

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 Ms1×Rf1 (ACS-BNØØ4-7×ACS-BNØØ1-4) hybrid oilseed rape, Ms1×Rf2 (ACS-BNØØ4-7×ACS-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)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

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 Articles 8(6) and 20(6) thereof,

Whereas:

- (1) Commission Decisions 2007/305/EC ⁽²⁾, 2007/306/EC ⁽³⁾ and 2007/307/EC ⁽⁴⁾ lay down the rules for the withdrawal from the market of Ms1×Rf1 (ACS-BNØØ4-7×ACS-BNØØ1-4) hybrid oilseed rape, Ms1×Rf2 (ACS-BNØØ4-7×ACS-BNØØ2-5) hybrid oilseed rape and Topas 19/2 (ACS-BNØØ7-1) oilseed rape respectively, as well as their derived products ('GM material'). Those decisions have been adopted after the authorisation holder, the company Bayer CropScience AG, indicated to the Commission that it had no intention of submitting an application for the renewal of the authorisation of that GM material in accordance with the first subparagraph of Article 8(4), Article 11, Article 20(4) and Article 23 of Regulation (EC) No 1829/2003.
- (2) All three Decisions provided for an initial transitional period of five years during which food and feed containing, consisting of or produced from this GM material were allowed to be placed on the market in a proportion no higher than 0,9 % and provided that that presence was adventitious or technically unavoidable. The purpose of that transitional period was to take into account the fact that minute traces of that GM material could sometimes be present in the food and feed chains, even after Bayer CropScience AG had decided to stop selling seeds derived from those genetically modified organisms and even if all measures were taken to avoid the presence of that GM material.
- (3) In light of experience after the withdrawal of that GM material from the market, Commission Implementing Decision 2012/69/EU ⁽⁵⁾ amended all three Decisions in order to extend the transition period until 31 December 2016. Given the very low trace levels which had been reported, that Decision reduced the tolerated presence of that GM material in food and feed to 0,1 % mass fraction.
- (4) Decisions 2007/305/EC, 2007/306/EC and 2007/307/EC also set out a series of measures that Bayer CropScience AG had to take in order to ensure the effective withdrawal from the market of this GM material and laid down reporting obligations on Bayer CropScience AG.
- (5) In December 2013 and in March 2016, Bayer CropScience AG reported that despite the measures taken to prevent the presence of those genetically modified organisms in accordance with Decisions 2007/305/EC, 2007/306/EC and 2007/307/EC, minute traces have been still detected in oilseed rape commodities in recent years. This persisting presence of traces can be explained by the biology of oilseed rapes which can remain

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Decision 2007/305/EC of 25 April 2007 on the withdrawal from the market of Ms1xRf1 (ACS-BNØØ4-7×ACS-BNØØ1-4) hybrid oilseed rape and its derived products (OJ L 117, 5.5.2007, p. 17).

⁽³⁾ Commission Decision 2007/306/EC of 25 April 2007 on the withdrawal from the market of Ms1xRf2 (ACS-BNØØ4-7×ACS-BNØØ2-5) hybrid oilseed rape and its derived products (OJ L 117, 5.5.2007, p. 20).

⁽⁴⁾ Commission Decision 2007/307/EC of 25 April 2007 on the withdrawal from the market of Topas 19/2 (ACS-BNØØ7-1) oilseed rape and its derived products (OJ L 117, 5.5.2007, p. 23).

⁽⁵⁾ Commission Implementing Decision 2012/69/EU of 3 February 2012 amending Decisions 2007/305/EC, 2007/306/EC and 2007/307/EC as regards the tolerance period for traces of Ms1×Rf1 (ACS-BNØØ4-7×ACS-BNØØ1-4) hybrid oilseed rape, Ms1×Rf2 (ACS-BNØØ4-7×ACS-BNØØ2-5) hybrid oilseed rape and Topas 19/2 (ACS-BNØØ7-1) oilseed rape, as well as of their derived products (OJ L 34, 7.2.2012, p. 12).

dormant for long periods as well as by farm practices which have been employed to harvest the seeds which may have resulted in accidental spillage, the level of which was difficult to estimate at the dates of adoption of Decisions 2007/305/EC, 2007/306/EC and 2007/307/EC and Implementing Decision 2012/69/EU. The occurrence of traces has continued to follow a decreasing trend.

