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Contents

II Non-legislative acts

REGULATIONS

- ★ **Commission Regulation (EU) 2017/1200 of 5 July 2017 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health ⁽¹⁾** 1
- ★ **Commission Regulation (EU) 2017/1201 of 5 July 2017 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health ⁽¹⁾** 4
- ★ **Commission Regulation (EU) 2017/1202 of 5 July 2017 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health ⁽¹⁾** 6
- ★ **Commission Regulation (EU) 2017/1203 of 5 July 2017 amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards organic silicon (monomethylsilanetriol) and calcium phosphoryl oligosaccharides (POs-Ca®) added to foods and used in the manufacture of food supplements ⁽¹⁾** 9
- ★ **Commission Implementing Regulation (EU) 2017/1204 of 5 July 2017 correcting the Slovak language version of Implementing Regulation (EU) 2015/2403 establishing common guidelines on deactivation standards and techniques for ensuring that deactivated firearms are rendered irreversibly inoperable ⁽¹⁾** 12
- Commission Implementing Regulation (EU) 2017/1205 of 5 July 2017 laying down the allocation coefficient to be applied to the quantities covered by the applications for import licences lodged from 23 June 2017 to 30 June 2017 under the tariff quotas opened by Implementing Regulation (EU) 2015/2081 for certain cereals originating in Ukraine 13

⁽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

★ Council Decision (EU) 2017/1206 of 4 July 2017 on the financial contributions to be paid by Member States to finance the European Development Fund, including the second instalment for 2017	15
★ Commission Implementing Decision (EU) 2017/1207 of 4 July 2017 renewing the authorisation for the placing on the market of genetically modified maize MON 810 (MON-ØØ81Ø-6) products pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2017) 4453) ⁽¹⁾	18
★ Commission Implementing Decision (EU) 2017/1208 of 4 July 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB119 (BCS-GHØØ5-8) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (notified under document C(2017) 4457) ⁽¹⁾	23
★ Commission Implementing Decision (EU) 2017/1209 of 4 July 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21, and genetically modified maize combining two, three or four of the events Bt11, 59122, MIR604, 1507 and GA21 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) 4460) ⁽¹⁾	28
★ Commission Implementing Decision (EU) 2017/1210 of 4 July 2017 on the identification of bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) as substances of very high concern according to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (notified under document C(2017) 4462) ⁽¹⁾	35
★ Commission Implementing Decision (EU) 2017/1211 of 4 July 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913 (DAS-24236-5 × DAS-21Ø23-5 × MON-88913-8) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (notified under document C(2017) 4495) ⁽¹⁾	38
★ Commission Implementing Decision (EU) 2017/1212 of 4 July 2017 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize DAS-40278-9, 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) 4503) ⁽¹⁾	43
★ Commission Implementing Decision (EU) 2017/1213 of 4 July 2017 on setting up the Integrated Structural Biology — European Research Infrastructure Consortium (Instruct-ERIC) (notified under document C(2017) 4507)	47

⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION REGULATION (EU) 2017/1200

of 5 July 2017

refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health**(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ⁽¹⁾, and in particular Article 18(5) thereof,

Whereas:

- (1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods, as defined in that Regulation, are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.
- (2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority', for a scientific assessment, as well as to the Commission and the Member States for information.
- (3) The Authority is to deliver an opinion on the health claim concerned.
- (4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.
- (5) Following an application from Ecopharma BVBA, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to Fabenol® Max, a standardised aqueous extract from *Phaseolus vulgaris* L., and the reduction of the absorption of carbohydrates (Question No EFSA-Q-2015-00123 ⁽²⁾). The claim proposed by the applicant was worded as follows: 'Fabenol® Max reduces the absorption of carbohydrates'.
- (6) On 23 February 2016, the Commission and the Member States received the scientific opinion from the Authority, which noted that the claimed effect was not sufficiently defined and that the applicant did not provide any further information as requested by the Authority. Therefore, on the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of Fabenol® Max and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

⁽¹⁾ OJ L 404, 30.12.2006, p. 9.⁽²⁾ EFSA Journal 2016;14(2):4401.

- (7) Following an application from DSM Nutritional Products, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to docosahexaenoic acid (DHA) and improvement of memory function (Question No EFSA-Q-2015-00456 ⁽¹⁾). The claim proposed by the applicant was worded as follows: 'DHA contributes to improved memory function'.
- (8) On 2 May 2016, the Commission and the Member States received the scientific opinion from the Authority, which concluded that, on the basis of the data presented, a cause and effect relationship had not been established between the consumption of DHA and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (9) Following an application from Tate & Lyle PLC, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to polydextrose and normal defecation (Question No EFSA-Q-2015-00550 ⁽²⁾). The claim proposed by the applicant was worded as follows: 'Polydextrose contributes to an improved bowel function by increasing stool bulk'.
- (10) On 25 May 2016, the Commission and the Member States received the scientific opinion from the Authority, which concluded that, on the basis of the data presented, a cause and effect relationship had not been established between the consumption of polydextrose and the claimed effect. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The health claims listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

Article 2

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, 5 July 2017.

For the Commission
The President
Jean-Claude JUNCKER

⁽¹⁾ EFSA Journal 2016;14(5):4455.

⁽²⁾ EFSA Journal 2016;14(5):4480.

ANNEX

Rejected health claims

Application — Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Fabenol® Max	Fabenol® Max reduces the absorption of carbohydrates	Q-2015-00123
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	DHA	DHA contributes to improved memory function	Q-2015-00456
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Polydextrose	Polydextrose contributes to an improved bowel function by increasing stool bulk	Q-2015-00550

COMMISSION REGULATION (EU) 2017/1201**of 5 July 2017****refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health****(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ⁽¹⁾, and in particular Article 18(5) thereof,

Whereas:

- (1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.
- (2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority', for a scientific assessment, as well as to the Commission and the Member States for information.
- (3) The Authority is to deliver an opinion on the health claim concerned.
- (4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.
- (5) Following an application from Beghin-Meiji and Tereos Syral, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to short-chain fructooligosaccharides from sucrose and maintenance of normal defecation (Question No EFSA-Q-2015-00377 ⁽²⁾). The applicant has proposed the following wording for the health claim: 'maintain normal intestinal regularity' or 'maintain intestinal regularity by increasing the frequency of bowel movements' or 'contributes to normal intestinal regularity or normal bowel function'.
- (6) On 8 January 2016, the Commission and the Member States received the scientific opinion from the Authority, which concluded that, on the basis of the data presented, a cause and effect relationship had not been established between the consumption of short-chain fructooligosaccharides from sucrose and maintenance of normal defecation under the conditions of use proposed by the applicant. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (7) The comments from the applicant received by the Commission pursuant to Article 16(6) of Regulation (EC) No 1924/2006 have been considered when setting the measures provided for in this Regulation.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The health claim listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

⁽¹⁾ OJ L 404, 30.12.2006, p. 9.

⁽²⁾ EFSA Journal 2016;14(1):4366.

Article 2

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, 5 July 2017.

For the Commission

The President

Jean-Claude JUNKER

*ANNEX***Rejected health claim**

Application — Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Short-chain fructooligosaccharides from sucrose	Maintain normal intestinal regularity	Q-2015-00377

COMMISSION REGULATION (EU) 2017/1202

of 5 July 2017

refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health

(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 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ⁽¹⁾, and in particular Article 18(5) thereof,

Whereas:

- (1) Pursuant to Regulation (EC) No 1924/2006 health claims made on foods are prohibited unless they are authorised by the Commission in accordance with that Regulation and included in a list of permitted claims.
- (2) Regulation (EC) No 1924/2006 also provides that applications for authorisations of health claims may be submitted by food business operators to the national competent authority of a Member State. The national competent authority is to forward valid applications to the European Food Safety Authority (EFSA), hereinafter referred to as 'the Authority', for a scientific assessment, as well as to the Commission and the Member States for information.
- (3) The Authority is to deliver an opinion on the health claim concerned.
- (4) The Commission is to decide on the authorisation of health claims taking into account the opinion delivered by the Authority.
- (5) Following an application from Granarolo S.p.A., submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to a low-fat fermented milk with a combination of fructooligosaccharides and live *Lactobacillus rhamnosus* GG (ATCC 53103), *Streptococcus thermophilus* (Z57) and *Lactobacillus delbrueckii* subsp. *bulgaricus* (LB2), and defence against reactivation of Herpes simplex virus in the orolabial epithelia (Question No EFSA-Q-2015-00488 ⁽²⁾). The claim proposed by the applicant was worded as follows: 'Consumption of low-fat fermented milk with a combination of fructooligosaccharides (FOS) and live *Lactobacillus rhamnosus* GG (ATCC 53103), *Streptococcus thermophilus* (Z57) and *Lactobacillus delbrueckii* subsp. *bulgaricus* (LB2) helps to reduce recurrence of lip cold sores caused by Herpes simplex virus infection in healthy susceptible individuals'.
- (6) On 19 July 2016, the Commission and the Member States received the scientific opinion from the Authority, which concluded that, on the basis of the data presented, a cause and effect relationship had not been established between the consumption of the low-fat fermented milk, which was the subject of the health claim, and defence against reactivation of Herpes simplex virus in the orolabial epithelia. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (7) Following an application from Food for Health Ireland, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to FHI LFC24, a bovine milk-derived casein hydrolysate, and a reduction of post-prandial blood glucose responses (Question No EFSA-Q-2015-00755 ⁽³⁾). The claim proposed by the applicant was worded as follows: 'FHI LFC24 helps to regulate blood glucose levels following food consumption'.
- (8) On 22 July 2016, the Commission and the Member States received the scientific opinion from the Authority, which noted that the evidence provided by the applicant does not establish that a reduction in post-prandial

⁽¹⁾ OJ L 404, 30.12.2006, p. 9.⁽²⁾ EFSA Journal 2016;14(7):4538⁽³⁾ EFSA Journal 2016;14(7):4540

glycaemic responses achieved by an increase in insulin secretion is a beneficial physiological effect for the target population of the claim. Therefore, on the basis of the data presented, the Authority concluded that a cause and effect relationship had not been established between the consumption of the food subject to the claim and a beneficial physiological effect for the target population. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.

