

# Official Journal of the European Union

L 23



English edition

Legislation

Volume 65

2 February 2022

## Contents

### II *Non-legislative acts*

#### REGULATIONS

- ★ **Commission Delegated Regulation (EU) 2022/139 of 16 November 2021 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the management, storage and replacement of stocks of the Union antigen, vaccine and diagnostic reagent banks and the biosecurity, biosafety and bio-containment requirements for the operation of those banks <sup>(1)</sup> ..... 1**
- ★ **Commission Implementing Regulation (EU) 2022/140 of 16 November 2021 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to the Union antigen, vaccine and diagnostic reagent banks <sup>(1)</sup> ..... 11**
- ★ **Commission Regulation (EU) 2022/141 of 21 January 2022 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sodium carbonates (E 500) and potassium carbonates (E 501) in unprocessed cephalopods <sup>(1)</sup> ..... 22**

#### DECISIONS

- ★ **Commission Implementing Decision (EU) 2022/142 of 31 January 2022 amending Implementing Decision (EU) 2019/1741 as regards the reporting on production volume and correcting that Implementing Decision (notified under document C(2022) 451) <sup>(1)</sup> ..... 25**

---

<sup>(1)</sup> Text with EEA relevance.

EN

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

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



## II

*(Non-legislative acts)*

## REGULATIONS

## COMMISSION DELEGATED REGULATION (EU) 2022/139

of 16 November 2021

**supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the management, storage and replacement of stocks of the Union antigen, vaccine and diagnostic reagent banks and the biosecurity, biosafety and bio-containment requirements for the operation of those banks**

*(Text with EEA relevance)*

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') <sup>(1)</sup>, and in particular Article 48(3) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules for the prevention and control of diseases which are transmissible to animals or humans, including rules for the establishment and management of the Union antigen, vaccine and diagnostic reagent banks. In accordance with Article 48(1) of that Regulation, the Commission may establish and be responsible for managing the Union antigen, vaccine and diagnostic reagent banks for the storage and replacement of stocks of antigens, vaccines, vaccine master seed-stocks and diagnostic reagents for the listed diseases referred to in Article 9(1), point (a), thereof, in respect of which vaccination is not prohibited by a delegated act adopted pursuant to Article 47 thereof. The establishment of Union antigen, vaccine and diagnostic reagent banks, in accordance with that Regulation, would promote the attainment of the Union's animal health objectives by permitting a quick and effective response when the resources of those banks are required in the event of the occurrence of a category A disease, as defined and categorised by Commission Implementing Regulation (EU) 2018/1882 <sup>(2)</sup>, and would represent an efficient use of limited resources.
- (2) Furthermore, Article 47(1) of Regulation (EU) 2016/429 empowers the Commission to adopt delegated acts laying down rules concerning the use of veterinary medicinal products, including vaccines, for the purpose of the prevention and control of listed diseases in terrestrial animals. Those delegated acts will specify the category A diseases which could be prevented or controlled by use of vaccines in kept and wild terrestrial animals. Therefore, this Regulation should supplement the rules laid down in Part III of Regulation (EU) 2016/429, and provide for the establishment of Union antigen and vaccine banks for category A diseases, for which vaccination is not prohibited, and for the establishment of Union diagnostic reagent banks for category A diseases covered by those delegated acts

<sup>(1)</sup> OJ L 84, 31.3.2016, p. 1.

<sup>(2)</sup> Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

that are to be adopted pursuant to Article 47(1) of Regulation (EU) 2016/429. In addition, Commission Implementing Regulation (EU) 2022/140 <sup>(3)</sup> provides a list of category A diseases for which the Union antigen, vaccine and diagnostic reagent banks are established and maintained.

