

Official Journal of the European Union

L 346



English edition

Legislation

Volume 60

28 December 2017

Contents

II Non-legislative acts

REGULATIONS

- ★ **Commission Implementing Regulation (EU) 2017/2446 of 19 December 2017 amending Implementing Regulation (EU) 2016/1368 establishing a list of critical benchmarks used in financial markets pursuant to Regulation (EU) 2016/1011 of the European Parliament and of the Council ⁽¹⁾** 1
- ★ **Commission Implementing Regulation (EU) 2017/2447 of 20 December 2017 amending Regulation (EC) No 1484/95 as regards fixing representative prices in the poultrymeat and egg sectors and for egg albumin** 4

DECISIONS

- ★ **Commission Implementing Decision (EU) 2017/2448 of 21 December 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 × 40-3-2 (DP-305423-1 × MON-04032-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (notified under document C(2017) 9040) ⁽¹⁾** 6
- ★ **Commission Implementing Decision (EU) 2017/2449 of 21 December 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-68416-4, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (notified under document C(2017) 9041) ⁽¹⁾** 12
- ★ **Commission Implementing Decision (EU) 2017/2450 of 21 December 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-44406-6, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (notified under document C(2017) 9042) ⁽¹⁾** 16

⁽¹⁾ Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

- ★ **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** *(notified under document C(2017) 9043)⁽¹⁾* 20
- ★ **Commission Implementing Decision (EU) 2017/2452 of 21 December 2017 renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council** *(notified under document C(2017) 9044)⁽¹⁾* 25
- ★ **Commission Implementing Decision (EU) 2017/2453 of 21 December 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified oilseed rapes MON 88302 × Ms8 × Rf3 (MON-883Ø2-9 × ACSBNØØ5-8 × ACS-BNØØ3-6), MON 88302 × Ms8 (MON-883Ø2-9 × ACSBNØØ5-8) and MON 88302 × Rf3 (MON-883Ø2-9 × ACS-BNØØ3-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed** *(notified under document C(2017) 9045)⁽¹⁾* 31

⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2446**of 19 December 2017****amending Implementing Regulation (EU) 2016/1368 establishing a list of critical benchmarks used in financial markets pursuant to Regulation (EU) 2016/1011 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/1011 of the European Parliament and of the Council of 8 June 2016 on indices used as benchmarks in financial instruments and financial contracts or to measure the performance of investments funds and amending Directives 2008/48/EC and 2014/17/EU and Regulation (EU) No 596/2014 ⁽¹⁾, and in particular Article 20(1), thereof,

Whereas:

- (1) Benchmarks play an important role in the determination of the price of many financial instruments and financial contracts and of the measurement of performance for many investment funds. The contribution to and administration of benchmarks are in many cases vulnerable to manipulation and persons involved often face conflict of interests.
- (2) In order to fulfil their economic role, benchmarks need to be representative of the underlying market or economic reality they reflect. Should a benchmark no longer be representative of an underlying market, such as interbank offered rates, there is a risk of negative effects on, inter alia, market integrity, the financing of households (loans and mortgages) and businesses in the Union.
- (3) Risks to users, markets and the economy of the Union generally increase where the total value of financial instruments, financial contracts and investment funds referencing a specific benchmark is high. Regulation (EU) 2016/1011 therefore establishes different categories of benchmarks and provides for additional requirements ensuring the integrity and robustness of certain benchmarks considered as being critical, including the power of competent authorities to mandate, under certain conditions, contributions to or the administration of a critical benchmark.
- (4) The additional obligations and powers of competent authorities of administrators of critical benchmarks require a formal process for the determination of critical benchmarks. In accordance with Article 20(1)(a) of Regulation (EU) 2016/1011, a benchmark is considered as being a critical benchmark where it is used directly or indirectly within a combination of benchmarks as a reference for financial instruments or financial contracts or for measuring the performance of investment funds, having a total value of at least EUR 500 billion on the basis of all the ranges of maturities or tenors of the benchmark, where applicable.

⁽¹⁾ OJ L 171, 29.6.2016, p. 1.

- (5) The London Interbank Offered Rate (LIBOR) measures unsecured inter-bank offered rates in five currencies, including the Euro, with seven maturities ranging from overnight to 12 months. It is one of the most important interest rate benchmark worldwide. It is used as the floating rate for many financial contracts, from interest rate swaps to student loans, mortgages and corporate funding instruments.
- (6) The Financial Conduct Authority (FCA) has identified approximately USD 156,8 trillion in over-the-counter derivatives that made a reference to LIBOR in October 2016.
- (7) In addition, the FCA points out that there is significant reference to LIBOR in exchange traded derivatives, bond and corporate debt markets and that these exposures are relevant with regard to systemic risk and the real economy.
- (8) The list of critical benchmarks established by Commission Implementing Regulation (EU) 2016/1368 ⁽¹⁾ should therefore be amended by adding LIBOR.
- (9) In light of the importance of LIBOR for interbank market and the high number of financial instruments in the Union referencing it, this Regulation should enter into force as a matter of urgency.
- (10) In accordance with Article 20(1) of Regulation (EU) 2016/1011, the applicability of this Regulation is dependent on the administrator providing a critical benchmark being located within the Union.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the European Securities Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2016/1368 is replaced by the text in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 19 December 2017.

For the Commission
The President
Jean-Claude JUNCKER

⁽¹⁾ Commission Implementing Regulation (EU) 2016/1368 of 11 August 2016 establishing a list of critical benchmarks used in financial markets pursuant to Regulation (EU) 2016/1011 of the European Parliament and of the Council (OJ L 217, 12.8.2016, p. 1).

ANNEX

List of critical benchmarks pursuant to Article 20(1) of Regulation (EU) 2016/1011

No	Benchmark	Administrator	Location
1	Euro Interbank Offered Rate (EURIBOR®)	European Money Markets Institute (EMMI)	Brussels, Belgium
2	Euro OverNight Index Average (EONIA®)	European Money Markets Institute (EMMI)	Brussels, Belgium
3	London Interbank Offered Rate (LIBOR)	ICE Benchmark Administration (IBA)	London, United Kingdom

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2447**of 20 December 2017****amending Regulation (EC) No 1484/95 as regards fixing representative prices in the poultrymeat and egg sectors and for egg albumin**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ⁽¹⁾, and in particular Article 183(b) thereof,

Having regard to Regulation (EU) No 510/2014 of the European Parliament and of the Council of 16 April 2014 laying down the trade arrangements applicable to certain goods resulting from the processing of agricultural products and repealing Council Regulations (EC) No 1216/2009 and (EC) No 614/2009 ⁽²⁾, and in particular Article 5(6)(a) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1484/95 ⁽³⁾ lays down detailed rules for implementing the system of additional import duties and fixes representative prices in the poultrymeat and egg sectors and for egg albumin.
- (2) Regular monitoring of the data used to determine representative prices for poultrymeat and egg products and for egg albumin shows that the representative import prices for certain products should be amended to take account of variations in price according to origin.
- (3) Regulation (EC) No 1484/95 should therefore be amended accordingly.
- (4) Given the need to ensure that this measure applies as soon as possible after the updated data have been made available, this Regulation should enter into force on the day of its publication,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 1484/95 is replaced by the text set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 December 2017.