- (9) Following an application from Pierre Fabre Medicament, submitted pursuant to Article 13(5) of Regulation (EC) No 1924/2006, the Authority was required to deliver an opinion on a health claim related to V0137, a 'DHA-enriched fish oil', and 'helps to slow the age-related cognitive decline in domains such as memory and executive function' (Question No EFSA- Q- 2016-00071 ⁽¹⁾). The claim proposed by the applicant was worded as follows: 'V0137, in association with physical and intellectual training, helps to slow the age-related cognitive decline in domains such as memory and executive function'.
- (10) On 5 August 2016, the Commission and the Member States received the scientific opinion from the Authority, which concluded that, on the basis of the data presented, a cause and effect relationship had not been established between the consumption of V0137, which was the subject of the health claim, and a reduced loss of cognitive function. Accordingly, as the claim does not comply with the requirements of Regulation (EC) No 1924/2006, it should not be authorised.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The health claims listed in the Annex to this Regulation shall not be included in the Union list of permitted claims as provided for in Article 13(3) of Regulation (EC) No 1924/2006.

Article 2

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, 5 July 2017.

For the Commission
The President
Jean-Claude JUNCKER

⁽¹⁾ EFSA Journal 2016;14(8):4539

ANNEX

Rejected health claims

Application — Relevant provisions of Regulation (EC) No 1924/2006	Nutrient, substance, food or food category	Claim	EFSA opinion reference
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	Low-fat fermented milk with a combination of fructo-oligosaccharides (FOS) and live <i>Lactobacillus rhamnosus</i> GG (ATCC 53103), <i>Streptococcus thermophilus</i> (Z57) and <i>Lactobacillus delbrueckii</i> subsp. <i>bulgaricus</i> (LB2).	Consumption of low-fat fermented milk with a combination of fructo-oligosaccharides (FOS) and live <i>Lactobacillus rhamnosus</i> GG (ATCC 53103), <i>Streptococcus thermophilus</i> (Z57) and <i>Lactobacillus delbrueckii</i> subsp. <i>bulgaricus</i> (LB2) helps to reduce recurrence of lip cold sores caused by Herpes simplex virus infection in healthy susceptible individuals.	Q-2015-00488
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	FHI LFC24, a bovine milk-derived casein hydrolysate.	FHI LFC24 helps to regulate blood glucose levels following food consumption.	Q-2015-00755
Article 13(5) health claim based on newly developed scientific evidence and/or including a request for the protection of proprietary data	V0137, a DHA enriched fish oil.	V0137, in association with physical and intellectual training, helps to slow the age-related cognitive decline in domains such as memory and executive function.	Q-2016-00071

COMMISSION REGULATION (EU) 2017/1203**of 5 July 2017****amending Directive 2002/46/EC of the European Parliament and of the Council and Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards organic silicon (monomethylsilanetriol) and calcium phosphoryl oligosaccharides (POs-Ca®) added to foods and used in the manufacture of food supplements****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements ⁽¹⁾, and in particular Article 4(5) thereof,

Having regard to Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods ⁽²⁾, and in particular Article 3(3) thereof,

Whereas:

- (1) Annex II to Directive 2002/46/EC establishes the list of vitamin and mineral substances, which may be used in the manufacture of food supplements.
- (2) According to Article 14 of Directive 2002/46/EC, provisions on vitamin and mineral substances in food supplements which may have an effect upon public health are to be adopted after consultation with the European Food Safety Authority ('the Authority').
- (3) Annex II to Regulation (EC) No 1925/2006 establishes the list of vitamin and mineral substances, and for each of them the forms, which may be added to foods.
- (4) According to Article 3(3) of Regulation (EC) No 1925/2006, modifications to the list provided in Annex II to that Regulation are to be adopted taking account of the opinion of the Authority.
- (5) Following a request for the addition of organic silicon as a source of silicon to the list set out in Annex II to Directive 2002/46/EC, on 9 March 2016 the Authority adopted a Scientific Opinion on the safety of organic silicon (monomethylsilanetriol; MMST) as a novel food ingredient for use as a source of silicon in food supplements and bioavailability of orthosilicic acid from the source ⁽³⁾.
- (6) It follows from that opinion that the use of organic silicon (monomethylsilanetriol) in food supplements is not of a safety concern as a source of silicon, provided that certain conditions are respected.
- (7) Taking into account the Authority's favourable opinion, organic silicon (monomethylsilanetriol) should be included in the list set out in Annex II to Directive 2002/46/EC.
- (8) Following a request for the addition of calcium phosphoryl oligosaccharides (POs-Ca®) as a source of calcium to the list set out in Annex II to Directive 2002/46/EC and to the list set out in Annex II to Regulation (EC) No 1925/2006, on 26 April 2016 the Authority adopted a Scientific Opinion on the safety of calcium phosphoryl oligosaccharides (POs-Ca®) as a source of calcium added for nutritional purposes to food, food supplements and foods for special medical purposes ⁽⁴⁾.
- (9) It follows from that opinion that the addition of calcium phosphoryl oligosaccharides (POs-Ca®) to food and its use in food supplements is not of a safety concern as a source of calcium, provided that certain conditions are respected.

⁽¹⁾ OJ L 183, 12.7.2002, p. 51.

⁽²⁾ OJ L 404, 30.12.2006, p. 26.

⁽³⁾ EFSA Journal 2016;14(4):4436

⁽⁴⁾ EFSA Journal 2016;14(6):4488

- (10) Taking into account the Authority's favourable opinion, calcium phosphoryl oligosaccharides (POs-Ca®) should be included in the list set out in Annex II to Directive 2002/46/EC and in the list set out in Annex II to Regulation (EC) No 1925/2006.
- (11) Interested parties were consulted through the Advisory Group on the Food Chain and Animal and Plant Health and the comments provided were taken into consideration.
- (12) Directive 2002/46/EC and Regulation (EC) No 1925/2006 should therefore be amended accordingly.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Directive 2002/46/EC is amended in accordance with the Annex to this Regulation.

Article 2

Annex II to Regulation (EC) No 1925/2006 is amended in accordance with the Annex to this Regulation.

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, 5 July 2017.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

1. Point B of Annex II to Directive 2002/46/EC is amended as follows:
 - (a) the following entry is inserted after the entry for 'silicic acid':
'organic silicon (monomethylsilanetriol);
 - (b) the following entry is inserted after the entry 'calcium sulphate':
'calcium phosphoryl oligosaccharides'.
 2. In point 2 of Annex II to Regulation (EC) No 1925/2006 the following entry is inserted after the entry 'calcium sulphate':
'calcium phosphoryl oligosaccharides'.
-

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1204**of 5 July 2017****correcting the Slovak language version of Implementing Regulation (EU) 2015/2403 establishing common guidelines on deactivation standards and techniques for ensuring that deactivated firearms are rendered irreversibly inoperable****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 91/477/EEC of 18 June 1991 on control of the acquisition and possession of weapons ⁽¹⁾, and in particular the second paragraph of Part III of Annex I thereto,

Whereas:

- (1) The Slovak language version of Commission Implementing Regulation (EU) 2015/2403 ⁽²⁾ contains an error in Article 1(2), whereby the word ‘unless’ was erroneously translated as ‘if’, thus conveying the contrary of the intended meaning. It is therefore necessary to correct the Slovak language version of the Regulation. All other language versions are not affected.
- (2) Implementing Regulation (EU) 2015/2403 should therefore be corrected accordingly.
- (3) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Directive 91/477/EEC,

HAS ADOPTED THIS REGULATION:

*Article 1**(Does not concern the English language)**Article 2*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, 5 July 2017.

*For the Commission**The President*

Jean-Claude JUNKER

⁽¹⁾ OJ L 256, 13.9.1991, p. 51.⁽²⁾ Commission Implementing Regulation (EU) 2015/2403 of 15 December 2015 establishing common guidelines on deactivation standards and techniques for ensuring that deactivated firearms are rendered irreversibly inoperable (OJ L 333, 19.12.2015, p. 62).

COMMISSION IMPLEMENTING REGULATION (EU) 2017/1205**of 5 July 2017****laying down the allocation coefficient to be applied to the quantities covered by the applications for import licences lodged from 23 June 2017 to 30 June 2017 under the tariff quotas opened by Implementing Regulation (EU) 2015/2081 for certain cereals originating in Ukraine**

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 188(1) and (3) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2015/2081 ⁽²⁾ opened import tariff quotas for certain cereals originating in Ukraine.
- (2) Article 1(1) of Implementing Regulation (EU) 2015/2081 set, for the period from 1 January 2017 to 31 December 2017 the quantity of the quota with order number 09.4307 at 270 000 tonnes.
- (3) The quantities covered by the applications for import licences lodged from 23 June 2017 from 13.00 to 30 June 2017 at 13.00 (Brussels time) exceed those available for the quota with order number 09.4307. The extent to which import licences may be issued should therefore be determined by fixing the allocation coefficient to be applied to the quantities requested under the quota concerned, calculated in accordance with Article 7(2) of Commission Regulation (EC) No 1301/2006 ⁽³⁾.
- (4) No further import licences should be issued for the tariff quota with order number 09.4307 referred to in Implementing Regulation (EU) 2015/2081 for the current quota period.
- (5) In order to ensure the efficiency of the measure, 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

1. The quantities covered by the applications for import licences under the quota with order number 09.4307 and referred to in the Annex to Implementing Regulation (EU) 2015/2081, lodged from 23 June 2017 from 13.00 to 30 June 2017 at 13.00 (Brussels time), shall be multiplied by an allocation coefficient of 56,118160 % for applications lodged under the tariff quota with order number 09.4307.