- (3) The Commission should purchase the antigens, vaccines and diagnostic reagents to be supplied to the Union antigen, vaccine and diagnostic reagent banks and should cover the expenses for the storage of the antigens, vaccines and diagnostic reagents therein. In order to establish and maintain those banks, the Commission should conclude appropriate contracts with selected manufacturers for the purchase, supply, storage and replacement of antigens, vaccines or diagnostic reagents. For that purpose, a procurement procedure should be carried out in accordance with the rules laid down in Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council <sup>(4)</sup>.
- (4) In addition, it is necessary to provide for a 'hybrid' mechanism, corresponding to framework supply contracts between the Commission and selected manufacturers to provide vaccines or diagnostic reagents to the Member States, third countries or territories, when requested by the Commission. Those Union antigen, vaccine and diagnostic reagents banks should be virtual given that the Commission does not keep any physical stocks, but rather calls upon a framework supply contract with one or more vaccine manufacturers for the release, shipment and delivery of the necessary vaccines or diagnostic reagents. The framework supply contracts may need to cover leasing costs. The terms of the framework supply contracts should allow the Commission to immediately require the manufacturers to release, ship and deliver vaccines or diagnostic reagents to a Member State, third country or territory that has been granted access to the Union antigen and vaccine banks. The availability of rolling stocks of vaccines or diagnostic reagents coupled with a fast decision-making process within the Commission would guarantee a service that rapidly provides high quality vaccines or diagnostic reagents.
- (5) In addition to framework supply contracts, the Commission should, in the framework of a grant agreement, be permitted to include the stockpiling of essential diagnostic reagents in the annual or multiannual work programmes of the European Union reference laboratories designated for the relevant diseases in accordance with Article 93(1) of Regulation (EU) 2017/625 of the European Parliament and of the Council <sup>(5)</sup>. Such Union diagnostic reagent banks are appropriate for the tasks of the European Union reference laboratories referred to in Article 94(2) of Regulation (EU) 2017/625, and in particular point (f), point k(iii) and point (l) thereof. The European Union reference laboratories have the necessary experience in the quality testing, storage, timely renewal and disposal of diagnostic reagents, and it would be an appropriate use of the infrastructures already in place. The annual or multiannual work programmes of the European Union reference laboratories are established in conformity with the objectives and priorities of the relevant work programmes referred to in Article 3(2), point (e), of Regulation (EU) 2021/690 of the European Parliament and of the Council <sup>(6)</sup> and adopted by the Commission, and thus provide the opportunity for regular review of the measures.

<sup>(3)</sup> Commission Implementing Regulation (EU) 2022/140 of 16 November 2021 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and the Council with regard to the Union antigen, vaccine and diagnostic reagent banks (See page 11 of this Official Journal).

<sup>(4)</sup> Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

<sup>(5)</sup> Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

<sup>(6)</sup> Regulation (EU) 2021/690 of the European Parliament and of the Council of 28 April 2021 establishing a programme for the internal market, competitiveness of enterprises, including small and medium-sized enterprises, the area of plants, animals, food and feed, and European statistics (Single Market Programme) and repealing Regulations (EU) No 99/2013, (EU) No 1287/2013, (EU) No 254/2014 and (EU) No 652/2014 (OJ L 153, 3.5.2021, p. 1).

