



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,

Draft

COMMISSION DECISION

of [...]

concerning the provisional prohibition in Greece of the use and sale of seed of varieties 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 the Council

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(Only the Greek text is authentic)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) N°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,

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. On 3 August 1998 the competent authorities of France granted such consent.
- (2) In July 2004, Monsanto notified MON810 under Articles 8(1)(a) and (b) and 20(1)(a) and (b) of Regulation (EC) N°1829/2003 on genetically modified food and feed³ as existing product⁴. 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 has expired.
- (3) 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 Articles 11(4) and

¹ OJ L 31, 1.2.2002, p.1.

² OJ L 131, 5.5.1998, p.32.

³ OJ L 268, 18.1.2003, p.1.

⁴ The scope covers any progeny derived from crosses of the product with any traditionally bred maize line.

23(4) of Regulation (EC) No 1829/2003, MON810 is authorized to remain on the market until a decision is made on its renewal.

- (4) 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")⁵. 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 catalogue⁶.
- (5) Under Article 16(1) of Directive 2002/53/EC, Member States shall ensure that, with effect from the publication referred to in Article 17, seed of varieties accepted in accordance with this Directive or in accordance with the principles corresponding to those of that Directive is not subject to any marketing restrictions relating to the variety.
- (6) On 3 February 2006, the Greek authorities informed the Commission that, pursuant to Article 18 of Directive 2002/53/EC and to Article 23(1) of Directive 2001/18/EC, it had introduced, on 30 January 2006, by Decision N°24983/1127 of the Deputy Minister of Agricultural Development and Food, a provisional prohibition of 18 months to market in its territory seeds of the 31 varieties of genetically modified maize hybrids containing genetically modified MON810 inscribed at that time in the common catalogue (hereafter "the initial prohibition") and gave reasons for their decision.
- (7) In addition to considerations regarding to the choice of Article 18 of Directive 2002/53/EC and Article 23(1) of Directive 2001/18/EC as legal basis, the Greek authorities listed in their communication the different elements that were taken into account to justify their measure: (i) the precautionary principle; (ii) the fact that the event MON810 was approved by Commission Decision 98/294/EC of 22 April 1998 on the basis of Council Directive 90/220/EEC from which they draw the observations that the initial assessment is now old and that the conditions for authorisations of GMOs set out in the legislative framework of that time were less comprehensive than those applicable following the currently in force legislation; (iii) the fact that, on 24 June 2005, the Council of Minister of European Union inter alia rejected by qualified majority proposals submitted by the Commission, along with the proposal to lift the safeguard measures which Austria had taken concerning the use and marketing of maize hybrids with the transgenic MON810; (iv), the international obligation of the Hellenic Republic and the European Union and, in particular, as regards the implementation of the Cartagena Protocol; (v) Section II of the Greek Constitution concerning personal and social rights, and, in particular, its Article 24 concerning environmental protection; (vi) the re-assessed scientific data which, according to Greek authorities, confirm the immediate hazard which may arise for the environment and human health as a result of the marketing and cultivation of seeds of maize hybrids with transgenic MON810 via the disturbance of the biodiversity of country's

⁵ OJ C 232A, 17.9.2004, p. 1.

⁶ OJ C 214A, 22.8.2008, p. 1.

fauna with particularly adverse effects on non-target animals species, via the risk of the increased transgenic pollination of varieties/hybrids of conventional and organic maize grown in Greece because of the country's highly developed beekeeping industry, the strong summer winds and the fact that farms consist of small parcels which are widely dispersed, via the risk of the emergence of undesirable resistance to Bt toxin in the most harmful Lepidoptera which attack varieties/hybrids of conventional and organic maize and cotton, and via the risk of adverse effects from human consumption of transgenic maize products suggested by reanalysis of a rat-feeding study; (vii) the need, when taking a risk management decision, to take into account other factors than the sole scientific risk assessment, including societal, economic, tradition, ethical and environmental factors as well as the feasibility of controls; (viii) the fact that the introduction into the country of GMOs should not be such as to adversely affect legal rights governing agricultural activities and should not impose the necessity to change already established production patterns in the neighbourhood. The Greek authorities concluded their communication by indicating that the measure taken was justified pending the adoption of coexistence measures in their country and with a view of ensuring a high level of protection of human health and the environment. Moreover they accompanied their communication by scientific data to support their decision.