2. The submission of new import licence applications under the quota with order number 09.4307 referred to in the Annex to Implementing Regulation (EU) 2015/2081 shall be suspended from 30 June 2017 at 13.00 (Brussels time) for the current quota period.

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ Commission Implementing Regulation (EU) 2015/2081 of 18 November 2015 opening and providing for the administration of import tariff quotas for certain cereals originating in Ukraine (OJ L 302, 19.11.2015, p. 81).

⁽³⁾ Commission Regulation (EC) No 1301/2006 of 31 August 2006 laying down common rules for the administration of import tariff quotas for agricultural products managed by a system of import licences (OJ L 238, 1.9.2006, p. 13).

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, 5 July 2017.

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

DECISIONS

COUNCIL DECISION (EU) 2017/1206

of 4 July 2017

on the financial contributions to be paid by Member States to finance the European Development Fund, including the second instalment for 2017

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the Partnership Agreement between the members of the African, Caribbean and Pacific Group of States of the one part, and the European Community and its Member States, of the other part, signed in Cotonou on 23 June 2000 ⁽¹⁾, as last amended ('ACP-EU Partnership Agreement'),

Having regard to the Internal Agreement between the Representatives of the Governments of the Member States of the European Union, meeting within the Council, on the financing of European Union aid under the multiannual financial framework for the period 2014 to 2020, in accordance with the ACP-EU Partnership Agreement, and on the allocation of financial assistance for the Overseas Countries and Territories to which Part Four of the Treaty on the Functioning of the European Union applies ⁽²⁾ ('the Internal Agreement') and in particular Article 7 thereof,

Having regard to Council Regulation (EU) 2015/323 of 2 March 2015 on the financial regulation applicable to the 11th European Development Fund ⁽³⁾ ('the 11th EDF Financial Regulation'), and in particular Article 21(3) and 21(4) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) In accordance with the procedure laid down in Article 21(3) of the 11th EDF Financial Regulation, the Commission is to present a proposal by 15 June 2017 specifying (a) the amount of the second instalment of the contribution for 2017, (b) a revised annual amount of the contribution for 2017, in cases where the amount deviates from actual needs.
- (2) In accordance with Article 52 of the 11th EDF Financial Regulation, the European Investment Bank (EIB) sent on 6 April 2017 to the Commission its updated estimates of commitments and payments under the instruments it manages.
- (3) Article 22(1) of the 11th EDF Financial Regulation provides that calls for contributions first use up the amounts provided for in previous European Development Funds (EDFs). Therefore a call for funds under the 10th and 11th EDF should be made.
- (4) By means of Decision (EU) 2016/2026 ⁽⁴⁾, the Council has adopted on 11 November 2016, on a proposal by the Commission, the Decision to set the ceiling for the annual amount of the Member States' EDF contributions for 2017 at EUR 3 850 000 000 for the Commission, and at EUR 150 000 000 for the EIB.

⁽¹⁾ OJ L 317, 15.12.2000, p. 3.

⁽²⁾ OJ L 210, 6.8.2013, p. 1.

⁽³⁾ OJ L 58, 3.3.2015, p. 17.

⁽⁴⁾ Council Decision (EU) 2016/2026 of 15 November 2016 on the financial contributions to be paid by Member States to finance the European Development Fund, including the ceiling for 2018, the annual amount for 2017, the first instalment for 2017 and an indicative and non-binding forecast for the expected annual amounts for the years 2019 and 2020 (OJ L 313, 19.11.2016, p. 25).

- (5) By means of Decision (EU) 2016/1337 ⁽¹⁾, the Council has adopted on the 2 August 2016 the allocation of funds decommitted from projects under the 10th EDF for the purpose of replenishing the African Peace Facility for the period 2016-2018. A corollary political agreement was reached by Member States in COREPER to refund a combined amount of EUR 200 million of decommitted amounts from Eighth and Ninth EDF and to have Member States make corresponding payment adjustments so as to refund each Member State according to the share it contributed to those amounts. Payments adjustments are due to take place by the third call for contributions 2017 and/or the first call for contributions 2018,

HAS ADOPTED THIS DECISION:

Article 1

The individual EDF contributions to be paid by Member States to the Commission and the EIB as the second instalment for 2017 are set out in the table in the Annex to this Decision.

Article 2

The shares of Member States' contributions set out in Article 1(2)(a) of the Internal Agreements of the Eighth and Ninth EDF shall be reduced accordingly for an amount of EUR 200 000 000 from funds decommitted under the Eighth and the Ninth EDF. According to each individual Member States preferences, the financial adjustment shall be implemented against the third instalment 2017 and/or the first instalment 2018.

Article 3

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

Done at Brussels, 4 July 2017.

For the Council

The President

M. MAASIKAS

⁽¹⁾ Council Decision (EU) 2016/1337 of 2 August 2016 concerning the allocation of funds decommitted from projects under the 10th European Development Fund for the purpose of replenishing the African Peace Facility (OJ L 212, 5.8.2016, p. 107).

ANNEX

MEMBER STATES	Key 10th EDF %	Key 11th EDF %	2nd instalment 2017				Total
			Commission 10th EDF	Commission 11th EDF	Commission Total	EIB 10th EDF	
BELGIUM	3,53	3,24927	2 586 394,39	39 859 803,57	42 446 197,96	1 765 000,00	44 211 197,96
BULGARIA	0,14	0,21853	102 576,55	2 680 775,34	2 783 351,88	70 000,00	2 853 351,88
CZECH REPUBLIC	0,51	0,79745	373 671,71	9 782 566,65	10 156 238,37	255 000,00	10 411 238,37
DENMARK	2,00	1,98045	1 465 379,26	24 294 794,82	25 760 174,08	1 000 000,00	26 760 174,08
GERMANY	20,50	20,5798	15 020 137,42	252 458 793,95	267 478 931,37	10 250 000,00	277 728 931,37
ESTONIA	0,05	0,08635	36 634,48	1 059 282,25	1 095 916,73	25 000,00	1 120 916,73
IRELAND	0,91	0,94006	666 747,56	11 532 007,79	12 198 755,35	455 000,00	12 653 755,35
GREECE	1,47	1,50735	1 077 053,76	18 491 130,29	19 568 184,04	735 000,00	20 303 184,04
SPAIN	7,85	7,93248	5 751 613,60	97 310 194,16	103 061 807,76	3 925 000,00	106 986 807,76
FRANCE	19,55	17,81269	14 324 082,27	218 513 796,75	232 837 879,02	9 775 000,00	242 612 879,02
CROATIA	0,00	0,22518	0,00	2 762 352,95	2 762 352,95	0,00	2 762 352,95
ITALY	12,86	12,53009	9 422 388,64	153 710 502,99	163 132 891,64	6 430 000,00	169 562 891,64
CYPRUS	0,09	0,11162	65 942,07	1 369 277,18	1 435 219,25	45 000,00	1 480 219,25
LATVIA	0,07	0,11612	51 288,27	1 424 480,08	1 475 768,35	35 000,00	1 510 768,35
LITHUANIA	0,12	0,18077	87 922,76	2 217 561,70	2 305 484,45	60 000,00	2 365 484,45
LUXEMBOURG	0,27	0,25509	197 826,20	3 129 268,20	3 327 094,40	135 000,00	3 462 094,40
HUNGARY	0,55	0,61456	402 979,30	7 538 998,26	7 941 977,56	275 000,00	8 216 977,56
MALTA	0,03	0,03801	21 980,69	466 280,47	488 261,16	15 000,00	503 261,16
NETHERLANDS	4,85	4,77678	3 553 544,71	58 598 242,83	62 151 787,53	2 425 000,00	64 576 787,53
AUSTRIA	2,41	2,39757	1 765 782,01	29 411 735,32	31 177 517,33	1 205 000,00	32 382 517,33
POLAND	1,30	2,00734	952 496,52	24 624 662,80	25 577 159,32	650 000,00	26 227 159,32
PORTUGAL	1,15	1,19679	842 593,07	14 681 394,38	15 523 987,45	575 000,00	16 098 987,45
ROMANIA	0,37	0,71815	271 095,16	8 809 768,94	9 080 864,11	185 000,00	9 265 864,11
SLOVENIA	0,18	0,22452	131 884,13	2 754 256,52	2 886 140,66	90 000,00	2 976 140,66
SLOVAKIA	0,21	0,37616	153 864,82	4 614 471,47	4 768 336,29	105 000,00	4 873 336,29
FINLAND	1,47	1,50909	1 077 053,76	18 512 475,41	19 589 529,16	735 000,00	20 324 529,16
SWEDEN	2,74	2,93911	2 007 569,59	36 054 974,58	38 062 544,17	1 370 000,00	39 432 544,17
UNITED KINGDOM	14,82	14,67862	10 858 460,32	180 067 187,34	190 925 647,66	7 410 000,00	198 335 647,66
TOTAL EU-28	100,00	100,00	73 268 963,00	1 226 731 037,00	1 300 000 000,00	50 000 000,00	1 350 000 000,00

COMMISSION IMPLEMENTING DECISION (EU) 2017/1207**of 4 July 2017****renewing the authorisation for the placing on the market of genetically modified maize MON 810 (MON-ØØ81Ø-6) products pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council***(notified under document C(2017) 4453)***(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 11(3) and 23(3) thereof,

Whereas:

