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P7 TA(2014)0036

Placing on the market for cultivation of a genetically modified maize product

European Parliament 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 (2013/2974(RSP))

(2016/C 482/14)

The European Parliament,

- having regard to 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 (COM(2013)0758),
- having regard to the draft Commission 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 (D003697/01), submitted to a vote in the committee referred to in Article 30 of Directive 2001/18/EC on 25 February 2009,
- having regard to 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 (¹), and in particular the first subparagraph of Article 18(1) thereof,
- having regard to the vote in the committee referred to in Article 30 of Directive 2001/18/EC on maize 1 507, of 25 February 2009, in which no opinion was delivered,
- having regard to the six scientific opinions concerning maize 1507 delivered by the European Food Safety Authority (EFSA) Panel on Genetically Modified Organisms from 2005 to November 2012,
- having regard to Commission Implementing Regulation (EU) No 365/2013 of 22 April 2013 amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance glufosinate (²),
- having regard to the Environment Council conclusions on genetically modified organisms (GMOs) adopted on 4 December 2008,
- having regard to its position adopted at first reading on 5 July 2011 with a view to the adoption of Regulation (EU) No .../2011 of the European Parliament and of the Council amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory (³),
- having regard to Special Eurobarometer 354 on food-related risks (4),
- having regard to the judgment of the General Court of the European Union (Seventh Chamber) of 26 September 2013 concerning the application for deliberate release into the environment of maize 1507 (Case T-164/10) (5),

⁽¹⁾ OJ L 106, 17.4.2001, p. 1.

⁽²) OJ L 111, 23.4.2013, p. 27.

⁽³⁾ OJ C 33 E, 5.2.2013, p. 350.

⁽⁴⁾ http://www.efsa.europa.eu/en/factsheet/docs/reporten.pdf

⁽⁵⁾ http://curia.europa.eu/juris/document/document_print.jsf?doclang=EN&text=&page&Index=0&part=1&mode=lst&doci-d=142241&occ=first&dir=&cid=127901

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- having regard to Articles 5(5) and 8 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (1),
- having regard to Rule 88(2) and (3) of its Rules of Procedure,
- A. whereas Article 18(1) of Directive 2001/18/EC stipulates that a decision on the deliberate release of a genetically modified organism (GMO) must contain the same information as that specified in Article 19(3);
- B. whereas Article 19(3) of Directive 2001/18/EC stipulates that the written consent referred to in Article 18 must, in all cases, explicitly specify, inter alia, conditions for the protection of particular ecosystems/environments and/or geographical areas;
- C. whereas such an indication is missing in the Commission proposal;
- D. whereas the standing committee's vote of 25 February 2009 on a Commission proposal for authorisation delivered no opinion; whereas only 6 Member States voted in favour of the proposal, while 12 voted against it and 7 abstained;
- E. whereas, on the basis of EFSA recommendations, and in order to fulfil the conditions for authorisation, the Commission substantially modified the proposal, e.g. as regards labelling rules, monitoring and the practices set out in the insect resistance management plan;
- F. whereas the modifications to the version voted on in the standing committee on 25 February 2009 include the deletion of references to the glufosinate-tolerant trait of maize 1507, and the insertion of a requirement to inform operators that they should not use the product 'with glufosinate herbicides in any manner differing from conventional practice with maize not tolerant to glufosinate';
- G. whereas the modified proposal was not discussed with Member State experts or voted on in the standing committee, but was referred directly to the Council of Ministers;
- H. whereas the ruling of the General Court of the European Union of 26 September 2013 regarding the application by Pioneer Hi-Bred International for deliberate release into the environment of maize 1507 does not prevent the Commission from reconsidering its position and presenting a new proposal to the standing committee, further to a resolution of Parliament, pursuant to Article 8(1) of Council Decision 1999/468/EC, recommending that maize 1507 not be authorised;

