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Contents

[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.

DECISIONS

[1] Text with EEA relevance

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

COUNCIL DECISION (EU) 2016/1210

of 18 July 2016

on the conclusion of a Protocol to the Partnership and Cooperation Agreement between the European Communities and their Member States, of the one part, and the Republic of Azerbaijan, of the other part, on a Framework Agreement between the European Union and the Republic of Azerbaijan on the general principles for the participation of the Republic of Azerbaijan in Union programmes

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 212, in conjunction with point (a) of the second subparagraph of Article 218(6) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament ([1]),

Whereas:

(1) The Protocol to the Partnership and Cooperation Agreement between the European Communities and their Member States, of the one part, and the Republic of Azerbaijan, of the other part, on a Framework Agreement between the European Union and the Republic of Azerbaijan on the general principles for the participation of the Republic of Azerbaijan in Union programmes ('the Protocol') was signed on behalf of the Union on 14 June 2014.

(2) The objective of the Protocol is to lay down the financial and technical rules enabling the Republic of Azerbaijan to participate in certain Union programmes. The horizontal framework established by the Protocol constitutes an economic, financial and technical cooperation measure which allows for access to assistance, in particular financial assistance, to be provided by the Union pursuant to those Union programmes. That framework applies only to those Union programmes for which the relevant constitutive legal acts provide for the possibility of the participation of the Republic of Azerbaijan. The conclusion of the Protocol therefore does not entail the exercise of powers under the various sectoral policies pursued by the programmes, which are exercised when establishing the programmes.

(3) The Protocol should be approved,

HAS ADOPTED THIS DECISION:

Article 1

The Protocol to the Partnership and Cooperation Agreement between the European Communities and their Member States, of the one part, and the Republic of Azerbaijan, of the other part, on a Framework Agreement between the European Union and the Republic of Azerbaijan on the general principles for the participation of the Republic of Azerbaijan in Union programmes ('the Protocol') is hereby approved on behalf of the Union ([2]).

([1]) Consent of 6 July 2016 (not yet published in the Official Journal).
([2]) The Protocol has been published in OJ L 19, 24.1.2015, p. 4 together with the decision on signature.

Article 2

The President of the Council shall, on behalf of the Union, give the notification provided for in Article 10 of the Protocol ([1]).

Article 3

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 18 July 2016.

For the Council
The President
F. MOGHERINI

([1]) The date of entry into force of the Protocol will be published in the *Official Journal of the European Union* by the General Secretariat of the Council.

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2016/1211

of 20 July 2016

concerning the classification of certain goods in the Combined Nomenclature

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code ([1]), and in particular Articles 57(4) and 58(2) thereof,

Whereas:

(1) In order to ensure uniform application of the Combined Nomenclature annexed to Council Regulation (EEC) No 2658/87 ([2]), it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.

(2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules apply also to any other nomenclature which is wholly or partly based on it or which adds any additional subdivision to it and which is established by specific provisions of the Union, with a view to the application of tariff and other measures relating to trade in goods.

(3) Pursuant to those general rules, the goods described in column (1) of the table set out in the Annex should be classified under the CN code indicated in column (2), by virtue of the reasons set out in column (3) of that table.

(4) It is appropriate to provide that binding tariff information issued in respect of the goods concerned by this Regulation which does not conform to this Regulation may, for a certain period, continue to be invoked by the holder in accordance with Article 34(9) of Regulation (EU) No 952/2013. That period should be set at three months.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The goods described in column (1) of the table set out in the Annex shall be classified within the Combined Nomenclature under the CN code indicated in column (2) of that table.

Article 2

Binding tariff information which does not conform to this Regulation may continue to be invoked in accordance with Article 34(9) of Regulation (EU) No 952/2013 for a period of three months from the date of entry into force of this Regulation.

([1]) OJ L 269, 10.10.2013, p. 1.
([2]) Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

Article 3

This Regulation shall enter into force on the twentieth 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, 20 July 2016.