*For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General*

Directorate-General for Agriculture and Rural Development

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ OJ L 150, 20.5.2014, p. 1.

⁽³⁾ Commission Regulation (EC) No 1484/95 of 28 June 1995 laying down detailed rules for implementing the system of additional import duties and fixing representative prices in the poultrymeat and egg sectors and for egg albumin, and repealing Regulation No 163/67/EEC (OJ L 145, 29.6.1995, p. 47).

ANNEX

'ANNEX I

CN code	Description	Representative price (EUR/100 kg)	Security under Article 3 (EUR/100 kg)	Origin ⁽¹⁾
0207 12 10	Fowls of the species <i>Gallus domesticus</i> , not cut in pieces, presented as "70 % chickens", frozen	115,7	0	AR
0207 12 90	Fowls of the species <i>Gallus domesticus</i> , not cut in pieces, presented as "65 % chickens", frozen	119,3	0	AR
		163,3	0	BR
0207 14 10	Fowls of the species <i>Gallus domesticus</i> , boneless cuts, frozen	250,6	15	AR
		225,2	22	BR
		303,0	0	CL
		241,5	18	TH
0207 27 10	Turkeys, boneless cuts, frozen	331,5	0	BR
		313,6	0	CL
0408 91 80	Eggs, not in shell, dried	320,6	0	AR
1602 32 11	Preparations of fowls of the species <i>Gallus domesticus</i> , uncooked	217,3	21	BR

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7). The code "ZZ" represents "other origins".

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2017/2448

of 21 December 2017

authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean 305423 × 40-3-2 (DP-305423-1 × MON-04032-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed

(notified under document C(2017) 9040)

(Only the Dutch and French texts are 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 Article 7(3) and Article 19(3) thereof,

Whereas:

- (1) On 20 September 2007, Pioneer Overseas Corporation submitted an application for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from 305423 × 40-3-2 soybean ('the application') to the national competent authority of the Netherlands in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application also covered the placing on the market of genetically modified soybean 305423 × 40-3-2 in products consisting of it or containing it for other uses than food and feed as any other soybean, with the exception of cultivation.
- (2) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾ and the data and information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects set out in Annex VII to that Directive.
- (3) On 18 August 2016, the European Food Safety Authority ('EFSA') gave a favourable opinion ⁽³⁾ in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. EFSA concluded that genetically modified soybean 305423 × 40-3-2, as described in the application, is as safe as the non-genetically modified comparator and other non-genetically modified conventional soybean varieties as regards the potential effects on human and animal health and the environment in the context of the scope of the application.
- (4) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (5) In its opinion, EFSA also concluded that the monitoring plan for environmental effects, consisting of a general surveillance plan submitted by the applicant, is in line with the intended uses of the products.
- (6) In addition, EFSA recommended that a post-market monitoring plan should be implemented, focusing on the collection of consumption data for the population of the Union.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

⁽³⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2016. Scientific Opinion on an application by Pioneer (EFSA-GMO-NL-2007-47) for the placing on the market of the herbicide-tolerant, high-oleic acid, genetically modified soybean 305423 × 40-3-2 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. *EFSA Journal* 2016; 14(8):4566, 31 pp. doi:10.2903/j.efsa.2016.4566.

- (7) Taking into account those considerations, authorisation should be granted to the products containing, consisting of, or produced from genetically modified soybean 305423 × 40-3-2.
- (8) A unique identifier should be assigned to each genetically modified organism ('GMO'), in accordance with Commission Regulation (EC) No 65/2004 ⁽¹⁾.
- (9) Food, food ingredients and feed containing, consisting of, or produced from 305423 × 40-3-2 soybean should be labelled in accordance with the requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003.
- (10) On the basis of the EFSA opinion confirming that fatty acid composition of the seeds of 305423 × 40-3-2 soybean and derived oil has been changed in relation to the conventional counterpart, specific labelling should be included in accordance with Article 13(2)(a) and Article 25(2)(c) of Regulation (EC) No 1829/2003.
- (11) On the basis of the EFSA opinion, no specific labelling requirements, other than those laid down in Article 13(1) and in Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽²⁾, appear necessary for the products covered by this Decision. However, in order to ensure the use of the products within the limits of the authorisation provided for by this Decision, the labelling of products containing or consisting of the GMO for which authorisation is requested, with the exception of food products, should be complemented by a clear indication that the products in question must not be used for cultivation.
- (12) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC ⁽³⁾.
- (13) The EFSA opinion does not justify either the imposition of specific conditions for the protection of particular ecosystems/environments or geographical areas, as provided for in Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.
- (14) The authorisation holder should also submit annual reports on the implementation and the results of the activities set out in the post-market monitoring plan.
- (15) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed, as provided for in Regulation (EC) No 1829/2003.
- (16) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽⁴⁾.
- (17) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified soybean (*Glycine max* (L.) Merr.) 305423 × 40-3-2, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DP-305423-1 × MON-Ø4Ø32-6, as provided for in Regulation (EC) No 65/2004.

⁽¹⁾ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

⁽²⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

⁽³⁾ Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

⁽⁴⁾ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 2***Authorisation**

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of, or produced from DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean;
- (b) feed containing, consisting of, or produced from DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean;
- (c) DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean in products containing it or consisting of it for any other use than those provided in points (a) and (b), with the exception of cultivation.

*Article 3***Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and Article 4(6) of Regulation (EC) No 1830/2003 the 'name of the organism' shall be 'soybean'.
2. For the purposes of the labelling requirements laid down in Article 13(2)(a) and Article 25(2)(c) of Regulation (EC) No 1829/2003, the words 'with increased monounsaturated fat and reduced polyunsaturated fat' shall appear after the name of the organism on the label or, where appropriate, in the documents accompanying the products.
3. The words 'not for cultivation' shall appear on the label of the product and in the documents accompanying products containing or consisting of DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean, with the exception of products referred to in point (a) of Article 2.

*Article 4***Monitoring plan for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
2. The authorisation holder shall submit annual reports on the implementation and the results of the activities set out in the monitoring plan to the Commission in accordance with Decision 2009/770/EC.

*Article 5***Post-market monitoring in accordance with Article 6(5)(e) of Regulation (EC) No 1829/2003**

1. The authorisation holder shall ensure that the post-market monitoring plan of the DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean oil, as set out in point (g) of the Annex, is put in place and implemented.
2. The authorisation holder shall submit annual reports on the implementation and the results of the activities set out in the post-market monitoring plan to the Commission for the duration of the authorisation.