- (1) On 11 and 18 April 2007, Monsanto Europe SA submitted to the Commission three applications, in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003, for the renewal of the authorisation of existing foods, food ingredients and feed produced from maize MON 810, of the authorisation of feed containing and consisting of maize MON 810 and of the authorisation of maize MON 810 in products consisting of it or containing it for other uses than food and feed, as any other maize, including cultivation. After the date of the entry into force of Regulation (EC) No 1829/2003, those products were notified to the Commission pursuant to Article 8(1)(a) and (b) and Article 20(1)(b) of that Regulation and included in the Community Register of genetically modified food and feed.
- (2) On 9 March 2016, Monsanto Europe SA sent a letter to the Commission requesting that the part of the application concerning cultivation be considered separately from the rest of the application. Therefore, this Decision does not cover the use of maize MON 810 seeds for cultivation.
- (3) The placing on the market of pollen produced from maize MON 810 was authorised by Commission Implementing Decision 2013/649/EU ⁽²⁾ and is therefore not covered by this Decision.
- (4) On 30 June 2009, the European Food Safety Authority ('EFSA') issued a favourable opinion (updated on 30 July 2009) in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that genetically modified maize MON 810, as described in the application, is as safe as its conventional counterpart with respect to potential adverse effects on human and animal health and is unlikely to have adverse effects on the environment taking into account its intended uses ⁽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 Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (6) Taking into account those considerations, the authorisation should be renewed for food and food ingredients produced from maize MON 810, with the exception of pollen, for feed containing or consisting of, or produced from maize MON 810 and for maize MON 810 in products consisting of it or containing it for other uses than food or feed, with the exception of cultivation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 1.

⁽²⁾ Commission Implementing Decision 2013/649/EU of 6 November 2013 authorising the placing on the market of pollen produced from maize MON 810 (MON-ØØ81Ø-6) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 302, 13.11.2013, p. 44).

⁽³⁾ Scientific Opinion of the Panel on Genetically Modified Organisms on applications (EFSA-GMORX-MON810) for the renewal of authorisation for the continued marketing of (1) existing food and food ingredients produced from genetically modified insect resistant maize MON810; (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON810, all under Regulation (EC) No 1829/2003 from Monsanto. EFSA Journal (2009) 1149, pp. 1-84.

- (7) A unique identifier has been assigned to genetically modified maize MON 810 in accordance with Commission Regulation (EC) No 65/2004 ⁽¹⁾, in the context of the initial authorisation of maize MON 810. That unique identifier should continue to be used.
- (8) On the basis of the EFSA opinion, no specific labelling requirements, other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003, appear to be necessary for food and food ingredients produced from maize MON 810 and for feed containing, consisting of, or produced from maize MON 810.
- (9) The authorisation holder should submit annual reports on the implementation and the results of the activities set out in this monitoring plan. Those results should be presented in accordance with Commission Decision 2009/770/EC ⁽²⁾.
- (10) The EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or for 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) 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 maize (*Zea mays* L.) MON 810, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier MON-ØØ81Ø-6, in accordance with Regulation (EC) No 65/2004.

Article 2

Renewal of the authorisation

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

- (a) foods and food ingredients produced from MON-ØØ81Ø-6 maize, with the exception of pollen;
- (b) feed containing, consisting of or produced from MON-ØØ81Ø-6 maize;
- (c) MON-ØØ81Ø-6 maize in products containing it or consisting of it for any other use than food or feed, with the exception of cultivation.

Article 3

Labelling

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 of the European Parliament and of the Council ⁽³⁾, the 'name of the organism' shall be 'maize'.

⁽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⁾ 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 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)

*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 to this Decision, 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 the format set out in 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 referred to in Article 28 of Regulation (EC) No 1829/2003.

*Article 6***Authorisation holder**

The authorisation holder shall be Monsanto Europe SA, 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 SA, Avenue de Tervuren 270-272, B-1150 Brussels, Belgium.

Done at Brussels, 4 July 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicant and authorisation holder:

Name: Monsanto Europe SA

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 produced from MON-ØØ81Ø-6 maize, with the exception of pollen;
- (2) feed containing, consisting of, or produced from MON-ØØ81Ø-6 maize;
- (3) MON-ØØ81Ø-6 maize in products containing it or consisting of it for any other use than food or feed, with the exception of cultivation.

The genetically modified MON-ØØ81Ø-6 maize as described in the applications expresses the Cry1Ab protein, derived from *Bacillus thuringiensis* subsp. *kurstaki*, which confers protection against predation by certain lepidopteran insect pests, including the European corn borer (*Ostrinia nubilalis*) and pink borers (*Sesamia* spp.).

(c) Labelling:

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';

(d) Method for detection:

- (1) Event-specific real-time PCR-based method for the quantification of MON-ØØ81Ø-6 maize;
- (2) Validated by the Federal Institute for Risk assessment (BfR) in collaboration with the Joint Research Centre of the European Commission and other parties, and verified by the EU Reference Laboratory established under Regulation (EC) No 1829/2003 on genomic DNA extracted from maize seeds, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>
- (3) Reference Material: ERM-BF413 and ERM-AD413 accessible via the Institute for Reference Materials and Measurements (IRMM) of the Joint Research Centre (JRC) of the European Commission at <https://crm.jrc.ec.europa.eu/>

(e) Unique identifier:

MON-ØØ81Ø- 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) 2017/1208**of 4 July 2017****authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton GHB119 (BCS-GHØØ5-8) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed***(notified under document C(2017) 4457)***(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 25 March 2011, Bayer 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 GHB119 cotton ('the application'). The application also covered the placing on the market of genetically modified cotton GHB119 in products consisting of it or containing it for other uses than food and feed as any other cotton, 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 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 included a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.
- (3) On 21 October 2016, 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 cotton GHB119, as described in the application, is as safe and as nutritious as its conventional counterpart 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 Articles 6(4) and Article 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.
- (6) Taking into account those considerations, authorisation should be granted to the products containing, consisting of, or produced from genetically modified cotton GHB119.
- (7) A unique identifier should be assigned to cotton GHB119, 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), 2016. Scientific opinion on application (EFSA-GMO-NL-2011-96) for the placing on the market of genetically modified insect-resistant and herbicide-tolerant cotton GHB119, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Bayer CropScience AG. *EFSA Journal* 2016;14(10):4586, 27 pp. doi:10.2903/j.efsa.2016.4586.

⁽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 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 ⁽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 cotton GHB119, 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 set out in Commission Decision 2009/770/EC ⁽²⁾. 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 Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003.
- (10) 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.
- (11) 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 ⁽³⁾.
- (12) 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 cotton (*Gossypium hirsutum* L.) GHB119, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier BCS-GHØØ5-8, in accordance with Regulation (EC) No 65/2004.

Article 2

Authorisation

The following products are authorised for the purposes of Articles 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 cotton GHB119;
- (b) feed containing, consisting of, or produced from cotton GHB119;
- (c) Cotton GHB119 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 in Article 4(6) of Regulation (EC) No 1830/2003, the 'name of the organism' shall be 'cotton'.
2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of cotton GHB119, 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 NV, Belgium, representing Bayer CropScience LP, 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 Bayer CropScience NV, J.E. Mommaertslaan 14, 1831, Diegem, Belgium.

Done at Brussels, 4 July 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Authorisation holder:

Name: Bayer CropScience NV.

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 — United States of America.

(b) Designation and specification of the products:

- (1) foods and food ingredients containing, consisting of, or produced from genetically modified cotton BCS-GHØØ5-8;
- (2) feed containing, consisting of, or produced from genetically modified cotton BCS-GHØØ5-8;
- (3) genetically modified cotton BCS-GHØØ5-8 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.

BCS-GHØØ5-8 as described in the application, expresses the PAT protein which confers tolerance to glufosinate ammonium-based herbicides and Cry2Ae protein which confers resistance to certain lepidopteran pests.

(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 'cotton'.
- (2) The words 'not for cultivation' shall appear on the label of and in the accompanying documents of the products containing or consisting of the cotton covered by this Decision, 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 BCS-GHØØ5-8 cotton.
- (2) Validated by the EU Reference Laboratory established under Regulation (EC) No 1829/2003 on genomic DNA extracted from seeds of BCS-GHØØ5-8 cotton, published at <http://gmo-crl.jrc.ec.europa.eu/statusofdossiers.aspx>
- (3) Reference Material: ERM-BF428 accessible via the Joint Research Centre (JRC) of the European Commission, at <https://crm.irmm.jrc.ec.europa.eu/jrc/en/reference-materials/catalogue>

(e) Unique identifier:

BCS-GHØØ5-8

(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 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) 2017/1209**of 4 July 2017**

authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21, and genetically modified maize combining two, three or four of the events Bt11, 59122, MIR604, 1507 and GA21 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) 4460)

(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), 9(2), 19(3) and 21(2) thereof,

Whereas:

- (1) On 1 July 2011, Syngenta submitted an application for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from Bt11 × 59122 × MIR604 × 1507 × GA21 maize (‘the application’) to the national competent authority of Germany 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 maize Bt11 × 59122 × MIR604 × 1507 × GA21 in products consisting of it or containing it for other uses than food and feed as any other maize, with the exception of cultivation.
- (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 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 Directive 2001/18/EC.
- (3) On 21 February 2014, Syngenta extended the scope of the application to all sub-combinations of the single genetic modification events constituting Bt11 × 59122 × MIR604 × 1507 × GA21 maize, except the sub-combination 1507 × 59122, which was already authorised by Commission Decision 2010/432/EU ⁽³⁾.
- (4) On 31 March 2016, Syngenta updated the scope of the application by excluding the following four sub-combinations, which were in the scope of another application: Bt11 × GA21 maize, MIR604 × GA21 maize, Bt11 × MIR604 maize, and Bt11 × MIR604 × GA21. These sub-combinations were authorised by Commission Implementing Decision (EU) 2016/1685 ⁽⁴⁾.
- (5) On 26 August 2016, the European Food Safety Authority (‘EFSA’) gave a favourable opinion in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003 ⁽⁵⁾. EFSA concluded that genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21, as described in the application, is as safe and as nutritious as its conventional

⁽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⁾ Commission Decision 2010/432/EU of 28 July 2010 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 1507 × 59122 (DAS-Ø15Ø7-1 × DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council (OJ L 202, 4.8.2010, p. 11).