For the Commission,
On behalf of the President,
Stephen QUEST
Director-General for Taxation and Customs Union

ANNEX

Description of the goods	Classification (CN-code)	Reasons
(1)	(2)	(3)
An article (so-called 'hammock with stand'), with dimensions of approximately 380 × 120 × 140 cm. The article consists of a wooden stand to be placed on the ground, on which a hammock, measuring 240 × 120 cm, made of cotton fabric, is hung. The narrow ends of the hammock are finished with wooden rods and are provided with cords to be attached to the stand. The article weighs approximately 32 kg and can cater for persons weighing up to 150 kg. (*) See an image.	9403 60 90	Classification is determined by general rules 1, 3(b) and 6 for the interpretation of the Combined Nomenclature, note 2 to Chapter 94, and by the wording of CN codes 9403, 9403 60 and 9403 60 90. Given its characteristics, namely its weight and inability to be easily disassembled, the article cannot be easily transported to be used when going camping. Consequently, classification as camping goods under heading 6306 is excluded. The article is 'movable' and given its objective characteristics, it is constructed for placing on the floor or ground. It is used, mainly with a utilitarian purpose, to equip outdoor areas such as gardens of private dwellings, hotels, restaurants etc. (see also the Harmonized System Explanatory Notes to Chapter 94, General, (A)). Consequently, the article is considered to be 'furniture' made of different materials and is to be classified under heading 9403 according to the material of which the support (stand) is made and which gives the article its essential character. The article is therefore to be classified under CN code 9403 60 90, as other wooden furniture.

(*) The image is purely for information.

COMMISSION IMPLEMENTING REGULATION (EU) 2016/1212

of 25 July 2016

laying down implementing technical standards with regard to standard procedures and forms for submitting information in accordance with Directive 2009/65/EC 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 Directive 2009/65/EC of the European Parliament and of the Council of 13 July 2009 on the coordination of laws, regulations and administrative provisions relating to undertakings for collective investment in transferable securities (UCITS) [1], and in particular Article 99e(3) thereof,

Whereas:

(1) It is appropriate to set out common procedures and forms for submitting information to the European Securities and Markets Authority (ESMA) by competent authorities with regard to penalties and measures they impose as referred to in Article 99e of Directive 2009/65/EC.

(2) In order to enable ESMA to correctly identify and register the information on penalties and measures imposed in accordance with Article 99 of Directive 2009/65/EC, it is appropriate to require competent authorities to provide it with detailed and harmonised information on penalties and measures notified.

(3) It is necessary to avoid potential double entries and negative conflicts of competence between multiple reporting authorities within a Member State. Designating a single contact point per Member State with ESMA is the most effective and least onerous means of pursuing such objective.

(4) With a view to including meaningful information in the annual report on penalties and measures to be published by ESMA in accordance with Article 99e(1) of Directive 2009/65/EC, competent authorities should report the information by using specific forms clearly indicating which Articles of Directive 2009/65/EC were infringed.

(5) The reporting of administrative penalties and measures disclosed to the public in accordance with Article 99e(2) of Directive 2009/65/EC should clearly identify penalties and measures by offering sufficient details. It is therefore appropriate to set out a form to be used by competent authorities for this purpose.

(6) This Regulation is based on the draft implementing technical standards submitted by ESMA to the Commission.

(7) ESMA did not conduct open public consultations on the draft implementing technical standards on which this Regulation is based, nor did it analyse potential related costs and benefits of introducing the standard forms and procedures for the relevant competent authorities, as this would have been disproportionate in relation to their scope and impact, taking into account that the addressees of the implementing technical standards would only be the national competent authorities of the Member States and not market participants. ESMA requested the opinion of the Securities and Markets Stakeholder Group established in accordance with Article 37 of Regulation (EU) No 1095/2010 of the European Parliament and of the Council [2],

[1] OJ L 302, 17.11.2009, p. 32.