*Article 6***Community register**

The information set out in the Annex shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 7***Authorisation holder**

The authorisation holder shall be Pioneer Overseas Corporation, representing Pioneer Hi-Bred International, Inc., United States.

*Article 8***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 9***Addressee**

This Decision is addressed to Pioneer Overseas Corporation, Avenue des Arts 44, B-1040 Brussels – Belgium.

Done at Brussels, 21 December 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) **Applicant and Authorisation holder:**

Name: Pioneer Overseas Corporation

Address: Avenue des Arts 44, 1040 Brussels - Belgium

On behalf of Pioneer Hi-Bred International, Inc. – 7100 NW 62nd Avenue – P.O. Box 1014 – Johnston, IA 50131-1014 - United States of America.

(b) **Designation and specification of the products:**

- (1) foods and food ingredients containing, consisting of, or produced from DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean;
- (2) feed containing, consisting of, or produced from DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean;
- (3) DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean in products containing it or consisting of it for any other use than those provided in points (1) and (2), with the exception of cultivation.

The genetically modified DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean, as described in the application, has a reduced expression of the soybean enzyme omega-6 desaturase, which results in a high oleic acid and reduced linoleic acid profile, expresses an optimised *Glycine max-hra* gene, which confers tolerance to acetolactate synthase-inhibiting herbicides and expresses the CP4 EPSPS protein which confers tolerance to glyphosate herbicides.

(c) **Labelling:**

- (1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean';
- (2) For the purposes of the labelling requirements laid down in Article 13(2)(a) and Article 25(2)(c) of Regulation (EC) No 1829/2003, the words 'with increased monounsaturated fat and reduced polyunsaturated fat' shall appear after the name of the organism on the label or, where appropriate, in the documents accompanying the products;
- (3) The words 'not for cultivation' shall appear on the label of and in the accompanying documents of the products containing or consisting of DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection:**

- (1) Event specific real-time quantitative PCR based methods for DP-3Ø5423-1 and MON-Ø4Ø32-6 soybeans; the detection methods are validated on the single-trait events and verified on genomic DNA extracted from seeds of DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean;
- (2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>
- (3) Reference Material: ERM-BF426 (for DP-3Ø5423-1) and ERM-BF410 (for MON-Ø4Ø32-6) are accessible via the Joint Research Centre (JRC) of the European Commission at <https://ec.europa.eu/jrc/en/reference-materials/catalogue>

(e) **Unique identifier:**

DP-3Ø5423-1 × MON-Ø4Ø32-6

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: published in the Community register of genetically modified food and feed when notified].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Post-market monitoring in accordance with Article 6(5)(e) of Regulation (EC) No 1829/2003

(1) The authorisation holder shall collect the following information:

- (i) Quantities of DP-3Ø5423-1 × MON-Ø4Ø32-6 soybean oil and DP-3Ø5423-1 × MON-Ø4Ø32-6 soybeans for oil extraction, imported into the European Union for the placing on the market as or in products for food.
- (ii) In case of import of products mentioned under (i), results of database searches in the FAOSTAT database on the quantities of vegetable oil consumption by Member State, including shifts in quantities between the different types of oils consumed.

(2) The authorisation holder shall, based on the information collected and reported, review the nutritional assessment conducted as part of the risk assessment.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the Community register of genetically modified food and feed*]

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

COMMISSION IMPLEMENTING DECISION (EU) 2017/2449**of 21 December 2017****authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-68416-4, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed***(notified under document C(2017) 9041)***(Only the English 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 Article 7(3) and Article 19(3) thereof,

Whereas:

- (1) Regulation (EC) No 1829/2003 lays down authorisation procedures for genetically modified food and feed. On 25 January 2011, Dow AgroSciences Europe submitted an application for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from genetically modified DAS-68416-4 soybean to the national competent authority of the Netherlands in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application also covered the placing on the market of genetically modified soybean DAS-68416-4 in products consisting of it or containing it for other uses than food and feed as any other soybean, with the exception of cultivation.
- (2) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾ and the data and information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.
- (3) On 17 March 2017, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ⁽³⁾. EFSA concluded that genetically modified soybean DAS-68416-4, as described in the application, is as safe and as nutritious as its conventional counterpart and non-genetically modified commercial varieties with regard to potential effects on human and animal health and the environment.
- (4) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (5) In addition, EFSA concluded that the monitoring plan for environmental effects, consisting of a general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.
- (6) Taking into account those considerations, authorisation should be granted to the products containing, consisting of, or produced from genetically modified soybean DAS-68416-4.
- (7) A unique identifier should be assigned to genetically modified soybean DAS-68416-4 in accordance with Commission Regulation (EC) No 65/2004 ⁽⁴⁾.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

⁽³⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2017. Scientific Opinion on an application by Dow AgroSciences LLC (EFSAGMO-NL-2011-91) for the placing on the market of genetically modified herbicide-tolerant soybean DAS-68416-4 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. *EFSA Journal* 2017;15(2):4719, 31 pp. doi:10.2903/j.efsa.2017.4719.

⁽⁴⁾ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

- (8) On the basis of the EFSA opinion, no specific labelling requirements, other than those laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽¹⁾, appear to be necessary for the products covered by this Decision. However, in order to ensure the use of those products within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of soybean DAS-68416-4, with the exception of food products, should be complemented by a clear indication that the products in question are not intended for cultivation.
- (9) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC ⁽²⁾.
- (10) The EFSA opinion does not justify the imposition of specific conditions for the protection of particular ecosystems/environments and geographical areas, as provided for in Article 6(5)(e) and Article 18(5) of Regulation (EC) No 1829/2003.
- (11) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed as provided for in Regulation (EC) No 1829/2003.
- (12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽³⁾.
- (13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified soybean (*Glycine max* (L.) Merr.) DAS-68416-4, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DAS-68416-4, in accordance with Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of, or produced from soybean DAS-68416-4;
- (b) feed containing, consisting of, or produced from soybean DAS-68416-4;
- (c) soybean DAS-68416-4 in products containing it or consisting of it for any other use than those provided in points (a) and (b), with the exception of cultivation.

⁽¹⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

⁽²⁾ Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

⁽³⁾ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 3***Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean'.
2. The words 'not for cultivation' shall appear on the label of the product and in the documents accompanying products containing or consisting of genetically modified soybean DAS-68416-4, with the exception of products referred to in Article 2(a).

*Article 4***Monitoring plan for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
2. The authorisation holder shall submit annual reports on the implementation and the results of the activities set out in the monitoring plan to the Commission in accordance with Decision 2009/770/EC.

*Article 5***Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of soybean DAS-68416-4.

*Article 6***Community register**

The information set out in the Annex shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 7***Authorisation holder**

The authorisation holder shall be Dow AgroSciences Europe on behalf of Dow AgroSciences LLC.