⁽⁴⁾ Commission Implementing Decision (EU) 2016/1685 of 16 September 2016 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize Bt11 × MIR162 × MIR604 × GA21, and genetically modified maize combining two or three of the events Bt11, MIR162, MIR604 and GA21, and repealing Decisions 2010/426/EU, 2011/892/EU, 2011/893/EU and 2011/894/EU (OJ L 254, 20.9.2016, p. 22).

⁽⁵⁾ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2016. Scientific Opinion on an application by Syngenta (EFSA-GMO-DE-2011-99) for the placing on the market of maize Bt11 × 59122 × MIR604 × 1507 × GA21 and twenty subcombinations, which have not been authorised previously independently of their origin, for food and feed uses, import and processing under Regulation (EC) No 1829/2003. EFSA Journal 2016;14(8):4567, 31 pp. doi:10.2903/j.efsa.2016.4567

counterpart and non-genetically modified commercial varieties as regards the potential effects on human health and the environment, and no safety concerns were identified for any of the 20 sub-combinations covered by the scope of the application.

- (6) 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.
- (7) 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.
- (8) In its opinion, EFSA recommended the collection of relevant information on expression levels of the newly expressed proteins, if any of the 20 sub-combinations were to be created via targeted breeding approaches and commercialised. In line with this recommendation, specific conditions should be laid down to that effect.
- (9) Taking into account those considerations, authorisation should be granted to the products containing, consisting of, or produced from genetically modified maize Bt11 × 59122 × MIR604 × 1507 × GA21, and the following twenty sub-combinations thereof, consisting of: five sub-combinations of four events (Bt11 × MIR604 × 1507 × GA21, Bt11 × 59122 × 1507 × GA21, Bt11 × 59122 × MIR604 × GA21, Bt11 × 59122 × MIR604 × 1507, 59122 × MIR604 × 1507 × GA21); nine sub-combinations of three events (Bt11 × 59122 × MIR604, Bt11 × 59122 × 1507, Bt11 × 59122 × GA21, Bt11 × MIR604 × 1507, Bt11 × 1507 × GA21, 59122 × MIR604 × 1507, 59122 × MIR604 × GA21, 59122 × 1507 × GA21, MIR604 × 1507 × GA21); and six sub-combinations of two events (Bt11 × 59122, Bt11 × 1507, 59122 × MIR604, 59122 × GA21, MIR604 × 1507 and 1507 × GA21).
- (10) A unique identifier should be assigned to each genetically modified organism (hereinafter 'GMO') in accordance with Commission Regulation (EC) No 65/2004 ⁽¹⁾.
- (11) 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 maize Bt11 × 59122 × MIR604 × 1507 × GA21 and the sub-combinations, with the exception of food products, should be complemented by a clear indication that the products in question are not intended 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 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.
- (14) The authorisation holder should also submit annual reports on the results of the activities set out in the specific conditions of this authorisation.
- (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.

⁽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).

- (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 Articles 9(1) and Article 15(2)(c) of Regulation (EC) No 1946/2003 of the European Parliament and of the Council ⁽¹⁾.
- (17) The Standing Committee on Plants, Animals, Food and Feed has not delivered an opinion within the time-limit laid down by its chair. 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 SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × 59122 × MIR604 × 1507 × GA21;
- (b) the unique identifier SYN-BTØ11-1 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × MIR604 × 1507 × GA21;
- (c) the unique identifier SYN-BTØ11-1 × DAS-59122-7 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × 59122 × 1507 × GA21;
- (d) the unique identifier SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4-5 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × 59122 × MIR604 × GA21;
- (e) the unique identifier SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 for genetically modified maize (*Zea mays* L.) Bt11 × 59122 × MIR604 × 1507;
- (f) the unique identifier DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) 59122 × MIR604 × 1507 × GA21;
- (g) the unique identifier SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4-5 for genetically modified maize (*Zea mays* L.) Bt11 × 59122 × MIR604;
- (h) the unique identifier SYN-BTØ11-1 × DAS-59122-7 × DAS-Ø15Ø7-1 for genetically modified maize (*Zea mays* L.) Bt11 × 59122 × 1507;
- (i) the unique identifier SYN-BTØ11-1 × DAS-59122-7 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × 59122 × GA21;
- (j) the unique identifier SYN-BTØ11-1 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 for genetically modified maize (*Zea mays* L.) Bt11 × MIR604 × 1507;
- (k) the unique identifier SYN-BTØ11-1 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) Bt11 × 1507 × GA21;
- (l) the unique identifier DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 for genetically modified maize (*Zea mays* L.) 59122 × MIR604 × 1507;
- (m) the unique identifier DAS-59122-7 × SYN-IR6Ø4-5 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) 59122 × MIR604 × GA21;
- (n) the unique identifier DAS-59122-7 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 for genetically modified maize (*Zea mays* L.) 59122 × 1507 × GA21;

⁽¹⁾ 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).

- (o) the unique identifier SYN-IR604-5 × DAS-01507-1 × MON-00021-9 for genetically modified maize (*Zea mays* L.) MIR604 × 1507 × GA21;
 - (p) the unique identifier SYN-BT011-1 × DAS-59122-7 for genetically modified maize (*Zea mays* L.) Bt11 × 59122;
 - (q) the unique identifier SYN-BT011-1 × DAS-01507-1 for genetically modified maize (*Zea mays* L.) Bt11 × 1507;
 - (r) the unique identifier DAS-59122-7 × SYN-IR604-5 for genetically modified maize (*Zea mays* L.) 59122 × MIR604;
 - (s) the unique identifier DAS-59122-7 × MON-00021-9 for genetically modified maize (*Zea mays* L.) 59122 × GA21;
 - (t) the unique identifier SYN-IR604-5 × DAS-01507-1 for genetically modified maize (*Zea mays* L.) MIR604 × 1507;
 - (u) the unique identifier DAS-01507-1 × MON-00021-9 for genetically modified maize (*Zea mays* L.) 1507 × GA21.
2. The genetically modified maize 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 'maize'.
- 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 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 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

Specific conditions for the placing on the market

- 1. The authorisation holder shall ensure that the specific conditions, referred to in point (g) of the Annex, are implemented.
- 2. The authorisation holder shall submit annual reports on the results of the activities set out in the specific conditions of this authorisation to the Commission 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 Syngenta Crop Protection NV/SA, Belgium, representing Syngenta Crop Protection AG, Switzerland.

*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 Syngenta Crop Protection NV/SA, Avenue Louise, 489, 1050 Brussels, Belgium.

Done at Brussels, 4 July 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Authorisation holder:

Name: Syngenta Crop Protection NV/SA

Address: 489, Avenue Louise, 1050 Brussels, Belgium

On behalf of Syngenta Crop Protection AG, Schwarzwaldallee 215, CH-4058 Basel, Switzerland.

(b) Designation and specification of the products:

- (1) foods and food ingredients containing, consisting of, or produced from genetically modified maizes (*Zea mays* L.) as specified in (e);
- (2) feed containing, consisting of, or produced from genetically modified maizes (*Zea mays* L.) as specified in (e);
- (3) genetically modified maizes (*Zea mays* 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.

SYN-BTØ11-1 maize expresses the Cry1Ab protein which confers protection against certain lepidopteran pests and a PAT protein which confers tolerance to glufosinate-ammonium herbicides.

DAS-59122-7 maize expresses the Cry34Ab1 and Cry35Ab1 proteins which confer protection against certain coleopteran pests and a PAT protein which confers tolerance to glufosinate-ammonium herbicides.

SYN-IR6Ø4-5 maize expresses the modified Cry3A protein which provides protection against certain coleopteran pests and PMI protein which was used as a selectable marker.

DAS-Ø15Ø7-1 maize expresses the Cry1F protein which confers protection against certain lepidopteran pests and the PAT protein, used as a selectable marker, which confers tolerance to the glufosinate-ammonium herbicide

MON-ØØØ21-9 maize expresses the mEPSPS 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 'maize';
- (2) The words 'not for cultivation' shall appear on the label of and in the accompanying documents of the products containing or consisting the maizes specified in (e) 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 SYN-BTØ11-1, DAS-59122-7, SYN-IR6Ø4-5, DAS-Ø15Ø7-1 and MON-ØØØ21-9 maizes; the detection methods are validated on the single-trait events and verified on genomic DNA extracted from seeds of SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9 maize;
- (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®-BF412 (for SYN-BTØ11-1), ERM®-BF424 (for DAS-59122-7), ERM®-BF423 (for SYN-IR6Ø4-5) and ERM®-BF418 (for DAS-Ø15Ø7) accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at <https://crm.jrc.ec.europa.eu> and AOCS 0407-A and AOCS 0407-B (for MON-ØØØ21-9) accessible via the American Oil Chemists Society at <http://www.aocs.org/LabServices/content.cfm?ItemNumber=19248>.