[2] Regulation (EU) No 1095/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Securities and Markets Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/77/EC (OJ L 331, 15.12.2010, p. 84).

HAS ADOPTED THIS REGULATION:

Article 1

Contact points

1. For each Member State, competent authorities shall designate a single contact point for sending the information referred to in Articles 2 and 3 and for communications on any issue relating to the submission of such information.

2. Competent authorities shall notify the European Securities and Markets Authority (ESMA) of the contact point referred to in paragraph 1.

3. ESMA shall designate a contact point for receiving the information referred to in Article 2 and for communications on any issue relating to the reception of the information referred to in Articles 2 and 3.

4. ESMA shall publish the contact point referred to in paragraph 3 on its website.

Article 2

Annual submission of aggregated information

Competent authorities shall provide ESMA with the information referred to in Article 99e(1) of Directive 2009/65/EC by filling in the form set out in Annex I to this Regulation.

That information shall refer to all the penalties and measures imposed during the previous calendar year.

The form shall be completed electronically and sent to ESMA by e-mail using the contact point referred to in Article 1(3) no later than 31 March of each year.

Article 3

Reporting procedures and forms

1. Competent authorities shall report to ESMA the administrative penalties and measures referred to in Article 99e(2) of Directive 2009/65/EC using the existing interfaces provided by the information technology system, and the related database, set up by ESMA to manage the receipt, storage and publication of information on those administrative penalties and measures in accordance with Article 99e of Directive 2009/65/EC.

2. The administrative penalties and measures shall be submitted to ESMA in a report file in the format set out in Annex II.

Article 4

Invalidation and updating of reports

1. Where a competent authority wishes to invalidate an existing report file it has previously submitted to ESMA in accordance with Article 3, it shall cancel the existing report and send a new report file.

2. Where a competent authority wishes to update an existing report file it has previously submitted to ESMA in accordance with Article 3, it shall resubmit the report file with the updated information.

Article 5

Entry into force and application

This Regulation shall enter into force on the twentieth 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, 25 July 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Form for annual submission of aggregated information regarding all penalties and measures imposed

Aggregated information regarding all penalties and measures imposed by
[name of the competent authority] in [*year*]

FROM:
Member State:
Competent authority:
Address:

(Contact details of the designated contact person)
Name:
Telephone:
E-mail:

TO:
ESMA

(Contact details of the designated contact person)
Name:
Telephone:
E-mail:

Dear [*insert appropriate name*]

In accordance with Article 99e(1) of Directive 2009/65/EC, I wish to provide you with aggregated information regarding all penalties and measures imposed by [*name of the competent authority].*

Penalties:

Article of Directive 2009/65/EC transposed by the national provisions which were infringed	**Number of penalties imposed in the reporting period**	**Amount of penalties imposed in the reporting period**
[number of the article, paragraph, subparagraph]	[number of penalties]	[amount of penalties (*)]
Total penalties	**[total number of penalties (†)]**	**[total amount of penalties (*) (†)]**

(*) Please insert value in Euro or in national currency. If the relevant penalties refer not only to breaches relating to the relevant article of Directive 2009/65/EC, but also to other provisions, add the mention 'AGGREGATED FIGURE' to each value.
(†) As penalties imposed may cover more than one legislative provision, the sum of the different lines (number of penalties/amount) may not correspond to the total number/amount of penalties imposed.

Measures:

Article of Directive 2009/65/EC transposed by the national provisions which were infringed	**Number of measures imposed in the reporting period**
[number of the article, paragraph, subparagraph]	[number of measures]
Total measures	**[total number of measures (†)]**

(†) As measures imposed may cover more than one legislative provision, the sum of the different number of measures may not correspond to the total number of measures imposed.