- (6) Against this background, it is appropriate to extend the transitional period for another three years until 31 December 2019 to allow for the complete removal of the remaining traces of Ms1×Rf1, Ms1×Rf2 and Topas 19/2 oilseed rapes in the food and feed chain.
- (7) In order to further contribute to the removal of that GM material, it is also appropriate that Bayer CropScience AG continues to implement the in-house programme required in accordance with Decisions 2007/305/EC, 2007/306/EC and 2007/307/EC and to gather data, as it previously did on a voluntary basis, on the presence of such material in oilseed rape commodities imported into the Union from Canada, the only country where those oilseed rapes were cultivated for commercial purposes. Bayer CropScience AG should report to the Commission on both aspects by 1 January 2019.
- (8) Bayer CropScience AG should ensure the continued availability of certified reference materials to enable control laboratories to perform their analysis during that transitional period.
- (9) Decisions 2007/305/EC, 2007/306/EC and 2007/307/EC should therefore be amended accordingly.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Decision 2007/305/EC is amended as follows:

- (1) Article 1 is replaced by the following:

'Article 1

The addressee shall implement an in-house program in order to ensure the effective withdrawal from the market of ACS-BNØØ4-7, ACS-BNØØ1-4 and the hybrid combination ACS-BNØØ4-7×ACS-BNØØ1-4 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.;

- (2) Article 2 is replaced by the following:

'Article 2

1. The presence of material which contains, consists of or is produced from ACS-BNØØ4-7, ACS-BNØØ1-4 and the hybrid combination ACS-BNØØ4-7×ACS-BNØØ1-4 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
- (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-BNØØ4-7×ACS-BNØØ1-4 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).)

- (3) the Annex is deleted.

Article 2

Decision 2007/306/EC is amended as follows:

(1) Article 1 is replaced by the following:

'Article 1

The addressee shall implement an in-house program in order to ensure the effective withdrawal from the market of ACS-BNØØ4-7, ACS-BNØØ2-5 and the hybrid combination ACS-BNØØ4-7×ACS-BNØØ2-5 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.;

(2) Article 2 is replaced by the following:

'Article 2

1. The presence of material which contains, consists of or is produced from ACS-BNØØ4-7, ACS-BNØØ2-5 and the hybrid combination ACS-BNØØ4-7×ACS-BNØØ2-5 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

(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-BNØØ4-7×ACS-BNØØ2-5 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).)

(3) the Annex is deleted.

Article 3

Article 1 of Decision 2007/307/EC is replaced by the following:

'Article 1

1. The addressee shall implement an in-house program in order to ensure the effective withdrawal from the market of ACS- BNØØ7-1 oilseed rape in breeding and seed production and shall gather data on the presence of that genetically modified organism 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.

2. The presence of material which contains, consists of or is produced from ACS-BNØØ7-1 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

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

3. The addressee shall ensure the availability of certified reference material for ACS- BNØØ7-1 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).)

Article 4

The entries in the Community Register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003, regarding ACS-BNØØ4-7, ACS-BNØØ1-4 and the hybrid combination ACS-BNØØ4-7×ACS-BNØØ1-4 oilseed rape, ACS-BNØØ4-7, ACS-BNØØ2-5 and the hybrid combination ACS-BNØØ4-7×ACS-BNØØ2-5 oilseed rape, and ACS-BNØØ7-1 oilseed rape shall be modified in order to take account of this Decision.

Article 5

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

Done at Brussels, 14 December 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission
