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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10.2.2009
COM(2009) 56 final

Proposal for a

COUNCIL DECISION

concerning the provisional prohibition of the use and sale in Austria of genetically modified maize (*Zea mays* L. line MON810) pursuant to Directive 2001/18/EC of the European Parliament and of the Council

**(Only the German text is authentic)
(Text with EEA relevance)**

EXPLANATORY MEMORANDUM

1. A genetically modified variety of *Zea mays* L. line MON810 was authorised for its placing on the market pursuant to Commission Decisions under Part C of Directive 90/220/EEC¹ and the French authorities granted consent for the placing on the market of this genetically modified organisms (GMO). The consent covers all uses of the product, namely import, processing into food and feed products and cultivation.
2. In accordance with Article 16 (safeguard clause) of Directive 90/220/EEC, Austria subsequently informed the Commission of its decision to provisionally prohibit or restrict the placing on the market of *Zea mays* L. line MON810 for all uses covered by the consent granted under Directive 90/220/EEC and provided its reasons for this decision.
3. The Scientific Committee on Plants was consulted and concluded in its opinions that the information submitted by Austria did not constitute new relevant scientific evidence that had not been taken into account during the original risk assessments for those GMOs and which would necessitate a review of its original scientific opinion concerning the safety of *Zea mays* L. line MON810.
4. Directive 90/220/EEC was replaced by Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms².
5. Products derived from *Zea mays* L. line MON810 (food and food ingredients produced from maize flour, maize gluten, maize semolina, maize starch, maize glucose and maize oil produced from *Zea mays* L. line MON810) are authorised under Regulation (EC) N° 258/97³ and Regulation (EC) N° 1829/2003⁴. These uses are not subject to the safeguard clause notified by Austria.
6. In January 2004, the Commission requested Austria to re-consider its safeguard clause in light of the new regulatory framework and if appropriate, to re-notify it under Directive 2001/18/EC.
5. In accordance with Article 23 of Directive 2001/18/EC, Austria submitted to the Commission further additional information in support of its existing safeguard clause measure.
6. Article 23 of Directive 2001/18/EC requires the Commission to take decisions 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.
7. In accordance with Article 28(1) of Directive 2001/18/EC, the European Food Safety Authority (EFSA), established by Regulation (EC) No 178/2002 of the European

¹ OJ L 117, 8.5.1990, p. 15

² OJ L 106, 17.4.2001, p. 1

³ OJ L 43, 14.2.1997, p. 1

⁴ OJ L 106, 18.10.2003, p. 1

Parliament and of the Council⁵, under which it has replaced the relevant scientific committees, was consulted and concluded, in its opinion of 8 July 2004⁶, that the information submitted by Austria did not constitute new scientific evidence which would invalidate the environmental risk assessment of *Zea mays* L. line MON810 and would justify a prohibition of this GMO in Austria.

8. A draft Commission Decision requesting Austria to repeal its national safeguard clause was therefore submitted for opinion, under Article 5(2) of Council Decision 1999/468/EC, to the Committee established under Article 30 of Directive 2001/18/EC.
9. The Committee was consulted on 29 November 2004 but delivered no opinion on the safeguard clause measure which requires that the Commission, under Article 5(4) of Council Decision 1999/468/EC, shall, without delay, submit to the Council proposals relating to the measures to be taken and shall inform the European Parliament.
10. In accordance with Article 5(6) of Council Decision 1999/468/EC, the Environment Council, on 24 June 2005, indicated its opposition by qualified majority, to the proposal requesting Austria to repeal its safeguard measure, which requires that the Commission re-examines its proposals.
11. 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'.
12. In November 2005, 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 opinion that assessed the safety of this GMO.
13. In its opinion of 29 March 2006 (published on 11 April 2006)⁷, EFSA, following investigation of the evidence presented in the Austrian submission, considered that the scientific evidence currently available does not sustain the arguments provided by Austria and 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 consents.

⁵ OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p.3).

⁶ Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Austrian invoke of Article 23 of Directive 2001/18/EC, The EFSA Journal (2004) 78, 1-13.

⁷ Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to genetically modified crops (Bt176 maize, MON810 maize, T25 maize, Topas 19/2 oilseed rape and Ms1xRf1 oilseed rape) subject to safeguard clauses invoked according to Article 16 of Directive 90/220/EEC, The EFSA Journal (2006) 338, 1-15.