- (8) On 11 October 2006, the Greek authorities notified to the Commission the adoption, on 6 September 2006, of a Ministerial Decision N°308974 (hereinafter "the second Ministerial Decision") extending the initial prohibition to five other varieties genetically modified maize hybrids containing genetically modified MON810 which had been in the meanwhile inscribed in the common catalogue⁷.
- (9) The Commission sought, on 4 May 2006, the opinion of the European Food Safety Authority (EFSA), as established by Regulation (EC) No 178/2002, regarding the information submitted by the Greek authorities.
- (10) The mandate given to EFSA was to determine whether the scientific report and the scientific publications submitted by the Greek authorities showed that there is an imminent danger for human health and the environment due to the cultivation of the maize varieties with the genetic modification MON810.
- (11) In its opinion which was adopted on 7 November 2006⁸ (published on 17 November 2006), EFSA concluded that there is no new data that would invalidate the initial risk assessment conducted on MON810 maize and that there is no specific scientific evidence, in terms of risk to human health and the environment, that would justify a prohibition of the cultivation of the MON810 maize in Greece.
- (12) On 13 September 2007 the Greek authorities notified to the Commission the Ministerial Decision 30361/7505/28, dated 28 June 2007, which prolonged the initial prohibition for another 24 months and extended its scope to eighteen other varieties genetically modified maize hybrids containing genetically modified MON810 which had been in the meanwhile inscribed in the common catalogue (hereinafter "the third Ministerial Decision"). Additionally, it completed the prohibition of marketing of these varieties by a prohibition of their deliberate release into the environment. In

⁷ OJ C68A, 21.3.2006 as amended by supplements 2 (OJ C93A, 21.4.2006 and 3 (OJ C146A, 22.6.2006).
⁸ The EFSA Journal (2006) 411, 1-26

addition to the scientific and technical data presented in their communication of 3 February 2006, they presented evidence which, in their view, indicated new risks for human health and the environment.

- (13) According to the above notification, the legal basis of the third Ministerial Decision are the one which had been assessed in the relevant information note of the documentation file of the initial ministerial decision, namely Article 18 of Directive 2002/53/EC and Article 23(1) of Directive 2001/18/EC. The Greek authorities pointed out that, especially the prohibition of the release into the environment is based on Article 23 of Directive 2001/18/EC and indicated that this Directive has also been under consideration in the initial Ministerial Decision.
- (14) Article 18 of Directive 2002/53/EC provides that if it is established that the cultivation of a variety included in the common catalogue of varieties could in any Member State be harmful from a point of view of plant health to the cultivation of other varieties or species, or present a risk for the environment or for human health, that Member State may upon application, be authorised to prohibit the marketing of the seed in question in all or part of its territory. Where there is imminent danger of the spread of harmful organisms or imminent danger for human health or for the environment, that prohibition may be imposed by the Member State concerned as soon as its application has been lodged until such time as a final decision has been taken.
- (15) According to Article 23 of Directive 2001/18/EC, where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory. In the event of a severe risk the same provision of the Directive requires the Member State to ensure that, emergency measures, such as suspension or termination of the placing on the market, shall be applied, including information to the public. The Member State shall immediately inform the Commission and the other Member States of actions taken under this Article and give reasons for its decision, supplying its review of the environmental risk assessment, indicating whether and how the conditions of the consent should be amended or the consent should be terminated, and, where appropriate, the new or additional information on which its decision is based.
- (16) Following Article 8(5) and 20(5) of Regulation (EC) No1829/2003, products referred to in the paragraph 1 of these Articles and food or feed containing them or produced from them are subject to the provisions of that Regulation, and in particular to those set out in its Article 34 (emergency measures).
- (17) Article 34 of Regulation (EC) No 1829/2003 provides that where it is evident that a product authorized by or in accordance with this Regulation is likely to constitute a serious risk to human health, animal health or the environment, measures shall be taken under the procedures provided for in Article 53 and 54 of Regulation (EC) No178/2002. Article 54 of Regulation (EC) N° 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.