Yours sincerely,

[*signature*]

ANNEX II

Form for reporting administrative penalties or measures disclosed to the public

Field	Description	Type
Legal Framework	The acronym of the Union legislative act under which the administrative penalty or measure has been imposed.	Mandatory
Member State	The acronym of the Member State of the competent authority submitting the administrative penalty or measure	Mandatory
Entity Identifier	The identification code used to uniquely identify a legal entity on which an administrative penalty or measure has been imposed.	Mandatory
Authority Key	The identifier of the competent authority submitting the administrative penalty or measure	Mandatory
Entity Legal Framework	The acronym of the Union legislative act that applies to the entity on which the administrative penalty or measure has been imposed.	Mandatory
Entity Full Name	Full name of the entity on which the administrative penalty or measure has been imposed	Optional
Person Full Name	Full name of the persons on whom an administrative penalty or measure has been imposed.	Mandatory (for natural persons only)
Sanctioning NCA	The acronym of the competent authority that has imposed the administrative penalty or measure.	Mandatory
Free Text	Text of the administrative penalty or measure in the main language	Mandatory
Free Text	Text of the administrative penalty or measure in other language (*)	Optional
Date	The date on which the administrative penalty or measure was imposed by the competent authority	Mandatory
Expiration date	Date on which the administrative penalty or measure ends	Optional

(*) Other language could be either a language customary in the sphere of international finance or another official language of the Member State.

COMMISSION IMPLEMENTING REGULATION (EU) 2016/1213

of 25 July 2016

establishing the standard import values for determining the entry price of certain fruit and vegetables

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]),

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ([2]), and in particular Article 136(1) thereof,

Whereas:

(1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

(2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed 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, 25 July 2016.

For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General for Agriculture and Rural Development

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) OJ L 157, 15.6.2011, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	MA	164,1
	ZZ	164,1
0707 00 05	TR	103,7
	ZZ	103,7
0709 93 10	TR	137,2
	ZZ	137,2
0805 50 10	AR	197,4
	AU	158,0
	CL	153,0
	TR	164,0
	UY	195,6
	ZA	178,4
	ZZ	174,4
0806 10 10	EG	269,9
	MA	245,1
	ZZ	257,5
0808 10 80	AR	121,6
	BR	101,0
	CL	132,0
	CN	74,5
	NZ	135,2
	US	157,1
	ZA	106,1
	ZZ	118,2
0808 30 90	AR	109,8
	CL	135,7
	NZ	171,3
	TR	187,7
	ZA	119,2
	ZZ	144,7
0809 10 00	TR	202,4
	ZZ	202,4
0809 29 00	TR	244,3
	US	535,2
	ZA	271,2
	ZZ	350,2
0809 30 10, 0809 30 90	TR	120,5
	ZZ	120,5

(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). Code 'ZZ' stands for 'of other origin'.

DIRECTIVES

COMMISSION DIRECTIVE (EU) 2016/1214

of 25 July 2016

amending Directive 2005/62/EC as regards quality system standards and specifications for blood establishments

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage, and distribution of human blood and blood components and amending Directive 2001/83/EC ([1]), and in particular point (h) of the second paragraph of Article 29 thereof,

Whereas:

(1) Article 2 of Commission Directive 2005/62/EC ([2]) requires Member States to ensure that the quality system in place in all blood establishments complies with the standards and specifications set out in the Annex to that Directive.

(2) Article 2 of Directive 2005/62/EC also requires the Commission to develop good practice guidelines for the interpretation of the standards and specifications referred to in that Article.

(3) Good Practice Guidelines (the 'GPG') have been jointly developed by the Commission and the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe and published by the Council of Europe ([3]).

(4) The GPG have been developed and are updated taking into account scientific and technical expertise. The GPG fully reflect the detailed principles and guidelines of good manufacturing practice established under Article 47 of Directive 2001/83/EC ([4]) which are relevant for blood establishments and their quality systems, and are already successfully used in blood establishments in the Union. Accordingly, they should be taken into account when implementing the standards and specifications set out in the Annex to Directive 2005/62/EC. Paragraph 2 of Article 2 of that Directive should therefore be amended accordingly.