14. In accordance with Article 5(6) of Council Decision 1999/468/EC, the Commission submitted a proposal to the Council requesting Austria to repeal its safeguard measure.
15. The Environment Council, on 18 December 2006, indicated its opposition to the proposal by qualified majority.
16. 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'.
17. In accordance with Article 5(6) of Council decision 1999/468/EC the Commission submitted an amended proposal requesting Austria to repeal only the prohibition of import and the processing into food and feed products.
18. On 30 October 2007, the Council voted on the proposal and did not reach a qualified majority in favour or against it. The Commission adopted therefore on 7 May 2008 Decision 2008/495/EC requesting Austria to take all necessary steps to terminate the prohibition of import and processing into food and feed products of *Zea mays* L. line MON810 at the latest 20 days after the notification. On 27 May 2008 Austria complied with this Decision and adopted the respective Regulation.
19. For the aspects of the safeguard measure that concern the sale and use of seeds (cultivation), Austria initiated work to collect any relevant scientific evidence which in its view would justify provisionally the maintenance of the safeguard measure, in particular in reference to "the different agricultural structures and regional ecological characteristics" as indicated in recital 3 of the Council Decision of 18 December. In November 2007, Austria submitted to the Commission the scientific information that resulted out of its work.
20. On 18 April 2008 the Commission requested EFSA, under Article 29(1) and in accordance with Article 22(2) and 22(5)(c) of Regulation(EC) No 178/2002, to assess whether the information submitted by Austria comprises information affecting the environmental risk assessment of existing information on the basis of new scientific knowledge such that detailed grounds exist to consider that maize MON810, for uses laid down in the corresponding consent, constitutes a risk to the environment.
21. On 4 December 2008, EFSA adopted its opinion (published on 11 December 2008) concluding that maize MON810 is unlikely to have adverse effects on human and animal health or the environment in the context of its proposed uses and reaffirmed its previous conclusions on the safety of maize MON810. Moreover, having considered the information submitted by Austria and a broad range of scientific literature, EFSA is of the opinion that there is no specific evidence, in terms of risk to human and animal health and the environment, that would justify the invocation of a safeguard clause under Article 23 of Directive 2001/18/EC for the marketing of maize MON810 for its intended uses in Austria. In conclusion, EFSA found that the scientific evidence currently available does not sustain the arguments provided by Austria and that cultivation of maize MON810 is unlikely to have an adverse effect on human and animal health and the environment in Austria.

22. Under these circumstances, Austria should repeal its safeguard measure with regards to the use and sale of seeds of *Zea mays* L. line MON810.
23. Following the Council Decision of 18 December 2006, 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.
24. 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.

Proposal for a

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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/EEC⁸, 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/EEC⁹ it was decided that consent was to be given for the placing on the market of that product.
- (2) On 3 August 1998 the French authorities granted such consent. The consent covers all uses of the product, namely import, processing into food and feed products and cultivation.
- (3) Pursuant to Article 35(1) of Directive 2001/18/EC which replaced Directive 90/220/EEC¹⁰, procedures in respect of notifications concerning the placing on the market of genetically modified organisms which have not been completed by 17 October 2002 are subject to Directive 2001/18/EC.
- (4) On 2 June 1999 Austria informed the Commission of its decision to prohibit provisionally the use and sale of *Zea mays* L. line MON810 for all uses and gave reasons for that decision in accordance with Article 16(1) of Directive 90/220/EEC.
- (5) Products derived from *Zea mays* L. line MON810 (food and food ingredients produced from maize flour, maize gluten, maize semolina, maize starch, maize glucose and maize oil produced from *Zea mays* L. line MON810) have been authorised under

⁸ OJ L 106, 17.4.2001, p. 1

⁹ OJ L 131, 5.5.1998, p. 32

¹⁰ OJ L 117, 8.5.1990, p. 15

Regulation (EC) No 258/97¹¹ and have been subsequently notified as existing products in accordance with Article 8 and 20 of Regulation (EC) No 1829/2003¹². These uses are not subject to the safeguard measure notified by Austria, as they do not fall under the scope of Directive 2001/18/EC

- (6) The Scientific Committee on Plants concluded on 20 July 2001 that the information submitted by Austria did not constitute new relevant scientific evidence which had not been taken into account during the original evaluation of the dossier and which would occasion a review of that Committee's original opinion on this product.
- (7) On 9 January 2004, as well as on 9 and 17 February 2004, Austria submitted to the Commission additional information in support of its national measures concerning maize line MON810.
- (8) In accordance with Article 28(1) of Directive 2001/18/EC, the Commission consulted the European Food Safety Authority (EFSA), as established by Regulation (EC) No 178/2002 of the European Parliament and of the Council¹³, under which it has replaced the relevant scientific committees.
- (9) The EFSA concluded on 8 July 2004¹⁴ that the information submitted by Austria did not constitute new scientific evidence sufficient to invalidate the environmental risk assessment of maize line MON810, justifying a prohibition of the use and sale of that product in Austria.
- (10) Since, under the circumstances, there was no reason to consider that the product constituted a risk to human health or the environment, the Commission submitted on 29 November 2004 a draft Decision, requesting Austria to repeal its provisional safeguard measure, for consideration by the Committee established under Article 30 of Directive 2001/18/EC, in accordance with the procedure laid down in Article 30(2) of that Directive.
- (11) However, that Committee did not deliver an opinion and, in accordance with Article 5(4) of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission¹⁵, the Commission submitted to the Council a proposal relating to the measures to be taken.
- (12) On 24 June 2005, in accordance with Article 5(6) of Decision 1999/468/EC, the Council, acting by qualified majority, rejected this proposal.
- (13) 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

¹¹ OJ L 43, 14.2.1997, p. 1

¹² OJ L 106, 18.10.2003, p. 1

¹³ OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p.3).

