

Commission Decision of 25 April 2007 on the withdrawal from the market of Ms1xRf1 (ACS-BN004-7xACS-BN001-4) hybrid oilseed rape and its derived products (notified under document number C(2007) 1805) (Only the German text is authentic) (2007/305/EC)

COMMISSION DECISION

of 25 April 2007

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

(notified under document number C(2007) 1805)

(Only the German text is authentic)

(2007/305/EC)

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 feed⁽¹⁾, 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 organisms⁽²⁾ 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 x 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 Directive 90/220/EEC has been recast and repealed by Directive 2001/18/EC.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 Metzg.* MS1, RF1) pursuant to Council Directive 90/220/EEC⁽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.
- (4) Processed oil from ACS-BN004-7, ACS-BN001-4 and the hybrid combination ACS-BN004-7xACS-BN001-4 oilseed rape was placed on the market in accordance with

Status: Point in time view as at 16/12/2016.

Changes to legislation: There are outstanding changes not yet made to Commission Decision of 25 April 2007 on the withdrawal from the market of Ms1xRf1 (ACS-BN004-7xACS-BN001-4) hybrid oilseed rape and its derived products (notified under document number C(2007) 1805) (Only the German text is authentic) (2007/305/EC). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

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 ingredients⁽⁵⁾.

- (5) ACS-BN004-7, ACS-BN001-4 and the hybrid combination ACS-BN004-7xACS-BN001-4 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-BN004-7xACS-BN001-4) 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-BN004-7xACS-BN001-4) (*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-BN004-7xACS-BN001-4, 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-BN004-7, ACS-BN001-4 and the hybrid combination ACS-BN004-7xACS-BN001-4 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-BN004-7xACS-BN001-4 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-BN004-7xACS-BN001-4. As a consequence of the non-availability of seeds, any products derived from ACS-BN004-7, ACS-BN001-4 and the hybrid combination ACS-BN004-7xACS-BN001-4 oilseed rape can be expected to disappear from the food and feed chain in a reasonable period of time.
- (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.

Status: Point in time view as at 16/12/2016.

Changes to legislation: There are outstanding changes not yet made to Commission Decision of 25 April 2007 on the withdrawal from the market of Ms1xRf1 (ACS-BN004-7xACS-BN001-4) hybrid oilseed rape and its derived products (notified under document number C(2007) 1805) (Only the German text is authentic) (2007/305/EC). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

- (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 or 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 or 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:

[^{F1} Article 1

The addressee shall implement an in-house program in order to ensure the effective withdrawal from the market of ACS-BN004-7, ACS-BN001-4 and the hybrid combination ACS-BN004-7xACS-BN001-4 oilseed rape in breeding and seed production and shall gather data on the presence of those genetically modified organisms in the oilseed rape shipments to the Union from Canada.

The addressee shall report to the Commission on the implementation of this program and on the presence of those genetically modified organisms in the oilseed rape shipments to the Union from Canada by 1 January 2019.]

Textual Amendments

- F1** Substituted by [Commission Implementing Decision \(EU\) 2016/2268 of 14 December 2016 amending Decisions 2007/305/EC, 2007/306/EC and 2007/307/EC as regards the tolerance period for traces of Ms1xRf1 \(ACS-BN004-7xACS-BN001-4\) hybrid oilseed rape, Ms1xRf2 \(ACS-BN004-7xACS-BN002-5\) hybrid oilseed rape and Topas 19/2 \(ACS-BN007-1\) oilseed rape, as well as their derived products \(notified under document C\(2016\) 8390\) \(Only the German text is authentic\).](#)

[^{F1} Article 2

1 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 point (a) of Article 8(1) and Article 20(1) of Regulation (EC) No 1829/2003 shall be tolerated until 31 December 2019, provided that this presence:

- a is adventitious or technically unavoidable; and

Status: Point in time view as at 16/12/2016.

Changes to legislation: There are outstanding changes not yet made to Commission Decision of 25 April 2007 on the withdrawal from the market of Ms1xRf1 (ACS-BN004-7xACS-BN001-4) hybrid oilseed rape and its derived products (notified under document number C(2007) 1805) (Only the German text is authentic) (2007/305/EC). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

b is in a proportion no higher than 0,1 % mass fraction.

2 The addressee shall ensure the availability of certified reference material for ACS-BN004-7xACS-BN001-4 oilseed rape via the American Oil Chemists Society at [https://www.aocs.org/attain-lab-services/certified-reference-materials-\(crms\)](https://www.aocs.org/attain-lab-services/certified-reference-materials-(crms)).]

Textual Amendments

F1 Substituted by Commission Implementing Decision (EU) 2016/2268 of 14 December 2016 amending Decisions 2007/305/EC, 2007/306/EC and 2007/307/EC as regards the tolerance period for traces of Ms1xRf1 (ACS-BN004-7xACS-BN001-4) hybrid oilseed rape, Ms1xRf2 (ACS-BN004-7xACS-BN002-5) hybrid oilseed rape and Topas 19/2 (ACS-BN007-1) oilseed rape, as well as their derived products (notified under document C(2016) 8390) (Only the German text is authentic).

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.

Status: Point in time view as at 16/12/2016.

Changes to legislation: There are outstanding changes not yet made to Commission Decision of 25 April 2007 on the withdrawal from the market of Ms1xRf1 (ACS-BNØØ4-7xACS-BNØØ1-4) hybrid oilseed rape and its derived products (notified under document number C(2007) 1805) (Only the German text is authentic) (2007/305/EC). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

F² ANNEX

Textual Amendments

- F2** Deleted by Commission Implementing Decision (EU) 2016/2268 of 14 December 2016 amending Decisions 2007/305/EC, 2007/306/EC and 2007/307/EC as regards the tolerance period for traces of Ms1xRf1 (ACS-BNØØ4-7xACS-BNØØ1-4) hybrid oilseed rape, Ms1xRf2 (ACS-BNØØ4-7xACS-BNØØ2-5) hybrid oilseed rape and Topas 19/2 (ACS-BNØØ7-1) oilseed rape, as well as their derived products (notified under document C(2016) 8390) (Only the German text is authentic).

Status: Point in time view as at 16/12/2016.

Changes to legislation: There are outstanding changes not yet made to Commission Decision of 25 April 2007 on the withdrawal from the market of Ms1xRf1 (ACS-BNØØ4-7xACS-BNØØ1-4) hybrid oilseed rape and its derived products (notified under document number C(2007) 1805) (Only the German text is authentic) (2007/305/EC). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

- (1) OJ L 268, 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, 8.5.1990, p. 15. Directive as repealed by Directive 2001/18/EC of the European Parliament and the Council (OJ L 106, 17.4.2001, p. 1).
- (3) OJ L 37, 15.2.1996, p. 30.
- (4) OJ L 164, 21.6.1997, p. 38.
- (5) OJ L 43, 14.2.1997, p. 1. Regulation as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

Status:

Point in time view as at 16/12/2016.

Changes to legislation:

There are outstanding changes not yet made to Commission Decision of 25 April 2007 on the withdrawal from the market of Ms1xRf1 (ACS-BNØØ4-7xACS-BNØØ1-4) hybrid oilseed rape and its derived products (notified under document number C(2007) 1805) (Only the German text is authentic) (2007/305/EC). Any changes that have already been made to the legislation appear in the content and are referenced with annotations.