(5) The Commission, which actively participates in the process leading to amendments of the GPG together with experts from the Member States, should inform the competent authorities designated by the Member States of any significant changes to the GPG, which should also be taken into account.

(6) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Directive 2002/98/EC,

([1]) OJ L 33, 8.2.2003, p. 30.
([2]) Commission Directive 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments (OJ L 256, 1.10.2005, p. 41).
([3]) Good Practice Guidelines, included in the Guide to the preparation, use and quality assurance of blood components, Appendix to Recommendation No. R (95) 15 of the Committee of Minsters on the preparation, use and quality assurance of blood components adopted on 12 October 1995.
([4]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

HAS ADOPTED THIS DIRECTIVE:

Article 1

In Article 2 of Directive 2005/62/EC, paragraph 2 is replaced by the following:

'2. Member States shall ensure that, in order to implement the standards and specifications set out in the Annex to this Directive, there are good practice guidelines available to and used by all blood establishments, in their quality system, good practice guidelines which take fully into account, where relevant for blood establishments, the detailed principles and guidelines of good manufacturing practice, as referred to in the first subparagraph of Article 47 of Directive 2001/83/EC. In doing so, Member States shall take into account the Good Practice Guidelines jointly developed by the Commission and the European Directorate for the Quality of Medicines and Healthcare of the Council of Europe and published by the Council of Europe (*).

(*) Good Practice Guidelines, included in the Guide to the preparation, use and quality assurance of blood components, Appendix to Recommendation No. R (95) 15 of the Committee of Minsters on the preparation, use and quality assurance of blood components adopted on 12 October 1995.'

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 15 February 2018 at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 25 July 2016.

For the Commission

The President

Jean-Claude JUNCKER

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2016/1215

of 22 July 2016

authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean FG72 (MST-FGØ72-2) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2016) 4576)

(Only the German text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed ([1]), and in particular Articles 7(3) and 19(3) thereof,

Whereas:

(1) On 24 June 2011, Bayer CropScience AG submitted to the competent authority of Belgium an application in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from FG72 soybean ('the application').

(2) The application also covers the placing on the market of genetically modified soybean FG72 in products consisting of it or containing it for other uses than food and feed as any other soybean, with the exception of cultivation.

(3) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council ([2]) and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to that Directive. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(4) On 16 July 2015, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ([3]). It concluded that genetically modified soybean FG72, as described in the application, is as safe as its conventional counterpart and other non-genetically modified soybean varieties with respect to potential adverse effects on human and animal health and the environment in the context of the scope of the application.

(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 18(4) of Regulation (EC) No 1829/2003.

(6) 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.

([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), 2015. Scientific Opinion on application (EFSA-GMO-BE-2011-98) for the placing on the market of herbicide tolerant genetically modified soybean FG72 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer. EFSA Journal 2015; 13(7):4167, 29 pp. doi:10.2903/j.efsa.2015.4167.

(7) Taking into account those considerations, authorisation should be granted to the products containing, consisting of, or produced from genetically modified soybean FG72.

(8) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') as provided for in Commission Regulation (EC) No 65/2004 ([1]).

(9) On the basis of the EFSA opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for food, food ingredients and feed containing, consisting of, or produced from genetically modified soybean FG72. 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 FG72, with the exception of food products, should be complemented by a clear indication that the products in question are not intended for cultivation.

(10) Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([2]) lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for those products are laid down in paragraphs 1 to 5 of Article 4 and traceability requirements for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(11) 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 Commission Decision 2009/770/EC ([3]). The EFSA opinion does not justify either 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 or specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Articles 6(5)(e) and 18(5)(e) 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 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. An implementing act was deemed to be necessary and the chair submitted the draft implementing act 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, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MST-FGØ72-2, 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 Articles 4(2) and 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 MST-FGØ72-2 soybean;

(b) feed containing, consisting of, or produced from MST-FGØ72-2 soybean;

(c) MST-FGØ72-2 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 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 'soybean'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of MST-FGØ72-2 soybean, with the exception of products referred to in point (a) of Article 2.

