COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 21.1.2009
COM(2009) 12 final

Proposal for a

COUNCIL DECISION

concerning the provisional prohibition of the use and sale in Hungary of genetically modified maize (Zea mays L. line MON810) expressing the Bt cry1Ab gene, pursuant to Directive 2001/18/EC of the European Parliament and of the Council

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. Concerning the placing on the market of genetically modified maize (*Zea mays* L. line MON810), it has been decided by Commission Decision 98/294/EC of 22 April 1998, pursuant to Council Directive 90/220/EEC, that consent shall be given for the placing on the market of the product.

2. On 3 August 1998 the French authorities granted consent for the placing on the market of that product. Pursuant to Article 13(5) of Directive 90/220/EEC, the product may be used throughout the Community.

3. In accordance with Article 23(1) of Directive 2001/18/EEC, the Hungarian authorities informed the Commission on 20 January 2005 of their decision to provisionally prohibit the use and sale of the genetically modified maize in question and gave reasons therefore.

4. On 8 June 2005 the European Food Safety Authority (EFSA) considered that the information submitted by Hungary did not constitute new scientific evidence which would invalidate the environmental risk assessment of *Zea mays* L. line MON810 and therefore would justify a prohibition of the use and sale of this product in Hungary.

5. The Commission took note of the declaration of the Environment Council on 24 June 2005, which, in order to indicate its opposition to a proposal requesting another Member State to repeal its safeguard clause measure on the same GMO, stated that there was still a degree of uncertainty in relation to the safeguard measure associated with the placing on the market of MON810 maize and called on the Commission to gather further scientific evidence and to further assess whether the national measure was justified and whether the authorisation of the GMO under Directive 90/220/EEC still met the safety requirements of Directive 2001/18/EC.

6. Therefore the Commission consulted EFSA in November 2005 as to whether there was any scientific reason to believe that the continued placing on the market of the GMOs subject to the safeguard clause measures, including *Zea mays* L. line MON810, was likely to cause any adverse effects to human health or the environment under the conditions of consent, and requested EFSA to take account of any further scientific information that has arisen subsequent to the previous scientific opinions that assessed the safety of these GMOs.

7. It has been considered appropriate to await this new EFSA opinion on *Zea mays* L. line MON810 before taking any action on the corresponding safeguard measure notified by Hungary, because of its possible implication on the previous opinion adopted in June 2005.

8. In its opinion of 29 March 2006 (published on 11 April 2006), EFSA concluded that there is no reason to believe that the continued placing on the market of *Zea mays* L. line MON810 is likely to cause any adverse effects for human and animal health or the environment under the conditions of their respective consents.

9. Under such circumstances Article 23 of Directive 2001/18/EC requires the Commission to take a decision in accordance with the procedures laid down in

Article 30(2) of the Directive to which Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

10. Since EFSA considered that the product did not constitute a risk to human health or the environment the Commission prepared a draft Decision asking Hungary to repeal its measures concerning *Zea mays* L. line MON810.

11. A draft of the measures to be taken was submitted, in accordance with Article 5(2) of Decision 1999/468/EC, for opinion, to the Committee set up under Article 30 of Directive 2001/18/EC.

12. The Committee, consulted on 18 September 2006, did not deliver an opinion, which required that the Commission, in accordance with Article 5(4) of Decision 1999/468/EC, submitted to the Council a proposal relating to the measures to be taken and informed the European Parliament .

13. The Environment Council, on 20 February 2007, indicated its opposition to the proposal by qualified majority.

14. In its Decision, the Council referred to the environmental risk assessment as provided in the Directive 2001/18/EC and indicated that 'the different agricultural structures and regional ecological characteristics in the European Union need to be taken into account in a more systematic manner in the environmental risk assessment'.

15. Hungary submitted to the Commission on 30 November 2007 additional information regarding the cultivation of *Zea mays* L. line MON810 to support its measure.

16. Consequently EFSA was requested on 18 April 2008 to assess whether the information submitted by Hungary comprises information affecting the environmental risk assessment such that detailed grounds exist to consider the above maize, for the uses laid down in the corresponding consent, constitute a risk to the environment.

17. In its opinion of 2 July 2008 (published on 11 July 2008), EFSA reaffirmed its previous conclusions on the safety of *Zea mays* L. line MON810 and stated that it did not identify any new data subject to scientific scrutiny or scientific information that would change the previous risk assessments conducted on this product. EFSA also concluded that the Hungarian submission did not supply scientific evidence that the environment of Hungary was different from other regions of the EU sufficient to merit separate risk assessments from those conducted for other regions in the EU.

18. Under these circumstances Hungary should repeal its safeguard measure with regard to the use and sale of *Zea mays* L. line MON810. Therefore, following the Council Decision of February 2007, and in accordance with Article 5(6)(2) of Council Decision 1999/468/EC, the Commission re-submitted its proposal relating to the measures to be taken and informed the European Parliament.

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(Only the Hungarian text is authentic)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

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 Article 23(2) thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) By Commission Decision 98/294/EC of 22 April 1998 concerning the placing on the market of genetically modified maize *(Zea mays* L. line MON810) pursuant to Council Directive 90/220/EEC[2] it was decided that consent was to be given for the placing on the market of that product.

