

# Official Journal of the European Union

# L 34



English edition

## Legislation

Volume 63

6 February 2020

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## I

(Legislative acts)

## REGULATIONS

## COMMISSION IMPLEMENTING REGULATION (EU) 2020/154

of 23 January 2020

registering a geographical indication of a spirit drink under Article 30(2) of Regulation (EU) 2019/787 of the European Parliament and of the Council 'Norsk Vodka'/'Norwegian Vodka'

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/787 of the European Parliament and of the Council of 17 April 2019 on the definition, description, presentation and labelling of spirit drinks, the use of the names of spirit drinks in the presentation and labelling of other foodstuffs, the protection of geographical indications for spirit drinks, the use of ethyl alcohol and distillates of agricultural origin in alcoholic beverages, and repealing Regulation (EC) No 110/2008 <sup>(1)</sup>, and in particular Article 30(2) thereof,

Whereas:

- (1) The Commission examined Norway's application of 25 November 2016 for registration of the geographical indication 'Norsk Vodka'/'Norwegian Vodka' pursuant to Article 17(5) of Regulation (EC) No 110/2008 of the European Parliament and of the Council <sup>(2)</sup>.
- (2) Regulation (EU) 2019/787, which replaces Regulation (EC) No 110/2008, entered into force on 25 May 2019. Under Article 49(1) of that Regulation, Chapter III of Regulation (EC) No 110/2008 on geographical indications was repealed with effect from 8 June 2019.
- (3) After concluding that the application complied with Regulation (EC) No 110/2008, the Commission published the main specifications of the technical file in the *Official Journal of the European Union* <sup>(3)</sup> as required by Article 17(6) of that Regulation, in accordance with the first subparagraph of Article 50(4) of Regulation (EU) 2019/787.
- (4) No notice of opposition has been received by the Commission under Article 27(1) of Regulation (EU) 2019/787.
- (5) The indication 'Norsk Vodka'/'Norwegian Vodka' should therefore be registered as a geographical indication,

HAS ADOPTED THIS REGULATION:

*Article 1*

The geographical indication 'Norsk Vodka'/'Norwegian Vodka' is hereby registered. This Regulation grants the name 'Norsk Vodka'/'Norwegian Vodka' the protection referred to in Article 21 of Regulation (EU) 2019/787 in accordance with Article 30(4) of that Regulation.

<sup>(1)</sup> OJ L 130, 17.5.2019, p. 1.

<sup>(2)</sup> Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 (OJ L 39, 13.2.2008, p. 16).

<sup>(3)</sup> OJ C 241, 17.7.2019, p. 11.

*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, 23 January 2020.

*For the Commission,  
On behalf of the President,  
Janusz WOJCIECHOWSKI  
Member of the Commission*

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## II

(Non-legislative acts)

## INTERNATIONAL AGREEMENTS

## COUNCIL DECISION (CFSP) 2020/155

of 24 October 2019

**on the signing and conclusion, on behalf of the Union, of the Agreement between the European Union and the Federal Republic of Somalia on the status of the European Union Capacity Building Mission in Somalia (EUCAP Somalia)**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 37 thereof, in conjunction with Article 218(5) and (6) of the Treaty on the Functioning of the European Union,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) On 16 July 2012, the Council adopted Decision 2012/389/CFSP <sup>(1)</sup> on the European Union Mission on Regional Maritime Capacity Building in the Horn of Africa (EUCAP NESTOR).
- (2) Article 8 of Decision 2012/389/CFSP provides that the status of EUCAP NESTOR and its staff, including where appropriate the privileges, immunities and further guarantees necessary for the completion and smooth functioning of EUCAP NESTOR, is to be the subject of an agreement concluded pursuant to Article 37 of the Treaty on European Union and in accordance with the procedure laid down in Article 218 of the Treaty on the Functioning of the European Union.
- (3) On 15 July 2012, the Prime Minister of the Transitional Federal Government of the Somali Republic, in a letter to the High Representative of the Union for Foreign Affairs and Security Policy, confirmed that 'the rights and obligations contained in the agreement on the status of the EU-led mission Atalanta concluded on 31 December 2008 will also be applicable to EUCAP NESTOR, its personnel, premises and assets'.
- (4) On 12 December 2016, the Council in Decision (CFSP) 2016/2240 <sup>(2)</sup> decided that EUCAP NESTOR should focus on assisting Somalia in strengthening its maritime security capacity in order to enable it to enforce maritime law more effectively. Decision (CFSP) 2016/2240 renamed EUCAP NESTOR as EUCAP Somalia. The conclusion of a formal status of mission agreement with the Federal Republic of Somalia specifically for EUCAP Somalia therefore seemed appropriate.
- (5) On 12 April 2018, the Council adopted a Decision authorising the opening of negotiations with the Federal Republic of Somalia for an agreement on the status of the European Union Capacity Building Mission in Somalia (EUCAP Somalia).
- (6) An agreement on the status of EUCAP Somalia in the Federal Republic of Somalia has been negotiated between the Union and the Federal Republic of Somalia.
- (7) The Agreement should be approved on behalf of the Union,

<sup>(1)</sup> Council Decision 2012/389/CFSP of 16 July 2012 on the European Union Mission on Regional Maritime Capacity Building in the Horn of Africa (EUCAP NESTOR) (OJ L 187, 17.7.2012, p. 40).

<sup>(2)</sup> Council Decision (CFSP) 2016/2240 of 12 December 2016 amending Decision 2012/389/CFSP on the European Union Mission on Regional Maritime Capacity Building in the Horn of Africa (EUCAP NESTOR) (OJ L 337, 13.12.2016, p. 18).

HAS ADOPTED THIS DECISION:

*Article 1*

The Agreement between the European Union and the Federal Republic of Somalia on the status of the European Union Capacity Building Mission in Somalia (EUCAP Somalia) ('the Agreement') is hereby approved on behalf of the Union.

The text of the Agreement is attached to this Decision.

*Article 2*

The President of the Council is hereby authorised to designate the person(s) empowered to sign the Agreement in order to bind the Union.

*Article 3*

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

Done at Luxembourg, 24 October 2019.

*For the Council*  
*The President*  
A.-K. PEKONEN

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## AGREEMENT

### **between the European Union and the Federal Republic of Somalia on the status of the European Union capacity building mission in Somalia (EUCAP Somalia)**

THE EUROPEAN UNION, hereinafter referred to as the 'EU',

of the one part, and

THE FEDERAL REPUBLIC OF SOMALIA, hereinafter referred to as the 'Host State',

of the other part,

together hereinafter referred to as the 'Parties',

TAKING INTO ACCOUNT:

- the letter of 11 January 2013 from the Prime Minister of the Federal Government of the Somali Republic to the High Representative of the Union for Foreign Affairs and Security Policy,
- Council Decision 2012/389/CFSP of 16 July 2012 on the European Union Capacity Building Mission in Somalia (EUCAP Somalia) <sup>(1)</sup>,
- that this Agreement will not affect the Parties' rights and obligations under international agreements and other instruments establishing international courts and tribunals, including the Statute of the International Criminal Court,

HAVE AGREED AS FOLLOWS:

#### *Article 1*

#### **Scope and definitions**

1. This Agreement shall apply to the European Union capacity building mission in Somalia (EUCAP Somalia) and its personnel.
2. This Agreement shall apply only within the territory of the Host State.
3. For the purposes of this Agreement:
  - (a) 'EUCAP Somalia' or the 'Mission' shall mean the EU Capacity Building Mission in Somalia (EUCAP Somalia), established by the Council of the European Union in Decision 2012/389/CFSP, including its components, units, headquarters and personnel deployed in the territory of the Host State and assigned to EUCAP Somalia;
  - (b) 'Head of Mission' shall mean the Head of Mission of EUCAP Somalia, appointed by the Council of the European Union;
  - (c) 'European Union' or 'EU' shall mean the permanent bodies of the EU and their staff;
  - (d) 'Sending State' shall mean any EU Member State or non-EU State that has seconded personnel to the Mission;
  - (e) 'EUCAP Somalia personnel' shall mean the Head of Mission, personnel seconded by EU Member States, by the European External Action Service (EEAS), by EU institutions and by non-EU States invited by the EU to participate in EUCAP Somalia, international staff recruited on a contractual basis by EUCAP Somalia deployed for the preparation, support and implementation of the Mission, and personnel travelling at the request of a Sending State, an EU institution or the EEAS in the framework of the Mission. It shall not include commercial contractors or personnel employed locally;
  - (f) 'headquarters' shall mean the headquarters of EUCAP Somalia in Mogadishu;
  - (g) 'facilities' shall mean all buildings, premises, installations and land required for the conduct of the activities of the Mission, as well as for the accommodation of EUCAP Somalia personnel;

<sup>(1)</sup> OJ L 187, 17.7.2012, p. 40.

- (h) 'personnel employed locally' shall mean personnel who are nationals of, or permanently resident in, the Host State;
- (i) 'official correspondence' shall mean all correspondence relating to EUCAP Somalia and its functions;
- (j) 'contractor' shall mean any person supplying to EUCAP Somalia goods or services related to the Mission's activities;
- (k) 'EUCAP Somalia assets' shall mean equipment, including means of transport, and consumer goods necessary for EUCAP Somalia.

#### *Article 2*

### **General provisions**

1. EUCAP Somalia and EUCAP Somalia personnel shall respect the laws and regulations of the Host State and shall refrain from any action or activity incompatible with the objectives of EUCAP Somalia.
2. EUCAP Somalia shall be autonomous with regard to the execution of its functions under this Agreement. The Host State shall respect the unitary and international nature of EUCAP Somalia.
3. The Head of Mission shall regularly inform the Government of the Host State of the number of EUCAP Somalia personnel stationed within the Host State's territory.

#### *Article 3*

### **Identification**

1. EUCAP Somalia personnel shall be provided with, and identified by, a Mission identification card, which they shall be obliged to carry with them at all times. The relevant authorities of the Host State shall be provided with a specimen of the Mission identification card.
2. EUCAP Somalia vehicles and any other means of transport shall bear distinctive EUCAP Somalia identification markings or registration plates or both, if security conditions allow. Specimens of those markings and plates shall be provided to the relevant authorities of the Host State.
3. EUCAP Somalia shall have the right to display the flag of the EU at its headquarters and elsewhere, alone or together with the flag of the Host State, as decided by the Head of Mission. National flags or insignia of the constituent national contingents of EUCAP Somalia may be displayed on EUCAP Somalia facilities, vehicles and any other means of transport, and uniforms, as decided by the Head of Mission.