Article 4

Monitoring 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 to the Commission 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 5

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 6

Authorisation holder

The authorisation holder shall be Bayer CropScience AG.

Article 7

Validity

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

Article 8

Addressee

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

Done at Brussels, 22 July 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

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

Name: Bayer CropScience AG

Address: Alfred-Nobel-Strasse 50, D — 40789 Monheim am Rhein — Germany.

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

(1) foods and food ingredients containing, consisting of, or produced from MST-FGØ72-2 soybean;

(2) feed containing, consisting of, or produced from MST-FGØ72-2 soybean;

(3) MST-FGØ72-2 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 MST-FGØ72-2 soybean, as described in the application, expresses the 2mEPSPS protein which confers tolerance to glyphosate herbicides and HPPD W336 protein which confers tolerance to isoxaflutole herbicides.

(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 '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 MST-FGØ72-2 soybean, with the exception of products referred to in point (a) of Article 2.

(d) **Method for detection:**

(1) Event specific real-time PCR based method for the quantification of MST-FGØ72-2 soybean;

(2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003 on genomic DNA extracted from seeds of MST-FGØ72-2 soybean, published at http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx;

(3) Reference Material: AOCS 0610-A3 and AOCS 0707-A6 accessible via the American Oil Chemists Society at http://www.aocs.org/LabServices/content.cfm?ItemNumber=19248.

(e) **Unique identifier:**

MST-FGØ72-2

(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) 2016/1216

of 22 July 2016

authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87708 × MON 89788 (MON-877Ø8-9 × MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2016) 4580)

(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 23 March 2012, Monsanto Europe S.A. submitted to the competent authority of the Netherlands an application in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from soybean MON 87708 × MON 89788 ('the application').

(2) The application also covers the placing on the market of genetically modified soybean MON 87708 × MON 89788 in products consisting of it or containing it for other uses than food and feed as any other soybean, with the exception of cultivation.

(3) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council ([2]) and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to that Directive. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(4) On 18 June 2015, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that genetically modified soybean MON 87708 × MON 89788, as described in the application, is as safe as its conventional counterpart and other non-genetically modified soybean varieties with respect to potential adverse effects on human and animal health and the environment in the context of the scope of the application ([3]).

(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 18(4) of Regulation (EC) No 1829/2003.

(6) 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.

(7) Taking into account those considerations, authorisation should be granted to the products containing, consisting of, or produced from genetically modified soybean MON 87708 × MON 89788.

([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]) Scientific Opinion on application (EFSA-GMO-NL-2012-108) for the placing on the market of herbicide tolerant genetically modified soybean MON 87708 × MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2015;13(6):4136, 26 pp. doi: 10.2903/j.efsa.2015.4136

(8) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') as provided for in Commission Regulation (EC) No 65/2004 ([1]).

(9) On the basis of the EFSA opinion, no specific labelling requirements, other than those provided for in Articles 13(1) and 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from genetically modified soybean MON 87708 × MON 89788. 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 MON 87708 × MON 89788, with the exception of food products, should be complemented by a clear indication that the products in question are not intended for cultivation.

(10) Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([2]) lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for those products are laid down in paragraphs 1 to 5 of Article 4 and traceability requirements for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(11) 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 Commission Decision 2009/770/EC ([3]). The EFSA opinion does not justify either 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 or specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Articles 6(5)(e) and 18(5)(e) 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 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. An implementing act was deemed to be necessary and the chair submitted the draft implementing act 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.) MON 87708 × MON 89788, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-877Ø8-9 × MON-89788-1, 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 Articles 4(2) and 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 MON-877Ø8-9 × MON-89788-1 soybean;

(b) feed containing, consisting of, or produced from MON-877Ø8-9 × MON-89788-1 soybean;

(c) MON-877Ø8-9 × MON-89788-1 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 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 'soybean'.