*Article 8***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 9***Addressee**

This Decision is addressed to Dow AgroSciences Europe, European Development Centre, 3 Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom.

Done at Brussels, 21 December 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) **Authorisation holder:**

Name: Dow AgroSciences Europe

Address: European Development Centre, 3 Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom.

On behalf of

Dow AgroSciences LLC, 9330 Zionsville Road Indianapolis, Indiana 46268-1054, USA

(b) **Designation and specification of the products:**

(1) foods and food ingredients containing, consisting of, or produced from soybean DAS-68416-4;

(2) feed containing, consisting of, or produced from soybean DAS-68416-4;

(3) soybean DAS-68416-4 in products containing it or consisting of it for any other use than those provided in points (1) and (2), with the exception of cultivation.

DAS-68416-4 soybean expresses the AAD-12 protein, which confers tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and other related phenoxy herbicides, and the PAT protein, which confers tolerance to glufosinate ammonium-based herbicides.

(c) **Labelling:**

(1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean';

(2) The words 'not for cultivation' shall appear on the label of the products and in the accompanying documents of the products containing or consisting of soybean DAS-68416-4 with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection:**

(1) Event specific real-time quantitative PCR based method for DAS-68416-4 soybean; the detection method is validated on the single-trait event using genomic DNA extracted from seeds of DAS-68416-4 soybean;

(2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>

(3) Reference Material: ERM®-BF432 accessible via the Joint Research Centre (JRC) of the European Commission at <https://crm.jrc.ec.europa.eu/>.

(e) **Unique identifier:**

DAS-68416-4;

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post market monitoring requirements for the use of the food for human consumption**

Not required.

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

COMMISSION IMPLEMENTING DECISION (EU) 2017/2450**of 21 December 2017****authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-44406-6, pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed***(notified under document C(2017) 9042)***(Only the English 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 Article 7(3) and Article 19(3) thereof,

Whereas:

- (1) Regulation (EC) No 1829/2003 lays down authorisation procedures for genetically modified food and feed. On 16 February 2012, Dow AgroSciences LLC and M.S. Technologies LLC submitted an application for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from genetically modified soybean DAS-44406-6 to the national competent authority of the Netherlands in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application also covered the placing on the market of genetically modified soybean DAS-44406-6 in products consisting of it or containing it for other uses than food and feed as any other soybean, with the exception of cultivation.
- (2) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the environmental risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾ and the data and information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.
- (3) On 21 March 2017, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ⁽³⁾. EFSA concluded that genetically modified soybean DAS-44406-6, as described in the application, is as safe and nutritious as its conventional counterpart and non-genetically modified reference varieties with respect to potential effects on human and animal health and the environment.
- (4) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (5) In addition, EFSA also concluded that the monitoring plan for environmental effects, consisting of a general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.
- (6) Taking into account those considerations, the placing on the market of products containing, consisting of, or produced from genetically modified soybean DAS-44406-6 for the uses listed in the application should be authorised.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.⁽²⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).⁽³⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2017. Scientific opinion on an application by Dow AgroSciences LLC (EFSAGMO-NL-2012-106) for the placing on the market of genetically modified herbicide-tolerant soybean DAS-44406-6 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. *EFSA Journal* 2017;15(3):4738, 33 pp. doi:10.2903/j.efsa.2017.4738.

- (7) A unique identifier should be assigned to genetically modified soybean DAS-44406-6 in accordance with Commission Regulation (EC) No 65/2004 ⁽¹⁾.
- (8) On the basis of the EFSA opinion, no specific labelling requirements, other than those laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽²⁾, appear to be necessary for the products covered by this Decision. However, in order to ensure the use of those products within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of genetically modified soybean DAS-44406-6, with the exception of food products, should be complemented by a clear indication that the products in question are not intended for cultivation.
- (9) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC ⁽³⁾.
- (10) The EFSA opinion does not justify the imposition of specific conditions for the protection of particular ecosystems/environments and geographical areas, as provided for in Article 6(5)(e) and Article 18(5) of Regulation (EC) No 1829/2003.
- (11) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed as provided for in Regulation (EC) No 1829/2003.
- (12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽⁴⁾.
- (13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified soybean (*Glycine max* (L.) Merr.) DAS-44406-6 (hereinafter “soybean DAS-44406-6”), as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DAS-44406-6, in accordance with Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of, or produced from soybean DAS-44406-6;
- (b) feed containing, consisting of, or produced from soybean DAS-44406-6;
- (c) soybean DAS-44406-6 in products containing it or consisting of it for any other use than those provided in points (a) and (b), with the exception of cultivation.

⁽¹⁾ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

⁽²⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

⁽³⁾ Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

⁽⁴⁾ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

*Article 3***Labelling**

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean'.
2. The words 'not for cultivation' shall appear on the label of the product and in the documents accompanying products containing or consisting of soybean DAS-44406-6, with the exception of foods and food ingredients.

*Article 4***Monitoring plan for environmental effects**

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
2. The authorisation holder shall submit annual reports on the implementation and the results of the activities set out in the monitoring plan to the Commission in accordance with Decision 2009/770/EC.

*Article 5***Method for detection**

The method set out in point (d) of the Annex shall apply for the detection of soybean DAS-44406-6.

*Article 6***Community register**

The information set out in the Annex shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

*Article 7***Authorisation holder**

The authorisation holder shall be Dow AgroSciences Europe, United Kingdom, representing Dow AgroSciences LLC, United States, and M.S. Technologies LLC, United States.

*Article 8***Validity**

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 9***Addressee**

This Decision is addressed to Dow AgroSciences Europe, European Development Centre, 3 Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom.

Done at Brussels, 21 December 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) **Authorisation holder:**

Name: Dow AgroSciences Europe

Address: European Development Centre, 3 Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom.

On behalf of

Dow AgroSciences LLC, 9330 Zionsville Road Indianapolis, Indiana 46268-1054, USA and

M.S. Technologies LLC, 103 Avenue D West Point, IA 52656, USA

(b) **Designation and specification of the products:**

(1) foods and food ingredients containing, consisting of, or produced from soybean DAS-44406-6;

(2) feed containing, consisting of, or produced from soybean DAS-44406-6;

(3) soybean DAS-44406-6 in products containing it or consisting of it for any other use than those provided in points (1) and (2), with the exception of cultivation.

Soybean DAS-44406-6 expresses the 2mEPSPS protein, which confers tolerance to glyphosate-based herbicides, the AAD-12 protein, which confers tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and other related phenoxy herbicides, and the PAT protein, which confers tolerance to glufosinate ammonium-based herbicides.

(c) **Labelling:**

(1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean';

(2) The words 'not for cultivation' shall appear on the label of and in the accompanying documents of the products containing or consisting of soybean DAS-44406-6, with the exception of foods and food ingredients.