#### *Article 4*

### **Border crossing and movement within the Host State's territory**

1. EUCAP Somalia personnel, assets, vehicles and any other means of transport shall cross the border of the Host Party at official border crossings, sea ports and via the international air corridors.
2. The Host State shall facilitate the entry into and the exit from the territory of the Host State for EUCAP Somalia personnel and EUCAP Somalia assets, vehicles and any other means of transport. Except for passport control on entry into and departure from the territory of the Host State, EUCAP Somalia personnel holding a Mission identification card or provisional proof of participation in EUCAP Somalia shall be exempt from regulations on customs controls and procedures, visa and immigration regulations, and any form of immigration inspection within the territory of the Host State.
3. EUCAP Somalia personnel shall be exempt from the regulations of the Host State governing the registration and control of aliens, but shall not acquire any right to permanent residence or domicile within the Host State's territory.
4. EUCAP Somalia assets, vehicles and any other means of transport entering, transiting or exiting the Host State's territory in support of EUCAP Somalia shall be exempt from any requirement to produce inventories or other customs documentation and from any inspection.



5. Vehicles and any other means of transport used in support of EUCAP Somalia shall not be subject to local licensing or registration requirements. Relevant international standards and regulations shall continue to apply.

If required, supplementary arrangements as referred to in Article 19 shall be concluded.

6. EUCAP Somalia personnel may drive vehicles, navigate vessels and operate aircraft and any other means of transport within the territory of the Host State provided they have valid national or international driving licences, ship masters certificates or pilot licences, as appropriate. The Host State shall accept as valid, without tax or fee, driving licences or permits carried by EUCAP Somalia personnel.

7. EUCAP Somalia and EUCAP Somalia personnel together with their vehicles and any other means of transport, equipment and supplies shall enjoy free and unrestricted movement throughout the territory of the Host State, including its territorial sea and airspace.

If required, supplementary arrangements may be concluded in accordance with Article 19.

8. For the purpose of travel on official duties, EUCAP Somalia personnel and personnel employed locally shall be entitled to use public roads, bridges, ferries, airports and ports without the payment of duties, fees, tolls, taxes or other charges. EUCAP Somalia shall not be exempt from reasonable charges for services requested and received under the conditions that apply to those provided to the Host State's nationals.

#### *Article 5*

### **Privileges and immunities of EUCAP Somalia granted by the Host State**

1. EUCAP Somalia facilities shall be inviolable. The Host State's agents shall not enter them without the consent of the Head of Mission.

2. EUCAP Somalia facilities, their furnishings and other assets therein as well as their means of transport shall be immune from search, requisition, attachment or execution.

3. EUCAP Somalia, its property and assets, wherever located and by whomsoever held, shall enjoy immunity from every form of legal process.

4. EUCAP Somalia archives and documents shall be inviolable at any time, wherever they may be.

5. EUCAP Somalia official correspondence shall be inviolable.

6. EUCAP Somalia, as well as its providers or contractors, shall be exempt from all national, regional and communal dues, taxes and charges of a similar nature in respect of purchased and imported goods, services provided and facilities used by EUCAP Somalia for the purposes of EUCAP Somalia. EUCAP Somalia shall not be exempt from dues, taxes or charges that represent payment for services rendered.

7. The Host State shall permit the entry of items required for the purpose of EUCAP Somalia and shall grant those items exemption from all customs duties, fees, tolls, taxes and similar charges other than charges for storage, transport and other services rendered.

#### *Article 6*

### **Privileges and immunities of EUCAP Somalia personnel granted by the Host State**

1. EUCAP Somalia personnel shall not be subject to any form of arrest or detention.

2. Papers, correspondence and assets of EUCAP Somalia personnel shall be inviolable, except in case of measures of execution which are permitted pursuant to paragraph 7.

3. The Host State shall provide, in accordance with its applicable laws and regulations, EUCAP Somalia personnel with a diplomatic identity card.

4. EUCAP Somalia personnel shall enjoy immunity from the criminal jurisdiction of the Host State under all circumstances. The immunity from criminal jurisdiction of EUCAP Somalia personnel may be waived by the Sending State or EU institution concerned, as the case may be. Such waiver must always be an express waiver.
5. EUCAP Somalia personnel shall enjoy immunity from the civil and administrative jurisdiction of the Host State in respect of words spoken or written and all acts performed by them in the exercise of their official functions. If any civil proceeding is instituted against EUCAP Somalia personnel before any Host State court, the Head of Mission and the competent authority of the Sending State or EU institution shall be notified immediately. Prior to initiation of the proceeding before the court, the Head of Mission and the competent authority of the Sending State or EU institution shall certify to the court whether the act in question was performed by EUCAP Somalia personnel in the exercise of their official functions. If the act was performed in the exercise of official functions, the proceeding shall not be initiated and Article 16 shall apply. If the act was not performed in the exercise of official functions, the proceeding may continue. The certification by the Head of Mission and the competent authority of the Sending State or EU institution shall be binding upon the jurisdiction of the Host State which may not contest it. The initiation of proceedings by EUCAP Somalia personnel shall preclude them from invoking immunity from jurisdiction in respect of any counter-claim directly connected with the principal claim.
6. EUCAP Somalia personnel shall not be obliged to give evidence as witnesses.
7. No measures of execution may be taken in respect of EUCAP Somalia personnel, except in the case where a civil proceeding not related to their official functions is instituted against them. Property of EUCAP Somalia personnel, which is certified by the Head of Mission to be necessary for the fulfilment of their official functions, shall be free from seizure for the satisfaction of a judgment, decision or order. In civil proceedings, EUCAP Somalia personnel shall not be subject to any restrictions on their personal liberty or to any other measures of constraint.
8. The immunity of EUCAP Somalia personnel from the jurisdiction of the Host State shall not exempt them from the jurisdictions of the respective Sending States.
9. EUCAP Somalia personnel shall, with respect to services rendered for EUCAP Somalia, be exempt from social security provisions which may be in force in the Host State.
10. EUCAP Somalia personnel shall be exempt from any form of taxation in the Host State on the salary and emoluments paid to them by EUCAP Somalia or the Sending States, as well as on any income received from outside the Host State.
11. The Host State shall, in accordance with such laws and regulations as it may adopt, permit the entry of articles for the personal use of EUCAP Somalia personnel, and shall grant exemption from all customs duties, taxes, and related charges other than charges for storage, transport and similar services, in respect of such articles. The Host State shall also allow the export of such articles. The purchase of goods and services on the domestic market by EUCAP Somalia personnel shall be exempt from VAT and taxes in accordance with the laws of the Host State.
12. The personal baggage of EUCAP Somalia personnel shall be exempt from inspection, unless there are serious grounds for considering that it contains articles that are not for the personal use of EUCAP Somalia personnel, or articles whose import or export is prohibited by the law or subject to quarantine regulations of the Host State. Inspection of such personal baggage shall be conducted only in the presence of EUCAP Somalia personnel concerned or of an authorised representative of EUCAP Somalia.

#### *Article 7*

#### **Personnel employed locally**

Personnel employed locally shall enjoy privileges and immunities only to the extent allowed by the Host State. However, the Host State shall exercise its jurisdiction over such personnel in such a manner as not to interfere unduly with the performance of the functions of EUCAP Somalia.

*Article 8***Criminal jurisdiction**

The competent authorities of a Sending State shall have the right to exercise on the territory of the Host State all the criminal jurisdiction and disciplinary powers conferred on them by the law of the Sending State with regard to EUCAP Somalia personnel.

*Article 9***Security**

1. The Host State, by its own means, shall assume full responsibility for the security of EUCAP Somalia personnel.
2. For the purposes of paragraph 1, the Host State shall take all necessary measures for the protection, safety and security of EUCAP Somalia and EUCAP Somalia personnel. Any specific provisions proposed by the Host State shall be agreed with the Head of Mission before their implementation. The Host State shall permit, and support free of any charge, activities relating to the medical evacuation of EUCAP Somalia personnel.

If required, supplementary arrangements as referred to in Article 19 shall be concluded.

3. EUCAP Somalia personnel shall have the right to carry small arms and ammunition, subject to an authorisation by the Head of Mission.
4. EUCAP Somalia shall be authorised to take the necessary measures within the territory of the Host State in this context, including the use of the necessary and proportionate force to protect EUCAP Somalia personnel, to protect its premises, vehicles and assets against acts which might endanger the life of EUCAP Somalia personnel or might cause them bodily harm, and, where necessary, to protect simultaneously other persons facing the same threat in close proximity to the Mission against acts which would endanger the life of those persons or which are likely to cause them serious bodily harm.
5. The list of EUCAP Somalia personnel designated and authorised by the Head of Mission to carry firearms and ammunition, including the transport of those, shall be communicated to the competent Host State authorities. The competent Host State authorities shall provide a transport and carrying license for those specifically designated and authorised EUCAP Somalia personnel.

*Article 10***Uniform**

1. EUCAP Somalia personnel shall wear national uniform or civilian dress with distinctive EUCAP Somalia identification.
2. The wearing of uniform shall be subject to rules issued by the Head of Mission.

*Article 11***Cooperation and access to information**

1. The Host State shall provide full cooperation and support to EUCAP Somalia and EUCAP Somalia personnel.
2. If requested and necessary for the accomplishment of EUCAP Somalia, the Host State shall provide EUCAP Somalia personnel with effective access to:
  - (a) facilities, locations and official vehicles within the control of the Host State which are relevant for the fulfilment of EUCAP Somalia's mandate;
  - (b) documents, materials and information within the control of the Host State, in so far as necessary for the fulfilment of EUCAP Somalia's mandate.

If required for the purposes of the first subparagraph, supplementary arrangements as referred to in Article 19 shall be concluded.

3. The Head of Mission and the Host State shall consult regularly and take appropriate measures to ensure close and reciprocal liaison at every appropriate level. The Host State may appoint a liaison officer to EUCAP Somalia.

#### Article 12

##### **Host State support and contracting**

1. The Host State shall assist, if requested, EUCAP Somalia in finding suitable facilities.
2. The Host State shall provide free of charge, if required and available, facilities which it owns, as well as facilities owned by private entities, in so far as such facilities are requested for the conduct of EUCAP Somalia's administrative and operational activities.
3. Within its means and capabilities, the Host State shall assist in the preparation, establishment and execution of and support for EUCAP Somalia, including co-location facilities and equipment for EUCAP Somalia experts.
4. The Host State's assistance and support to EUCAP Somalia shall be provided under at least the same conditions as the assistance and support that it gives to its own nationals.
5. EUCAP Somalia shall have the necessary legal capacity under the laws and regulations of the Host State in order to fulfil its mission, and in particular for the purposes of opening bank accounts, acquiring or disposing of assets and being party to legal proceedings.
6. The law applicable to contracts concluded by EUCAP Somalia in the Host State shall be determined by the relevant provisions in those contracts.
7. The contracts concluded by EUCAP Somalia may stipulate that the dispute settlement procedure referred to in Article 16(3) and (4) shall be applicable to disputes arising from the implementation of that contract.
8. The Host State shall facilitate the implementation of contracts concluded by EUCAP Somalia with commercial entities for the purpose of the Mission.

#### Article 13

##### **Change to facilities**

1. EUCAP Somalia shall be authorised to construct, alter or otherwise modify facilities as required for its operational requirements.
2. The Host State shall not claim any compensation from EUCAP Somalia in respect of constructions, alterations or modifications to facilities.

#### Article 14

##### **Deceased EUCAP Somalia personnel**

1. The Head of Mission shall have the right to take charge of and make suitable arrangements for the repatriation of any deceased EUCAP Somalia personnel, as well as of their personal property.
2. No autopsy shall be performed on any deceased EUCAP Somalia personnel without the agreement of the Sending State concerned, and the presence of a representative of EUCAP Somalia or a representative of the Sending State concerned or both.
3. The Host State and EUCAP Somalia shall cooperate to the fullest extent possible with a view to the early repatriation of deceased EUCAP Somalia personnel.

*Article 15***Communications**

1. EUCAP Somalia may install and operate radio sending and receiving stations, as well as satellite systems. It shall cooperate with the Host State's competent authorities with a view to avoiding conflicts in the use of appropriate frequencies. The Host State shall grant access to the frequency spectrum free of charge.
2. EUCAP Somalia shall enjoy the right to unrestricted communication by radio (including satellite, mobile and hand-held radio), telephone, telegraph, facsimile and other means, as well as the right to install the equipment necessary for the maintenance of such communications within and between EUCAP Somalia facilities, including the laying of cables and land lines, for the purpose of EUCAP Somalia.
3. Within its facilities EUCAP Somalia may make the necessary arrangements for the conveyance of mail addressed to and from EUCAP Somalia or EUCAP Somalia personnel.

*Article 16***Claims for death, injury, damage and loss**

1. EUCAP Somalia and EUCAP Somalia personnel shall not be liable for any damage to or loss of civilian or government property which is related to operational necessities or caused by activities in connection with civil disturbances or the protection of EUCAP Somalia.
2. With a view to reaching an amicable settlement, claims for damage to, or loss of, civilian or government property not covered by paragraph 1, as well as claims for death of, or injury to, persons and claims for damage to, or loss of, EUCAP Somalia property, shall be forwarded to EUCAP Somalia via the competent authorities of the Host State, with regard to claims brought by a legal or natural person from the Host State, and to the competent authorities of the Host State, with regard to claims brought by EUCAP Somalia.
3. Where no amicable settlement can be found, the claim shall be submitted to a claims commission composed on an equal basis of representatives of EUCAP Somalia and representatives of the Host State. Settlement of claims shall be reached by common agreement.
4. Where no settlement can be reached within the claims commission, the dispute shall be settled by diplomatic means between the Host State and EU representatives for claims up to and including EUR 40 000. For claims exceeding that amount, the dispute shall be submitted to an arbitration tribunal, whose decisions shall be binding.
5. The arbitration tribunal referred to in paragraph 4 shall be composed of three arbitrators, one being appointed by the Host State, one being appointed by EUCAP Somalia and the third being appointed jointly by the Host State and EUCAP Somalia. Where one of the parties does not appoint an arbitrator within two months or where no agreement can be found between the Host State and EUCAP Somalia on the appointment of the third arbitrator, the arbitrator in question shall be appointed by the President of the Court of Justice of the European Union.
6. An administrative arrangement shall be concluded between EUCAP Somalia and the administrative authorities of the Host State in order to determine the terms of reference of the claims commission and the arbitration tribunal, the procedure applicable within these bodies and the conditions under which claims are to be lodged.

*Article 17***Liaison and disputes**

1. All issues arising in connection with the application of this Agreement shall be examined jointly by representatives of EUCAP Somalia and the Host State's competent authorities.
2. Failing any prior settlement, disputes concerning the interpretation or application of this Agreement shall be settled exclusively by diplomatic means between the Host State and EU representatives.

*Article 18***Other provisions**

1. The Government of the Host State shall be responsible for the implementation and for the observance by the appropriate local authorities of the Host State of the privileges, immunities and rights of EUCAP Somalia and of EUCAP Somalia personnel as provided for in this Agreement.
2. Nothing in this Agreement is intended or may be construed so as to derogate from any rights that may attach to an EU Member State or to any other State contributing to EUCAP Somalia under other agreements.

*Article 19***Implementing arrangements**

For the purpose of the application of this Agreement, operational, administrative and technical matters may be the subject of separate arrangements to be concluded between the Head of Mission and the Host State's administrative authorities.

*Article 20***Entry into force and termination**

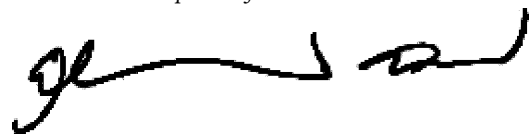
1. This Agreement shall enter into force on the day on which it is signed and shall remain in force until the date of departure of the last EUCAP Somalia personnel, as notified by EUCAP Somalia.
2. Notwithstanding paragraph 1, the provisions contained in Article 4(8), Article 5(1) to (3), (6) and (7), Article 6(1), (3), (4), (6) and (8) to (10) and Articles 13 and Article 16 shall be deemed to have applied from the date on which the first EUCAP Somalia personnel were deployed if that date was earlier than the date of entry into force of this Agreement.
3. This Agreement may be amended or terminated by written agreement between the Parties.
4. Termination of this Agreement shall not affect any rights or obligations arising out of the execution of this Agreement before such termination.

Done at Mogadishu, on 11 January 2020, in duplicate, in the English language.

*For the European Union*



*For the Federal Republic of Somalia*



# REGULATIONS

## COMMISSION IMPLEMENTING REGULATION (EU) 2020/156

of 23 January 2020

registering a geographical indication of a spirit drink under Article 30(2) of Regulation (EU) 2019/787 of the European Parliament and of the Council 'Norsk Akevitt'/'Norsk Aquavit'/'Norsk Akvavit'/'Norwegian Aquavit'

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/787 of the European Parliament and of the Council of 17 April 2019 on the definition, description, presentation and labelling of spirit drinks, the use of the names of spirit drinks in the presentation and labelling of other foodstuffs, the protection of geographical indications for spirit drinks, the use of ethyl alcohol and distillates of agricultural origin in alcoholic beverages, and repealing Regulation (EC) No 110/2008 <sup>(1)</sup>, and in particular Article 30(2) thereof,

Whereas:

- (1) The Commission examined Norway's application of 25 November 2016 for registration of the geographical indication 'Norsk Akevitt'/'Norsk Aquavit'/'Norsk Akvavit'/'Norwegian Aquavit' pursuant to Article 17(5) of Regulation (EC) No 110/2008 of the European Parliament and of the Council <sup>(2)</sup>.
- (2) Regulation (EU) 2019/787, which replaces Regulation (EC) No 110/2008, entered into force on 25 May 2019. Under Article 49(1) of that Regulation, Chapter III of Regulation (EC) No 110/2008 on geographical indications was repealed with effect from 8 June 2019.
- (3) After concluding that the application complied with Regulation (EC) No 110/2008, the Commission published the main specifications of the technical file in the *Official Journal of the European Union* <sup>(3)</sup> as required by Article 17(6) of that Regulation, in accordance with the first subparagraph of Article 50(4) of Regulation (EU) 2019/787.
- (4) No notice of opposition has been received by the Commission under Article 27(1) of Regulation (EU) 2019/787.
- (5) The indication 'Norsk Akevitt'/'Norsk Aquavit'/'Norsk Akvavit'/'Norwegian Aquavit' should therefore be registered as a geographical indication,

HAS ADOPTED THIS REGULATION:

### Article 1

The geographical indication 'Norsk Akevitt'/'Norsk Aquavit'/'Norsk Akvavit'/'Norwegian Aquavit' is hereby registered. This Regulation grants the name 'Norsk Akevitt'/'Norsk Aquavit'/'Norsk Akvavit'/'Norwegian Aquavit' the protection referred to in Article 21 of Regulation (EU) 2019/787 in accordance with Article 30(4) of that Regulation.

### 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*.

<sup>(1)</sup> OJ L 130, 17.5.2019, p. 1.

<sup>(2)</sup> Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 (OJ L 39, 13.2.2008, p. 16).

<sup>(3)</sup> OJ C 239, 16.7.2019, p. 9.

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

Done at Brussels, 23 January 2020.

*For the Commission,  
On behalf of the President,  
Janusz WOJCIECHOWSKI  
Member of the Commission*

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**COMMISSION IMPLEMENTING REGULATION (EU) 2020/157****of 5 February 2020****concerning the authorisation of tartrazine as a feed additive for dogs, cats, ornamental fish, grain-eating ornamental birds and small rodents****(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition <sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10(2) of Regulation (EC) No 1831/2003 provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC <sup>(2)</sup>.
- (2) Tartrazine was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for ornamental fish belonging to the group 'colourants, including pigments', under the heading 'other colourants'. It was also authorised without a time limit as a feed additive for dogs and cats belonging to the group 'colourants, including pigments', under the heading 'colouring agents authorised for colouring foodstuffs by Community rules'. The additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003. It was also further authorised without a time limit by Commission Regulation (EC) No 358/2005 <sup>(3)</sup> as a feed additive for grain-eating ornamental birds and small rodents belonging to the group 'colourants, including pigments', under the heading 'other colourants'.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of tartrazine as a feed additive for ornamental fish, dogs and cats, grain-eating ornamental birds and small rodents. The applicant requested the additive to be classified in the additive category 'sensory additives' and in the functional group 'colourants'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 18 October 2016 <sup>(4)</sup> that, under the proposed conditions of use, tartrazine does not have an adverse effect on animal health. It also concluded that the inhalation exposure to tartrazine is regarded as hazardous for the user of the additive, it is considered as a skin sensitiser and that no conclusion could be drawn on the irritancy to skin or eyes. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. In accordance with Commission Regulation (EC) No 429/2008 <sup>(5)</sup>, phase I of the environmental risk assessment has determined that tartrazine, as an additive intended for non-food producing animals, is exempted from further assessment due to the unlikelihood of a significant environmental effect, there being no scientifically-based evidence for concern having been identified by the Authority in its above-mentioned opinion. The Authority further concluded that tartrazine is effective in adding colour to feedingstuffs and in favourably affecting the colour of ornamental fish and grain-eating ornamental birds. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).

<sup>(3)</sup> Commission Regulation (EC) No 358/2005 of 2 March 2005 concerning the authorisations without a time limit of certain additives and the authorisation of new uses of additives already authorised in feedingstuffs (OJ L 57, 3.3.2005, p. 3).

<sup>(4)</sup> EFSA Journal 2016; 14(11):4613.

<sup>(5)</sup> Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1).

- (5) The assessment of tartrazine shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that additive should be authorised as specified in the Annex to this Regulation.
- (6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substance concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (7) 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*

**Authorisation**

The substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'colourants', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

*Article 2*

**Transitional measures**

1. The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 26 August 2020 in accordance with the rules applicable before 26 February 2020 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Feed materials and compound feed containing the substance specified in the Annex which are produced and labelled before 26 February 2022 in accordance with the rules applicable before 26 February 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

*Article 3*

**Entry into force**

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 February 2020.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

## ANNEX

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of active substance	of kg of complete feedingstuff with a moisture content of 12 %		
<b>Category: Sensory additives. Functional group: Colourants.</b> (i) substances that add or restore colour in feedingstuffs								
2a102	Tartrazine	<p><i>Additive composition</i></p> <p>Tartrazine is described as the sodium salt as the principal component Solid form</p> <p><i>Characterisation of the active substance as the sodium salt</i></p> <p>Tartrazine consists essentially of trisodium 5- hydroxy-1-(4-sulfonatophenyl)-4-(4-sulfonatophenylazo)-H-pyrazole- 3-carboxylate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. The calcium and the potassium salts are also permitted Chemical formula: <math>C_{16}H_9N_4Na_3O_9S_2</math> Solid form produced by chemical synthesis CAS number 1934-21-0</p> <p>Purity criteria: Colouring matter calculated as the sodium salt: <math>\geq 85</math> % (assay) Subsidiary colouring matter: <math>\leq 1</math> % Organic compounds other than colouring matters <math>\leq 0,5</math> %: — 4-hydrazinobenzene sulfonic acid, — 4-aminobenzene-1-sulfonic acid, — 5-oxo-1-(4-sulfofenyl)-2-pyrazoline-3-carboxylic acid, — 4,4'-diazoaminodi(benzene sulfonic acid),</p>	Cats	-	-	433	<p>1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye, skin and breathing protection.</p>	26.2.2030
			Dogs	-	-	520		
			Small rodents	-	-	2 000		
			Grain-eating ornamental birds	-	-	63		

Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of active substance of feedingstuff with a moisture content of	kg of complete with a moisture content of 12 %		
		<p>— Tetrahydroxysuccinic acid</p> <p>Un sulfonated primary aromatic amines: ≤ 0,01 %</p> <p>Ether extractable matter ≤ 0,2 % under neutral conditions</p> <p><i>Analytical method (1)</i></p> <p>For the quantification of total colouring matters content of tartrazine in the feed additive:</p> <p>— Spectrophotometry at 426 nm (FAO JECFA monographs No 1, Vol. 4 and Commission Regulation (EU) No 231/2012).</p> <p>For the quantification of tartrazine in feedingstuffs:</p> <p>— high performance liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS)</p>						

**Category: Sensory additives. Functional group: Colourants.** (iii) substances which favourably affect the colour of ornamental fish or birds

2a102	Tartrazine	<p><i>Additive composition</i></p> <p>Tartrazine described as the sodium salt as the principal component. Solid form</p> <p><i>Characterisation of the active substance as the sodium salt</i></p> <p>Tartrazine consists essentially of trisodium 5- hydroxy-1-(4-sulfonatophenyl)-4-(4-sulfonatophenylazo)-H-pyrazole- 3-carboxylate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components. The calcium and the potassium salts are also permitted.</p>	Ornamental fish	-	-	1 924	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.</li> <li>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye, skin and breathing protection.</li> </ol>	26.2.2030
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Identification number of the additive	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of active substance of kg of complete feedingstuff with a moisture content of 12 %			
		<p>Chemical formula:  <math>C_{16}H_9N_4Na_3O_9S_2</math>  Solid form produced by chemical synthesis  CAS number 1934-21-0</p> <p>Purity criteria:  Colouring matter calculated as the sodium salt: <math>\geq 85</math> % (assay)  Subsidiary colouring matter: <math>&lt; 1</math> %  Organic compounds other than colouring matters <math>\leq 0,5</math> %:  — 4-hydrazinobenzene sulfonic acid,  — 4-aminobenzene-1-sulfonic acid,  — 5-oxo-1-(4-sulfofenyl)-2-pyrazoline-3-carboxylic acid,  — 4,4'-diazaminodi(benzene sulfonic acid),  — Tetrahydroxysuccinic acid  Unulfonated primary aromatic amines: <math>\leq 0,01</math> %  Ether extractable matter <math>\leq 0,2</math> % under neutral conditions</p> <p><i>Analytical method</i> <sup>(1)</sup>  For the quantification of total colouring matters content of tartrazine in the feed additive:  — Spectrophotometry at 426 nm (FAO JECFA monographs No 1, Vol. 4 and Commission Regulation (EU) No 231/2012).  For the quantification of tartrazine in feedingstuffs:  — high performance liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS)</p>						

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

**COMMISSION IMPLEMENTING REGULATION (EU) 2020/158**  
**of 5 February 2020**  
**amending Implementing Regulation (EU) 2016/799 for the purpose of on-board weighing equipment**  
**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 165/2014 of the European Parliament and of the Council of 4 February 2014 on tachographs in road transport <sup>(1)</sup>, and in particular Article 11 thereof,

Whereas:

- (1) Installation of on-board weighing equipment is an option provided for the Member States by Article 10d(5) of Council Directive 96/53/EC <sup>(2)</sup> for carrying out the control of vehicles or vehicle combinations that are likely to have exceeded the maximum authorised weight.
- (2) Commission Implementing Regulation (EU) 2019/1213 <sup>(3)</sup> lays down detailed provisions ensuring uniform interoperability and compatibility rules of on-board weighing equipment.
- (3) Since the requirements of Commission Implementing Regulation (EU) 2019/1213 are in conflict with the provisions on on-board weighing equipment set out in Appendix 14 to Annex IC to Implementing Regulation (EU) 2016/799 <sup>(4)</sup>, that Annex should therefore be amended in order to delete point 5.5 of Appendix 14.
- (4) The measures provided for in this Commission Implementing Regulation are in accordance with the opinion of the Road Transport Committee, referred to in Article 42(3) of Regulation (EU) No 165/2014,

HAS ADOPTED THIS REGULATION:

*Article 1*

Point 5.5 of Appendix 14 to Annex IC to Implementing Regulation (EU) 2016/799 is deleted.

<sup>(1)</sup> Regulation (EU) No 165/2014 of the European Parliament and of the Council of 4 February 2014 on tachographs in road transport, repealing Council Regulation (EEC) No 3821/85 on recording equipment in road transport and amending Regulation (EC) No 561/2006 of the European Parliament and of the Council on the harmonisation of certain social legislation relating to road transport (OJ L 60, 28.2.2014, p. 1).

<sup>(2)</sup> Council Directive 96/53/EC of 25 July 1996 laying down for certain road vehicles circulating within the Community the maximum authorised dimensions in national and international traffic and the maximum authorised weights in international traffic (OJ L 235, 17.9.1996, p. 59).

<sup>(3)</sup> Regulation (EU) 2019/1213 of 12 July 2019 laying down detailed provisions ensuring uniform conditions for the implementation of interoperability and compatibility of on-board weighing equipment pursuant to Council Directive 96/53/EC (OJ L 192, 18.7.2019, p. 1).

<sup>(4)</sup> Commission Implementing Regulation (EU) 2016/799 of 18 March 2016 implementing Regulation (EU) No 165/2014 of the European Parliament and of the Council laying down the requirements for the construction, testing, installation, operation and repair of tachographs and their components (OJ L 139, 26.5.2016, p. 1).

*Article 2***Entry into force and application**

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

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

Done at Brussels, 5 February 2020.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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**COMMISSION IMPLEMENTING REGULATION (EU) 2020/159****of 5 February 2020****concerning the renewal of the authorisation of *Enterococcus faecium* DSM 7134 as a feed additive for weaned piglets and pigs for fattening and repealing Regulation (EC) No 538/2007 (holder of authorisation Lactosan Starterkulturen GmbH & Co)****(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition <sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.
- (2) *Enterococcus faecium* DSM 7134 was authorised for 10 years as a feed additive for weaned piglets and pigs for fattening by Commission Regulation (EC) No 538/2007 <sup>(2)</sup>.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted by the holder of that authorisation for the renewal of the authorisation of *Enterococcus faecium* DSM 7134 as a feed additive for weaned piglets and pigs for fattening, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 February 2019 <sup>(3)</sup> that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation. The Authority concluded that *Enterococcus faecium* DSM 7134 remains safe under the authorised conditions of use for the target animals, consumers, users and the environment. The Authority also concluded that the additive is considered a potential skin and respiratory sensitiser. Therefore the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.
- (5) The assessment of *Enterococcus faecium* DSM 7134 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.
- (6) As a consequence of the renewal of the authorisation of *Enterococcus faecium* DSM 7134 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 538/2007 should be repealed.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> Commission Regulation (EC) No 538/2007 of 15 May 2007 concerning the authorisation of a new use of *Enterococcus faecium* DSM 7134 (Bonvital) as a feed additive (OJ L 128, 16.5.2007, p. 16).

<sup>(3)</sup> EFSA Journal 2019; 17(3):5650.



HAS ADOPTED THIS REGULATION:

*Article 1*

The authorisation of the additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is renewed subject to the conditions laid down in that Annex.

*Article 2*

Regulation (EC) No 538/2007 is repealed.

*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 February 2020.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive (Trade name)	Composition, chemical formula, description, analytical method.	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
<b>Category of zootechnical additives. Functional group: gut flora stabilisers.</b>									
4b1841	Lactosan Starterkulturen GmbH & Co	<i>Enterococcus faecium</i> DSM 7134	<p><b>Additive composition:</b> Preparation of <i>Enterococcus faecium</i> DSM 7134 containing a minimum of: Powder: <math>1 \times 10^{10}</math> CFU/g of additive Granules (microencapsulated): <math>1 \times 10^{10}</math> CFU/g of additive</p> <p><b>Characterisation of the active substance:</b> Viable cells of <i>Enterococcus faecium</i> DSM 7134</p> <p><b>Analytical method</b> <sup>(1)</sup> For enumeration: spread plate method using bile esculin azide agar (EN 15788) For identification: pulsed field gel electrophoresis (PFGE)</p>	Piglets (weaned)	—	$0,5 \times 10^9$	$4 \times 10^9$	<p>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing, skin and eye protections.</p>	26 February 2030
				Pigs for fattening	—	$0,2 \times 10^9$	$1 \times 10^9$		26 February 2030

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

**COMMISSION IMPLEMENTING REGULATION (EU) 2020/160****of 5 February 2020****concerning the authorisation of the preparation of oregano oil, caraway oil, carvacrol, methyl salicylate and L-menthol as a feed additive for weaned piglets (holder of authorisation Biomin GmbH)****(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition <sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of oregano oil, caraway oil, carvacrol, methyl salicylate and L-menthol. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) That application concerns the authorisation of a preparation of oregano oil, caraway oil, carvacrol, methyl salicylate and L-menthol as a feed additive for weaned piglets, to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 2 April 2019 <sup>(2)</sup> that, under the proposed conditions of use, the preparation of oregano oil, caraway oil, carvacrol, methyl salicylate and L-menthol does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that exposure to users by inhalation is unlikely and that no conclusion could be drawn on skin or eyes sensitisation. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority concluded that the additive has the potential to be efficacious in improving zootechnical performance. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of the preparation of oregano oil, caraway oil, carvacrol, methyl salicylate and L-menthol shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.
- (6) 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 preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> EFSA Journal 2019;17(4):5688.

*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 February 2020.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of additive/kg of complete feedingstuff with a moisture content of 12 %			

**Category of zootechnical additives. Functional group: other zootechnical additives (improvement of zootechnical performance).**

4d19	Biomin GmbH	Oregano oil, caraway oil, carvacrol, methyl salicylate and L-menthol	<p><b>Additive composition</b> Preparation of:</p> <ul style="list-style-type: none"> <li>— essential oils of oregano (<i>Origanum vulgare</i> L.) (60-80 mg/g) and caraway seed (<i>Carum carvi</i> L.) (5-10 mg/g),</li> <li>— carvacrol (60-80mg/g), methyl salicylate (10-40 mg/g) and L-menthol (30-55 mg/g)</li> </ul> <p>Solid form</p> <p><b>Characterisation of the active substance:</b> Oregano oil (<i>Origanum vulgare</i> L.) (CAS number: 8007-11-2) with a content of linalool of 1,8-16 mg/g; Caraway seed oil (<i>Carum carvi</i> L.) (CAS number: 8000-42-8) with a content of D-carvone of 2,5-6,5 mg/g; Carvacrol oil (CAS number: 499-75-2) ≥ 99 % with a content of carvacrol of 95-140 mg/g (from oregano and pure carvacrol); Methyl salicylate (CAS number: 119-36-8); L-Menthol (CAS number: 2216-51-8).</p> <p><b>Analytical method</b> <sup>(1)</sup> Quantification of the active substances in the feed additive: gas chromatography coupled with flame ionisation detection (GC-FID).</p>	Weaned piglets	—	75	125	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin and eye protections.</li> </ol>	26 February 2030
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<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

**COMMISSION IMPLEMENTING REGULATION (EU) 2020/161****of 5 February 2020****concerning the renewal of the authorisation of *Bacillus subtilis* DSM 17299 as a feed additive for chickens for fattening and repealing Regulation (EC) No 1137/2007 (holder of authorisation Chr. Hansen A/S)****(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition <sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.
- (2) *Bacillus subtilis* DSM 17299 was authorised for 10 years as a feed additive for chickens for fattening by Commission Regulation (EC) No 1137/2007 <sup>(2)</sup>.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted by the holder of that authorisation for the renewal of the authorisation of *Bacillus subtilis* DSM 17299 as a feed additive for chickens for fattening, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 2 April 2019 <sup>(3)</sup> that the applicant has provided data demonstrating that the additive complies with the existing conditions of authorisation. The Authority confirmed its previous conclusions that *Bacillus subtilis* DSM 17299 is considered safe for the target species, consumers of products from animals fed with the additive and the environment. It also concluded that there is a potential for users to be exposed via inhalation and that no conclusion could be drawn on the potential for skin and eyes irritancy and dermal sensitisation. Therefore the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive
- (5) The assessment of *Bacillus subtilis* DSM 17299 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.
- (6) As a consequence of the renewal of the authorisation of *Bacillus subtilis* DSM 17299 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 1137/2007 should be repealed.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> Commission Regulation (EC) No 1137/2007 of 1 October 2007 concerning the authorisation of *Bacillus subtilis* (O35) as a feed additive (OJ L 256, 2.10.2007, p. 5).

<sup>(3)</sup> EFSA Journal 2019;17(4):5687.

HAS ADOPTED THIS REGULATION:

*Article 1*

The authorisation of the additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is renewed subject to the conditions laid down in that Annex.

*Article 2*

Regulation (EC) No 1137/2007 is repealed.

*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 February 2020.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			

**Category of zootechnical additives. Functional group: gut flora stabilisers**

4b1821	Chr. Hansen A/S	<i>Bacillus subtilis</i> DSM 17299	<b>Additive composition</b> Preparation of <i>Bacillus subtilis</i> DSM 17299, containing a minimum of $1,6 \times 10^{10}$ CFU/g of additive Solid form	Chickens for fattening	—	$8 \times 10^8$	—	<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>2. The use is permitted in feed containing one of the following authorised coccidiostats: diclazuril, halofuginone, robenidine, decoquinat, narasin/nicarbazin, lasalocid sodium, maduramycin ammonium, monensin sodium, narasin, salinomycin sodium or semduramycin sodium.</li> <li>3. The compatibility of this additive with formic acid has been shown.</li> <li>4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing, skin and eye protections.</li> </ol>	26 February 2030
			<b>Characterisation of the active substance</b> Viable spore of <i>Bacillus subtilis</i> DSM 17299						
			<b>Analytical method</b> <sup>(1)</sup> Enumeration spread plate method using tryptone soya agar (EN 15784) Identification of <i>Bacillus subtilis</i> DSM 17299 in the feed additive: Pulsed Field Gel Electrophoresis (PFGE).						

<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>



**COMMISSION IMPLEMENTING REGULATION (EU) 2020/162****of 5 February 2020****concerning the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 as a feed additive for turkeys for fattening (holder of authorisation Danstar Ferment AG represented by Lallemand SAS)****(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition <sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1079. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) That application concerns the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 as a feed additive for turkeys for fattening, to be classified in the additive category 'zootechnical additives'.
- (4) The preparation of *Saccharomyces cerevisiae* CNCM I-1079 was already authorised as a feed additive by Commission Implementing Regulation (EU) 2017/1905 <sup>(2)</sup> for chickens for fattening and for minor poultry species for fattening and by Commission Implementing Regulation (EU) 2018/347 <sup>(3)</sup> for piglets and sows.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 2 April 2019 <sup>(4)</sup> that, under the proposed conditions of use, the preparation of *Saccharomyces cerevisiae* CNCM I-1079 does not have an adverse effect on animal health, consumer safety or the environment, and when used in feed for turkeys, it is efficacious in reducing carcass contamination with *Salmonella* spp. It also concluded that the not-coated form of the additive should be considered a respiratory sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> Commission Implementing Regulation (EU) 2017/1905 of 18 October 2017 concerning an authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 as a feed additive for chickens for fattening and for minor poultry species for fattening (holder of authorisation Danstar Ferment AG represented by Lallemand SAS) (OJ L 269, 19.10.2017, p. 30).

<sup>(3)</sup> Commission Implementing Regulation (EU) 2018/347 of 5 March 2018 concerning the authorisation of the preparation of *Saccharomyces cerevisiae* CNCM I-1079 as a feed additive for piglets and sows and amending Regulations (EC) No 1847/2003 and (EC) No 2036/2005 (holder of authorisation Danstar Ferment AG represented by Lallemand SAS) (OJ L 67, 9.3.2018, p. 21).

<sup>(4)</sup> EFSA Journal 2019;17(4):5693.

HAS ADOPTED THIS REGULATION:

*Article 1*

**Authorisation**

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

*Article 2*

**Entry into force**

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 February 2020.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %			

**Category of zootechnical additives. Functional group: other zootechnical additives (reduction of *Salmonella* spp. contamination on carcasses through its decrease in faeces)**

4d1703	Danstar Ferment AG represented by Lallemand SAS	<i>Saccharomyces cerevisiae</i> CNCM I-1079	<p><b>Additive composition</b> Preparation of <i>Saccharomyces cerevisiae</i> CNCM I-1079 containing a minimum of: 2 × 10<sup>10</sup> CFU/g of additive (not-coated form) 1 × 10<sup>10</sup> CFU/g of additive (coated form)</p> <p><b>Characterisation of the active substance</b> Viable cells of <i>Saccharomyces cerevisiae</i> CNCM I-1079</p> <p><b>Analytical method</b> <sup>(1)</sup> Enumeration: pour plate method using chloramphenicol destrose yeast extract agar (EN15789:2009) Identification: polymerase chain reaction (PCR) method (CEN/TS 15790:2008)</p>	Turkeys for fattening	-	1 × 10 <sup>9</sup>		<ol style="list-style-type: none"> <li>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</li> <li>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.</li> </ol>	26 February 2030
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<sup>(1)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

**COMMISSION IMPLEMENTING REGULATION (EU) 2020/163****of 5 February 2020****concerning the authorisation of a preparation of muramidase produced by *Trichoderma reesei* DSM 32338 as a feed additive for turkeys for fattening, turkeys reared for breeding, chickens reared for breeding and other poultry species reared for breeding (holder of authorisation DSM Nutritional Products Ltd. represented in the Union by DSM Nutritional Products Sp. Z o.o)**

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition <sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation muramidase produced by *Trichoderma reesei* DSM 32338. That application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) That application concerns the authorisation of a preparation of muramidase produced by *Trichoderma reesei* DSM 32338 as a feed additive for turkeys for fattening, turkeys reared for breeding, chickens reared for breeding and other poultry species reared for breeding, to be classified in the additive category 'zootechnical additives'.
- (4) The preparation of muramidase produced by *Trichoderma reesei* DSM 32338 was already authorised as a feed additive by Commission Implementing Regulation (EU) 2019/805 <sup>(2)</sup> for chickens for fattening and for minor poultry species for fattening.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 2 April 2019 <sup>(3)</sup> that, under the proposed conditions of use, the preparation of muramidase produced by *Trichoderma reesei* DSM 32338 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive may have a skin/eyes irritancy potential and skin and respiratory sensitisation potential. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. It concluded that the additive has the potential to be efficacious showing improvements of the feed to gain ratio. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of the preparation of muramidase produced by *Trichoderma reesei* DSM 32338 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised as specified in the Annex to this Regulation.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> Commission Implementing Regulation (EU) 2019/805 of 17 May 2019 concerning the authorisation of a preparation of muramidase produced by *Trichoderma reesei* DSM 32338 as a feed additive for chickens for fattening and minor poultry species for fattening (holder of authorisation DSM Nutritional Products Ltd. represented in EU by DSM Nutritional Products Sp. Z o.o) (OJ L 132, 20.5.2019, p. 33).

<sup>(3)</sup> EFSA Journal 2019;17(4):5686.

HAS ADOPTED THIS REGULATION:

*Article 1*

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

*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 February 2020.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Unit of activity/kg of complete feedingstuff with a moisture content of 12 %			
<b>Category of zootechnical additives. Functional group: other zootechnical additives.</b>									
4d16	DSM Nutritional Products Ltd. represented in the Union by DSM Nutritional Products Sp. Z o.o	Muramidase (EC 3.2.1.17)	<p><b>Additive composition</b> Preparation of muramidase (EC 3.2.1.17) (lysozyme) produced by <i>Trichoderma reesei</i> (DSM 32338) having a minimum activity of 60 000 LSU(F) <sup>(1)</sup> /g Solid and liquid form</p> <p><b>Characterisation of the active substance:</b> muramidase (EC 3.2.1.17) (lysozyme) produced by <i>Trichoderma reesei</i> (DSM 32338)</p> <p><b>Analytical method</b> <sup>(2)</sup> For the quantification of muramidase: fluorescence-based enzyme assay method that determines the enzyme-catalyzed depolymerisation of a fluorescein-labelled peptidoglycan preparation at pH 6,0 and 30 °C.</p>	<p>Chickens reared for breeding</p> <p>Turkeys for fattening</p> <p>Turkeys reared for breeding</p> <p>Other poultry species reared for breeding</p>	—	25 000 LSU(F)		<p>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including skin and breathing protections.</p>	26 February 2030

<sup>(1)</sup> One LSU(F) is defined as the amount of enzyme that increases the fluorescence of 12,5 µg/ml fluorescein-labelled peptidoglycan per minute at pH 6,0 and 30 °C by a value that<sup>22</sup> corresponds to the fluorescence of approximately 0,06 nmol fluorescein isothiocyanate isomer.

<sup>(2)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

## COMMISSION IMPLEMENTING REGULATION (EU) 2020/164

of 5 February 2020

**concerning the authorisation of 6-phytase produced by *Schizosaccharomyces pombe* (ATCC 5233) as a feed additive for all avian species and all swine species and repealing Regulation (EC) No 379/2009 (holder of authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.)**

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition <sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.
- (2) 6-phytase produced by *Schizosaccharomyces pombe* (ATCC 5233) was authorised for 10 years as a feed additive for chickens for fattening, turkeys for fattening, laying hens, ducks for fattening, piglets (weaned), pigs for fattening and sows by Commission Regulation (EC) No 379/2009 <sup>(2)</sup>.
- (3) In accordance with Article 14 of Regulation (EC) No 1831/2003, in conjunction with Article 7 of that Regulation, an application was submitted by the holder of that authorisation for the renewal of the authorisation of 6-phytase produced by *Schizosaccharomyces pombe* (ATCC 5233) as a feed additive for chickens for fattening, turkeys for fattening, laying hens, ducks for fattening, piglets (weaned), pigs for fattening and sows, requesting that additive to be classified in the additive category 'zootechnical additives' and for a new use for all avian species for fattening other than chickens, turkeys and ducks and all avian species for laying other than hens and for all avian species reared for laying and breeding, suckling piglets and minor porcine species. That application was accompanied by the particulars and documents required under Article 14(2) and Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 April 2019 <sup>(3)</sup> that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation. It was also concluded that the additive does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that the additive may have respiratory sensitisation potential. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users. The Authority concluded that the additive is efficacious in improving digestibility of feed for all avian species for fattening, for laying, reared for laying or for breeding purposes, and for all swine species. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of 6-phytase produced by *Schizosaccharomyces pombe* (ATCC 5233) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation for use of that additive should be renewed as specified in the Annex to this Regulation.
- (6) As a consequence of the renewal of the authorisation of 6-phytase produced by *Schizosaccharomyces pombe* (ATCC 5233) as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 379/2009 should be repealed.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> Commission Regulation (EC) No 379/2009 of 8 May 2009 concerning the authorisation of a new use of 6-phytase EC 3.1.3.26 as a feed additive for chickens for fattening, turkeys for fattening, laying hens, ducks for fattening, piglets (weaned), pigs for fattening and sows (holder of the authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.) (OJ L 116, 9.5.2009, p. 6).

<sup>(3)</sup> EFSA Journal 2019;17(5):5702.

HAS ADOPTED THIS REGULATION:

*Article 1*

**Authorisation**

The authorisation of the additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is renewed as additive in animal nutrition subject to the conditions laid down in that Annex.

*Article 2*

**Repeal of Regulation (EC) No 379/2009**

Regulation (EC) No 379/2009 is repealed.

*Article 3*

**Entry into force**

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 February 2020.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Unit of activity/kg of complete feedingstuff with a moisture content of 12 %			

**Category of zootechnical additives. Functional group: digestibility enhancers**

4a1 640	Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.	6-phytase EC 3.1.3.26	<b>Additive composition</b> Preparation of 6-phytase (EC 3.1.3.26) produced by <i>Schizosaccharomyces pombe</i> (ATCC 5233) having a minimum activity of: 10 000 FTU <sup>(1)</sup> /g Liquid and solid coated form	All avian species other than laying birds	—	250 FTU	—	1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.	26 February 2030
			<b>Characterisation of the active substance:</b> 6-phytase (EC 3.1.3.26) produced by <i>Schizosaccharomyces pombe</i> (ATCC 5233)	All avian species for laying	—	150 FTU	—		
			<b>Analytical method <sup>(2)</sup></b> Determination of 6-phytase in feed additive: colorimetric method based on the quantification of inorganic phosphate released by the enzyme from sodium phytate. Determination of 6-phytase in premixtures and feedingstuff: colorimetric method based on the quantification of inorganic phosphate released by the enzyme from sodium phytate (after dilution with heat-treated whole grain flour) (EN ISO 30024)	Piglets (weaned) Pigs for fattening	—	250 FTU	—		
				All porcine species other than weaned piglets and pigs for fattening	—	500 FTU	—		

<sup>(1)</sup> One FTU is the amount of enzyme which liberates one micromole of inorganic phosphate per minute from a sodium phytate substrate at pH 5,5 and 37 °C.

<sup>(2)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>.

## COMMISSION IMPLEMENTING REGULATION (EU) 2020/165

of 5 February 2020

**concerning the authorisation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* DSM 32052 as a feed additive for chickens for fattening, for chickens reared for laying, turkeys for fattening or reared for breeding and for minor poultry species and repealing Regulation (EC) No 786/2007 (holder of authorisation Elanco GmbH)**

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition <sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.
- (2) Endo-1,4-beta-mannanase produced by *Paenibacillus lentus* ATCC 55045 was authorised for 10 years as a feed additive for chickens for fattening by Commission Regulation (EC) No 786/2007 <sup>(2)</sup>.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, in conjunction with Article 7 thereof, an application was submitted by the holder of that authorisation for the renewal of the authorisation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* DSM 32052 (formerly produced by *Paenibacillus lentus* ATCC 55045) as a feed additive for chickens for fattening, requesting that additive to be classified in the additive category 'zootechnical additives' and for a new use for chickens reared for laying, turkeys for fattening or reared for breeding and minor poultry species. That application was accompanied by the particulars and documents required under Article 14(2) and Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 26 February 2019 <sup>(3)</sup> that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation. It was also concluded that the additive is safe for the target species, consumers of products from animals fed with the additive and the environment. It also concluded that the product should be regarded as a potential respiratory sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The additive has a potential to be efficacious in improving digestibility of feed for chickens reared for laying, turkeys for fattening or reared for breeding and minor poultry species.
- (5) The assessment of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* DSM 32052 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.
- (6) As a consequence of the renewal of the authorisation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* ATCC 55045 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 786/2007 should be repealed.
- (7) Since safety reasons do not require the immediate application of the amendments made by this Regulation, it is appropriate to provide for a transitional period during which the existing stocks of the preparation of endo-1,4-beta-mannanase produced by *Paenibacillus lentus* ATCC 55045, which are in conformity with the provisions applying before the date of entry into force of this Regulation, may continue to be placed on the market and used until they are exhausted.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> Commission Regulation (EC) No 786/2007 of 4 July 2007 concerning the authorisation of endo-1,4-beta-mannanase EC 3.2.1.78 (Hemicell) as a feed additive (OJ L 175, 5.7.2007, p. 8).

<sup>(3)</sup> EFSA Journal 2019;17(3):5641.

HAS ADOPTED THIS REGULATION:

*Article 1*

The authorisation of the additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is renewed subject to the conditions laid down in that Annex.

*Article 2*

Regulation (EC) No 786/2007 is repealed.

*Article 3*

Endo-1,4-beta-mannanase produced by *Paenibacillus lentus* ATCC 55045, premixtures and compound feed containing that substance, which are produced and labelled before 26 February 2020 in accordance with the rules applicable before 26 February 2020 may continue to be placed on the market and used until the existing stock are exhausted.

*Article 4*

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 February 2020.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Unit of activity/kg of complete feedingstuff with a moisture content of 12 %			

**Category of zootechnical additives. Functional group: digestibility enhancers**

4a3i	Elanco GmbH	Endo-1,4-beta-mannanase EC 3.2.1.78	<p><i>Additive composition</i></p> <p>Preparation of endo-1,4-beta-mannanase, produced by <i>Paenibacillus lentus</i> (DSM 32052) having a minimum activity of <math>7,2 \times 10^5</math> U <sup>(1)</sup>/ml Liquid form</p> <p><i>Characterisation of the active substance</i></p> <p>Endo-1,4-beta-mannanase produced by <i>Paenibacillus lentus</i> (DSM 32052)</p> <p><i>Analytical method</i> <sup>(2)</sup></p> <p>colorimetric method based on the reaction between reducing sugars (mannose equivalent) with 3,5-dinitrosalicylic acid (DNS)</p>	Chickens for fattening	-	79 200 U	-	<p>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.</p>	26.2.2030
				Turkeys for fattening					
				Chickens reared for laying					
				Turkeys reared for breeding					
				Minor poultry species for fattening or reared for laying/breeding					

<sup>(1)</sup> One unit of activity (U) is the amount of the enzyme which liberates 0,72 micrograms of reducing sugars (mannose equivalents) from a mannan-containing substrate (locust bean gum) per minute at pH 7,5 and 40 °C.

<sup>(2)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

**COMMISSION IMPLEMENTING REGULATION (EU) 2020/166****of 5 February 2020****concerning the renewal of the authorisation of 6-phytase produced by *Schizosaccharomyces pombe* (ATCC 5233) as a feed additive for chickens for fattening, laying hens, turkeys for fattening, ducks for fattening, weaned piglets, pigs for fattening and sows and repealing Regulation (EC) No 785/2007 (holder of authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.)****(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition <sup>(1)</sup>, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.
- (2) The preparation of 6-phytase produced by *Schizosaccharomyces pombe* (ATCC 5233) was authorised for 10 years as a feed additive for chickens for fattening, turkeys for fattening, laying hens, ducks for fattening, piglets (weaned), pigs for fattening, and sows by Commission Regulation (EC) No 785/2007 <sup>(2)</sup>.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted by the holder of that authorisation for the renewal of the authorisation of the preparation of 6-phytase produced by *Schizosaccharomyces pombe* (ATCC 5233) as a feed additive for chickens for fattening, laying hens, turkeys for fattening, ducks for fattening, weaned piglets, pigs for fattening and sows requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 4 April 2019 <sup>(3)</sup> that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation.
- (5) The assessment of the preparation of 6-phytase produced by *Schizosaccharomyces pombe* (ATCC 5233) shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.
- (6) As a consequence of the renewal of the authorisation of the preparation of 6-phytase produced by *Schizosaccharomyces pombe* (ATCC 5233) as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 785/2007 should be repealed.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(1)</sup> OJ L 268, 18.10.2003, p. 29.