(e) Unique identifier:

SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9;

SYN-BTØ11-1 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9;

SYN-BTØ11-1 × DAS-59122-7 × DAS-Ø15Ø7-1 × MON-ØØØ21-9;

SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4-5 × MON-ØØØ21-9;
 SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1;
 DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9;
 SYN-BTØ11-1 × DAS-59122-7 × SYN-IR6Ø4-5;
 SYN-BTØ11-1 × DAS-59122-7 × DAS-Ø15Ø7-1;
 SYN-BTØ11-1 × DAS-59122-7 × MON-ØØØ21-9;
 SYN-BTØ11-1 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1;
 SYN-BTØ11-1 × DAS-Ø15Ø7-1 × MON-ØØØ21-9;
 DAS-59122-7 × SYN-IR6Ø4-5 × DAS-Ø15Ø7-1;
 DAS-59122-7 × SYN-IR6Ø4-5 × MON-ØØØ21-9;
 DAS-59122-7 × DAS-Ø15Ø7-1 × MON-ØØØ21-9;
 SYN-IR6Ø4-5 × DAS-Ø15Ø7-1 × MON-ØØØ21-9;
 SYN-BTØ11-1 × DAS-59122-7;
 SYN-BTØ11-1 × DAS-Ø15Ø7-1;
 DAS-59122-7 × SYN-IR6Ø4-5;
 DAS-59122-7 × MON-ØØØ21-9;
 SYN-IR6Ø4-5 × DAS-Ø15Ø7-1;
 DAS-Ø15Ø7-1 × MON-ØØØ21-9.

(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:

Specific conditions in accordance with Article 6(5)(e) and Article 18(5)(e) of Regulation (EC) No 1829/2003:

- (1) The authorisation holder shall inform the Commission if any of the sub-combinations were to be created via targeted breeding approaches and commercialised.
- (2) If it is the case, the authorisation holder shall collate information on the expression levels of the newly expressed proteins.

(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) 2017/1210**of 4 July 2017****on the identification of bis(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) and diisobutyl phthalate (DIBP) as substances of very high concern according to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council***(notified under document C(2017) 4462)***(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 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ⁽¹⁾, and in particular Article 59(9) thereof,

Whereas:

- (1) Bis(2-ethylhexyl) phthalate (DEHP), (EC No 204-211-0, CAS No 117-81-7), dibutyl phthalate (DBP) (EC No 201-557-4, CAS No 84-74-2), benzyl butyl phthalate (BBP) (EC No 201-622-7, CAS No 85-68-7) and diisobutyl phthalate (DIBP) (EC No 201-553-2, CAS No 84-69-5) are included in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006 as substances toxic for reproduction (category 1B) according to Article 57(c) of that Regulation. Those substances are also listed in Annex XIV to that Regulation.
- (2) In accordance with Article 59(3) of Regulation (EC) No 1907/2006, on 26 August 2014 Denmark submitted to the European Chemicals Agency (hereinafter referred to as 'the Agency') four dossiers in accordance with Annex XV to that Regulation (hereinafter referred to as 'Annex XV dossiers') for the identification of DEHP, DBP, BBP and DIBP as substances of very high concern under Article 57(f) of that Regulation due to their endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in paragraphs (a) to (e) of Article 57.
- (3) When the four Annex XV dossiers were considered by the Member State Committee of the Agency ('MSC'), they were considered in two parts each, one covering the human health aspects and the other covering the environmental aspects of the dossier, respectively.
- (4) As for the Annex XV dossiers for DBP, BBP and DIBP, the dossier submitter subsequently withdrew the part of its proposal concerning identification of these substances as having endocrine disrupting properties whose effects in relation to the environment give rise to an equivalent level of concern according to Article 57(f) of Regulation (EC) No 1907/2006, in order to further elaborate on the justifications provided in the documentation.
- (5) On 11 December 2014 the MSC adopted its opinions ⁽²⁾ on the remaining part of the Annex XV dossiers. The MSC reached a unanimous agreement on the identification of DEHP as having endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which give rise to an equivalent level of concern according to Article 57(f) of Regulation (EC) No 1907/2006. Accordingly the Agency amended the DEHP entry in the candidate list on 17 December 2014.
- (6) The MSC unanimously acknowledged that for DEHP, BBP, DBP and DIBP there is scientific evidence on the endocrine activity and on the link between this activity and the adverse effects to human health and further, that the substances can be considered endocrine disruptors for human health as they fulfil the WHO/IPCS definition for an endocrine disruptor and the recommendations from the European Commission's Expert Advisory Group for a substance to be identified as an endocrine disruptor.

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.⁽²⁾ <http://echa.europa.eu/role-of-the-member-state-committee-in-the-authorisation-process/svhc-opinions-of-the-member-state-committee>

- (7) However, the MSC did not reach unanimous agreement on the identification of the four substances under Article 57(f) of Regulation (EC) No 1907/2006 as giving rise to an equivalent level of concern to those of other substances listed in points (a) to (c) of that Article due to endocrine disrupting properties in relation to human health. According to four members of the MSC the effects for human health pointed out in the Annex XV dossiers were the same effects, caused by the same mode of action, as those already taken into account when the substances were included in the candidate list due to their toxicity for reproduction according to Article 57(c) of that Regulation.
- (8) On 20 February 2015, pursuant to Article 59(9) of Regulation (EC) No 1907/2006, the MSC referred its opinion to the Commission for a decision on the identification of the four substances as having endocrine disrupting properties for human health giving rise to an equivalent level of concern according to Article 57(f).
- (9) The Commission notes the unanimous agreement in MSC that the four substances have endocrine disrupting properties and that the adverse effects caused by this mode of action are the same effects that led to their classification as toxic for reproduction and their identification as substances of very high concern according to Article 57(c) of Regulation (EC) No 1907/2006. The Commission also notes that the majority of members of the MSC considered that the level of concern of those effects is equivalent to those of substances referred to in Article 57(a) to (e).
- (10) The Commission notes that Article 57 does not preclude identifying a substance as being of very high concern several times based on more than one intrinsic property causing the same effect on human health.
- (11) Therefore DEHP, BBP, DBP and DIBP should be identified under Article 57(f) as substances of very high concern due to their endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those of other substances listed in paragraph(s) (a) to (e) of that Article.
- (12) This Decision is without prejudice to the outcome of the on-going activities related to the definition of criteria for the identification of endocrine disruptors in accordance with the provisions of Regulation (EC) No 1107/2009 of the European Parliament and of the Council ⁽¹⁾, and Regulation (EU) No 528/2012 of the European Parliament and of the Council ⁽²⁾.
- (13) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Sole Article

1. The following substances are identified as substances having endocrine disrupting properties whose effects to human health give rise to an equivalent level of concern according to Article 57(f) of Regulation (EC) No 1907/2006:

- Bis(2-ethylhexyl) phthalate (DEHP), (EC No 204-211-0, CAS No 117-81-7)
- Dibutyl phthalate (DBP) (EC No 201-557-4, CAS No 84-74-2)
- Benzyl butyl phthalate (BBP) (EC No 201-622-7, CAS No 85-68-7)
- Diisobutyl phthalate (DIBP) (EC No 201-553-2, CAS No 84-69-5)

⁽¹⁾ Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

⁽²⁾ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

2. The entry of the substances specified in paragraph 1 in the candidate list referred to in Article 59(1) of Regulation (EC) No 1907/2006 shall be amended by adding, under 'Reason for inclusion', 'Equivalent level of concern having probable serious effects to human health'.

This Decision is addressed to the European Chemicals Agency.

Done at Brussels, 4 July 2017.

For the Commission
Elżbieta BIENKOWSKA
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2017/1211**of 4 July 2017**

authorising the placing on the market of products containing, consisting of, or produced from genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913 (DAS-24236-5 × DAS-21023-5 × MON-88913-8) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council

(notified under document C(2017) 4495)

(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) On 12 March 2009, Dow AgroSciences Europe 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 281-24-236 × 3006-210-23 × MON 88913 cotton.
- (2) The application also covers the placing on the market of 281-24-236 × 3006-210-23 × MON 88913 cotton in products consisting of it or containing it for any other uses than food and feed as any other cotton, with the exception of cultivation.
- (3) In accordance with Article 5(5) and Article 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 Directive 2001/18/EC. It also includes a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC.
- (4) On 8 April 2016, the European Food Safety Authority ('EFSA') issued a favourable opinion ⁽³⁾ in accordance with Articles 6 and 18 of Regulation (EC) No 1829/2003. It concluded that genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913 is as safe and as nutritious as its conventional counterpart in the context of its intended uses.
- (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 Article 6(4) and Article 18(4) of Regulation (EC) No 1829/2003.
- (6) In its opinion, EFSA also concluded that the environmental monitoring plan, 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 cotton 281-24-236 × 3006-210-23 × MON 88913.
- (8) A unique identifier should be assigned to genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913 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), 2016. Scientific Opinion on application EFSA-GMO-NL-2012-68 for the placing on the market of genetically modified cotton 281-24-236 × 3006-210-23 × MON 88913 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. *EFSA Journal* 2016; 14(4):4430, 21 pp. doi:10.2903/j.efsa.2016.4430.

⁽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).

- (9) On the basis of the EFSA opinion, no specific labelling requirements other than those provided for in Article 13(1) and Article 25(2) of Regulation (EC) No 1829/2003 appear to be necessary for foods, food ingredients and feed containing, consisting of, or produced from cotton 281-24-236 × 3006-210-23 × MON 88913. However, in order to ensure the use of the products containing or consisting of cotton 281-24-236 × 3006-210-23 × MON 88913 within the limits of the authorisation provided for by this Decision, the labelling of those products, with the exception of food products, should be complemented by a clear indication that the products in question must not be used for cultivation.
- (10) 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 ⁽¹⁾.
- (11) The EFSA opinion does not justify the imposition of specific conditions or restrictions for the placing on the market and/or of specific conditions or restrictions for the use and handling, including post-market monitoring requirements for the use of the food and feed, or of specific conditions for the protection of particular ecosystems/environment and/or geographical areas, as provided for in Article 6(5)(e) and Article 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 referred to in Regulation (EC) No 1829/2003.
- (13) 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 cotton (*Gossypium hirsutum* L.) 281-24-236 × 3006-210-23 × MON 88913, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DAS-24236-5×DAS-21Ø23-5×MON-88913-8, 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 DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton;
- (b) feed containing, consisting of, or produced from DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton;
- (c) DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton in products containing it or consisting of it for any other use than (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 of the European Parliament and of the Council ⁽²⁾, the 'name of the organism' shall be 'cotton'.