(d) **Method for detection:**

(1) Event specific real-time quantitative PCR based method for DAS-44406-6 soybean; the detection method is validated on the single-trait event using genomic DNA extracted from seeds of DAS-44406-6 soybean;

(2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu>;

(3) Reference Material: ERM®-BF436 accessible via the Joint Research Centre (JRC) of the European Commission.

(e) **Unique identifier:**

DAS-44406-6.

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post market monitoring requirements for the use of the food for human consumption**

Not required.

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

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***(notified under document C(2017) 9043)***(Only the Dutch and French texts are 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 Article 7(3) and Article 19(3) thereof,

Whereas:

- (1) Regulation (EC) No 1829/2003 lays down authorisation procedures for genetically modified food and feed. On 10 December 2013, Bayer CropScience LP and M.S. Technologies, LLC submitted to the national competent authority of the Netherlands, in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003, an application for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from genetically modified soybean FG72 × A5547-127. The application also covered the placing on the market of genetically modified soybean FG72 × A5547-127 in products consisting of it or containing it for other uses than food and feed as any other soybean, with the exception of cultivation.
- (2) In accordance with Article 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the environmental risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾ and the data and information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.
- (3) On 6 April 2017, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. EFSA concluded that genetically modified soybean FG72 × A5547-127, as described in the application, is as safe as the non-genetically modified comparator and non-genetically modified soybean reference varieties with respect to potential effects on human and animal health and the environment in the context of its intended uses ⁽³⁾. However, the EFSA GMO Panel could not conclude on the use of forage from genetically modified soybean FG72 × A5547-127 as or in feed, as no compositional data on forage was submitted by the applicants. That use should therefore be excluded from the scope of this authorisation. Since forage is usually used where the cultivation takes place, no import is expected thereof in the Union and the exclusion of forage from the scope of the authorisation does not need to be accompanied by further measures.
- (4) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (5) In addition, EFSA also concluded that the monitoring plan for environmental effects, consisting of a general surveillance plan, submitted by the applicants, is in line with the intended uses of the products.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

⁽³⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2017. Scientific opinion on application EFSA-GMO-NL-2013-120 for authorisation of genetically modified soybean FG72 × A5547-127 for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Bayer CropScience LP and M.S. Technologies LLC. *EFSA Journal* 2017;15(4):4744, 23 pp. doi:10.2903/j.efsa.2017.4744

- (6) Taking into account those considerations, the placing on the market of products containing, consisting of, or produced from genetically modified soybean FG72 × A5547-127 for the uses listed in the application, with the exception of the use of forage as or in feed, should be authorised.
- (7) A unique identifier should be assigned to genetically modified soybean FG72 × A5547-127 in accordance with Commission Regulation (EC) No 65/2004 ⁽¹⁾.
- (8) On the basis of the EFSA opinion, no specific labelling requirements, other than those laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽²⁾, appear to be necessary for the products covered by this Decision. However, in order to ensure the use of those products within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of genetically modified soybean FG72 × A5547-127, with the exception of food products, should contain a clear indication that the products in question are not intended for cultivation.
- (9) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC ⁽³⁾.
- (10) The EFSA opinion does not justify the imposition of specific conditions for the protection of particular ecosystems/environments and geographical areas, as provided for in Article 6(5)(e) and Article 18(5) of Regulation (EC) No 1829/2003.
- (11) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed as provided for in Regulation (EC) No 1829/2003.
- (12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Article 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽⁴⁾.
- (13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified soybean (*Glycine max* (L.) Merr.) FG72 × A5547-127 (hereinafter 'soybean FG72 × A5547-127'), as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MST-FGØ72-2 × ACS-GMØØ6-4, in accordance with Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of, or produced from soybean FG72 × A5547-127;

⁽¹⁾ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

⁽²⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

⁽³⁾ Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

⁽⁴⁾ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

- (b) feed containing, consisting of, or produced from soybean FG72 × A5547-127 with the exception of forage;
- (c) soybean FG72 × A5547-127, in products containing it or consisting of it for any other use than those provided in points (a) and (b), with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean'.
2. The words 'not for cultivation' shall appear on the label of the product and in the documents accompanying products containing or consisting of soybean FG72 × A5547-127, with the exception of foods and food ingredients.

Article 4

Monitoring plan for environmental effects

1. The authorisation holder shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
2. The authorisation holder shall submit annual reports on the implementation and the results of the activities set out in the monitoring plan to the Commission in accordance with Decision 2009/770/EC.

Article 5

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of soybean FG72 × A5547-127.

Article 6

Community register

The information set out in the Annex shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

Article 7

Authorisation holder

The authorisation holder shall be Bayer CropScience N.V., Belgium, representing Bayer CropScience LP, United States, and M.S. Technologies, LLC, United States.

Article 8

Validity

This Decision shall apply for a period of 10 years from the date of its notification.

Article 9

Addressee

This Decision is addressed to Bayer CropScience N.V., J.E. Mommaertsiaan 14, 1831 Diegem, Belgium.

Done at Brussels, 21 December 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) **Applicant and Authorisation holder:**

Name: Bayer CropScience N.V.

Address: J.E. Mommaertslaan 14, 1831 Diegem, Belgium

On behalf of

Bayer CropScience LP, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, RTP - North Carolina 27709, USA

and

M.S. Technologies, LLC, 103 Avenue D, West Point, Iowa 52656, USA

(b) **Designation and specification of the products:**

- (1) foods and food ingredients containing, consisting of, or produced from soybean FG72 × A5547-127;
- (2) feed containing, consisting of, or produced from soybean FG72 × A5547-127, with the exception of forage;
- (3) soybean FG72 × A5547-127 in products containing it or consisting of it for any other use than those provided in points (1) and (2), with the exception of cultivation.

Soybean FG72 × A5547-127, as described in the application, expresses the PAT protein, which confers tolerance to glufosinate ammonium-based herbicides, the 2mEPSPS protein, which confers tolerance to glyphosate-based herbicides and the HPPD W336 protein, which confers tolerance to isoxaflutole.

(c) **Labelling:**

- (1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'soybean';
- (2) The words 'not for cultivation' shall appear on the label of and in the accompanying documents of the products containing or consisting the soybeans specified in (e) with the exception of foods and food ingredients.

(d) **Method for detection:**

- (1) A PCR detection method for soybean FG72 × A5547-127 has been developed. The detection method for soybean FG72 × A5547-127 is based on the validated detection methods that are available for genetically modified soybeans FG72 and A5547-127 (<http://gmo-crl.jrc.ec.europa.eu/gmomethods/>).
- (2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/>.
- (3) Reference Material: Certified reference material for genetically modified soybean FG72 and genetically modified soybean A5547-127 is available at the American Oil Chemists' Society (AOCS): <http://aocs.igx.rdn.net/crm#soybean>, with the respective product code 0610-A3 and 0707-C5.

