COMMISSION IMPLEMENTING DECISION (EU) 2019/1195

of 10 July 2019

amending Decisions 2008/730/EC, 2008/837/EC, 2009/184/EC, 2011/354/EU, Implementing Decisions 2012/81/EU, 2013/327/EU, (EU) 2015/690, (EU) 2015/697, (EU) 2015/699, (EU) 2016/1215, (EU) 2017/1208 and (EU) 2017/2451 as regards the authorisation holder and the representative for the placing on the market of genetically modified soybean, cotton, oilseed rape and maize

(notified under document C(2019) 5093)

(Only the German text is authentic)

(Text with EEA relevance)

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 of the Council of 22 September 2003 on genetically modified food and feed (¹), and in particular to Article 9(2) and Article 21(2) thereof,

Whereas:

- (1) Bayer CropScience AG, based in Germany, is the authorisation holder for the placing on the market of genetically modified food and feed (soybean, cotton, oilseed rape and maize) under Regulation (EC) No 1829/2003, covered by Commission Decisions 2008/730/EC (²), 2008/837/EC (³), 2009/184/EC (⁴), 2011/354/EU (⁵), Commission Implementing Decisions 2012/81/EU (⁶), 2013/327/EU (ˀ), (EU) 2015/690 (⁶), (EU) 2015/697 (⁶), (EU) 2015/699 (¹¹) and (EU) 2016/1215 (¹¹).
- (2) Bayer CropScience N.V., based in Belgium, is the authorisation holder for the placing on the market of a genetically modified food and feed (cotton) and represents Bayer CropScience LP, based in the United States, for the authorisation under Commission Implementing Decision (EU) 2017/1208 (12).
- (3) Bayer CropScience N.V., based in Belgium, is the authorisation holder for the placing on the market of a genetically modified food and feed (soybean) and represents M.S. Technologies LLC, based in the United States, for the authorisation under Commission Implementing Decision (EU) 2017/2451 (13).
- (4) By letter dated 1 August 2018, Bayer CropScience AG, Germany, Bayer CropScience N.V., Belgium and Bayer CropScience LP, United States, requested, that the Commission transfers their rights and obligations pertaining to all authorisations and pending applications for genetically modified products, to BASF Agricultural Solutions Seed US LLC, based in the United States.
- (5) By letter dated 19 October 2018, BASF Agricultural Solutions Seed US LLC confirmed their consent to this transfer and authorised BASF SE, based in Germany, to act as its EU representative.
- (6) On 11 October 2018, M.S. Technologies LLC confirmed in writing its agreement with the change of their representative.
- (7) Annexes to Decisions 2008/730/EC, 2008/837/EC, 2009/184/EC and 2011/354/EU contain links to the webpages of The American Oil Chemists' Society, where the reference materials for detection method are available, which are linked to Bayer, therefore, these links should be adapted accordingly.

- (8) The proposed amendments to the authorisation decisions are purely administrative in nature and do not entail a new assessment of the products concerned. The same applies to the addressees of the authorisation decisions concerned, which should also be adapted accordingly.
- (9) The implementation of the requested changes requires the amendment of decisions authorising the placing on the market of genetically modified products for which Bayer CropScience AG and Bayer CropScience N.V. are the authorisation holders. In particular, the following decisions should therefore be amended accordingly: Decisions 2008/730/EC, 2008/837/EC, 2009/184/EC, 2011/354/EU, Implementing Decisions 2012/81/EU, 2013/327/EU, (EU) 2015/690, (EU) 2015/697, (EU) 2015/699, (EU) 2016/1215, (EU) 2017/1208 and (EU) 2017/2451.
- (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

Amendment to Decision 2008/730/EC

Decision 2008/730/EC is amended as follows:

- (1) In Article 6, 'Bayer CropScience AG' is replaced by 'BASF Agricultural Solutions Seed US LLC, USA, represented by BASF SE, Germany';
- (2) In Article 8, 'Bayer CropScience AG, Alfred-Nobel-Straße 50, D-40789 Monheim am Rhein' is replaced by 'BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen';
- (3) Point (a) of the Annex is replaced by the following:

'(a) Applicant and authorisation holder:

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue, Florham Park, New Jersey 07932, United States of America

Represented by BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany.'

- (4) Point (d), third indent, of the Annex is replaced by the following:
 - '— reference material: AOCS 0707-A and AOCS 0707-B accessible via the American Oil Chemists Society at https://www.aocs.org/crm'.

Article 2

Amendment to Decision 2008/837/EC

Decision 2008/837/EC is amended as follows:

- (1) In Article 6, 'Bayer CropScience AG' is replaced by 'BASF Agricultural Solutions Seed US LLC, USA, represented by BASF SE, Germany';
- (2) In Article 8, 'Bayer CropScience AG, Alfred-Nobel-Strasse 50, D-40789 Monheim am Rhein' is replaced by 'BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen';
- (3) Point (a) of the Annex is replaced by the following:

'(a) Applicant and authorisation holder:

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue, Florham Park, New Jersey 07932, United States of America

Represented by BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany.';

- (4) Point (d), third indent, of the Annex is replaced by the following:
 - '— reference material: AOCS 0306-A and AOCS 0306-E accessible via the American Oil Chemists Society at https://www.aocs.org/crm'.

