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Legislation

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(Non-legislative acts)

# REGULATIONS

#### COMMISSION IMPLEMENTING REGULATION (EU) 2017/2200

#### of 28 November 2017

opening and providing for the administration of import tariff quotas of certain cereals from 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 its Article 187 points (a) and (c) thereof,

Whereas:

- Regulation (EU) 2017/1566 of the European Parliament and of the Council (2) provides for preferential (1)arrangements as regards customs duties for the import of certain goods originating in Ukraine. The import tariff quotas referred to in Annex II of that Regulation are to be administered by the Commission in accordance with Article 184 of Regulation (EU) No 1308/2013. They shall apply for three years as from1 January 2018.
- To ensure that imports of certain cereals originating in Ukraine covered by the tariff quotas are orderly and not (2)speculative, it is appropriate to provide that these imports are managed through the use of import licences. To this end, Commission Regulations (EC) No 1301/2006 (3), (EC) No 1342/2003 (4) and Commission Implementing Regulation (EU) 2016/1239 (3) should apply, save where derogations are laid down in this Regulation.
- To ensure the proper management of these quotas, deadlines for the lodging of import licence applications (3) should be laid down and the information to be included in applications and licences should be specified.

 <sup>(&</sup>lt;sup>1</sup>) OJ L 347, 20.12.2013, p. 671.
 (<sup>2</sup>) Regulation (EU) 2017/1566 of the European Parliament and of the Council of 13 September 2017 on the introduction of temporary autonomous measures for Ukraine supplementing the trade concessions available under the Association Agreement (OJ L 254, 30.9.2017, p. 1).

<sup>(3)</sup> 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).

Commission Regulation (EC) No 1342/2003 of 28 July 2003 laying down special detailed rules for the application of the system of import and export licences for cereals and rice, (OJ L 189, 29.7.2003, p. 12). Commission Implementing Regulation (EU) 2016/1239 of 18 May 2016 laying down detailed rules for the application of Regulation

<sup>(</sup>EU) No 1308/2013 of the European Parliament and of the Council with regard to the system of import and export licences (OJ L 206, 30.7.2016, p. 44).

- (4) In the interests of efficient administration, when notifying the Commission in accordance with this Regulation, Member States should use the information systems provided for in Commission Delegated Regulation (EU) 2017/1183 (<sup>1</sup>) and Commission Implementing Regulation (EU) 2017/1185 (<sup>2</sup>).
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

#### Article 1

#### Opening and management of tariffs quotas

1. The import tariff quotas for certain products originating in Ukraine, referred to in the Annex, shall be open annually from 1 January 2018 to 31 December 2020.

2. Duties on imports within the import tariff quota referred to in paragraph 1 shall be levied at a rate of EUR 0 per tonne.

3. Regulations (EC) No 1342/2003, (EC) No 1301/2006 and Implementing Regulation (EU) 2016/1239 shall apply, save as otherwise provided for in this Regulation.

#### Article 2

#### Rules for submitting import licence applications and issuing import licences

1. Notwithstanding Article 6(1) of Regulation (EC) No 1301/2006, applicants may not submit more than one import licence application per order number and per week. Where applicants lodge more than one application, none of those applications shall be admissible and the securities lodged when the applications were submitted shall be forfeited to the Member State concerned.

Import licence applications shall be lodged with the competent authorities of the Member States each week no later than Friday at 13.00 (Brussels time).

2. Each import licence application shall indicate, in whole numbers, a quantity in kilograms which may not exceed the total quantity of the quota concerned.

3. Import licences shall be issued on the fourth working day following the deadline for the notification referred to in Article 4(1).

4. Section 8 of the import licence application and the import licence shall contain the name Ukraine and the 'Yes' box shall be marked with a cross. Licences shall be valid only for products originating in Ukraine.

#### Article 3

#### Validity of import licences

Import licences shall be valid from the period running from the actual day of issue, in accordance with Article 7(2) of Implementing Regulation (EU) 2016/1239, until the end of the second month following the month in question.

#### Article 4

#### Notifications

1. No later than 18.00 (Brussels time) on the Monday following the week in which the import licence application was lodged, Member States shall send the Commission, by electronic means, each application by order number with the origin of the product and the quantity applied for by CN code, including 'nil' notifications. The notification shall be made in accordance with Delegated Regulation (EU) 2017/1183 and Implementing Regulation (EU) 2017/1185.

<sup>(&</sup>lt;sup>1</sup>) Commission Delegated Regulation (EU) 2017/1183 of 20 April 2017 on supplementing Regulations (EU) No 1307/2013 and (EU) No 1308/2013 of the European Parliament and of the Council with regard to the notifications to the Commission of information and documents (OJ L 171, 4.7.2017, p. 100).

<sup>(2)</sup> Commission Implementing Regulation (EU) 2017/1185 of 20 April 2017 laying down rules for the application of Regulations (EU) No 1307/2013 and (EU) No 1308/2013 of the European Parliament and of the Council as regards notifications to the Commission of information and documents and amending and repealing several Commission Regulations (OJ L 171, 4.7.2017, p. 113).

2. Member States shall communicate to the Commission, by electronic means, on the day of issue of the import licences, the information on the licences issued as referred to in Article 11(1)(b) of Regulation (EC) No 1301/2006, with the total quantities by CN code for which import licences have been issued.

## Article 5

#### Entry into force

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

It shall apply from 1 January 2018 to 31 December 2020.

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

Done at Brussels, 28 November 2017.

For the Commission The President Jean-Claude JUNCKER

#### ANNEX

Notwithstanding the rules for the interpretation of the Combined Nomenclature, the wording of the description of the products is to be considered as having no more than an indicative value, the scope of the preferential scheme being determined, within the context of this Annex, by CN codes as they exist on 1 January 2017. When the CN code is preceded by 'ex', the application of the preferential arrangements is determined on the basis of the CN code and the description of the product.

Order No	Product	CN code	Quantity in tonnes
09.4277	Spelt, common wheat and meslin, other than seed	1001 99 00	65 000
	Common wheat flour and spelt flour,	1101 00 15	
	Meslin flour	1101 00 90	
	Cereal flour other than wheat, meslin, rye, maize, barley, oat, rice	1102 90 90	
	Groats and meal of common wheat and spelt	1103 11 90	
	Wheat pellets	1103 20 60	
09.4278	Maize other than seed	1005 90 00	625 000
	Maize flour	1102 20	
	Groats and meal of maize	1103 13	
	Maize pellets	1103 20 40	
	Worked grains of maize	1104 23	
09.4279	Barley other than seed	1003 90 00	325 000
	Barley flour	1102 90 10	
	Barley pellets	ex 1103 20 25	

# DECISIONS

#### COMMISSION IMPLEMENTING DECISION (EU) 2017/2201

of 27 November 2017

authorising the placing on the market of 2'-fucosyllactose produced with Escherichia coli strain BL21 as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2017) 7662)

(Only the German text is authentic)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (1), and in particular Article 7 thereof,

#### Whereas:

- (1)On 4 August 2014, the company Jennewein Biotechnologie GmbH made a request to the competent authority of the Netherlands to place powder and liquid concentrate of the oligosaccharide 2'-fucosyllactose produced with a genetically modified strain of Escherichia coli BL21 on the Union market as novel food ingredient within the meaning of point (d) of Article 1(2) of Regulation (EC) No 258/97. The target population is the infant population.
- 2'-fucosyllactose falls outside the scope of Regulation (EC) No 1829/2003 of the European Parliament and of the (2)Council (2) as the genetically modified strain of Escherichia coli BL21 is used as a processing aid and the material derived from the genetically modified microorganism is not present in the novel food.
- (3) On 3 June 2016, the competent authority of the Netherlands issued its initial assessment report. In that report it came to the conclusion that powder and liquid concentrate of the oligosaccharide 2'-fucosyllactose produced with a genetically modified strain of Escherichia coli BL21 meets the criteria for novel food ingredients set out in Article 3(1) of Regulation (EC) No 258/97.
- (4) On 13 June 2016, the Commission forwarded the initial assessment report to the other Member States.
- (5) Reasoned objections were raised within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97. In particular, objections concerning elevated intake levels of 2'-fucosyllactose were raised. In accordance with Article 7(1) of Regulation (EC) No 258/97, a decision should be adopted taking into account the objections raised. The applicant consequently modified the request concerning the maximum amount of 2'-fucosyllactose in infant formulae and follow- on formulae. That change and additional explanations provided by the applicant alleviated the concerns to the satisfaction of Member States and of the Commission.
- Regulation (EU) No 609/2013 of the European Parliament and of the Council (3) lays down requirements for (6)food intended for infants and young children. The use of 2'-fucosyllactose powder and liquid concentrate should be authorised without prejudice to that Regulation and to any other legislation that applies in parallel to Regulation (EC) No 258/97.

 <sup>(&</sup>lt;sup>1</sup>) OJ L 43, 14.2.1997, p. 1.
 (<sup>2</sup>) Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p. 1). Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young

children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC, and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

#### Article 1

Without prejudice to Regulation (EU) No 609/2013, 2'-fucosyllactose powder and liquid concentrate as specified in Annex I to this Decision may be placed on the Union market as a novel food ingredient for the uses defined and at the maximum level established in Annex II to this Decision.

#### Article 2

The designation of 2'-fucosyllactose powder and liquid concentrate authorised by this Decision on the labelling of the foodstuffs shall be '2'-fucosyllactose' for the powder and for the liquid concentrate.

#### Article 3

This Decision is addressed to Jennewein Biotechnologie GmbH, Maarweg 32, 53619 Rheinbreitbach, Germany.

Done at Brussels, 27 November 2017.

For the Commission Vytenis ANDRIUKAITIS Member of the Commission

#### ANNEX I

## SPECIFICATIONS OF 2'-FUCOSYLLACTOSE

# **Definition:**

Chemical name	$\alpha$ -L-fucopyranosyl-(1 $\rightarrow$ 2)- $\beta$ -D-galactopyranosyl-(1 $\rightarrow$ 4)-D-glucopyranoside
Chemical formula	C <sub>18</sub> H <sub>32</sub> O <sub>15</sub>
Molecular mass	488,44 Da
CAS No.	41263-94-9

**Description:** 2'-fucosyllactose powder produced with a genetically modified strain of *Escherichia coli* BL21 is a white to ivory powder that is derived from 2'-fucosyllactose liquid concentrate by spray drying. The 2'-fucosyllactose liquid concentrate is a colourless to slight yellow clear 45 % w/v  $\pm$  5 % w/v aqueous solution.

# Specifications of 2'-fucosyllactose powder

Specification Parameter		Limits
Physical parameter	White to ivory colour	
Chemical analysis	2'-fucosyllactose	≥ 90 %
	Lactose	≤ 5 %
	3-fucosyllactose	≤ 5 %
	Difucosyllactose	≤ 5 %
	Fucosylgalactose	≤ 3 %
	Glucose	≤ 3 %
	Galactose	≤ 3 %
	Fucose	≤ 3 %
GMO detection	Negative	
Water content		≤ 9,0 %
Protein content		≤ 100 µg/g
Total Ash		≤ 0,5 %
Contaminants	Lead	≤ 0,02 mg/kg
	Arsenic	$\leq 0.2 \text{ mg/kg}$
	Cadmium	$\leq 0.1 \text{ mg/kg}$
	Mercury	$\leq$ 0,5 mg/kg
	Aflatoxin M <sub>1</sub>	≤ 0,025 µg/kg
Microbial Parameters	Total Plate Count (TPC)	$\leq 10^4 \text{ CFU/g}$
	Enterobacteria/Coliforms	absent in 11 g
	Yeast and Mould	≤ 100 CFU/g
	Salmonella spp.	Negative/100 g
	Cronobacter spp.	Negative/100 g
	Endotoxins	≤ 100 EU/g

CFU: Colony Forming Units; EU: Endotoxin Units

# Specifications of 2'-fucosyllactose liquid concentrate

	Limits	
Physical parameter Solids content	Colourless to slightly yellow, clear solution	45 % w/v (+/- 5 % w/v) dry matter in water
Chemical analysis	2'-fucosyllactose Lactose 3-fucosyllactose Difucosyllactose Fucosylgalactose Glucose Galactose Fucose	<ul> <li>≥ 90 %</li> <li>≤ 5 %</li> <li>≤ 5 %</li> <li>≤ 5 %</li> <li>≤ 3 %</li> <li>≤ 3 %</li> <li>≤ 3 %</li> <li>≤ 3 %</li> </ul>
GMO detection	Negative	
Protein content Total Ash		≤ 100 μg/g ≤ 0,5 %
Contaminants	Lead Arsenic Cadmium Mercury Aflatoxin M <sub>1</sub>	<ul> <li>≤ 0,02 mg/kg</li> <li>≤ 0,2 mg/kg</li> <li>≤ 0,1 mg/kg</li> <li>≤ 0,5 mg/kg</li> <li>≤ 0,025 µg/kg</li> </ul>
Microbial Parameters	Total Plate Count (TPC) Enterobacteria/Coliforms Yeast and Mould Salmonella spp. Cronobacter spp. Endotoxins	<ul> <li>≤ 5 000 CFU/g</li> <li>absent in 11 g</li> <li>≤ 50 CFU/g</li> <li>Negative/200 ml</li> <li>Negative/200 ml</li> <li>≤ 100 EU/ml</li> </ul>

CFU: Colony Forming Units; EU: Endotoxin Units

# ANNEX II

# Authorised uses of 2'-fucosyllactose powder and liquid concentrate

Food category	Maximum level	
Infant formulae and follow-on formulae	1,2 gram 2'-fucosyllactose per litre final product ready for use mar- keted as such or reconstituted as instructed by the manufacturer.	

# ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

#### DECISION No 1/2017 OF THE JOINT CARIFORUM-EU COUNCIL

established by the Economic Partnership Agreement between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part,

#### of 17 November 2017

#### concerning the amendment of Annex IX to Protocol I: Overseas countries and territories [2017/2202]

THE JOINT CARIFORUM-EU COUNCIL,

Having regard to the Economic Partnership Agreement between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part ('the Agreement'), and in particular Article 41 of Protocol I thereof,

Whereas:

- Protocol I of the Agreement Concerning the Definition of the Concept of 'Originating Products' and Methods of (1)Administrative Cooperation — defines overseas countries and territories (OCTs) to mean the overseas countries and territories set out in Annex IX thereto;
- (2)Following the change of status of Mayotte (1) and Saint-Barthélemy (2), and the entry into force of Council Decision 2013/755/EU (3) on the association of the overseas countries and territories with the European Union, the list of overseas countries and territories in Annex IX to Protocol I of the Agreement should be updated,

HAS DECIDED AS FOLLOWS:

#### Article 1

Annex IX to Protocol I is replaced by the Annex which is annexed to this Decision.

#### Article 2

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

Done at Brussels, 17 November 2017.

For the CARIFORUM States K. JOHNSON SMITH

For the EU Party C. MALMSTRÖM

<sup>(1)</sup> European Council Decision 2012/419/EU of 11 July 2012 amending the status of Mayotte with regard to the European Union (OJ EU L 204, 31.7.2012, p. 131).

European Council Decision 2010/718/EU of 29 October 2010 amending the status with regard to the European Union of the island of Saint-Barthélemy (OJ EU L 325, 9.12.2010, p. 4). Council Decision 2013/755/EU of 25 November 2013 on the association of the overseas countries and territories with the European

Union (OJ L 344, 19.12.2013, p. 1).

#### ANNEX

#### 'ANNEX IX TO PROTOCOL I

#### Overseas countries and territories

For the purposes of this Protocol "overseas countries and territories" means the following countries and territories referred to in Annex II to the Treaty on the Functioning of the European Union listed below:

(This list is without prejudice to the status of these countries and territories, or future changes in their status.)

- 1. Overseas countries and territories that have special relations with the Kingdom of Denmark:
  - Greenland.
- 2. Overseas countries and territories that have special relations with the French Republic:
  - New Caledonia and Dependencies,
  - French Polynesia,
  - Saint Pierre and Miquelon,
  - Saint Barthélemy,
  - French Southern and Antarctic Territories,
  - Wallis and Futuna.
- 3. Overseas countries and territories that have special relations with the Kingdom of the Netherlands:
  - Aruba,
  - Bonaire,
  - Curaçao,
  - Saba,
  - Sint Eustatius,
  - Sint Maarten.
- 4. Overseas countries and territories that have special relations with the United Kingdom of Great Britain and Northern Ireland:
  - Anguilla,
  - Bermuda,
  - Cayman Islands,
  - Falkland Islands,
  - South Georgia and the South Sandwich Islands,
  - Montserrat,
  - Pitcairn,
  - Saint Helena and Dependencies,
  - British Antarctic Territory,
  - British Indian Ocean Territory,
  - Turks and Caicos Islands,
  - British Virgin Islands.'

# DECISION No 2/2017 OF THE JOINT CARIFORUM-EU COUNCIL

established by the Economic Partnership Agreement between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part,

#### of 17 November 2017

#### as regards the establishment of a list of arbitrators [2017/2203]

THE JOINT CARIFORUM-EU COUNCIL,

Having regard to the Economic Partnership Agreement between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part, and in particular Article 221(1) thereof,

HAS ADOPTED THIS DECISION:

Article 1

The list of 15 arbitrators provided for in Article 221(1) annexed to this Decision is adopted by the Parties.

Article 2

The CARIFORUM-EU Trade and Development Committee may amend the list of arbitrators annexed to this Decision.

Article 3

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

Done at Brussels, 17 November 2017.

For the CARIFORUM States K. JOHNSON SMITH For the EU Party C. MALMSTRÖM

#### ANNEX

#### List of arbitrators referred to in Article 221(1) of the Agreement

Arbitrators selected by the CARIFORUM States:

- Ms Tracy BENN-ROBERTS (Antigua and Barbuda)
- Ms Nicole FOSTER (Barbados)
- Ms Bertha COOPER ROSSEAU (The Bahamas)
- Ms Michelle A. BROWN (Jamaica)
- Ms Fabiola MEDINA GARNES (Dominican Republic)

Arbitrators selected by the EU:

Mr Jacques BOURGEOIS (Belgium)

Mr Claus - Dieter EHLERMANN (Germany)

Mr Pieter Jan KUIJPER (Netherlands)

- Mr Giorgio SACERDOTI (Italy)
- Mr Ramon TORRENT (Spain)
- Arbitrators jointly selected by the Parties:
- Mr Frederick ABBOTT (United States)
- Mr James BACCHUS (United States)
- Mr Armand DE MESTRAL (Canada)
- Ms Claudia OROZCO (Colombia)

Mr Helge SELAND (Norway)

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