(e) **Unique identifier:**

MST-FGØ72-2 × ACS-GMØØ6-4.

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post market monitoring requirements for the use of the food for human consumption**

Not required.

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

COMMISSION IMPLEMENTING DECISION (EU) 2017/2452**of 21 December 2017****renewing the authorisation for the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2017) 9044)***(Only the Dutch, English and French texts are 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 Articles 11(3) and 23(3) thereof,

Whereas:

- (1) On 27 February 2015, Pioneer Overseas Corporation and Dow AgroSciences Ltd jointly submitted to the Commission an application, in accordance with Article 11 and Article 23 of Regulation (EC) No 1829/2003, for renewal of the authorisation for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from genetically modified maize 1507 (hereinafter 'maize 1507'). The scope of the renewal application also covers products other than food and feed containing or consisting of maize 1507. The scope of the application does not include cultivation.
- (2) The placing on the market of the products covered by the scope of the renewal application was previously authorised by two separate decisions: Commission Decision 2005/772/EC ⁽²⁾ and Commission Decision 2006/197/EC ⁽³⁾.
- (3) On 12 January 2017, the European Food Safety Authority ('EFSA') issued a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. Based on the data provided, it concluded ⁽⁴⁾ that no new hazards or modified exposure and no new scientific uncertainties were identified for the application for renewal that would change the conclusions of the original risk assessment ⁽⁵⁾ on maize 1507.
- (4) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003.
- (5) EFSA also concluded that the monitoring plan for environmental effects, consisting of a general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Decision 2005/772/EC of 3 November 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (*Zea mays* L., line 1507) genetically modified for resistance to certain lepidopteran pests and for tolerance to the herbicide glufosinate-ammonium (OJ L 291, 5.11.2005, p. 42).

⁽³⁾ Commission Decision 2006/197/EC of 3 March 2006 authorising the placing on the market of food containing, consisting of, or produced from genetically modified maize line 1507 (DAS-Ø15Ø7-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 70, 9.3.2006, p. 82).

⁽⁴⁾ Scientific opinion on an application for renewal of authorisation for continued marketing of maize 1507 and derived food and feed submitted under Articles 11 and 23 of Regulation (EC) No 1829/2003 by Pioneer Overseas Corporation and Dow AgroSciences LLC. *The EFSA Journal* (2017); 15(1):4659.

⁽⁵⁾ Opinion of the Scientific Panel on Genetically Modified Organisms on an application for the placing on the market of insect-tolerant genetically modified maize 1507, for food use, under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred International/Mycogen Seeds. *EFSA Journal* (2005) 182, 1-22; and Scientific Opinion of the Panel on Genetically Modified Organisms on Application (EFSA-GMO-RX-1507) for renewal of authorisation for the continued marketing of existing products produced from maize 1507 for feed use, under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred International, Inc./Mycogen Seeds. *EFSA Journal* (2009) 1138, 1-11.

- (6) Taking into account those considerations, the authorisation for the placing on the market of food and feed containing, consisting of, or produced from maize 1507 and of products consisting of it or containing it for other uses than food or feed, with the exception of cultivation, should be renewed.
- (7) A unique identifier has been assigned to genetically modified maize 1507, in accordance with Commission Regulation (EC) No 65/2004 ⁽¹⁾, by Decision 2005/772/EC. That unique identifier should continue to be used.
- (8) On the basis of the abovementioned EFSA opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽²⁾, appear to be necessary for the products covered by this Decision. However, in order to ensure the use of those products remains within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of maize 1507, with the exception of food products, should contain a clear indication that the products in question are not intended for cultivation. Since an application for the authorisation for the placing on the market of maize 1507 seeds for cultivation is pending, this labelling requirement should only apply until that authorisation is granted.
- (9) The authorisation holders should submit joint annual reports on the implementation and the results of the activities set out in the monitoring plan. These results should be presented in accordance with Commission Decision 2009/770/EC ⁽³⁾.
- (10) The EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or the use and handling of the food and feed, including post-market monitoring requirements.
- (11) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed referred to in Regulation (EC) No 1829/2003.
- (12) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Articles 9(1) and 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽⁴⁾.
- (13) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified maize (*Zea mays* L.) line 1507, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DAS-Ø15Ø7-1, in accordance with Regulation (EC) No 65/2004.

Article 2

Renewal of authorisation

The authorisation for the placing on the market of the following products is renewed in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of or produced from maize 1507;

⁽¹⁾ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

⁽²⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

⁽³⁾ Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

⁽⁴⁾ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

- (b) feed containing, consisting of or produced from maize 1507;
- (c) maize 1507 in products containing it or consisting of it for any other use than those provided for in points (a) and (b), with the exception of cultivation.

Article 3

Labelling

1. For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
2. The words 'not for cultivation' shall appear either on a label or in a document accompanying the products containing or consisting of maize 1507, with the exception of food and food ingredients.

This requirement shall apply until the placing on the market of maize 1507 seeds for the purpose of cultivation is authorised.

Article 4

Method of detection

The method set out in point (d) of the Annex shall apply for the detection of maize 1507.

Article 5

Monitoring for environmental effects

1. The authorisation holders shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex to this Decision is put in place and implemented.
2. The authorisation holders shall submit to the Commission joint annual reports on the implementation and the results of the activities set out in the monitoring plan in accordance with Decision 2009/770/EC.

Article 6

Community register

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed referred to in Article 28 of Regulation (EC) No 1829/2003.

Article 7

Authorisation holders

1. The authorisation holders shall be:
 - (a) Pioneer Overseas Corporation, Belgium, representing Pioneer Hi-Bred International, Inc., United States, and
 - (b) Dow AgroSciences Ltd, United Kingdom, representing Dow AgroSciences LLC, United States.
2. Both authorisation holders shall be responsible for fulfilling the duties imposed on authorisation holders by this Decision and Regulation (EC) No 1829/2003.

Article 8

Validity

This Decision shall apply for a period of 10 years from the date of its notification.

*Article 9***Addressee**

This Decision is addressed to:

- (a) Pioneer Overseas Corporation, Avenue des Arts 44, B-1040 Brussels — Belgium, and
- (b) Dow AgroSciences Europe Ltd., European Development Center, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN — United Kingdom.

Done at Brussels, 21 December 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) **Applicants and Authorisation holders:**

Name: Pioneer Overseas Corporation

Address: Avenue des Arts 44, B-1040 Brussels, Belgium

On behalf of Pioneer Hi-Bred International, Inc., 7100 NW 62nd Avenue, P.O. Box 1014, Johnston, IA 50131-1014, United States

and

Name: Dow AgroSciences Europe Ltd.

Address: European Development Center, 3B Park Square, Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom

On behalf of Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268-1054, United States

(b) **Designation and specification of the products:**

- (1) foods and food ingredients containing, consisting of, or produced from maize 1507;
- (2) feed containing, consisting of, or produced from maize 1507;
- (3) maize 1507 in products containing it or consisting of it for any other use than those provided for in points (1) and (2), with the exception of cultivation.