- (6) When deciding on the principles for selecting strains and variations of antigens and vaccines to be supplied to the Union antigen, vaccine and diagnostic reagent banks in order to ensure sufficient quantities, the required quality and the appropriate types of stocks in those banks, the Commission should take account of the advice of experts, including experts from institutions such as the European Union reference laboratories, or any other international standard setting bodies relevant to the disease in question, including the European Commission for the Control of Foot-and-Mouth Disease (EuFMD).
- (7) The contract concluded with a selected manufacturer should guarantee appropriate conditions for the destruction and safe disposal of any unused antigen, vaccine or diagnostic reagent stored in the Union antigen, vaccine and diagnostic reagent banks after the expiry of its validity period. In cases where an antigen is supplied to a Union antigen bank and remains in that bank after the expiry of its validity period, the contract may lay down conditions for a buy-back of the antigen by the contracted manufacturer.
- (8) Biosecurity, biosafety and bio-containment requirements for the operation of the Union antigen, vaccine and diagnostic reagent banks should be established in this Regulation, taking into account the recommendations of Chapter 1.1.4 'Biosafety and biosecurity: Standard for managing biological risk in the veterinary laboratory and animal facilities' of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE), Edition 2021. The antigens, vaccines and diagnostic reagents should also comply with recognised quality standards, such as those laid down in Chapter 1.1.5 'Quality management in veterinary testing laboratories', in Chapter 1.1.8 'Principles of veterinary vaccine production', in Chapter 1.1.10 'Vaccine banks', and in disease-specific chapters of that Manual.
- (9) It is important to verify compliance with the biosecurity, biosafety and bio-containment requirements of operations carried out by the Union antigen, vaccine and diagnostic reagent banks through controls. Therefore, in addition to regular and risk-based controls of manufactures and laboratories carried out by the competent authorities of the Member States, the Commission should perform controls at the Union antigen, vaccine and diagnostic reagent banks to ensure continuous compliance with the relevant standards agreed to in the contracts concluded between the Commission and the manufacturers. Those inspections should be carried out in accordance with Regulation (EU) 2017/625.
- (10) Prior to the date of application of Regulation (EU) 2016/429 on 21 April 2021, the Commission already established and maintained the following Union banks: the foot-and-mouth disease antigen and vaccine bank in accordance with Council Decision 91/666/EEC <sup>(7)</sup> and with Article 80(1) of Council Directive 2003/85/EC <sup>(8)</sup>; the classical swine fever vaccine bank in accordance with Article 18(2) of Council Directive 2001/89/EC <sup>(9)</sup> and with Commission Decision 2007/682/EC <sup>(10)</sup>; and the lumpy skin disease vaccine bank, peste des petits ruminants vaccine bank and sheep pox and goat pox vaccine bank in accordance with Article 6(5) of Regulation (EU) No 652/2014 of the European Parliament and of the Council <sup>(11)</sup>. Directives 2001/89/EC and 2003/85/EC and Decision 91/666/EEC are repealed by Regulation (EU) 2016/429 with effect from 21 April 2021. In addition, Commission Delegated Regulation (EU) 2020/687 <sup>(12)</sup> provides that Directives 2001/89/EC and 2003/85/EC, as well as the acts adopted on the basis thereof, including Decision 2007/682/EC, are to cease to apply with effect

<sup>(7)</sup> Council Decision 91/666/EEC of 11 December 1991 establishing Community reserves of foot-and-mouth disease vaccines (OJ L 368, 31.12.1991, p. 21).

<sup>(8)</sup> Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (OJ L 306, 22.11.2003, p. 1).

<sup>(9)</sup> Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever (OJ L 316, 1.12.2001, p. 5).

<sup>(10)</sup> Commission Decision 2007/682/EC of 18 October 2007 on the renewal of the Community stocks of live attenuated vaccine against classical swine fever (OJ L 281, 25.10.2007, p. 25).

<sup>(11)</sup> Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC (OJ L 189, 27.6.2014, p. 1).

<sup>(12)</sup> Commission Delegated Regulation (EU) 2020/687 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (OJ L 174, 3.6.2020, p. 64).

from 21 April 2021. Regulation (EU) No 652/2014 is repealed by Regulation (EU) 2021/690 of the European Parliament and of the Council with effect from 1 January 2021. Article 24(1) of Regulation (EU) 2021/690 ensures that Union financial contributions for the establishment of those Union banks awarded under Article 6(5) of Regulation (EU) No 652/2014 continue to be applicable as of 1 January 2021. Therefore, the Union banks established based on those repealed acts should be maintained after the date of application of this Regulation until the date of expiry of the relevant contracts.

- (11) In order to ensure the time needed for the establishment of the Union antigen, vaccine and diagnostic reagent banks based on the new rules, this Regulation should apply from 1 May 2022,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

### **Subject matter and scope**

1. This Regulation supplements the rules laid down in Article 48 of Regulation (EU) 2016/429 as regards the Union antigen, vaccine and diagnostic reagent banks for category A diseases.
2. This Regulation lays down:
  - (a) the rules on the management, storage and replacement of stocks of antigens, vaccines and diagnostic reagents in the Union antigen, vaccine and diagnostic reagent banks, and in particular on:
    - (i) rules on the contracts and grants for the supply and storage of antigens, vaccines and diagnostic reagents;
    - (ii) the conditions for the supply and storage of antigens, vaccines and diagnostic reagents;
    - (iii) the principles of selecting strains and variations of antigens, vaccines and diagnostic reagents;
    - (iv) the destruction and safe disposal of antigens, vaccines and diagnostic reagents which have reached the end of their validity period;
    - (v) the possibilities of buy-back of the antigens for which the validity period has expired;
  - (b) the biosecurity, biosafety and bio-containment requirements for the operation of the Union antigen, vaccine and diagnostic reagent banks;
  - (c) transitional provisions for the Union antigen and vaccine banks established and maintained prior to the date of application of this Regulation.