⁽¹⁾ 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).

⁽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).

2. The words 'not for cultivation' shall appear on the label of and in the documents accompanying products containing or consisting of DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton with the exception of the 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 the format set out in 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 referred to in Article 28 of Regulation (EC) No 1829/2003.

Article 6

Authorisation holder

The authorisation holder shall be Dow AgroSciences Europe, United Kingdom, representing Mycogen Seeds, United States.

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 Dow AgroSciences Europe, European Development Centre 3 Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom.

Done at Brussels, 4 July 2017.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

(a) Applicant and Authorisation holder:

Name: Dow AgroSciences Europe, representing Mycogen Seeds, United States.

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

(b) Designation and specification of the products:

- (1) foods and food ingredients containing, consisting of, or produced from DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton;
- (2) feed containing, consisting of, or produced from DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton;
- (3) DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton in products containing it or consisting of it for any other than (1) and (2), with the exception of cultivation.

The genetically modified DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton, as described in the application, expresses the phosphinothricin acetyl transferase (PAT) protein which confers tolerance to glufosinate-ammonium herbicides and the modified CP4 5-enolpyruvyl-shikimate-3-phosphate synthase (CP4EPSPS) protein which confers tolerance to glyphosate herbicides, Cry1F and Cry1Ac proteins, conferring protection against certain lepidopteran insect pests.

(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 'cotton';
- (2) The words 'not for cultivation' shall appear on the label of and in documents accompanying products containing or consisting of DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton 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 DAS-24236-5, DAS-21Ø23-5 and MON-88913-8 cottons; the detection methods have been validated on genomic DNA extracted from seeds DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton and on genomic DNA extracted from seeds of the single-trait events and verified on genomic DNA extracted from seeds of DAS-24236-5×DAS-21Ø23-5×MON-88913-8 cotton;
- (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®-BF422 for 281-24-236 × 3006-210-23 cotton is accessible via accessible via the Joint Research Centre (JRC) of the European Commission, Institute for Reference Materials and Measurements (IRMM) at <https://crm.jrc.ec.europa.eu/> and
 - AOCS 0906-D and AOCS 0804-A for MON 88913 cotton is accessible via the American Oil Chemists Society at <https://www.aocs.org/crm>

(e) Unique identifier:

DAS-24236-5×DAS-21Ø23-5×MON-88913-8

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

Biosafety Clearing-House, Record ID: see [to be completed 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 on the internet*]

(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) 2017/1212**of 4 July 2017****authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize DAS-40278-9, 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) 4503)***(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 Articles 7(3) and 19(3) thereof,

Whereas:

- (1) On 11 November 2010, Dow AgroSciences Europe submitted an application for the placing on the market of foods, food ingredients, and feed containing, consisting of, or produced from DAS-40278-9 maize (‘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 maize DAS-40278-9 in products consisting of it or containing it for other uses than food and feed as any other maize, with the exception of cultivation.
- (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 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 Directive 2001/18/EC.
- (3) On 5 December 2016, 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 maize DAS-40278-9, as described in the application, is as safe and as nutritious as its conventional counterpart and non-genetically modified commercial varieties as regards the potential effects on human 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 Articles 6(4) and Article 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.
- (6) Taking into account those considerations, authorisation should be granted to the products containing, consisting of, or produced from genetically modified maize DAS-40278-9.
- (7) A unique identifier should be assigned to the genetically modified organism (hereinafter ‘GMO’) 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), 2016. Scientific Opinion on an application by DOW AgroSciences LLC (EFSA-GMO-NL-2010-89) for placing on the market the genetically modified herbicide-tolerant maize DAS-40278-9 for food and feed uses, import and processing under Regulation (EC) No 1829/2003. EFSA Journal 2016;14(12):4633, 25 pp. doi: 10.2903/j.efsa.2016.4633.

⁽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 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 ⁽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 maize DAS-40278-9, 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/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.
- (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 Articles 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 maize (*Zea mays* L.) DAS-40278-9, as specified in point (b) of the Annex to this Decision, is assigned the unique identifier DAS-40278-9, 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 the GMO referred to in Article 1;
- (b) feed containing, consisting of, or produced from GMO referred to in Article 1;
- (c) The GMO referred to in Article 1 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 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 on the label of and in the documents accompanying products containing or consisting of the GMO referred to in Article 1, 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 (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 monitoring plan to the Commission 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 Dow AgroSciences Europe.

*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 Dow AgroSciences Europe, European Development Centre, 3 Milton Park, Abingdon, Oxon OX14 4RN, United Kingdom.

Done at Brussels, 4 July 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.

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

- (1) foods and food ingredients containing, consisting of, or produced from maize DAS-40278-9;
- (2) feed containing, consisting of, or produced from maize DAS-40278-9;
- (3) Maize DAS-40278-9 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.

DAS40278-9 maize expresses the AAD-1 protein which confers tolerance to 2,4-dichlorophenoxyacetic acid (2,4-D) and aryloxyphenoxypropionate (AOPP) 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 'maize';
- (2) The words 'not for cultivation' shall appear on the label of and in the accompanying documents of the products containing or consisting of maize DAS-40278-9 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-40278-9 maize; the detection method is validated on the single-trait event using genomic DNA extracted from seeds of DAS-40278-9 maize;
- (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®-BF433 accessible via the Joint Research Centre (JRC) of the European Commission at <https://crm.jrc.ec.europa.eu/>.

(e) **Unique identifier:**

DAS-40278-9;

(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) **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*]

(h) **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) 2017/1213**of 4 July 2017****on setting up the Integrated Structural Biology — European Research Infrastructure Consortium (Instruct-ERIC)***(notified under document C(2017) 4507)***(Only the Czech, Danish, Dutch, English, French, Italian, Portuguese and Slovak texts are authentic)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) ⁽¹⁾, and in particular point (a) of Article 6(1) thereof,

Whereas:

- (1) Belgium, the Czech Republic, Denmark, France, Greece, Israel, Italy, the Netherlands, Portugal, Slovakia, Spain, Sweden, the United Kingdom and the European Molecular Biology Laboratory (EMBL) requested the Commission to set up the Integrated Structural Biology — European Research Infrastructure Consortium (Instruct-ERIC). Greece, Spain, Sweden and the European Molecular Biology Laboratory have made known their decision to participate in Instruct-ERIC initially as an observer. They have agreed that the United Kingdom will be the host Member State of Instruct-ERIC.
- (2) Since the United Kingdom notified on 29 March 2017 its intention to leave the Union, pursuant to Article 50 of the Treaty on European Union, the Treaties will cease to apply to the United Kingdom from the date of entry into force of the withdrawal agreement or, failing that, 2 years after the notification, unless the European Council, in agreement with the United Kingdom, decides to extend that period. As a consequence, and without prejudice to any provisions of the withdrawal agreement, this Decision only applies until the United Kingdom ceases to be a Member State.
- (3) If the United Kingdom ceases to be a Member State and without prejudice to the provisions of a possible withdrawal agreement, the Statutory Seat of Instruct-ERIC will be relocated to the territory of a Member State or associated country in accordance with Article 8(1) of Regulation (EC) No 723/2009.
- (4) The Commission has, in accordance with Article 5(2) of Regulation (EC) No 723/2009, assessed the application and concluded that it meets the requirements set out in that Regulation.
- (5) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 20 of Regulation (EC) No 723/2009,

HAS ADOPTED THIS DECISION:

Article 1

1. The Integrated Structural Biology — European Research Infrastructure Consortium named 'Instruct-ERIC' is set up.
2. The essential elements of the Statutes of Instruct-ERIC are set out in the Annex.

⁽¹⁾ OJ L 206, 8.8.2009, p. 1.

Article 2

This Decision is addressed to the Kingdom of Belgium, the Czech Republic, the Kingdom of Denmark, the French Republic, the State of Israel, the Italian Republic, the Kingdom of the Netherlands, the Portuguese Republic, the Slovak Republic and the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 4 July 2017.

For the Commission

Carlos MOEDAS

Member of the Commission

ANNEX

ESSENTIAL ELEMENTS OF THE STATUTES OF INSTRUCT-ERIC

The following Articles and paragraphs of the Articles of the Statutes of Instruct-ERIC provide for the essential elements in accordance with 6(3) of Regulation (EC) No 723/2009

1. Objectives and Activities

(Article 4 of the Statutes of Instruct-ERIC)

1. The objective of Instruct-ERIC is to establish and operate a distributed pan-European Research Infrastructure called Instruct, specifically:

- (a) to facilitate the advancement of integrative structural cell biology;
- (b) to make available a managed access to state-of-the-art European structural biology facilities and specialist expertise;
- (c) to further the development of the Instruct technology; and
- (d) to provide training in integrative techniques in the field of structural biology.