Maize 1507, as described in the application, expresses the Cry1F protein, derived from *Bacillus thuringiensis* subsp. *aizawai*, which confers resistance to the European corn borer (*Ostrinia nubilalis*) and certain other lepidopteran pests, and the PAT protein, derived from *Streptomyces viridochromogenes* strain Tü494, which confers tolerance to the herbicide glufosinate-ammonium.

(c) **Labelling:**

- (1) For the purposes of the labelling requirements laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'maize'.
- (2) The words 'not for cultivation' shall appear either on a label or in a document accompanying the products containing or consisting of maize 1507, with the exception of food and food ingredients.

This requirement shall apply until the placing on the market of maize 1507 seeds for the purpose of cultivation is authorised.

(d) **Method for detection:**

- (1) Event specific real-time quantitative PCR based method for detection of the genetically modified maize DAS-Ø15Ø7-1.
- (2) Validated by the Community reference laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/StatusOfDossiers.aspx>
- (3) Reference Material: ERM®-BF418 (for DAS-Ø15Ø7-1) is accessible via the Joint Research Centre (JRC) of the European Commission at <https://ec.europa.eu/jrc/en/reference-materials/catalogue/>

(e) **Unique identifier:**

DAS-Ø15Ø7-1

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: published in the Community register of genetically modified food and feed when notified].

(g) **Conditions or restrictions on the placing on the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post-market monitoring requirements for the use of the food for human consumption:**

Not required.

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

COMMISSION IMPLEMENTING DECISION (EU) 2017/2453

of 21 December 2017

authorising the placing on the market of products containing, consisting of, or produced from genetically modified oilseed rapes MON 88302 × Ms8 × Rf3 (MON-88302-9 × ACSBN005-8 × ACS-BN003-6), MON 88302 × Ms8 (MON-88302-9 × ACSBN005-8) and MON 88302 × Rf3 (MON-88302-9 × ACS-BN003-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed

*(notified under document C(2017) 9045)***(Only the Dutch and French texts are 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 Articles 7(3) and 19(3) thereof,

Whereas:

- (1) On 3 December 2013, Monsanto Europe S.A. and Bayer CropScience N.V. submitted an application for the placing on the market of foods, food ingredients and feed containing, consisting of, or produced from genetically modified oilseed rape MON 88302 × Ms8 × Rf3 to the national competent authority of the Netherlands in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003. The application also covered the placing on the market of genetically modified oilseed rape MON 88302 × Ms8 × Rf3 in products consisting of it or containing it for other uses than food and feed as any other oilseed rape, with the exception of cultivation. The application covered, for those uses, all sub-combinations of the single genetic modification events constituting oilseed rape MON 88302 × Ms8 × Rf3.
- (2) In accordance with Articles 5(5) and Article 17(5) of Regulation (EC) No 1829/2003, the application included information and conclusions about the environmental risk assessment carried out in accordance with the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council ⁽²⁾ and the data and information required by Annexes III and IV to that Directive. It also included a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.
- (3) On 10 April 2017, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ⁽³⁾. EFSA concluded that genetically modified oilseed rape MON 88302 × Ms8 × Rf3, as described in the application, is as safe and nutritious as its conventional counterpart and non-genetically modified reference varieties as respect to potential effects on human and animal health and the environment, and no safety concerns were identified for the sub-combinations covered by the scope of the application.
- (4) On 23 May 2017, Monsanto Europe S.A. and Bayer CropScience N.V. updated the scope of the application by excluding the sub-combination Ms8 × Rf3, which is already authorised by Commission Decision 2007/232/EC ⁽⁴⁾ and Commission Implementing Decision 2013/327/EU ⁽⁵⁾.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

⁽³⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2017. Scientific Opinion on application EFSA-GMO-NL-2013-119 for authorisation of genetically modified glufosinate-ammonium- and glyphosate-tolerant oilseed rape MON 88302 × MS8 × RF3 and subcombinations independently of their origin, for food and feed uses, import and processing submitted in accordance with Regulation (EC) No 1829/2003 by Monsanto Company and Bayer CropScience. *EFSA Journal* 2017;15(4):4767, 25 pp. doi:10.2903/j.efsa.2017.4767.

⁽⁴⁾ Commission Decision 2007/232/EC of 26 March 2007 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of oilseed rape products (*Brassica napus* L., lines Ms8, Rf3 and Ms8 × Rf3) genetically modified for tolerance to the herbicide glufosinate-ammonium (OJ L 100, 17.4.2007, p. 20).

⁽⁵⁾ 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).

- (5) In its opinion, EFSA considered all the specific questions and concerns raised by the Member States in the context of the consultation of the national competent authorities as provided for by Articles 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (6) EFSA also concluded that the monitoring plan for environmental effects, consisting of a general surveillance plan, submitted by the applicant, is in line with the intended uses of the products.
- (7) Taking into account those considerations, the placing on the market of products containing, consisting of, or produced from genetically modified oilseed rapes MON 88302 × Ms8 × Rf3, MON 88302 × Ms8 and MON 88302 × Rf3, for the uses listed in the application should be authorised.
- (8) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') in accordance with Commission Regulation (EC) No 65/2004 ⁽¹⁾.
- (9) On the basis of the EFSA opinion, no specific labelling requirements, other than those laid down in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003 of the European Parliament and of the Council ⁽²⁾, appear to be necessary for the products covered by this Decision. However, in order to ensure the use of those products within the limits of the authorisation granted by this Decision, the labelling of the products containing or consisting of genetically modified oilseed rapes MON 88302 × Ms8 × Rf3, MON 88302 × Ms8 and MON 88302 × Rf3, with the exception of food products, should be complemented by a clear indication that the products in question are not intended for cultivation.
- (10) The authorisation holders should submit annual reports on the implementation and the results of the activities set out in the monitoring plan for environmental effects. Those results should be presented in accordance with the standard reporting format requirements laid down in Commission Decision 2009/770/EC ⁽³⁾.
- (11) The EFSA opinion does not justify the imposition of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in point (e) of Article 6(5) and Article 18(5) of Regulation (EC) No 1829/2003.
- (12) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed as provided for in Regulation (EC) No 1829/2003.
- (13) This Decision is to be notified through the Biosafety Clearing-House to the Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, pursuant to Articles 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽⁴⁾.
- (14) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time limit laid down by its Chairman. This implementing act was deemed to be necessary and the chair submitted it to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

1. The following unique identifiers for genetically modified organisms (GMOs) are assigned in accordance with Regulation (EC) No 65/2004:

- (a) the unique identifier MON-88302-9 × ACS-BN005-8 × ACS-BN003-6 for genetically modified oilseed rape (*Brassica napus* L.) MON 88302 × Ms8 × Rf3;

⁽¹⁾ Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms (OJ L 10, 16.1.2004, p. 5).