- (18) According to constant case-law of the European Court of Justice⁹ if examination of a Community measure reveals that it pursues a twofold purpose or that it has a twofold component and if one of these is identifiable as the main or predominant purpose or component, whereas the other is merely incidental, the act must be based on a single legal basis, namely that required by the main or predominant purpose or component. In this context, it should be observed that, on the one hand, the Greek authorities have provided scientific elements which according to them show evidence of a risk to human health arising from the consumption of MON810. Those grounds are mentioned in both Article 34 of Regulation (EC) No. 1829/2003 and Article 18 of Directive 2002/53/EC. On the other hand the Greek authorities did not provide neither evidence nor justification demonstrating a risk for plant health deriving, more particularly, from the cultivation of one or some of the specific varieties included in the common catalogue of varieties, a ground specifically provided under Article 18 of Directive 2002/53/EC. On the contrary, the Greek authorities focus on risks to environment arising from the cultivation of any genetically modified maize derived from the event MON810. It follows that Article 34 of Regulation (EC) No 1829/2003 (and by way of reference Article 54 of Regulation (EC) No 178/2002) should be regarded as having the predominant purpose in light of the justifications provided by the Greek authorities. Consequently this Decision should be based on that provision.
- (19) On the basis of the additional evidence submitted by the Hellenic Republic, the Commission sought on 18 April 2008 a scientific opinion of EFSA as to whether there is any scientific reason to deem that the placing on the market of MON810 seeds is likely to cause any adverse effects on human health and the environment justifying the Greek safeguard measure.
- (20) EFSA adopted a decision on 3 July 2008 (published on 11 July 2008) concluding that there is no new data that would invalidate the previous risk assessments carried out on maize MON810, and that there is no specific scientific evidence, in terms of risk to human health and the environment, that would justify a prohibition of the placing on the market of maize MON810 in Greece.
- (21) Consequently, there is no reason to consider that the product constitutes a risk to human or animal health or to the environment.
- (22) In addition to the justifications relating to risk to health or to the environment which have been assessed by EFSA in its different opinions, the Greek authorities have indicated that their prohibition was also based on other considerations.
- (23) As regards the invocation by them of the precautionary principle, the Court has already ruled that the aim of safeguard clauses is to give specific expression of this principle¹⁰. Reference to it can thus not be used as an autonomous justification for invoking a safeguard clause. As regards the justifications put forward by the Greek authorities relating to the age of the initial authorisation granted to MON810 and the fact that the initial authorisation granted to MON810 was based on a legislation which

⁹ ECJ, 17 March 1993, *Commission v. Council*, case C-155/91, rec. p. I-939, point 7.

¹⁰ ECJ, 9 September 2003, *Monsanto s.a.*, case C-236/01, rec. p. I-08105, point 133.

was less comprehensive than the one currently applicable, it should be recalled that this product has since then been assessed at different occasions by EFSA and that none of these assessment put in evidence a need to withdraw or modify the authorisation granted to MON810. Against the justification provided by the Greek authorities that the Council has rejected different Commission proposals asking Member States to repeal their measures against the cultivation of GMOs, it should be noted that this argument, of political nature, cannot substitute itself to the need for the Member State which invokes a safeguard clause to put forward evidence of a risk to health and environment. As regards the invocation by the Greek authorities of the need to respect the Cartagena protocol on Biosafety which was approved by Council Decision 2002/628/EC concerning the conclusion, on behalf of the European Community, of the Cartagena Protocol on Biodiversity¹¹ it should be observed that no explanation is given by the Greek authorities of how this international obligation could be infringed. In this context it should be recalled that the Protocol foresees in particular the need to establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol associated with the use, handling and transboundary movements of living modified organisms. In light of the existing Community framework on the placing on the market of GMOs and given that the different risk assessments done by EFSA on MON810 have not provided evidence of risks to environment arising from the cultivation of this GMO, there is no reason to consider that the Hellenic Republic - or the Community - could be in infringement with international engagements. The same reasoning should apply as regards the respect of that article of the Greek Constitution which refers to protection of environment. As regards the need, when adopting a risk management decision, to take into account other factors than the sole scientific risk assessment, including societal, economic, tradition, ethical and environmental factors as well as the feasibility of controls it should be observed that, whilst Regulation (EC) No 1829/2003 explicitly refers to the possibility to take them into account when authorising a genetically modified food and feed under articles 7 and 16, they are not mentioned among the different elements that have to be considered in the context of the application of Article 53 and 54 of Regulation (EC) No 178/2002 to which Article 34 of Regulation (EC) N°1829/2003 refers.. The same applies for considerations regarding the economic impact of coexistence of cultures of seed of genetically modified varieties and seed of conventional varieties as well as for possible change in already established production patterns in the neighbourhood, which do not as such allow to evidence a risk to health and environment.

- (24) It follows that none of the other considerations raised by the Greek authorities are relevant to justify the safeguard measures adopted.
- (25) Greece should therefore repeal its measures against the use and sale of varieties of maize hybrids with the genetic modification MON810.
- (26) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health.

¹¹ OJ L 201, 31.7.2002, p.48.

HAS ADOPTED THIS DECISION:

Article 1

The Hellenic Republic is not authorised to prohibit the use and sale of seeds of maize hybrids with the genetic modification MON810 inscribed in the common catalogue of varieties.

Article 2

The Hellenic 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 Hellenic Republic.

Done at Brussels,

For the Commission
Stavros DIMAS
Androulla VASSILIOU
Members of the Commission