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of MON-877Ø8-9 × MON-89788-1 soybean, with the exception of products referred to in point (a) of Article 2.

Article 4

Monitoring 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 to the Commission 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 5

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 6

Authorisation holder

The authorisation holder shall be Monsanto Europe S.A., Belgium, representing Monsanto Company, United States of America.

Article 7

Validity

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

Article 8

Addressee

This Decision is addressed to Monsanto Europe S.A., Avenue de Tervuren 270-272, B-1150 Brussels, Belgium.

Done at Brussels, 22 July 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

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

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 of America.

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

(1) foods and food ingredients containing, consisting of, or produced from MON-877Ø8-9 × MON-89788-1 soybean;

(2) feed containing, consisting of, or produced from MON-877Ø8-9 × MON-89788-1 soybean;

(3) MON-877Ø8-9 × MON-89788-1 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 MON-877Ø8-9 × MON-89788-1 soybean, as described in the application, expresses the DMO proteins which confer tolerance to dicamba-based herbicides and the CP4 EPSPS protein which confers tolerance to glyphosate-based herbicides.

(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 'soybean';

(2) The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of MON-877Ø8-9 × MON-89788-1 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 MON-877Ø8-9 and MON-89788-1 soybeans; the detection methods are validated on the single-trait events and verified on genomic DNA extracted from seeds of MON-877Ø8-9 × MON-89788-1 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: AOCS 0311-A and AOCS 0906-A (for MON-877Ø8-9), and AOCS 0906-B and AOCS 0906-A (for MON-89788-1) accessible via the American Oil Chemists Society at http://www.aocs.org/LabServices/content.cfm?ItemNumber=19248

(e) **Unique identifier:**

MON-877Ø8-9 × MON-89788-1

(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) 2016/1217

of 22 July 2016

authorising the placing on the market of products containing, consisting of, or produced from genetically modified soybean MON 87705 × MON 89788 (MON-877Ø5-6 × MON-89788-1) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2016) 4582)

(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 11 August 2011, Monsanto Europe S.A. submitted to the competent authority of the Netherlands an application in accordance with Articles 5 and 17 of Regulation (EC) No 1829/2003 for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from MON 87705 × MON 89788 soybean ('the application').

(2) The application also covers the placing on the market of genetically modified soybean MON 87705 × MON 89788 in products consisting of it or containing it for other uses than food and feed as any other soybean, with the exception of cultivation.

(3) In accordance with Articles 5(5) and 17(5) of Regulation (EC) No 1829/2003, the application includes the data and information required by Annexes III and IV to Directive 2001/18/EC of the European Parliament and of the Council ([2]) and information and conclusions about the risk assessment carried out in accordance with the principles set out in Annex II to that Directive. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.

(4) On 16 July 2015, the European Food Safety Authority ('EFSA') gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ([3]). It concluded that genetically modified soybean MON 87705 × MON 89788, as described in the application, is as safe as its non-genetically modified counterpart and other non-genetically modified soybean reference varieties with respect to potential adverse effects on human and animal health and the environment in the context of the scope of the application.

(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 18(4) of Regulation (EC) No 1829/2003.

(6) 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.

(7) In addition, EFSA recommended a post-market monitoring plan to be implemented, focusing on the collection of consumption data for the European population.

([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]) Scientific Opinion on application (EFSA-GMO-NL-2011-110) for the placing on the market of the herbicide-tolerant, increased oleic acid genetically modified soybean MON 87705 × MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal 2015; 13(7):4178, 30 pp. doi:10.2903/j.efsa.2015.4178

(8) Taking into account those considerations, authorisation should be granted to the products containing, consisting of, or produced from genetically modified soybean MON 87705 × MON 89788.

(9) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') as provided for in Commission Regulation (EC) No 65/2004 ([1]).