<sup>(2)</sup> Commission Regulation (EC) No 785/2007 of 4 July 2007 concerning the authorisation of 6-phytase EC 3.1.3.26 (Phyzyme XP 5000G Phyzyme XP 5000L) as a feed additive (OJ L 175, 5.7.2007, p. 5).

<sup>(3)</sup> EFSA Journal 2019;17(5):5701.

HAS ADOPTED THIS REGULATION:

*Article 1*

The authorisation of the additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is renewed subject to the conditions laid down in that Annex.

*Article 2*

Regulation (EC) No 785/2007 is repealed.

*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 February 2020.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Unit of activity/kg of complete feedingstuff with a moisture content of 12 %			
<b>Category of zootechnical additives. Functional group: digestibility enhancers</b>									
4a1640	Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B. V.	6-phytase EC 3.1.3.26	<p><b>Additive composition</b> Preparation of 6-phytase (EC 3.1.3.26) produced by <i>Schizosaccharomyces pombe</i> (ATCC 5233) having a minimum activity of: 5 000 FTU <sup>(1)</sup> /g Solid coated and liquid form</p> <p><b>Characterisation of the active substance:</b> 6-phytase (EC 3.1.3.26) produced by <i>Schizosaccharomyces pombe</i> (ATCC 5233)</p> <p><b>Analytical method</b> <sup>(2)</sup> Determination of 6-phytase EC 3.1.3.26 in feed additive: colorimetric method based on the quantification of inorganic phosphate released by the enzyme from sodium phytate. Determination of 6-phytase EC 3.1.3.26 in feed premixtures and feedingstuff: EN ISO 30024: colorimetric method based on the quantification of inorganic phosphate released by the enzyme from sodium phytate (after dilution with heat-treated whole grain flour).</p>	Chickens for fattening	—	250 FTU	—	<p>1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated.</p> <p>2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection.</p>	26.2.2030
				Turkeys for fattening	—	150 FTU	—		
				Ducks for fattening	—	250 FTU	—		
				Laying hens	—	500 FTU	—		
				Piglets (weaned)	—				
				Pigs for fattening	—				
				Sows	—				

<sup>(1)</sup> One FTU is the amount of enzyme which liberates one micromole of inorganic phosphate per minute from a sodium phytate substrate at pH 5,5 and 37 °C.

<sup>(2)</sup> Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

# DECISIONS

## COMMISSION IMPLEMENTING DECISION (EU) 2020/167

of 5 February 2020

### on the harmonised standards for radio equipment drafted in support of Directive 2014/53/EU of the European Parliament and of the Council

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council <sup>(1)</sup>, and in particular Article 10(6) thereof,

Whereas:

- (1) In accordance with Article 16 of Directive 2014/53/EU of the European Parliament and of the Council, <sup>(2)</sup> radio equipment which is in conformity with harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, is to be presumed to be in conformity with the essential requirements set out in Article 3 of that Directive, covered by those harmonised standards or parts thereof.
- (2) By Commission Implementing Decision C(2015) 5376 <sup>(3)</sup>, the Commission made a request to the European Committee for Electrotechnical Standardisation and the European Telecommunications Standards Institute (ETSI) for the drafting and revision of harmonised standards for radio equipment in support of Directive 2014/53/EU.
- (3) On the basis of the request set out in Implementing Decision C(2015) 5376, ETSI drafted harmonised standards EN 300 328 V2.2.2 for data transmission equipment operating in the 2,4 GHz band, EN 300 698 V2.3.1 for radio telephone transmitters and receivers for the maritime mobile service, EN 303 098 V2.2.1 for maritime low power personal locating devices, EN 303 520 V1.2.1 for Ultra Low Power (ULP) wireless medical capsule endoscopy devices and EN 300 674-2-2 V 2.2.1 for Transport and Traffic Telematics (TTT) systems.
- (4) The Commission, together with ETSI, has assessed whether those harmonised standards comply with the request set out in Implementing Decision C(2015) 5376.
- (5) Harmonised standards EN 300 328 V2.2.2, EN 303 098 V2.2.1 and EN 300 674-2-2 V 2.2.1 satisfy the essential requirements which they aim to cover and which are set out in Directive 2014/53/EU. It is therefore appropriate to publish the references of those standards in the *Official Journal of the European Union*.
- (6) Clause 8.2.3 of the harmonised standard EN 300 698 V2.3.1 allows manufacturers to deviate from the maximum radio-frequency power declared under Article 10(8) of Directive 2014/53/EU and demonstrated in the technical documentation drawn up in accordance with Article 21 of that Directive. The reference of that harmonised standard should therefore be published in the *Official Journal of the European Union* with restriction.

<sup>(1)</sup> OJ L 316, 14.11.2012, p. 12.

<sup>(2)</sup> Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62).

<sup>(3)</sup> Commission Implementing Decision C(2015) 5376 final of 4 August 2015 on a standardisation request to the European Committee for Electrotechnical Standardisation and to the European Telecommunications Standards Institute as regards radio equipment in support of Directive 2014/53/EU of the European Parliament and of the Council.



- (7) The harmonised standard EN 303 520 V1.2.1 allows manufacturers to negotiate certain test methods with testing laboratories. Moreover, it allows manufacturers to test equipment at temperatures that may not correspond to the intended use. The level of allowed negotiation and interpretation in that harmonised standard can have an impact on the demonstration of the conformity of the radio equipment with the essential requirements set out in Article 3 (2) of Directive 2014/53/EU. The reference of that harmonised standard should therefore be published in the *Official Journal of the European Union* with restriction.
- (8) On the basis of Implementing Decision C(2015) 5376, ETSI replaced the following harmonised standards the references to which are published in the *Official Journal of the European Union* <sup>(4)</sup>: EN 300 328 V2.1.1 replaced by EN 300 328 V2.2.2; EN 303 098 V2.1.1 replaced by EN 303 098 V2.2.1; EN 303 520 V1.1.1 replaced by EN 303 520 V1.2.1; EN 300 698 V2.2.1 replaced by EN 300 698 V2.3.1; and EN 300 674-2-2 V2.1.1 replaced by EN 300 674-2-2 V2.2.1.
- (9) Harmonised standard EN 302 065-3 V2.1.1 the reference to which is published in the *Official Journal of the European Union* <sup>(5)</sup> does not describe trigger-before-transmit mitigation techniques. Commission Implementing Decision (EU) 2019/785 <sup>(6)</sup>, however, imposes, as of 16 November 2019, technical requirements to be used within the bands 3,8-4,2 GHz and 6-8,5 GHz for vehicular access systems using trigger-before-transmit. Implementing Decision (EU) 2019/785 provides that trigger-before-transmit mitigation techniques that provide an appropriate level of performance in order to comply with the essential requirements of Directive 2014/53/EU are to be used for vehicular access systems. As harmonised standard EN 302 065-3 V2.1.1 does not address trigger-before-transmit mitigation techniques, it is necessary to indicate that compliance with that harmonised standard does not ensure compliance with the requirements of Implementing Decision (EU) 2019/785 which relate to those techniques and accordingly does not confer a presumption of conformity with those essential requirements set out in Article 3(2) of Directive 2014/53/EU which relate to those techniques. The reference of that harmonised standard should therefore be published in the *Official Journal of the European Union* with restriction.
- (10) Harmonised standard EN 302 752 V1.1.1, the reference to which is published in the *Official Journal of the European Union* <sup>(7)</sup> with restriction, was adopted by ETSI in 2009 under Directive 1999/5/EC of the European Parliament and of the Council <sup>(8)</sup>. When bringing this harmonised standard in line with Directive 2014/53/EU, ETSI stopped the related work, considering that 'no stakeholder interest has been identified', that 'no consequences are foreseen if no harmonised standard is available for active radar target enhancers since no industry interest has been identified' and that 'the harmonised standard can be considered obsolete and should be withdrawn'.
- (11) It is therefore necessary to withdraw the references of the replaced standards, the reference to harmonised standard EN 302 065-3 V2.1.1 which should be published with restriction and the reference to harmonised standard EN 302 752 V1.1.1 which is considered obsolete, from the *Official Journal of the European Union* <sup>(9)</sup>. In order to give manufacturers sufficient time to prepare for application of the replacing harmonised standards, it is necessary to defer the withdrawal of the references of the standards that are replaced. In order also to give manufacturers time to prepare for the withdrawal of the reference to harmonised standard EN 302 752 V1.1.1, it is necessary to defer the withdrawal of the reference to that standard.
- (12) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the day of its publication,

<sup>(4)</sup> OJ C 326, 14.9.2018, p. 114.

<sup>(5)</sup> OJ C 326, 14.9.2018, p. 114.

<sup>(6)</sup> Commission Implementing Decision (EU) 2019/785 of 14 May 2019 on the harmonisation of radio spectrum for equipment using ultra-wideband technology in the Union and repealing Decision 2007/131/EC (OJ L 127, 16.5.2019, p. 23).

<sup>(7)</sup> OJ C 326, 14.9.2018, p. 114.

<sup>(8)</sup> Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity (OJ L 91, 7.4.1999, p. 10).

<sup>(9)</sup> OJ C 326, 14.9.2018, p. 114.

HAS ADOPTED THIS DECISION:

*Article 1*

The references to harmonised standards for radio equipment drafted in support of Directive 2014/53/EU listed in Annex I to this Decision, are hereby published in the *Official Journal of the European Union*.

The references to harmonised standards for radio equipment drafted in support of Directive 2014/53/EU listed in Annex II to this Decision, are hereby published in the *Official Journal of the European Union* with restriction.

*Article 2*

The references to harmonised standards for radio equipment drafted in support of Directive 2014/53/EU listed in Annex III to this Decision, are hereby withdrawn from the *Official Journal of the European Union* as from the dates set out in that Annex.