⁽²⁾ Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p. 24).

⁽³⁾ Commission Decision 2009/770/EC of 13 October 2009 establishing standard reporting formats for presenting the monitoring results of the deliberate release into the environment of genetically modified organisms, as or in products, for the purpose of placing on the market, pursuant to Directive 2001/18/EC of the European Parliament and of the Council (OJ L 275, 21.10.2009, p. 9).

⁽⁴⁾ Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p. 1).

- (b) the unique identifier MON-88302-9 × ACS-BN005-8, for genetically modified oilseed rape (*Brassica napus* L.) MON 88302 × Ms8;
 - (c) the unique identifier MON-88302-9 × ACS-BN003-6 for genetically modified oilseed rape (*Brassica napus* L.) MON 88302 × Rf3.
2. The genetically modified oilseed rapes referred to in paragraph 1 are specified in point (b) of the Annex.

Article 2

Authorisation

The following products are authorised for the purposes of Article 4(2) and Article 16(2) of Regulation (EC) No 1829/2003 in accordance with the conditions set out in this Decision:

- (a) foods and food ingredients containing, consisting of, or produced from the GMOs referred to in Article 1(1);
- (b) feed containing, consisting of, or produced from the GMOs referred to in Article 1(1);
- (c) GMOs referred to in Article 1(1) in products containing them or consisting of them for any other use than those provided in points (a) and (b), with the exception of cultivation.

Article 3

Labelling

- 1. For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'oilseed rape'.
- 2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of the GMOs referred to in Article 1(1), with the exception of foods and food ingredients.

Article 4

Method for detection

The method set out in point (d) of the Annex shall apply for the detection of genetically modified oilseed rapes MON 88302 × Ms8 × Rf3, MON 88302 × Ms8 and MON 88302 × Rf3.

Article 5

Monitoring for environmental effects

- 1. The authorisation holders shall ensure that the monitoring plan for environmental effects, as set out in point (h) of the Annex, is put in place and implemented.
- 2. The authorisation holders shall submit joint annual reports on the implementation and the results of the activities set out in the monitoring plan to the Commission in accordance with Decision 2009/770/EC.

Article 6

Community register

The information set out in the Annex to this Decision shall be entered in the Community register of genetically modified food and feed, as provided for in Article 28 of Regulation (EC) No 1829/2003.

Article 7

Authorisation holders

- 1. The authorisation holders shall be:
 - (a) Monsanto Europe S.A., Belgium, representing Monsanto Company, United States;
 - and
 - (b) Bayer CropScience N.V., Belgium, representing Bayer CropScience LP, United States.

2. Both authorisation holders shall be responsible for fulfilling the duties imposed on authorisation holders by this Decision and Regulation (EC) No 1829/2003.

Article 8

Validity

This Decision shall apply for a period of 10 years from the date of its notification.

Article 9

Addressee

This Decision is addressed to:

(a) Monsanto Europe S.A., Avenue de Tervuren 270-272, B-1150 Brussels, Belgium;

and

(b) Bayer CropScience N.V., J.E. Mommaertslaan 14, 1831, Diegem, Belgium.

Done at Brussels, 21 December 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) **Authorisation holders:**

- (1) Name: Monsanto Europe S.A.

Address: Avenue de Tervuren 270-272, B-1150 Brussels, Belgium.

On behalf of

Monsanto Company, 800 N. Lindbergh Boulevard, St Louis, Missouri, 63167, United States;

and

- (2) Name: Bayer CropScience N.V.

Address: J.E. Mommaertsiaan 14, 1831, Diegem, Belgium.

On behalf of

Bayer CropScience LP, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, RTP, North Carolina 27709, United States.

(b) **Designation and specification of the products:**

- (1) foods and food ingredients containing, consisting of, or produced from genetically modified oilseed rapes (*Brassica napus* L.) as specified in (e);
- (2) feed containing, consisting of, or produced from genetically modified oilseed rapes (*Brassica napus* L.) as specified in (e);
- (3) genetically modified oilseed rapes (*Brassica napus* L.) as specified in (e) in products containing them or consisting of them for any other use than those provided in points (1) and (2), with the exception of cultivation.

MON-883Ø2-9 oilseed rape expresses the CP4 EPSPS protein, which confers tolerance to glyphosate-based herbicides;

ACS-BNØØ5-8 oilseed rape expresses the barnase protein and the PAT protein, which confers tolerance to glufosinate ammonium-based herbicides;

ACS-BNØØ3-6 oilseed rape expresses the barstar protein and PAT protein, which confers tolerance to glufosinate ammonium-based herbicides.

The expression of barnase and barstar proteins from *Bacillus amyloliquefaciens* constitutes the basis of a male fertility control system, through the use of the barnase gene, which removes male fertility in order to promote hybridisation, and the barstar gene which restores male fertility with oilseed rape lines ACS-BNØØ5-8 and ACS-BNØØ3-6 for obtaining heterosis (hybrid vigour).

(c) **Labelling:**

- (1) For the purposes of the labelling requirements laid down in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, and in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'oilseed rape';
- (2) The words 'not for cultivation' shall appear on the label of and in the accompanying documents of the products containing or consisting the oilseed rapes specified in (e), with the exception of foods and food ingredients.

(d) **Method for detection:**

- (1) Event specific real-time quantitative PCR based methods for MON-883Ø2-9, ACSBNØØ5-8 and ACS-BNØØ3-6 oilseed rapes; the detection methods are validated on the single events and verified on genomic DNA extracted from seeds of MON-883Ø2-9 × ACSBNØØ5-8 × ACS-BNØØ3-6 oilseed rape;
- (2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>;
- (3) Reference Material: AOCS 1011-A (for MON-883Ø2-9), AOCS 0306-F6 (for ACSBNØØ5-8) and AOCS 0306-G5 (for ACS-BNØØ3-6) accessible via the American Oil Chemists Society at <http://www.aocs.org/LabServices/content.cfm?ItemNumber=19248>.

(e) **Unique identifiers:**

MON-883Ø2-9 × ACSBNØØ5-8 × ACS-BNØØ3-6;

MON-883Ø2-9 × ACSBNØØ5-8;

MON-883Ø2-9 × ACS-BNØØ3-6.

(f) **Information required under Annex II to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity:**

[Biosafety Clearing-House, Record ID number: *published in the Community register of genetically modified food and feed when notified*].

(g) **Conditions or restrictions on the placing of the market, use or handling of the products:**

Not required.

(h) **Monitoring plan for environmental effects:**

Monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

[Link: *plan published in the Community register of genetically modified food and feed*]

(i) **Post market monitoring requirements for the use of the food for human consumption**

Not required.

Note: links to relevant documents may need to be modified over the time. Those modifications will be made available to the public via the updating of the Community register of genetically modified food and feed.

