COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 23.11.2006
COM(2006) 713 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 cryIA(b) gene, pursuant to Directive 2001/18/EC of the European Parliament and of the Council

(Only the Hungarian text is authentic)

(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. On 24 June 2005, the Environment Council indicated its opposition by qualified majority, to a proposal requesting Austria to repeal its safeguard clause measure on *Zea mays* L. line MON810.

6. The Council, in its declaration, stated that 'there is still a degree of uncertainty in relation to the national safeguard measures on the market of [the] genetically modified maize variet[y] […] MON810' and called on the Commission 'to gather further evidence on the GMO in question and further assess, whether the measure taken by [Austria] aimed at suspending as a temporary precautionary measure [its] placing on the market [is] justified and, whether the authorisation of such [an] organism still meets the safety requirements of Directive 2001/18/EC'.

7. In November 2005, EFSA was therefore consulted 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 in particular, was requested 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. 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 clause notified by Hungary, because of its possible implication on the previous opinion adopted in June 2005.

9. 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 its respective consent.

10. 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.

11. 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.

12. 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.

13. The Committee, consulted on 18 September 2006, has not delivered an opinion, which requires that the Commission, in accordance with Article 5(4) of Decision 1999/468/EC, shall, without delay, submit to the Council a proposal relating to the measures to be taken and inform the European Parliament (informed on 19 September 2006). The European Parliament may consider appropriate to take a position in accordance with Article 8 of the above Decision.

14. Article 5(6) of Decision 1999/468/EC provides that the Council may, where appropriate in view of any such position, act by qualified majority within a period set at three months in accordance with Article 30(2) of Directive 2001/18/EC. If within that three-month period, the Council has indicated by qualified majority that it opposes the proposal, the Commission should re-examine it; whereas if, on expiry of that period the Council has neither adopted the proposed implementing act nor indicated its opposition, then the proposed implementing act should be adopted by the Commission.

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

(Only the Hungarian text is authentic)

(Text with EEA relevance)

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,

Having regard to the proposal from the Commission,

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.

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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).

(5) On 8 June 2005, and following investigation of the evidence presented in the Hungarian submission, the EFSA concluded that the scientific evidence currently 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) On 24 June 2005, the Environment Council indicated its opposition by qualified majority, to the proposal requesting Austria to repeal its safeguard clause measure on MON810;

(7) The Council, in its declaration, stated that 'there is still a degree of uncertainty in relation to the national safeguard measures on the market of [the] genetically modified maize variet[y] […] MON810' and called on the Commission 'to gather further evidence on the GMO in question and further assess, whether the measure taken by [Austria] aimed at suspending as a temporary precautionary measure [its] placing on the market [is] justified and, whether the authorisation of such [an] organism still meets the safety requirements of Directive 2001/18/EC';

(8) In November 2005, the EFSA was consulted 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, was requested to take account of any further scientific information that has arisen subsequent to the previous scientific opinions that assessed the safety of these GMOs.

(9) In its opinion of 29 March 2006, the 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.

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

(11) Hungary should therefore repeal the safeguard clause measures concerning *Zea mays* L. line MON810.

(12) 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

(13) The Commission, under Article 5(4) of Council Decision 1999/468/EC, should, without delay, submit to the Council proposals relating to the measures to be taken and should inform the European Parliament (informed on 19 September 2006).

HAS ADOPTED THIS DECISION:

Article 1

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

Article 2

Hungary shall take the necessary steps to 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