(2) On 3 August 1998 the competent authorities of France granted such consent.

(3) On 20 January 2005 Hungary informed the Commission that, pursuant to the first subparagraph of Article 23(1) of Directive 2001/18/EC, it had introduced a provisional prohibition on the use and sale of *Zea mays* L. line MON810 and gave reasons for its decision.

(4) The Commission sought the opinion of the European Food Safety Authority (EFSA), as established by 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 of food safety[3], regarding the information submitted by Hungary.

(5) On 8 June 2005, and following investigation of the evidence presented in the Hungarian submission, the EFSA concluded that the scientific evidence currently

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1 OJ L 106, 17.4.2001, p. 1.
2 OJ No L 131, 5.5.1998, p.32.
3 OJ L 31, 1.2.2002, p.1. Regulation as last amended by Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).

available does not sustain the arguments provided by Hungary and that the information submitted by Hungary did not constitute new scientific evidence sufficient to invalidate the environmental risk assessment of *Zea mays* L. line MON810 established under Directive 90/220/EEC, justifying a prohibition of the use and sale of that product in Hungary.

(6) The Commission took note of the declaration of the Environment Council on 24 June 2005, which, in order to indicate its opposition to a proposal requesting another Member State to repeal its safeguard measure on the same GMO, stated that there was still a degree of uncertainty in relation to the safeguard measure associated with the placing on the market of MON810 maize and called on the Commission to gather further scientific evidence and to further assess whether the national measure was justified and whether the authorisation of the GMO under Directive 90/220/EEC still met the safety requirements of Directive 2001/18/EC.

(7) Therefore the Commission consulted EFSA in November 2005 as to whether there was any scientific reason to believe that the continued placing on the market of *Zea mays* L. line MON810 was likely to cause any adverse effects to human health or the environment under the conditions of consent and in particular, and requested EFSA to take account of any further scientific information that has arisen subsequent to the previous scientific opinions that assessed the safety of these GMOs.

(8) In its opinion of 29 March 2006, EFSA, supported by the assessment of several applications on hybrids containing MON810 maize, concluded that there is no reason to believe that the continued placing on the market of *Zea mays* L. line MON810 is likely to cause any adverse effects for human and animal health or the environment under the conditions of consent.

(9) Consequently, there was no reason to consider that the product constitutes a risk to human or animal health or to the environment.

(10) Hungary had therefore to repeal the safeguard clause measures concerning *Zea mays* L. line MON810.

(11) The Committee established under Article 30 of Directive 2001/18/EC has not delivered an opinion on the measures laid down in a draft Commission Decision, following its consultation, on 18 September 2006, in accordance with the procedure laid down in Article 30(2) of that Directive

(12) The Commission, under Article 5(4) of Council Decision 1999/468/EC submitted to the Council proposals relating to the measures to be taken and informed the European Parliament.

(13) The Environment Council, on 20 February 2007, indicated its opposition to the proposal by qualified majority.

(14) In its Decision, the Council referred to the environmental risk assessment as provided in the Directive 2001/18/EC and indicated that 'the different agricultural structures and regional ecological characteristics in the European Union need to be taken into account in a more systematic manner in the environmental risk assessment'.

(15) Hungary submitted to the Commission on 30 November 2007 additional information regarding the cultivation of *Zea mays* L. line MON810 to support its safeguard measure.

(16) Consequently EFSA was requested on 18 April 2008 to assess whether the information submitted by Hungary comprises information affecting the environmental risk assessment such that detailed grounds exist to consider that the above maize, for the uses laid down in the corresponding consent, constitutes a risk to the environment.

(17) In its opinion of 2 July 2008 (published 11 July 2008), EFSA reaffirmed its previous conclusions on the safety of *Zea mays* L. line MON810 and stated that it did not identify any new data subject to scientific scrutiny or scientific information that would change the previous risk assessments conducted on this product. EFSA also concluded that the Hungarian submission did not supply scientific evidence that the environment of Hungary was different from other regions of the EU sufficient to merit separate risk assessments from those conducted for other regions in the EU.

(18) Under these circumstances Hungary should repeal its safeguard measure with regard to the use and sale of *Zea mays* L. line MON810.

(19) Following the Council Decision of February 2007, and in accordance with Article 5(6)(2) of Council Decision 1999/468/EC, the Commission re-submitted its proposal relating to the measures to be taken and informed the European Parliament.

(20) Article 5(6)(1) of Council Decision 1999/468/EC provides that the Council may act by qualified majority within a period set at three months in accordance with Article 30(2) of Directive 2001/18/EC.

HAS ADOPTED THIS DECISION:

Article 1

The measures taken by the Republic of Hungary to prohibit the use and sale of the genetically modified maize, *Zea mays* L. line MON810, expressing the Bt *cry1Ab* gene, authorised for placing on the market by Decision 98/294/EC are not justified under Directive 2001/18/EC.

Article 2

The Republic of Hungary shall take the necessary steps to repeal the measures adopted to prohibit the use and sale of the genetically modified maize, *Zea mays* L. line MON810, on its territory, and comply with this Decision by no later than 20 days after its notification.

Article 3

This Decision is addressed to the Republic of Hungary.

Done at Brussels,

For the Council
The President