Article 3

Amendment to Decision 2009/184/EC

Decision 2009/184/EC is amended as follows:

- (1) In Article 7, 'Bayer CropScience AG' is replaced by 'BASF Agricultural Solutions Seed US LLC, USA, represented by BASF SE, Germany';
- (2) In Article 9, 'Bayer CropScience AG, Alfred-Nobel-Straße 50, 40789 Monheim am Rhein' is replaced by 'BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen';
- (3) Point (a) of the Annex is replaced by the following:

'(a) Applicant and authorisation holder:

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue, Florham Park, New Jersey 07932, United States of America

Represented by BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany.';

- (4) Point (d), third indent, of the Annex is replaced by the following:
 - '— reference material: AOCS 0208-A accessible via the American Oil Chemists Society at https://www.aocs.org/crm'.

Article 4

Amendment to Decision 2011/354/EU

Decision 2011/354/EU is amended as follows:

- (1) In Article 6, 'Bayer CropScience AG' is replaced by 'BASF Agricultural Solutions Seed US LLC, USA, represented by BASF SE, Germany';
- (2) In Article 8, 'Bayer CropScience AG, Alfred-Nobel-Straße 50, 40789 Monheim am Rhein' is replaced by 'BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen';
- (3) Point (a) of the Annex is replaced by the following:

'(a) Applicant and authorisation holder:

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue, Florham Park, New Jersey 07932, United States of America

Represented by BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany.';

- (4) Point (d), third indent, of the Annex is replaced by the following:
 - '— reference material: AOCS 1108-A and 0306-A is accessible via the American Oil Chemists Society at https://www.aocs.org/crm'.

Article 5

Amendment to Implementing Decision 2012/81/EU

Implementing Decision 2012/81/EU is amended as follows:

- (1) In Article 6, 'Bayer CropScience AG' is replaced by 'BASF Agricultural Solutions Seed US LLC, USA, represented by BASF SE, Germany';
- (2) In Article 8, 'Bayer CropScience AG, Alfred-Nobel-Strasse 50, 40789 Monheim am Rhein' is replaced by 'BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen';

(3) Point (a) of the Annex is replaced by the following:

'(a) Applicant and authorisation holder:

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue, Florham Park, New Jersey 07932, United States of America

Represented by BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany.'

Article 6

Amendment to Implementing Decision 2013/327/EU

Implementing Decision 2013/327/EU is amended as follows:

- (1) In Article 6, 'Bayer CropScience AG' is replaced by 'BASF Agricultural Solutions Seed US LLC, USA, represented by BASF SE, Germany';
- (2) In Article 8, 'Bayer CropScience AG, Alfred-Nobel-Strasse 50, 40789 Monheim am Rhein' is replaced by 'BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen';
- (3) Point (a) of the Annex is replaced by the following:

'(a) Applicant and authorisation holder:

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue, Florham Park, New Jersey 07932, United States of America

Represented by BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany.'

Article 7

Amendment to Implementing Decision (EU) 2015/690

Implementing Decision (EU) 2015/690 is amended as follows:

- (1) In Article 6, 'Bayer CropScience AG' is replaced by 'BASF Agricultural Solutions Seed US LLC, USA, represented by BASF SE, Germany';
- (2) In Article 8, 'Bayer CropScience AG, Alfred-Nobel-Strasse 50, D-40789 Monheim am Rhein' is replaced by 'BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen';
- (3) Point (a) of the Annex is replaced by the following:

'(a) Applicant and authorisation holder:

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue, Florham Park, New Jersey 07932, United States of America

Represented by BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany.'

Article 8

Amendment to Implementing Decision (EU) 2015/697

Implementing Decision (EU) 2015/697 is amended as follows:

- (1) In Article 6, 'Bayer CropScience AG' is replaced by 'BASF Agricultural Solutions Seed US LLC, USA, represented by BASF SE, Germany';
- (2) In Article 8, 'Bayer CropScience AG, Alfred-Nobel-Strasse 50, D-40789 Monheim am Rhein' is replaced by 'BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen';

(3) Point (a) of the Annex is replaced by the following:

'(a) Applicant and authorisation holder:

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue, Florham Park, New Jersey 07932, United States of America

Represented by BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany.'

Article 9

Amendment to Implementing Decision (EU) 2015/699

Implementing Decision (EU) 2015/699 is amended as follows:

- (1) In Article 6, 'Bayer CropScience AG' is replaced by 'BASF Agricultural Solutions Seed US LLC, USA, represented by BASF SE, Germany';
- (2) In Article 8, 'Bayer CropScience AG, Alfred-Nobel-Strasse 50, D-40789 Monheim am Rhein' is replaced by 'BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen';
- (3) Point (a) of the Annex is replaced by the following:

'(a) Applicant and authorisation holder:

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue, Florham Park, New Jersey 07932, United States of America

Represented by BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany.'

