

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 18 April 2005

on emergency measures regarding the non-authorised genetically modified organism Bt10 in maize products

(notified under document number C(2005) 1257)

(Text with EEA relevance)

(2005/317/EC)

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 safety⁽¹⁾, and in particular Article 53(1) thereof,

Whereas:

- (1) Articles 4(2) and 16(2) of Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed⁽²⁾ provide that no genetically modified food or feed shall be placed on the Community market unless it is covered by an authorisation granted in accordance with that Regulation. Articles 4(3) and 16(3) of the same Regulation lay down that no genetically modified food and feed shall be authorised unless it has been adequately and sufficiently demonstrated that it does not have adverse effects on human health, animal health or the environment and that it does not mislead the consumer or the user, and differ from the food or feed it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for humans or animals.
- (2) On 22 March 2005, the authorities of the United States of America (the US authorities) informed the Commission that maize products contaminated with the genetically modified maize called Bt10 (the

contaminated products), which have not been authorised for placing on the market in the Community, were likely to have been exported to the Community since 2001 and to continue to be exported. In addition, these authorities informed the Commission that those products were not authorised for placing on the market in the United States of America either.

- (3) Without prejudice to the control obligations of the Member States, the measures to be adopted further to the likely imports of contaminated products should be subject to a comprehensive and common approach allowing rapid and effective action to be taken and avoiding disparities between Member States in the treatment of the situation.
- (4) Article 53 of Regulation (EC) No 178/2002 provides for the possibility to adopt appropriate Community emergency measures for food and feed imported from a third country in order to protect human health, animal health or the environment, where the risk can not be contained satisfactorily by means of measures taken by the Member States concerned.
- (5) Although the contamination of products was reported by Syngenta, which is the company that developed the genetically modified maize Bt10, to the US authorities in December 2004, no data enabling a safety assessment of the genetically modified maize Bt10 by the European Food Safety Authority (the Authority) according to the standards laid down in Regulation (EC) No 1829/2003 were provided by Syngenta or the US authorities. According to the Authority⁽³⁾, in the absence of this information, the safety of Bt10 has yet to be confirmed.

⁽¹⁾ OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

⁽²⁾ OJ L 268, 18.10.2003, p. 1.

⁽³⁾ Statement of the European Food Safety Authority issued on 12 April 2005.

- (6) Considering the absence of sufficient data enabling a safety assessment of the genetically modified maize Bt10 in order to achieve the high level of health protection chosen in the Community, and the presumption of risk on products not authorised according to Regulation (EC) No 1829/2003, which takes into account the precautionary principle laid down in Article 7 of Regulation (EC) No 178/2002, it is appropriate to take emergency measures in order to prevent the placing on the market in the Community of the contaminated products.
- (7) According to the general requirements laid down in Regulation (EC) No 178/2002, food and feed business operators have primary legal responsibility for ensuring that foods or feeds within the businesses under their control satisfy the requirements of food law and for verifying that such requirements are met. The duty to prove the absence of placing on the market of the contaminated products should therefore rely on the operator responsible for the first placing on the market. To this end, the emergency measures should require that consignments of specific products originating from the United States of America may be placed on the market only if an analytical report demonstrating that the products are not contaminated with the genetically modified maize Bt10 is provided. The analytical report should be issued by an accredited laboratory according to internationally recognised standards.
- (8) In order to facilitate controls, all genetically modified food and feed placed on the market should be subject to a validated method of detection. Syngenta has been requested to provide the method for the event-specific detection of the genetically modified maize Bt10 as well as control samples. Consequently, the Community reference laboratory referred to in Article 32 of Regulation (EC) No 1829/2003 (the CRL) has been asked to validate the detection method for this product on the basis of data provided by Syngenta. The detection method is made available by Syngenta and can also be found at the following address: <http://gmo-crl.jrc.it>
- (9) Considering that the measures provided for in this Decision must be proportionate and no more restrictive of trade than is required, only products considered as likely to be contaminated with genetically modified maize Bt10 should be covered. According to the information received from the US authorities, neither genetically modified maize grain nor any product derived therefrom are imported from the United States of America to the Community, with the exception of corn gluten feed and brewers grains for feed use. Accordingly, the latter products should be the subject of the said measures.
- (10) Despite requests made by the Commission, the US authorities were not in a position to provide any guarantee on the absence of Bt10 in corn gluten feed and brewers grains containing or produced from genetically modified organisms, which are imported in the Community, considering the lack of segregation or traceability measures in the United States of America on these products.
- (11) With regard to food products, according to the information made available to the Commission, no genetically modified maize imported from the United States of America is used in the production of food in the Community. Member States should however monitor whether genetically modified maize food products are present on the market and whether these have been contaminated by Bt10. On the basis of the information provided by Member States, the Commission will consider the need of any appropriate measure.
- (12) These measures should be evaluated after six months in order to assess whether they are still necessary.
- (13) 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

Scope

This Decision applies to the following products originating from the United States of America:

- corn gluten feed containing or produced from genetically modified maize within CN code 2309 90 20,
- brewers grains containing or produced from genetically modified maize within CN code 2303 30 00.

Article 2

Conditions for first placing on the market

1. Member States shall allow the first placing on the market of the products referred to in Article 1 only where an original analytical report based on a suitable and validated method for the event-specific detection of genetically modified maize Bt10 and issued by an accredited laboratory accompanying the consignment demonstrates that the product does not contain Bt10 maize or feed produced from Bt10 maize.

If a consignment of products referred to in Article 1 is split, a certified copy of the analytical report provided for in paragraph 1 shall accompany each part of the split consignment.

2. In the absence of such an analytical report, the operator established in the Community who is responsible for the first placing on the market of the product shall have the products referred to in Article 1 tested to demonstrate that they do not contain Bt10 maize or feed produced from Bt10 maize. Pending availability of the analytical report, the consignment shall not be placed on the market of the Community.

3. Member States shall inform the Commission of positive (unfavourable) results through the Rapid Alert System for food and feed.

Article 3

Other control measures

Member States shall take appropriate measures, including random sampling and analysis, concerning the products referred to in Article 1 already on the market in order to verify the absence of Bt10 maize or feed produced from Bt10 maize. They shall inform the Commission of positive (unfavourable) results through the Rapid Alert System for food and feed.

Article 4

Contaminated consignments

Member States shall take the necessary measures to ensure that the products referred to in Article 1 that are found to contain

Bt10 maize or feed produced from Bt10 maize are not placed on the market.

Article 5

Recovery of costs

Member States shall ensure that the costs incurred in the implementation of Articles 2 and 4 are borne by the operators responsible for the first placing on the market.

Article 6

Review of the measure

This Decision shall be reviewed by 31 October 2005 at the latest.

Article 7

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 18 April 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission