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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,
C(2007)

final

Draft

COMMISSION DECISION

of

**on the withdrawal from the market of Ms1xRf1 (ACS-BN004-7xACS-BN001-4)
hybrid oilseed rape and its derived products**

(Memorandum from Mr M. KYPRIANOU)

Draft

COMMISSION DECISION

of

on the withdrawal from the market of Ms1xRf1 (ACS-BN004-7xACS-BN001-4) hybrid 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 hybrid oilseed rape Ms1xRf1 (ACS-BN004-7xACS-BN001-4) 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 96/158/EC of 6 February 1996 concerning the placing on the market of a product consisting of a genetically modified organism, hybrid herbicide-tolerant swede-rape seeds (*Brassica napus* L. *oleifera* Metzq. MS1Bn × RF1Bn)³ for the use of growing for obtaining seed but not for the use for human food or animal feed. Directive 90/220/EEC has been recast and repealed by Directive 2001/18/EC.
- (2) Seeds of hybrid oilseed rape ACS-BN004-7xACS-BN001-4 have been granted consent pursuant to Council Directive 90/220/EEC by Commission Decision 97/392/EC of 6 June 1997 concerning the placing on the market of genetically modified swede-rape (*Brassica napus* L. *oleifera* Metzq. MS1, RF1)⁴ for the intended use of growing and handling in the environment before and during processing to non-viable fractions.
- (3) The consents were based on the information contained in the dossiers submitted under Directive 90/220/EEC and all the information submitted by the Member States.

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 Directive as repealed by Directive 2001/18/EC (OJ L 106, 17.4.2001, p. 1).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 37 of 15.2.1996, p. 30.

⁴ OJ L 164 of 21.6.1997, p. 38.

- (4) Processed oil from ACS-BNØØ4-7, ACS-BNØØ1-4 and the hybrid combination ACS-BNØØ4-7xACS-BNØØ1-4 oilseed rape 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.
- (5) ACS-BNØØ4-7, ACS-BNØØ1-4 and the hybrid combination ACS-BNØØ4-7xACS-BNØØ1-4 oilseed rape and their 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 the male sterile MS1Bn (B91-4) oilseed rape line and all conventional crosses, the fertility restorer RF1Bn (B93-101) oilseed rape line and all conventional crosses and the hybrid combination MS1xRF1 (ACS-BNØØ4-7xACS-BNØØ1-4) as well as feed containing or consisting of oilseed swede-rape derived from the male sterile MS1 (B91-4), cultivar Drakkar, oilseed rape line (*Brassica napus* L. *oleifera* Metzg.), the fertility restorer RF1 (B93-101), cultivar Drakkar, oilseed rape line (*Brassica napus* L. *oleifera* Metzg.) and the hybrid combination MS1xRF1 (ACS-BNØØ4-7xACS-BNØØ1-4) (*Brassica napus* L. *oleifera* Metzg. MS1Bn x RF1Bn) for the intended uses of growing and handling in the environment before and during processing to non-viable fractions.
- (6) The notifier of hybrid oilseed rape ACS-BNØØ4-7xACS-BNØØ1-4, 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.
- (7) The notifier has further indicated to the Commission that it has no intention to submit an application for renewal of the authorisation of ACS-BNØØ4-7, ACS-BNØØ1-4 and the hybrid combination ACS-BNØØ4-7xACS-BNØØ1-4 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 neither the cultivation nor the placing on the market of ACS-BNØØ4-7xACS-BNØØ1-4 hybrid oilseed rape and its derived products will be authorised in the Community after 18 April 2007.
- (8) Measures should therefore be adopted in order to ensure effective withdrawal from the market of seeds of hybrid oilseed rape ACS-BNØØ4-7xACS-BNØØ1-4. As a consequence of the non-availability of seeds, any products derived from ACS-BNØØ4-7, ACS-BNØØ1-4 and the hybrid combination ACS-BNØØ4-7xACS-BNØØ1-4 oilseed rape can be expected to disappear from the food and feed chain in a reasonable period of time.

⁵ OJ L 43 of 14.2.1997, p. 1.

- (9) Since the notifier has stopped selling seeds of hybrid oilseed rape ACS-BN004-7xACS-BN001-4 after the 2003 planting season, stocks of products derived from ACS-BN004-7, ACS-BN001-4 and the hybrid combination ACS-BN004-7xACS-BN001-4 oilseed rape 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 ACS-BN004-7, ACS-BN001-4 and the hybrid combination ACS-BN004-7xACS-BN001-4 oilseed rape might remain present in food or feed products for a certain period of time.
- (10) 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.
- (11) 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.
- (12) The entries in the Community Register of genetically modified food and feed, as provided for in Article 28 of the Regulation, regarding ACS-BN004-7, ACS-BN001-4 and the hybrid combination ACS-BN004-7xACS-BN001-4 oilseed rape should be modified in order to take account of this Decision.
- (13) The notifier has been consulted on the measures provided for in this Decision.
- (14) 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 of hybrid oilseed rape ACS-BN004-7xACS-BN001-4 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 ACS-BN004-7, ACS-BN001-4 and the hybrid combination ACS-BN004-7xACS-BN001-4 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 3

The entries in the Community Register of genetically modified food and feed, as provided for in Article 28 of the Regulation, regarding ACS-BN004-7, ACS-BN001-4 and the hybrid combination ACS-BN004-7xACS-BN001-4 oilseed rape shall be modified in order to take account of this Decision.

Article 4

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

ANNEX

Measures to be complied with by the notifier in order to ensure effective withdrawal from the market of seeds of hybrid oilseed rape ACS-BN004-7xACS-BN001-4 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.