Article 10

Amendment to Implementing Decision (EU) 2016/1215

Implementing Decision (EU) 2016/1215 is amended as follows:

- (1) In Article 6, 'Bayer CropScience AG' is replaced by 'BASF Agricultural Solutions Seed US LLC, USA, represented by BASF SE, Germany';
- (2) In Article 8, 'Bayer CropScience AG, Alfred-Nobel-Strasse 50, D-40789 Monheim am Rhein' is replaced by 'BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen';
- (3) Point (a) of the Annex is replaced by the following:

'(a) Applicant and authorisation holder:

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue, Florham Park, New Jersey 07932, United States of America

Represented by BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany.'

Article 11

Amendment to Implementing Decision (EU) 2017/1208

Implementing Decision (EU) 2017/1208 is amended as follows:

(1) Article 6 is replaced by the following:

'Article 6

Authorisation holder

The authorisation holder shall be BASF Agricultural Solutions Seed US LLC, United States, represented by BASF SE, Germany.';

(2) In Article 8, 'Bayer CropScience NV, J.E. Mommaertslaan 14, 1831, Diegem, Belgium' is replaced by 'BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany';

(3) Point (a) of the Annex is replaced by the following:

'(a) Authorisation holder:

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue, Florham Park, New Jersey 07932, United States of America

Represented by BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany.'

Article 12

Amendment to Implementing Decision (EU) 2017/2451

Implementing Decision (EU) 2017/2451 is amended as follows:

(1) Article 7 is replaced by the following:

'Article 7

Authorisation holders

The authorisation holders shall be

- (a) BASF Agricultural Solutions Seed US LLC, United States, represented by BASF SE, Germany; and
- (b) BASF SE, Germany, representing M.S. Technologies, LLC, United States.';
- (2) In Article 9, 'Bayer CropScience N.V., J.E. Mommaertslaan 14, 1831 Diegem, Belgium' is replaced by 'BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany';
- (3) Point (a) of the Annex is replaced by the following:

'(a) Applicants and authorisation holders:

Name: BASF Agricultural Solutions Seed US LLC

Address: 100 Park Avenue, Florham Park, New Jersey 07932, United States of America

Represented by BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany;

and

Name: BASF SE Germany

Address: Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany

On behalf of M.S. Technologies LLC, 103, Avenue D, West Point, Iowa 52656, United States of America.'

Article 13

Addressee

This Decision is addressed to BASF SE, Carl-Bosch-Str. 38, 67063 Ludwigshafen, Germany.

Done at Brussels, 10 July 2019.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Decision 2008/730/EC of 8 September 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean A2704-12 (ACS-GMØØ5-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 247, 16.9.2008, p. 50).

⁽³⁾ Commission Decision 2008/837/EC of 29 October 2008 authorising the placing on the market of products containing, consisting of, or produced from genetically modified LLCotton25 (ACS-GHØØ1-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 299, 8.11.2008, p. 36).

- (4) Commission Decision 2009/184/EC of 10 March 2009 authorising the placing on the market of products containing or produced from genetically modified oilseed rape T45 (ACS-BNØØ8-2) resulting from the commercialisation of this oilseed rape in third countries until 2005 pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 68, 13.3.2009, p. 28).
- (5) Commission Decision 2011/354/EU of 17 June 2011 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB614 (BCS-GHØØ2-5) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 160, 18.6.2011, p. 90).
- (6) Commission Implementing Decision 2012/81/EU of 10 February 2012 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean A5547-127 (ACS-GMØØ6-4) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 40, 14.2.2012, p. 10).
- (7) Commission Implementing Decision 2013/327/EU of 25 June 2013 authorising the placing on the market of food containing or consisting of genetically modified oilseed rape Ms8, Rf3 and Ms8 × Rf3, or food and feed produced from those genetically modified organisms pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 175, 27.6.2013, p. 57).
- (8) Commission Implementing Decision (EU) 2015/690 of 24 April 2015 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB614×LLCotton25 (BCS-GHØØ2-5×ACS-GHØØ1-3) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 112, 30.4.2015, p. 35).
- (°) Commission Implementing Decision (EU) 2015/697 of 24 April 2015 authorising the placing on the market of genetically modified maize T25 (ACS-ZMØØ3-2) and renewing the existing maize T25 (ACS-ZMØØ3-2) products, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 112, 30.4.2015, p. 66).
- (10) Commission Implementing Decision (EU) 2015/699 of 24 April 2015 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton T304-40 (BCS-GHØØ4-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 112, 30.4.2015, p. 77).
- (¹¹) Commission Implementing Decision (EU) 2016/1215 of 22 July 2016 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean FG72 (MST-FGØ72-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 199, 26.7.2016, p. 16).
- (12) Commission Implementing Decision (EU) 2017/1208 of 4 July 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB119 (BCS-GHØØ5-8) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (OJ L 173, 6.7.2017, p. 23).
- (13) Commission Implementing Decision (EU) 2017/2451 of 21 December 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean FG72 × A5547-127, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (OJ L 346, 28.12.2017, p. 20).