*Article 3*

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

Done at Brussels, 5 February 2020.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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## ANNEX I

No	Reference of the standard
1.	EN 300 328 V2.2.2 Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz band; Harmonised Standard for access to radio spectrum
2.	EN 300 674-2-2 V2.2.1 Transport and Traffic Telematics (TTT); Dedicated Short Range Communication (DSRC) transmission equipment (500 kbit/s/250 kbit/s) operating in the 5 795 MHz to 5 815 MHz frequency band; Part 2: Harmonised Standard for access to radio spectrum; Sub-part 2: On-Board Units (OBU)
3.	EN 303 098 V2.2.1 Maritime low power personal locating devices employing AIS; Harmonised Standard for access to radio spectrum

## ANNEX II

No	Reference of the standard
1.	<p data-bbox="308 349 507 383">EN 300 698 V2.3.1</p> <p data-bbox="308 405 1417 461">Radio telephone transmitters and receivers for the maritime mobile service operating in the VHF bands used on inland waterways; Harmonised Standard for access to radio spectrum and for features for emergency services</p> <p data-bbox="308 483 1417 602"><i>Notice:</i> Compliance with this harmonised standard does not confer a presumption of conformity to the essential requirement set out in Article 3(2) of Directive 2014/53/EU if, in clause 8.2.3 of this harmonised standard, the sentence 'With the output power switch set at maximum, the carrier power shall be within <math>\pm 1,5</math> dB of the rated output power under normal test conditions' is applied.</p>
2.	<p data-bbox="308 613 528 647">EN 302 065-3 V2.1.1</p> <p data-bbox="308 669 1417 752">Short Range Devices (SRD) using Ultra Wide Band technology (UWB); Harmonised Standard covering the essential requirements of Article 3.2 of the Directive 2014/53/EU; Part 3: Requirements for UWB devices for ground based vehicular applications</p> <p data-bbox="308 775 1417 981"><i>Notice:</i> This harmonised standard does not set out technical specifications for 'trigger-before-transmit techniques'. Implementing Decision (EU) 2019/785, however, imposes, as of 16 November 2019, technical requirements to be used within the bands 3,8-4,2 GHz and 6-8,5 GHz for vehicular access systems using trigger-before-transmit. Therefore compliance with this harmonised standard does not ensure compliance with Implementing Decision (EU) 2019/785 and accordingly does not confer a presumption of conformity with those essential requirements set out in Article 3(2) of Directive 2014/53/EU which relate to 'trigger-before-transmit techniques'.</p>
3.	<p data-bbox="308 992 507 1025">EN 303 520 V1.2.1</p> <p data-bbox="308 1048 1417 1104">Short Range Devices (SRD); Ultra Low Power (ULP) wireless medical capsule endoscopy devices operating in the band 430 MHz to 440 MHz; Harmonised Standard for access to radio spectrum</p> <p data-bbox="308 1126 1417 1182"><i>Notice:</i> Compliance with this harmonised standard does not confer a presumption of conformity with the essential requirement set out in Article 3(2) of Directive 2014/53/EU if any of the following are applied:</p> <ul data-bbox="308 1205 1417 1317" style="list-style-type: none"> <li data-bbox="308 1205 1417 1261">— with respect to clause B.1 of Annex B: 'The manufacturer and test laboratory may agree on alternative suitable implementation of human torso simulator, which shall be then fully described in the test report';</li> <li data-bbox="308 1261 1417 1317">— with respect to clause C.1 of Annex C: 'Alternatively, the manufacturer and test laboratory may agree to use a Semi-Anechoic Room, the setup of which shall be then fully described in the test report'.</li> </ul> <p data-bbox="308 1339 1209 1368"><i>Notice:</i> The temperature referred to in clause B.2 of Annex B shall reflect the intended use.</p>

## ANNEX III

No	Reference of the standard	Date of withdrawal
1.	EN 300 328 V2.1.1 Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of Article 3.2 of Directive 2014/53/EU	6 August 2021
2.	EN 300 698 V2.2.1 Radio telephone transmitters and receivers for the maritime mobile service operating in the VHF bands used on inland waterways; Harmonised Standard covering the essential requirements of Articles 3.2 and 3.3(g) of Directive 2014/53/EU	6 August 2021
3.	EN 300 674-2-2 V2.1.1 Transport and Traffic Telematics (TTT); Dedicated Short Range Communication (DSRC) transmission equipment (500 kbit/s/250 kbit/s) operating in the 5 795 MHz to 5 815 MHz frequency band; Part 2: Harmonised Standard covering the essential requirements of Article 3.2 of Directive 2014/53/EU; Sub-part 2: On-Board Units (OBU)	6 August 2021
4.	EN 302 065-3 V2.1.1 Short Range Devices (SRD) using Ultra Wide Band technology (UWB); Harmonised Standard covering the essential requirements of Article 3.2 of the Directive 2014/53/EU; Part 3: Requirements for UWB devices for ground based vehicular applications	6 February 2020
5.	EN 302 752 V1.1.1 Electromagnetic compatibility and Radio spectrum Matters (ERM); Active radar target enhancers; Harmonised EN covering the essential requirements of Article 3.2 of the R&TTE Directive	6 February 2021
6.	EN 303 098 V2.1.1 Maritime low power personal locating devices employing AIS; Harmonised Standard covering the essential requirements of Article 3.2 of the Directive 2014/53/EU	6 February 2021
7.	EN 303 520 V1.1.1 Short Range Devices (SRD); Ultra Low Power (ULP) wireless medical capsule endoscopy devices operating in the band 430 MHz to 440 MHz; Harmonised Standard for access to radio spectrum	6 August 2021

## ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

### DECISION NO 1/2020 OF THE EU-REPUBLIC OF MOLDOVA ASSOCIATION COMMITTEE IN TRADE CONFIGURATION

of 23 January 2020

**concerning the update of Annex XV (Elimination of customs duties) to the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part [2020/168]**

THE ASSOCIATION COMMITTEE IN TRADE CONFIGURATION,

Having regard to the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part, signed in Brussels on 27 June 2014, and in particular Article 147(4) and (5), Article 148(5) and Article 438(3) thereof,

Whereas:

- (1) The Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part ('the Agreement') entered into force on 1 July 2016.
- (2) Following consultations the EU and the Republic of Moldova have agreed on a reciprocal basis, in accordance with Article 147 of the Agreement, to increase the volume of some products subject to annual duty-free tariff rate quotas.
- (3) The EU has agreed to increase the volume of the tariff rate quotas ('TRQs') for goods originating in the Republic of Moldova for table grapes and plums, and to introduce a new TRQ for cherries. The Republic of Moldova has agreed to gradually increase the volume of the TRQs for goods originating in the EU for the following products included in the schedule of concessions (Republic of Moldova) set out in Annex XV-D to the Agreement: pork (TRQ 1), poultry (TRQ 2), dairy (TRQ 3) and sugar (TRQ 5).
- (4) Following a request made by the Republic of Moldova in accordance with Article 148 of the Agreement, the Union has agreed to increase the trigger volume for wheat (flour and pellets), barley (flour and pellets), maize (flour and pellets) and cereal processed.
- (5) On 16 December 2014 the Association Council, by means of Decision No 3/2014, delegated to the Association Committee in Trade configuration, as referred to in Article 438(4) of the Agreement, the power to update or amend certain trade-related Annexes to the Agreement,

HAS ADOPTED THIS DECISION:

#### *Article 1*

Annex XV to the Agreement is amended as follows:

- (1) Annex XV-A is replaced by the text set out in the Annex to this Decision;
- (2) in Annex XV-B, in the list of products subject to entry price, the entry with the CN code 2012 0809 29 00 and the product description 'Cherries (excl. sour cherries), fresh' is deleted;
- (3) in Annex XV-C, the trigger volumes for the following product categories are amended as follows:
  - (a) for product category 6 ('Wheat, flour and pellets'), in the column with the title 'Trigger volume (tonnes)', the amount '75 000' is replaced by the amount '150 000';
  - (b) for product category 7 ('Barley, flour and pellets'), in the column with the title 'Trigger volume (tonnes)', the amount '70 000' is replaced by the amount '100 000';

- (c) for product category 8 ('Maize, flour and pellets'), in the column with the title 'Trigger volume (tonnes)', the amount '130 000' is replaced by the amount '250 000'; and
  - (d) for product category 10 ('Cereal processed'), in the column with the title 'Trigger volume (tonnes)', the amount '2 500' is replaced by the amount '5 000';
- (4) in Annex XV-D, in the schedule of concessions (Republic of Moldova), the fourth column with the title 'Category' is amended as follows:
- (a) all references to 'TRQ 1 (4 000 t)' are replaced by 'TRQ 1 (4 500 t; for the year 2021: 5 000 t; and as of the year 2022: 5 500 t);
  - (b) all references to 'TRQ 2 (4 000 t)' are replaced by 'TRQ 2 (5 000 t; for the year 2021: 5 500 t; and as of the year 2022: 6 000 t);
  - (c) all references to 'TRQ 3 (1 000 t)' are replaced by 'TRQ 3 (1 500 t; and as of the year 2021: 2 000 t);
  - (d) all references to 'TRQ 5 (5 400 t)' are replaced by 'TRQ 5 (7 000 t; for the year 2021: 8 000 t; and as of the year 2022: 9 000 t)';

*Article 2*

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

Done at Brussels, 23 January 2020.

*For the Association Committee  
in Trade Configuration*

P. SOURMELIS  
*The Chair*

A. FERNÁNDEZ DÍEZ C. CEBAN  
*Secretaries*

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## ANNEX

## 'ANNEX XV-A

**PRODUCTS SUBJECT TO ANNUAL DUTY-FREE TARIFF-RATE QUOTAS (UNION)**

Order No	CN code 2012	Product description	Volume (tonnes)	Rate of duty
1	0702 00 00	Tomatoes, fresh or chilled	2 000	free
2	0703 20 00	Garlic, fresh or chilled	220	free
3	0806 10 10	Table grapes, fresh	20 000	free
4	0808 10 80	Apples, fresh (excl. cider apples, in bulk, from 16 September to 15 December)	40 000	free
5	0809 29 00	Cherries (excl. sour cherries), fresh	1 500	free
6	0809 40 05	Plums, fresh	15 000	free
7	2009 61 10	Grape juice, incl. grape must, unfermented, Brix value $\leq$ 30 at 20 °C, value of > EUR 18 per 100 kg, whether or not containing added sugar or other sweetening matter (excl. containing spirit)	500	free
	2009 69 19	Grape juice, incl. grape must, unfermented, Brix value > 67 at 20 °C, value of > EUR 22 per 100 kg, whether or not containing added sugar or other sweetening matter (excl. containing spirit)		
	2009 69 51	Concentrated grape juice, incl. grape must, unfermented, Brix value > 30 but $\leq$ 67 at 20 °C, value of > EUR 18 per 100 kg, whether or not containing added sugar or other sweetening matter (excl. containing spirit)		
	2009 69 59	Grape juice, incl. grape must, unfermented, Brix value > 30 but $\leq$ 67 at 20 °C, value of > EUR 18 per 100 kg, whether or not containing added sugar or other sweetening matter (excl. concentrated or containing spirit)		





ISSN 1977-0677 (electronic edition)  
ISSN 1725-2555 (paper edition)



**Publications Office of the European Union**  
2985 Luxembourg  
LUXEMBOURG

**EN**