2. To this end Instruct-ERIC shall undertake and coordinate a variety of activities, including but not limited to:

- (a) those offered by Instruct Centres such as the provision of infrastructure to the structural biology user community and other Instruct training, networking and dissemination activities;
- (b) the creation and operation of the Instruct Hub that provides the central coordinating role for all Instruct Activities offered through Instruct Centres;
- (c) the provision of access to structural biology infrastructure at Instruct Centres using an Instruct web-portal incorporating peer review and scheduling for access reserved for Instruct users by an Instruct Centre;
- (d) the coordination by the Instruct Hub of training courses and workshops on techniques and methods relevant to structural cell biology, enabling the dissemination of expertise, the stimulation for exchange and co-development with industry;
- (e) the coordination by the Instruct Hub of joint programmes between Instruct Centres that support new technical and technological approaches that enable better integration across structural biology technologies;
- (f) the coordination of programmes with companies that develop innovative structural biology technologies enabling their effective uptake by Instruct Centres, making these available for access to academic and industrial researchers in Europe;
- (g) the bridging of structural, cell and systems biology communities by coordinating joint actions including meetings, conferences and workshops;
- (h) any other related action that helps strengthen research in the European Research Area.

3. Instruct-ERIC shall construct and operate on a non-economic basis, in order to further promote innovation as well as transfer of knowledge and technology. Limited economic activities may be carried out provided that they are closely related to its principal mission and that they do not jeopardise the achievements thereof.

2. Establishment of Instruct-ERIC

(Article 2 of the Statutes of Instruct-ERIC)

1. There shall be a European Research Infrastructure called the 'Integrated Structural Biology', hereinafter referred to as 'Instruct'.

2. Instruct shall have the legal form of a European Research Infrastructure Consortium (ERIC) incorporated under the provision of the ERIC Regulation (EC) No 723/2009 modified by Council Regulation (EU) No 1261/2013 ⁽¹⁾ and be named 'Instruct-ERIC'.

⁽¹⁾ Council Regulation (EU) No 1261/2013 of 2 December 2013 amending Regulation (EC) No 723/2009 concerning the Community legal framework for a European Research Infrastructures Consortium (ERIC) (OJ L 326, 6.12.2013, p. 1).

3. Seat

(Article 3 of the Statutes of Instruct-ERIC)

Instruct-ERIC shall have its statutory seat in Oxford, United Kingdom.

4. Duration

(Article 29 of the Statutes of Instruct-ERIC)

Instruct-ERIC shall exist for an indefinite period of time. It may be wound-up in accordance with Article 30.

5. Winding up

(Article 30 of the Statutes of Instruct-ERIC)

1. The winding up of Instruct-ERIC shall follow a decision of the Council in accordance with Article 13.
2. Without undue delay and in any event within 10 days after adoption of the decision to wind up Instruct-ERIC and again on closure of Instruct-ERIC, Instruct-ERIC shall notify the European Commission about the decision.
3. Assets remaining after payment of Instruct-ERIC debts shall be apportioned among the Members in proportion to their accumulated annual in-cash contribution to Instruct-ERIC. Liabilities remaining after winding up, including Instruct-ERIC assets, shall be apportioned among the Members in proportion to their accumulated annual in-cash contribution to Instruct-ERIC and not exceeding the amount of one annual contribution.
4. Instruct-ERIC shall cease to exist on the day on which the European Commission publishes the appropriate notice in the *Official Journal of the European Union*.

6. Liability

(Article 21 of the Statutes of Instruct-ERIC)

1. Instruct-ERIC shall be liable for its debts.
2. The Members are not jointly liable for the debts of Instruct-ERIC.
3. Each Member's financial liability for Instruct-ERIC's debts and liabilities shall be limited to their respective contributions provided to Instruct-ERIC as set out in Annex 2.
4. Instruct-ERIC shall take appropriate insurance to cover the risks specific to the construction and operation of Instruct-ERIC.

7. Access Policy

(Article 25 of the Statutes of Instruct-ERIC)

1. Each Member hosting one or more Instruct Centre shall provide infrastructure access, subject to the approved access procedure, to successful applicant(s). Each Instruct Centre shall identify the fraction of their infrastructure capacity that is made available for Instruct-approved access projects. Approval of Instruct-ERIC access proposals is granted by the Access Committee based on the international expert review driven by scientific excellence first, also taking account of technical and operational feasibility.
2. The delivery of access services shall be overseen by the Director taking into account:
 - (a) the scientific (peer) review of the project;
 - (b) the logistic assessment performed by the Instruct Centre(s) involved on the technical feasibility of the project, the expected timeline and scheduling of the work at the Centre; and
 - (c) the resources made available, financial and in-kind, by the Instruct Centre and the Instruct Hub to support the requested access, specifically the capacity for Instruct access at the requested Instruct Centre, and sufficient central access funds, managed by the Instruct Hub.

3. Instruct-ERIC shall accept proposals from any user for access to Instruct-ERIC infrastructure.
4. Instruct-ERIC shall ensure open access for researchers from institutions in the Members includes access to data, tools and services offered by Instruct Centres. Member users shall be eligible to apply for Instruct-ERIC funded access to infrastructure, training courses, workshops, attendance at conferences or any other activity offered and supported by Instruct-ERIC. Access to data and tools shall be governed by the Instruct-ERIC Data Management and Biologicals Policies and in the case of collaborative work, agreement between all users, as defined in Article 27.
5. Users from non-Members may apply for access using the proposal system. For academic or pre-competitive research, an academic fee will be charged for access. Academic fees may also be charged to non-commercial users requesting access through an Intergovernmental Organisation and that are not located in one of the Members.
6. Users requesting access to Instruct infrastructure for proprietary research shall be charged a commercial fee for access. In this case, the data arising from access will belong to the user and there shall be no obligation to disclose or publish it.
7. Priority for access shall always be given to the Members.
8. Users of Instruct-ERIC infrastructure for non-proprietary research shall agree to publish the data arising from the access and make the data publicly available.

8. Independent Scientific Advisory Board (ISAB)

(Article 17 of the Statutes of Instruct-ERIC)

1. The ISAB shall be established to advise the Council on any scientific and strategic matters relevant to Instruct-ERIC. The ISAB shall review the performance of the Instruct Centres in order to provide the Instruct Council with recommendations of approval or removal of research facilities as Instruct Centres and with advice on progress and future strategic and scientific goals, needs, opportunities, taking account of the global context.
2. The ISAB shall comprise a minimum of five and a maximum of eight scientific and technical experts appointed by the Council. The ISAB shall elect a Chairperson from its members by simple majority. The mandate of the appointed Chairperson shall be automatically extended so that they can fulfil their term in the Chair. The ISAB members shall not be directly involved in the management of Instruct-ERIC, and shall be usually experts from outside Europe. Members of the ISAB may be proposed to the Council by the Director. Any potential conflicts of interest should be declared before consideration by the Council. Members of the ISAB are appointed for a 3-year term, renewable once, by 1 to 3 years. Members of the ISAB shall be required to sign a non-disclosure agreement no later than 30 days after their nomination or before any confidential information is exchanged, whichever date is earlier.
3. The ISAB shall meet at least once per year to assess the overall scientific and strategic progress made by Instruct-ERIC against its scientific vision and other challenges.
4. Members of the ISAB shall be reimbursed by Instruct-ERIC for reasonable travel and accommodation expenses, as directed by the Council.

9. Dissemination Policy

(Article 26 of the Statutes of Instruct-ERIC)

1. Instruct-ERIC shall be a facilitator of research and shall as a general rule encourage as free access as possible to research data. Irrespective of this principle Instruct-ERIC shall promote high quality research and shall support a culture of 'best practice' through training activities.
2. Instruct-ERIC shall generally encourage researchers to make their research results publicly available and shall request all users to acknowledge Instruct-ERIC accordingly.
3. The dissemination policy shall describe the various target groups, and Instruct-ERIC shall use several channels to reach the target audiences, such as web portals, newsletter, workshops, presence in conferences, articles in magazines, daily newspapers and social media.
4. Publications arising from Instruct-ERIC supported activities should acknowledge the support of staff and the use of experimental resources of Instruct-ERIC.

10. Data Management, Intellectual Property and Biologicals Policies

(Article 27 of the Statutes of Instruct-ERIC)

1. Generally open source and open access principles shall be favoured.
2. All data generated as a result of Instruct-ERIC activities should, in the first case, remain the property of the originating scientist or his/her employing institution. Subject to pre-existing obligations including to various establishments, grant funding agencies or other third parties, Users of Instruct infrastructure may require agreements on intellectual property rights to be in place before work commences. Intellectual property protection for the Users shall be the sole responsibility of the users.
3. Where access to Instruct-ERIC infrastructure is provided for collaborative projects, the users shall agree shared ownership of experimental data or materials prior to commencement of the access work. Shared intellectual property protection for all users in the collaborative work is the responsibility of the users.
4. Instruct-ERIC shall provide guidance (in the form of its Data Management and Biologicals Policies) to users of Instruct-ERIC infrastructure to ensure that research undertaken using material made accessible through Instruct-ERIC shall be undertaken within a framework that recognises, to the extent applicable under the laws and regulations of its host country, the rights of data owners and privacy of individuals, and ownership of data and tools generated as a result of Instruct-ERIC activity must be clearly defined.

11. Employment Policy

(Article 28 of the Statutes of Instruct-ERIC)

1. Instruct-ERIC may employ staff which shall be appointed and dismissed by the Director.
2. The Council shall approve the staff plan prepared by the Director while approving the workplan.
3. The Director shall provide the Council with information in advance on employment vacancies and the staff plan. The Council shall decide which positions require its approval in terms of selected candidates.
4. The selection procedures for Instruct-ERIC staff positions shall be transparent, non-discriminatory, respect equal job opportunities and affirmative action consistent with the applicable labour laws. Where employment contracts are offered, these shall follow the national laws of the country in which staff are employed.

12. Procurement Policy

(Article 24(1) of the Statutes of Instruct-ERIC)

The Council shall approve detailed rules on procurement procedures and criteria which Instruct-ERIC shall be obliged to follow. This procurement policy shall respect the principles of transparency, proportionality, mutual recognition, equal treatment and non-discrimination.

