for the renewal of the authorisation of existing foods, food ingredients and feed produced from MON 810 maize, of the authorisation of feed containing and consisting of MON 810 maize and of the authorisation of MON 810 maize in products consisting of it or containing it for uses other than food and feed, as any other maize, including cultivation; whereas after the date of entry into force of Regulation (EC) No 1829/2003, those products were notified to the Commission pursuant to Article 8(1)(a) and (b) and Article 20(1)(b) of that Regulation and included in the Community Register of genetically modified food and feed;
- B. whereas on 9 March 2016, Monsanto Europe S.A. sent a letter to the Commission requesting that the part of the application concerning cultivation be considered separately from the rest of the application;
- C. whereas the genetically modified MON 810 maize as described in the application expresses the Cry1Ab protein, derived from Bacillus thuringiensis subsp. kurstaki, which confers protection against certain lepidopteran insect pests, including the European Corn Borer (ECB) (Ostrinia nubilalis) and pink borers (Sesamia spp.);
- D. whereas the placing on the market of genetically modified MON 810 maize seeds for cultivation was initially authorised pursuant to Council Directive 90/220/EEC (2) by Commission Decision 98/294/EC (3); whereas on 3 August 1998, France granted consent to Monsanto Europe S.A. (hereinafter 'Monsanto') for the placing on the market of MON 810 maize products;
- E. whereas, pursuant to Article 26c(2) of Directive 2001/18/EC, the cultivation of genetically modified MON 810 maize shall be prohibited in the following territories: Wallonia (Belgium); Bulgaria; Denmark; Germany (except for research purposes); Greece; France; Croatia; Italy; Cyprus; Latvia; Lithuania; Luxembourg; Hungary; Malta; the Netherlands; Austria; Poland; Slovenia; Northern Ireland (United Kingdom); Scotland (United Kingdom); Wales (United Kingdom);
- F. whereas, according to the European Food Safety Authority (EFSA), evidence indicates that approximately 95 %-99 % of the pollen released is deposited within some 50 metres of the pollen source, though vertical wind movements or gusts during pollen shedding can lift pollen up high into the atmosphere and distribute it over significant distances of up to several kilometres;
- G. whereas EFSA arbitrarily excluded cross-pollination in maize from the scope of its scientific opinions on MON 810 maize, thereby overlooking the potential risks to biological diversity;

Texts adopted, P7_TA(2014)0036.

 $[\]binom{1}{2}$ Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms (OJ L 117, 8.5.1990, p. 15).

Commission Decision 98/294/EC of 22 April 1998 concerning the placing on the market of genetically modified maize (Zea mays L. line MON 810), pursuant to Council Directive 90/220/EEC (OJ L 131, 5.5.1998, p. 32).

Thursday 6 October 2016

- H. whereas teosintes, the ancestors of cultivated maize, have been present in Spain since 2009; whereas teosinte populations might become recipients for transgenic DNA stemming from genetically engineered MON 810 maize, which is cultivated in Spain in some of the regions where teosinte is spreading widely; whereas gene flow to teosinte may occur, causing it to produce the Bt toxin, and confer greater fitness to the hybrids of maize and teosinte in comparison with the native teosinte plants; whereas this is a scenario carrying major risks for farmers and the environment;
- I. whereas the Spanish competent authorities informed the Commission about the presence of teosinte in Spanish maize fields, including the very limited presence in GM maize fields; whereas the available information indicates, in addition, that teosinte has also been identified in France;
- J. whereas on 13 July 2016, the Commission requested that EFSA assess by the end of September 2016 whether, based on the existing scientific literature and any other relevant information, new evidence has emerged which would change the conclusions and recommendations of the EFSA scientific opinions on cultivation of the genetically modified maizes MON 810, Bt11, 1507 and GA21;
- K. whereas in point 22 of its draft implementing decision the Commission claims that, as regards local mortality, EFSA considered two levels of 'acceptable' local mortality (0,5 % and 1 %), but whereas in its scientific opinion adopted on 28 May 2015 updating risk management recommendations to limit exposure of non-target Lepidoptera of conservation concern in protected habitats to Bt-maize pollen, EFSA actually clearly states that 'any specific protection level used here for illustration by the EFSA GMO Panel is intended as an example only' and that 'any threshold applied must, by necessity, be arbitrary and should be subject to amendment according to the protection goals in operation within the EU':
- L. whereas in its draft implementing decision the Commission chose the level of local mortality of below 0,5% and provides in its annex for arbitrary isolation distances of at least 5 metres between a MON 810 maize field and a protected habitat as defined in Article 2(3) of Directive 2004/35/EC, despite the fact that EFSA clearly states, as confirmed, that imposing an isolation distance of 20 metres around a protected habitat from the nearest crop of maize Bt11/MON 810, which is four times further than the distance proposed by the Commission, would be expected to reduce local mortality even of highly sensitive non-target lepidopteran larvae to a level below 0,5%;
- M. whereas in its scientific opinion adopted on 28 May 2015 updating risk management recommendations to limit exposure of non-target Lepidoptera of conservation concern in protected habitats, EFSA stated that 'currently, there are insufficient data available to allow Bt-related larval mortality to be put into the context of overall mortality';
- N. whereas there is a record of continuous lack of enforcement of post-market environmental monitoring, as EFSA observes that the 2014 PMEM report shows partial non-compliance with the implementation of non-Bt refugia in Spain as observed in previous years, and that methodological shortcomings similar to those found in previous annual PMEM reports on MON 810 maize were identified in the analysis of farmer questionnaires and the conduct of the literature review;
- O. whereas the EFSA GMO Panel strongly reiterates in vain each year its recommendations on MON 810 post-market environmental monitoring, namely to provide more detailed information on the sampling methodology, reduce the possibility of selection bias in farmer questionnaires and ensure that all relevant scientific publications are identified; whereas, with regard to improving the sampling frame of the farmer survey, the GMO Panel reiterates in vain each year the importance of national GMO cultivation registers and its recommendations to consent holders to consider how they may make best use of the information recorded in national registers and foster dialogue with those responsible for the administration of these registers where MON 810 maize is cultivated;

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Thursday 6 October 2016

- 1. Considers that the draft Commission implementing decision exceeds the implementing powers provided for in Regulation (EC) No 1829/2003;
- 2. Considers the risk assessment on the cultivation conducted by EFSA to be incomplete and the risk management recommendations proposed by the Commission to be inadequate;
- 3. Considers that the draft Commission implementing decision is not consistent with Union law, in that it is not compatible with the objective of Regulation (EC) No 1829/2003, which is, in accordance with the general principles laid down in Regulation (EC) No 178/2002, to provide the basis for ensuring a high level of protection of human life and health, animal health and welfare, the environment and consumer interests in relation to genetically modified food and feed, whilst ensuring the effective functioning of the internal market;
- 4. Calls on the Commission to withdraw its draft implementing decision;
- 5. Instructs its President to forward this resolution to the Council, the Commission, and the governments and parliaments of the Member States.