#### *Article 2*

### **Definitions**

For the purposes of this Regulation, the following definitions shall apply:

1. 'category A disease' means a listed disease that does not normally occur in the Union and for which immediate eradication measures must be taken as soon as it is detected, as referred to in Article 9(1), point (a), of Regulation (EU) 2016/429;
2. 'Union antigen bank' means a Commission-managed reserve of antigenic components that can be rapidly formulated into the final product for emergency use or other vaccination campaigns in Member States or third countries or territories granted access by the Union;
3. 'Union vaccine bank' means a Commission-managed reserve of ready-to-use vaccines for emergency use or other vaccination campaigns in Member States or third countries or territories granted access by the Union;

4. 'Union diagnostic reagent bank' means a Commission-managed reserve of diagnostic reagents or components thereof for the rapid diagnosis of category A diseases in Member States or third countries or territories granted access by the Union;
5. 'European Union reference laboratories' means laboratories designated in accordance with Article 93(1) of Regulation (EU) 2017/625;
6. 'contracted manufacturer' means a selected manufacturer with whom the Commission has concluded a contract referred to in Articles 3(1) and 4(1);
7. 'bovine animal' means an animal of the species of ungulates belonging to the genera *Bison*, *Bos* (including the subgenera *Bos*, *Bibos*, *Novibos*, *Poephagus*) and *Bubalus* (including the subgenus *Anoa*) and the offspring of crossings of those species;
8. 'ovine animal' means an animal of the species of ungulates belonging to the genus *Ovis* and the offspring of crossings of those species;
9. 'caprine animal' means an animal of the species of ungulates belonging to the genus *Capra* and the offspring of crossings of those species;
10. 'porcine animal' means an animal of the species of ungulates of family *Suidae* listed in Annex III to Regulation (EU) 2016/429.

#### Article 3

##### **Rules on the contracts with manufacturers required for the management of the Union antigen, vaccine and diagnostic reagent banks**

1. The Commission shall conclude contracts with selected manufacturers in order to manage, for category A diseases as referred to in Article 3 of Commission Implementing Regulation (EU) 2022/140, the following banks:
  - (a) Union antigen banks;
  - (b) Union vaccine banks;
  - (c) Union diagnostic reagent banks.
2. The Commission shall implement a public procurement procedure, in accordance with the rules laid down in Regulation (EU, Euratom) 2018/1046, for the selection of the manufacturers for the contracts referred to in paragraph 1.
3. The contracts referred to in paragraph 1 shall cover at least the following matters:
  - (a) conditions for the supply of various quantities and types of antigens, vaccines or diagnostic reagents to the Union antigen, vaccine and diagnostic reagent banks;
  - (b) conditions for the secure storage and replacement of antigens, vaccines or diagnostic reagents;
  - (c) in the case of Union antigen banks, guarantees and conditions for:
    - (i) the rapid formulation of the antigens into vaccines;
    - (ii) the production, bottling and labelling of vaccines reconstituted from the antigens;
  - (d) conditions for the release, shipment and delivery of vaccines or diagnostic reagents;
  - (e) conditions for the destruction and safe disposal of the antigens, vaccines or diagnostic reagents, or for the buy-back of antigens, for which the validity period has expired.

#### Article 4

##### **Framework supply contracts for the vaccines and diagnostic reagents**

1. The Commission may conclude the contracts referred to in Article 3(1) in the form of framework supply contracts with selected manufacturers ('framework supply contracts').

2. By way of derogation from Article 3(3), framework supply contracts shall be required to cover at least the release, shipment and delivery of vaccines or diagnostic reagents upon the request of the Commission.
3. Framework supply contracts may cover leasing costs.

