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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
C(2007)

final

Draft

COMMISSION DECISION

of

on the withdrawal from the market of Bt176 (SYN-EV176-9) maize and its derived products

(Memorandum from Mr M. KYPRIANOU)

Draft

COMMISSION DECISION

of

on the withdrawal from the market of Bt176 (SYN-EV176-9) maize and its derived products

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and the Council of 22 September 2003 on genetically modified food and feed¹, and in particular Article 8(6) and 20(6) thereof,

Whereas:

- (1) Bt176 (SYN-EV176-9) maize has been granted consent pursuant to Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms² by Commission Decision 97/98/EC of 23 January 1997 concerning the placing on the market of genetically modified maize (*Zea mays* L.) with the combined modification for insecticidal properties conferred by the Bt-endotoxin gene and increased tolerance to the herbicide glufosinate ammonium³ Directive 90/220/EEC has been recast and repealed by Directive 2001/18/EC.
- (2) The consent was based on the respective opinions of the Scientific Committee for Animal Nutrition established by Commission Decision 76/791/EEC⁴ of the Scientific Committee for Food established by Commission Decision 95/273/EC⁵ and of the Scientific Committee for Pesticides established by Commission Decision 78/436/EEC⁶.

¹ OJ L 268 of 18.10.2003, p. 1. Regulation as amended by Commission Regulation (EC) No 1981/2006 (OJ L 368, 23.12.2006, p. 99).

² OJ L 117 of 8.5.1990, p. 15. Directive as repealed by Directive 2001/18/EC (OJ L 106, 17.4.2001, p. 1).

³ OJ L 31 of 1.2.1997, p. 69.

⁴ OJ L 279, 9.10.1976, p. 35.

⁵ OJ L 167, 18.7.1995, p. 22.

⁶ OJ L 124, 12.5.1978, p. 16.

- (3) SYN-EV176-9 maize and its derived products have subsequently been notified by Syngenta Crop Protection AG (hereafter "the notifier") as existing products under Article 8(1) and Article 20(1) of Regulation (EC) No 1829/2003 (hereafter "the Regulation") and entered in the Community Register of genetically modified food and feed. The scope of the notification covered food consisting of and/or containing or produced from SYN-EV176-9 maize, food additives produced from SYN-EV176-9 maize, feed consisting of and/or containing SYN-EV176-9 maize, feed materials produced from SYN-EV176-9 maize and feed additives produced from SYN-EV176-9 maize.
- (4) The notifier of SYN-EV176-9 maize, in a letter to the Commission dated 19 September 2005, indicated that it has stopped selling seeds of SYN-EV176-9 maize in the Community after the 2005 planting season.
- (5) The notifier has further indicated to the Commission that it has no intention to submit an application for renewal of the authorisation of SYN-EV176-9 maize under the Regulation in accordance with Article 8(4), Article 11, Article 20(4) and Article 23 respectively. Therefore neither the cultivation nor the placing on the market of SYN-EV176-9 maize and its derived products will be authorised in the Community after 18 April 2007.
- (6) Measures should therefore be adopted in order to ensure effective withdrawal from the market of seeds from inbred lines and hybrids derived from SYN-EV176-9 maize. As a consequence of the non-availability of seeds, any products derived from SYN-EV176-9 maize can be expected to disappear from the food and feed chain in a reasonable period of time.
- (7) Since the notifier has stopped selling seeds of SYN-EV176-9 maize in the Community after the 2005 planting season, stocks of products derived from SYN-EV176-9 maize have been used up and are not expected to be present on the market after 18 April 2007. However, minute traces of genetically modified material from SYN-EV176-9 maize might remain present in food or feed products for a certain period of time.
- (8) For reasons of legal certainty, it is therefore necessary to provide for a transitional period of time within which food and feed products may contain such material without being considered to be in breach of Article 4(2) or Article 16(2) of the Regulation where this presence is adventitious and technically unavoidable.
- (9) The tolerated level and the period of time should be set taking into account the time needed until the effective withdrawal from the market of the seeds produces its effects throughout the food and feed chain. In all cases, the tolerated level shall remain below the labelling and traceability threshold of no higher than 0,9 % provided for by the Regulation for the adventitious and technically unavoidable presence of GM material in food and feed.
- (10) The entries in the Community Register of genetically modified food and feed, as provided for in Article 28 of the Regulation, regarding SYN-EV176-9 maize should be modified in order to take account of this Decision.

- (11) The notifier has been consulted on the measures provided for in this Decision.
- (12) 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

In order to ensure effective withdrawal from the market of seeds from inbred lines and hybrids derived from SYN-EV176-9 maize for the purpose of cultivation the notifier shall comply with the measures set out in the Annex.

Within 6 months from the date of notification of this Decision, the notifier shall submit to the Commission a report on the implementation of the measures set out in the Annex.

Article 2

The presence of material which contains, consists of or is produced from SYN-EV176-9 maize in food or feed products notified under Article 8(1) and Article 20(1) of the Regulation shall be tolerated until 5 years after the date of notification of this Decision:

- (a) provided that this presence is adventitious or technically unavoidable; and
- (b) in a proportion no higher than 0,9 %.

Article 3

The entries in the Community Register of genetically modified food and feed, as provided for in Article 28 of the Regulation, regarding SYN-EV176-9 maize shall be modified in order to take account of this Decision.

Article 4

This Decision is addressed to Syngenta Crop Protection AG, P.O. Box, CH - 4002 Basel, Switzerland.

Done at Brussels,

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX

Measures to be complied with by the notifier in order to ensure effective withdrawal from the market of seeds from inbred lines and hybrids derived from SYN-EV176-9 maize for the purpose of cultivation

- (a) Inform commercial operators in the Community of the commercial and legal status of the seed.
- (b) Recall remaining commercial seed stock held by operators.
- (c) Destroy remaining commercial seed stock.
- (d) Conclude product discontinuation agreements with third parties instructing them to either send back seed or to verify and attest that the seed has been destroyed.
- (e) Undertake all necessary steps for the deregistration of registered varieties of the seed from the national seed catalogues.
- (f) Implement an in-house program to avoid presence of the event in breeding and seed production.