II

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)

DECISIONS

COMMISSION

COMMISSION DECISION

of 7 May 2008

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

(notified under document number C(2008) 1718)

(Only the German text is authentic)

(Text with EEA relevance)

(2008/495/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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 the first subparagraph of Article 18(1) 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 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 Council Directive 90/220/EEC [3], 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) are authorised under Regulations (EC) No 258/97 [4] and (EC) No 1829/2003 of the European Parliament and of the Council [5]. These uses are not subject to the safeguard clause notified by Austria.

[1] OJ L 106, 17.4.2001, p. 1. Directive as last amended by Directive 2008/27/EC (OJ L 81, 20.3.2008, p. 45).
[2] OJ L 131, 5.5.1998, p. 32.
[3] OJ L 117, 8.5.1990, p. 15.
[4] OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).
[5] OJ L 268, 18.10.2003, p. 1. Regulation as amended by Regulation (EC) No 298/2008 (OJ L 97, 9.4.2008, p. 64).

(6) The Scientific Committee on Plants concluded on 24 September 1999 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 Council [1], under which it has replaced the relevant scientific committees.

(9) The EFSA concluded on 8 July 2004 [2] 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 Commission [3], 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 [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 2006 [4], 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 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 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'.

[1] OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 202/2008 (OJ L 60, 5.3.2008, p. 17).

[2] 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.

[3] OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

[4] 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.

(19) In accordance with Article 5(6) of Decision 1999/468/EC the Commission submitted an amended proposal in order to take into account the Council Decision of 18 December 2006 which refers only to the environmental aspects of the Austrian safeguard clause, namely cultivation aspects.

(20) Austria has initiated work to collect any relevant scientific evidence on these aspects, which in the view of Austria justifies provisionally the maintenance of the safeguard clause, in particular in reference to 'the different agricultural structures and regional ecological characteristics' as indicated in recital 3 of the abovementioned Council decision. In accordance with Article 23 of Directive 2001/18/EC, Austria is invited to provide the Commission with all the scientific evidence that it has collected as well as any new risk assessment as soon as it is completed and inform all Member States thereof.

(21) On the basis of Austria's submission and its scientific assessment, the Commission will act in accordance with Article 23 of Directive 2001/18/EC on these aspects of the Austrian measure.

(22) The food and feed safety aspects of *Zea mays* L. line MON810 covered by the consent granted under Directive 90/220/EEC (including import and processing) are identical throughout Europe and have been assessed by the EFSA, which concluded that this product is unlikely to cause any adverse effects for human and animal health.

(23) The Commission proposal takes into account only food and feed aspects of the Austrian prohibition namely the prohibition on import and processing of unprocessed kernels as source materials for further processing or for direct food or feed use.

(24) Under these circumstances Austria should repeal its safeguard measures at least with regard to import and processing into food and feed of *Zea mays* L. line MON810.

(25) The measures provided for in this Decision are not in accordance with the opinion of the Committee established under Article 30 of Directive 2001/18/EC and the Commission therefore submitted to the Council a proposal relating to these measures. Since on the expiry of the period laid down in Article 30(2) of Directive 2001/18/EC, the Council had neither adopted the proposed measures nor indicated its opposition to them, in accordance with Article 5(6) of Decision 1999/468/EC, the measures should be adopted by the Commission,

HAS ADOPTED THIS DECISION:

Article 1

The measures taken by Austria to prohibit the import and the processing into food and feed products 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 import and processing into food and feed products of *Zea mays* L. line MON810 at the latest 20 days after its notification.

Article 3

This Decision is addressed to the Republic of Austria.

Done at Brussels, 7 May 2008.

For the Commission
Stavros DIMAS
Member of the Commission