



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,

Draft

COMMISSION DECISION

of [...]

concerning the provisional prohibition in France of the cultivation of seeds of genetically modified maize (*Zea mays L.* line MON810) expressing the Bt *cry1Ab* gene, pursuant to Article 54 of Regulation (EC) No 178/2002 of the European Parliament and of the Council

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 safety¹, and in particular Article 54(1) thereof,

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/EEC², it was decided that consent was to be given for the placing on the market of that product. On 3 August 1998 the competent authorities of France granted such consent.
- (2) In accordance with Article 17 of Directive 2002/53/EC, the Commission published on 17 September 2004 in the C series of the *Official Journal of the European Union* a list of seventeen genetically modified varieties of maize derived from the genetically modified organism (hereinafter "GMO") MON810 in the 13th supplement to the 22nd complete edition of the common catalogue of varieties of agricultural plant species (hereafter "the common catalogue")³. Since then, this list has been subsequently updated and, following a last modification on 22 August 2008, a total number of 93 genetically modified varieties of maize derived from the genetically modified organism MON810 are inscribed in the common catalogue⁴ and can therefore circulate throughout the Community.

¹ OJ L 31, 1.2.2002, p.1.

² OJ L 131, 5.5.1998, p.32.

³ OJ C 232A, 17.9.2004, p. 1.

⁴ OJ C 214A, 22.8.2008, p. 1.

- (3) In July 2004, Monsanto notified MON810 under Articles 8(1)(a) and (b) - and 20(1)(a) and (b) of Regulation (EC) No 1829/2003 on genetically modified food and feed⁵ as existing product⁶. The notification included seeds for cultivation and for further food and feed use. As a consequence, the product remained legally on the market as existing product as defined by Articles 8 and 20 of Regulation (EC) No 1829/2003 even after that the consent granted under Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms⁷ has expired.
- (4) On 18 April 2007, Monsanto submitted an application under Article 8(4) and 20(4) for the renewal of the authorization of MON810, including the marketing of seeds for cultivation and for further food and feed use. In accordance with Article 11(4) and 23(4) of the Regulation, MON810 will remain legally on the market until a decision is taken on its renewal.
- (5) On 8 February 2008, the French authorities informed the Commission of the adoption on 7 February 2008, as emergency measure, of a Ministerial Order (hereafter "the Order of 7 February") whose Article 1 prohibited *"the cultivation in view of the placing on the market"* of varieties of seeds derived from GM maize MON810 until a decision has been taken on the renewal of the authorisation to place on the market this organism. Article 23 of Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC⁸ and Regulation (EC) N° 1829/2003 are mentioned in the recitals of this measure. The same recitals also refer to justifications provided by the authorization holder on 30 January 2008 which are declared insufficient.
- (6) By a communication dated 11 February 2008, the French authorities designated Article 23 of Directive 2001/18/EC as the legal base of the Order of 7 February and informed the Commission of the reasons supporting its adoption. They referred in particular to an opinion of the Preparatory Committee ("Comité de préfiguration") of the High Authority of GMOs in France, dated 9 January 2008, which highlighted that new scientific elements were available concerning the impact of this maize on the environment. These new scientific elements consist in different studies on (i) the characterization of the pollen dispersal and its consequence in term of cross-pollination between fields with GMOs and fields without GMOs at local scale as well as in term of dissemination and persistence of the Bt toxin; (ii) the apparition of resistances on target organism and (iii) the effects on non targeted organisms. In addition, the French authorities indicates that the preparatory Committee of the High Authority of GMOs has underlined the need to deepen the evaluation of the biological and microbiological effect of the dissemination or the persistence observed of Bt molecules or of the transgens in soil as well as the importance of a follow up in real time and on long term of the effects of cultivation in open field on fauna, flora, fungi, ecosystems in the framework of a program of biovigilance.
- (7) On 12 February 2008, the French authorities re-notified the Order of 7 February to the Commission. The only change introduced in this notification compared to the previous

⁵ OJ L 268, 18.1.2003, p.1.

⁶ The scope covers any progeny derived from crosses of the product with any traditional line bred maize.

⁷ OJ L 117, 8.5.1990, p. 15.

⁸ OJ L 106, 17.4.2001, p. 1.

one was that Article 34 of Regulation (EC) N°1829/2003 was declared to be the legal base of that Order.

- (8) On 20 February 2008, the French authorities notified to the Commission another Ministerial Order dated 13 February 2008 modifying the Order of 7 February to delete from its Article 1 the terms "in view of their placing on the market". In their communication, the French authorities explained that this modification was to prohibit the cultivation of varieties of seed of maize MON810 for all purposes, including auto-consumption. They also recalled that the Order of 7 February was based on Article 23 of Directive 2001/18/EC.
- (9) As far as the legal base is concerned, it should be recalled that according to Article 8(5) and 20(5) of Regulation (EC) No 1829/2003, products falling under the scope of these two articles (existing products) are subject to the provision of that Regulation, in particular as regards Article 34 "emergency measures". This was acknowledged by the French authorities in their second notification dated 12 February 2008 by which they designated this provision as the legal base of their measure.
- (10) According to Article 34 of Regulation (EC) No 1829/2003, where it is evident that products authorised by or in accordance with this Regulation are likely to constitute a serious risk to human health, animal health or the environment, or where, in the light of an opinion of the Authority (EFSA) issued under Article 10 or Article 22, the need to suspend or modify urgently an authorization arises, measures shall be taken under the procedures provided for in Articles 53 and 54 of 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 safety⁹. Article 54 of Regulation (EC) No 178/2002 foresees that where a Member State officially informs the Commission of the need to take emergency measures and where the Commission has not acted in accordance with Article 53, the Member State may adopt interim measures.
- (11) On the substance, given the complexity of the matter and the scientific content of the studies, the Commission sought, on 27 February 2008, the opinion of the European Food Safety Authority, as established by Regulation (EC) No 178/2002, to assess the evidence and justifications submitted by the French Republic.
- (12) EFSA has been asked to assess the opinion of the Preparatory Committee, the position on Monsanto's justifications, the scientific evidence presented in the accompanying note of the notification of the Order and the scientific justification of the duration of the measure.
- (13) On 29 October 2008, EFSA issued an opinion (published on 30 October 2008)¹⁰ stating that it "did not identify any new data subject to scientific scrutiny or scientific information that would change previous risk assessments conducted on maize MON810 which currently has marketing consent in the EU. Having considered the overall information package submitted by the French authorities as well as a broad range of relevant scientific literature, the GMO Panel is of the opinion that there is no

⁹ OJ L 31, 1.2.2002, p. 1.

¹⁰ The EFSA Journal (2008) 850, 1-45

specific scientific 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 and an emergency measure under Article 34 under Regulation (EC) No 1829/2003."

- (14) Consequently, there is no reason to consider that the product constitutes a risk to human or animal health or to the environment.
- (15) The French Republic should therefore repeal its measures against the cultivation of seeds of genetically modified maize MON810.
- (16) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health

HAS ADOPTED THIS DECISION:

Article 1

The French Republic is not authorised to prohibit the cultivation of seeds of maize hybrids with the genetic modification MON810.

Article 2

The French Republic shall take the necessary steps to comply with this Decision by no later than 20 days after its notification, at the latest.

Article 3

This Decision is addressed to the French Republic.

Done at Brussels,

For the Commission
Stavros Dimas
Androulla Vassiliou
Members of the Commission