

EN

SANCO/617/2007 Rev. 1 (POOL/E1/2007/617/617R1-EN.doc)

EN

EN



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
C(2007)

final

Draft

COMMISSION DECISION

of

**on the withdrawal from the market of Topas 19/2 (ACS-BN007-1) oilseed rape and its
derived products**

(Memorandum from Mr M. KYPRIANOU)

Draft

COMMISSION DECISION

of

on the withdrawal from the market of Topas 19/2 (ACS-BNØØ7-1) oilseed rape 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) Seeds of oilseed rape (*Brassica napus* L. spp. *oleifera*) derived from traditional breeding crosses between non-genetically modified oilseed rape and a line resulting from transformation event Topas 19/2 (ACS-BNØØ7-1) have 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 98/291/EC of 22 April 1998 concerning the placing on the market of genetically modified spring swede rape (*Brassica napus* L. ssp. *oleifera*)³ for handling in the environment during import and before and during storage and processing. Directive 90/220/EEC has been recast and repealed by Directive 2001/18/EC.
- (2) The consent was based on the opinion of 10 February 1998 of the Scientific Committee on Plants established by Commission Decision 97/579/EC⁴.
- (3) Processed oil from seeds of oilseed rape ACS-BNØØ7-1 and all conventional crosses was placed on the market in accordance with Article 5 of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients⁵.

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 Directive as repealed by Directive 2001/18/EC (OJ L 106, 17.4.2001, p. 1).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 131 of 5.5.1998, p. 26.

⁴ OJ L 237 of 28.8.1997, p. 18.

⁵ OJ L 43 of 14.2.1997, p. 1.

- (4) ACS-BN007-1 oilseed rape and its derived products have subsequently been notified by Bayer CropScience AG (hereafter "the notifier") as existing products under Article 8(1)(a) 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 (processed oil) produced from seeds of oilseed rape ACS-BN007-1 and all conventional crosses as well as feed containing or consisting of or produced from ACS-BN007-1 oilseed rape for the placing on the market of the product or handling in the environment during import and before and during storage and processing.
- (5) The notifier of oilseed rape ACS-BN007-1, in a letter to the Commission dated 15 November 2005, indicated that varieties containing this event were no longer offered for sale on a global basis and that all inventory seed were recalled and destroyed after the 2003 sales season.
- (6) The notifier has further indicated to the Commission that it has no intention to submit an application for renewal of the authorisation of ACS-BN007-1 oilseed rape under the Regulation in accordance with the first sub-paragraph of Article 8(4), Article 11, Article 20(4) and Article 23 respectively. Therefore ACS-BN007-1 oilseed rape and its derived products cannot be placed on the market in the Community after 18 April 2007.
- (7) Measures to ensure effective withdrawal from the market of seeds of oilseed rape ACS-BN007-1 for the purpose of cultivation are not necessary since these seeds could never be legally placed on the market in the Community. Since the notifier has stopped selling seeds of oilseed rape ACS-BN007-1 after the 2003 planting season, stocks of products derived from ACS-BN007-1 oilseed rape have been used up and are not expected to be present on the market after 18 April 2007. However, minute traces of ACS-BN007-1 oilseed rape 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 ACS-BN007-1 oilseed rape 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

The presence of material which contains, consists of or is produced from ACS-BN007-1 oilseed rape in food or feed products notified under Article 8(1)(a) 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 2

The entries in the Community Register of genetically modified food and feed, as provided for in Article 28 of the Regulation, regarding ACS-BN007-1 oilseed rape shall be modified in order to take account of this Decision.

Article 3

This Decision is addressed to Bayer CropScience AG, Alfred-Nobel-Str. 50, D - 40789 Monheim am Rhein, Germany.

Done at Brussels,

For the Commission
Markos KYPRIANOU
Member of the Commission