EFSA risk assessment

- I. whereas, following the vote in the standing committee, the EFSA produced, at the Commission's request, three scientific opinions updating its previous risk assessments and risk management recommendations;
- J. whereas, in its opinion of February 2012, the EFSA explicitly disagreed with the applicant's conclusion that the study cited by the applicant provided adequate evidence that maize 1507 poses a negligible risk to non-target lepidoptera in the EU, but instead pointed to the fact that highly sensitive non-target butterflies and moths may be at risk when exposed to maize 1507 pollen (2);
- K. whereas the Bt-toxin produced by maize 1507, Cry1F, is different from the usual types of Bt-toxin and has proven to have different effects on non-target lepidoptera; whereas few studies have been conducted regarding the Cry1F protein, and none on its effects on aquatic species or soil organisms; whereas the EFSA states that the amount of Cry1F protein in maize 1507 pollen is about 350 times the Cry1Ab protein content expressed in maize MON 810 pollen (2);

⁽¹⁾ OJ L 184, 17.7.1999, p. 23.

⁽²⁾ http://www.efsa.europa.eu/en/efsajournal/pub/2429.htm

⁽³⁾ http://www.efsa.europa.eu/en/efsajournal/doc/2429.pdf

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- L. whereas Pioneer refused, following a request by the Commission, to revise its application for authorisation and present additional documents regarding monitoring and risk-mitigating measures for non-target organisms;
- M. whereas the EFSA acknowledges that in its risk assessment it did not consider potential risks linked to the other trait of maize 1507, namely its tolerance to the herbicide glufosinate ammonium (1), even though this characteristic may result in increased use of glufosinate;

Glufosinate

- N. whereas the EFSA is required to evaluate 'indirect effects such as a usage of pesticides [...] as part of the environmental risk assessment' and to assess 'the possible effects on biodiversity and non-target organisms which any individual GM herbicide-tolerant crop may cause due to the change in agricultural practices (including those due to different herbicide uses)' (2);
- O. whereas glufosinate is classified as toxic to reproduction and thus falls under the exclusion criteria set out in Regulation (EC) No 1107/2009; whereas for substances that have already been approved, the exclusion criteria apply when the approval needs to be renewed; whereas the approval of glufosinate expires in 2017 (3); whereas the use of glufosinate should therefore in principle end in 2017;
- P. whereas in countries other than the EU, e.g. in the United States and Canada, maize 1507 is marketed by its producer as a glufosinate-tolerant crop, while in the application in the EU the applicant argues that the gene for glufosinate tolerance was only to be used as a marker gene;
- Q. whereas it is unclear how the Commission intends to implement the impending ban on glufosinate, as long as it is still available on the market;

General situation with regard to GMOs in the EU

- R. whereas no GMO has been authorised for cultivation in the EU since 2010, when the Amflora potato was authorised; whereas this authorisation was annulled by the General Court of the European Union on 13 December 2013, and whereas the only other crop authorised for cultivation is Monsanto's maize MON 810, the renewal of the authorisation for which has been pending for some years;
- S. whereas it is broadly accepted as confirmed by the aforementioned Environment Council conclusions of 4 December 2008 that the long-term effects of GMO cultivation and the effects on non-target organisms have, thus far, not been adequately taken into account in the risk assessment framework;
- T. whereas both the Council (4) and Parliament (5) acknowledge the necessity for stricter assessment of the long-term effects of GMOs, and for independent research on the potential risks involved in the deliberate release or the placing on the market of GMOs, including the need to give independent researchers access to all relevant material;
- U. whereas the large majority of consumers are concerned about genetically modified food, as indicated in, inter alia, *Special Eurobarometer* 354 of 2010; whereas genetically modified maize 1507 offers no benefit to consumers;
- 1. Opposes the adoption of 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) http://www.efsa.europa.eu/en/efsajournal/pub/2429.htm

(2) Commission letter to the EFSA of 8 September 2008, concerning the environmental risk assessment of herbicide tolerant plants.

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2013:111:0027:0029:EN:PDF

Environment Council conclusions of 4 December 2008.

See its above mentioned position of 5 July 2011.

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- 2. Considers that the proposal for a Council decision exceeds the implementing powers conferred under Directive 2001/18/EC;
- 3. Calls on the Council to reject the Commission proposal;
- 4. Calls on the Commission not to propose to authorise any new GMO variety and not to renew old ones until the risk assessment methods have been significantly improved;
- 5. Instructs its President to forward this resolution to the Council and the Commission, and to the governments and parliaments of the Member States.