¹⁴ Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the Austrian invoke of Article 23 of Directive 2001/18/EC, The EFSA Journal (2004) 78, 1-13.

¹⁵ OJ L 184, 17.7. 1999, p. 23.

[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'.

- (14) In November 2005, the EFSA was consulted again by the Commission as to whether there was any scientific reason to believe that the continued placing on the market of MON810 maize was likely to cause any adverse effects to human health or the environment under the conditions of consent. In particular, the EFSA was requested to take account of any further scientific information that had arisen subsequent to the previous scientific opinion concerning the safety of this GMO.
- (15) In its opinion of 29 March 2006¹⁶, EFSA concluded that there is no reason to believe that the continued placing on the market of MON810 maize is likely to cause any adverse effects for human and animal health or the environment under the conditions of its consent.
- (16) In accordance with Article 5(6) of Council Decision 1999/468/EC, the Commission submitted a proposal to the Council requesting Austria to repeal its safeguard measure.
- (17) In accordance with Article 5(6) of Council Decision 1999/468/EC, the Environment Council, on 18 December 2006, indicated its opposition by qualified majority, to the proposal.
- (18) 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'.
- (19) In accordance with Article 5(6) of Council decision 1999/468/EC the Commission submitted an amended proposal requesting Austria to repeal only the prohibition of import and the processing into food and feed products.
- (20) On 30 October 2007, the Council voted on the proposal and did not reach a qualified majority in favour or against it. The Commission adopted therefore on 7 May 2008 Decision 2008/495/EC requesting Austria to take all necessary steps to terminate the prohibition of import and processing into food and feed products of *Zea mays* L. line MON810 at the latest 20 days after the notification. On 27 May 2008 Austria complied with this Decision and amended accordingly its national legislation.
- (21) For the aspects of the safeguard measure that concern the sale and use of seeds (cultivation), Austria initiated work to collect any relevant scientific evidence which in its view would justify provisionally the maintenance of the safeguard measure, in particular in reference to "the different agricultural structures and regional ecological characteristics" as indicated in recital 3 of the Council Decision of 18 December. In November 2007, Austria submitted to the Commission the scientific information that resulted out of its work.

¹⁶ Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to genetically modified crops (Bt176 maize, MON810 maize, T25 maize, Topas 19/2 oilseed rape and Ms1xRf1 oilseed rape) subject to safeguard clauses invoked according to Article 16 of Directive 90/220/EEC, The EFSA Journal (2006) 338, 1-15.

- (22) On 18 April 2008 the Commission requested EFSA, under Article 29(1) and in accordance with Article 22(2) and 22(5)(c) of Regulation(EC) No 178/2002, to assess whether the information submitted by Austria comprises information affecting the environmental risk assessment of existing information on the basis of new scientific knowledge such that detailed grounds exist to consider that maize MON810, for uses laid down in the corresponding consent, constitutes a risk to the environment.
- (23) On 4 December 2008, EFSA adopted its opinion (published on 11 December 2008) concluding that maize MON810 is unlikely to have adverse effects on human and animal health or the environment in the context of its proposed uses and reaffirmed its previous conclusions on the safety of maize MON810. Moreover, having considered the information submitted by Austria and a broad range of scientific literature, EFSA is of the opinion that there is no specific evidence, in terms of risk to human and animal health and the environment, that would justify the invocation of a safeguard clause under Article 23 of Directive 2001/18/EC for the marketing of maize MON810 for its intended uses in Austria. In conclusion, EFSA found that the scientific evidence currently available does not sustain the arguments provided by Austria and that cultivation of maize MON810 is unlikely to have an adverse effect on human and animal health and the environment in Austria.
- (24) Under these circumstances, Austria should repeal its safeguard measure with regards to the use and sale of seeds of *Zea mays* L. line MON810.
- (25) Following the Council Decision of 18 December 2006, 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.
- (26) 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 Austria to prohibit the use and sale of seeds of the *Zea mays* L. line MON810, authorised for placing on the market by Decision 98/294/EC are not justified under Article 23 of Directive 2001/18/EC.

Article 2

Austria shall take the necessary steps to terminate the prohibition of use and sale of seeds of the *Zea mays* L. line MON810, on its territory, and shall comply with this Decision by no later than 20 days after its notification.

Article 3

This Decision is addressed to the Republic of Austria.

Done at Brussels, [...]2009.

*For the Council
The President*