(10) Food, food ingredients and feed containing, consisting of, or produced from MON 87705 × MON 89788 soybean should be labelled in accordance with the requirements provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003.

(11) On the basis of the EFSA opinion, confirming that fatty acid composition of the seeds of MON 87705 × MON 89788 soybean and derived oil has been changed in relation to the conventional counterpart, a specific labelling appears to be necessary in accordance with Articles 13(2)(a) and 25(2)(c) of Regulation (EC) No 1829/2003.

(12) Regulation (EC) No 1830/2003 of the European Parliament and of the Council ([2]) lays down labelling requirements in Article 4(6) for products containing or consisting of GMOs. Traceability requirements for those products are laid down in paragraphs 1 to 5 of Article 4 and traceability requirements for food and feed produced from GMOs are laid down in Article 5 of that Regulation.

(13) 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.

(14) 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 Commission Decision 2009/770/EC ([3]). The EFSA opinion does not justify either 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 or specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.

(15) 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.

(16) All relevant information on the authorisation of the products should be entered in the Community register of genetically modified food and feed provided for in Regulation (EC) No 1829/2003.

(17) 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]).

(18) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time-limit laid down by its Chairman. An implementing act was deemed to be necessary and the chair submitted the draft implementing act to the appeal committee for further deliberation. The appeal committee did not deliver an opinion,

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([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).

HAS ADOPTED THIS DECISION:

Article 1

Genetically modified organism and unique identifier

Genetically modified soybean (*Glycine max* (L.) Merr.) MON 87705 × MON 89788, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-877Ø5-6 × MON-89788-1, as provided for in Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Articles 4(2) and 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 MON-877Ø5-6 × MON-89788-1 soybean;

(b) feed containing, consisting of, or produced from MON-877Ø5-6 × MON-89788-1 soybean;

(c) MON-877Ø5-6 × MON-89788-1 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 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 documents accompanying products containing or consisting of MON-877Ø5-6 × MON-89788-1 soybean, with the exception of products referred to in point (a) of Article 2.

Article 4

Monitoring 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 to the Commission 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 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 MON-877Ø5-6 × MON-89788-1 soybean oil, as set out in point (g) of the Annex, is put in place and implemented.

2. The authorisation holder shall submit to the Commission annual reports on the implementation and the results of the activities set out in the post-market monitoring plan for the duration of the authorisation.

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 holder

The authorisation holder shall be Monsanto Europe S.A., Belgium, representing Monsanto Company, United States of America.

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

Done at Brussels, 22 July 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

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

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 of America.

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

(1) foods and food ingredients containing, consisting of, or produced from MON-877Ø5-6 × MON-89788-1 soybean;

(2) feed containing, consisting of, or produced from MON-877Ø5-6 × MON-89788-1 soybean;

(3) MON-877Ø5-6 × MON-89788-1 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 MON-877Ø5-6 × MON-89788-1 soybean, as described in the application, has a reduced expression of fatty acid Δ12-desaturase (FAD2) and palmitoyl acyl carrier protein thioesterase (FATB) enzymes, which results in increased oleic acid and reduced linoleic acid profile 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 MON-877Ø5-6 × MON-89788-1 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 MON-877Ø5-6 and MON-89788-1 soybeans; the detection methods are validated on the single-trait events and verified on genomic DNA extracted from seeds of MON-877Ø5-6 × MON-89788-1 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: AOCS 0210-A and AOCS 0906-A (for MON-877Ø5-6) and AOCS 0906-B and AOCS 0906-A (for MON-89788-1) are accessible via the American Oil Chemists Society at http://www.aocs.org/LabServices/content.cfm?ItemNumber=19248.

(e) **Unique identifier:**

MON-877Ø5-6 × MON-89788-1

(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:**

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 MON-877Ø5-6 × MON-89788-1 soybean oil and MON-877Ø5-6 × MON-89788-1 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.

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