#### *Article 5*

### **The management of the Union diagnostic reagent banks through grants awarded to European Union reference laboratories**

1. The Commission may establish and maintain Union diagnostic reagent banks for category A diseases as referred to in Article 3 of Implementing Regulation (EU) 2022/140 at the European Union reference laboratories.
2. The Commission shall include the management and maintenance of the Union diagnostic reagent banks referred to in paragraph 1 of this Article in the annual or multiannual work programmes of the European Union reference laboratories referred to in Article 94(2) of Regulation (EU) 2017/625 for which grants have been awarded in accordance with Article 180 of Regulation (EU, Euratom) 2018/1046.
3. The annual or multiannual work programmes, referred to in paragraph 2, for the purpose of the Union diagnostic reagent banks shall cover at least the following:
  - (a) the supply of various quantities and types of diagnostic reagents to the Union diagnostic reagent banks;
  - (b) the secure storage and replacement of diagnostic reagents;
  - (c) the release, shipment and delivery of diagnostic reagents;
  - (d) the destruction and safe disposal of the diagnostic reagents for which the validity period has expired.

#### *Article 6*

### **Conditions for the supply and storage of antigens, vaccines and diagnostic reagents**

1. The Commission shall ensure that the contracts, referred to in Articles 3(1) and 4(1), and the annual or multiannual work programmes of the European Union reference laboratories for the Union diagnostic reagent banks, referred to in Article 5(2), guarantee conditions for the supply and storage of the antigens, vaccines or diagnostic reagents that are at least equivalent to those laid down in Annex I.
2. In addition to the requirements laid down in paragraph 1 of this Article, the contracts referred to in Articles 3(1) and 4(1) for the purchase, supply, storage and replacement of the concentrated inactivated antigens of the foot and mouth disease virus for the production of foot and mouth disease vaccines shall guarantee conditions for the supply and storage of concentrated inactivated antigens of the foot and mouth disease virus that are at least equivalent to those laid down in Annex II.

#### *Article 7*

### **Principles of selecting strains and variations of antigens, vaccines and diagnostic reagents**

The Commission, in consultation with experts from scientific and reference institutions, including the European Union reference laboratories, and international standard setting bodies, shall select the vaccine strains and decide the characteristics of the antigens, vaccines and diagnostic reagents held in the Union antigen, vaccine and diagnostic reagent banks.

*Article 8***Destruction and safe disposal of antigens, vaccines and diagnostic reagents**

The Commission shall ensure that the contracts, referred to in Article 3(1), or the annual or multiannual work programmes of the European Union reference laboratories, referred to in Article 5(2), guarantee appropriate conditions for the destruction and safe disposal of any unused antigen, vaccine or diagnostic reagent after the expiry of its validity period.

*Article 9***Buy-back of the antigens for which the validity period has expired**

By way of derogation from Article 8, the Commission may agree with contracted manufacturers on the buy-back of the antigen supplied to a Union antigen bank and remaining in that bank after the expiry of its validity period.

*Article 10***Biosecurity, biosafety and bio-containment requirements for the operation of the Union antigen, vaccine and diagnostic reagent banks**

The Union antigen, vaccine and diagnostic reagent banks shall operate at least in accordance with the following biosecurity, biosafety and biocontainment requirements:

- (a) the facilities where the antigens, vaccines and diagnostic reagents are stored shall:
  - (i) comply with the recognised quality standards provided for in international standards referred to in point 3 of Annex I and in point 4 of Annex II;
  - (ii) be subjected to controls by the Commission to ensure continuous compliance with the recognised quality standards referred to in point (i), in addition to regular and risk-based controls by the competent authorities;
  - (iii) be secure and protected from accidental or intentional damage, including microbial contamination;
- (b) where a Union antigen, vaccine or diagnostic reagent bank is co-located with a laboratory or other facility where pathogens are handled, the storage facilities referred to in point (a) shall be effectively protected from contamination by physical separation and biosafety procedures for the personnel;
- (c) the personnel shall, where they have had possible exposure to relevant pathogens of the category A diseases referred to in Article 3(1) or 5(1), comply with a quarantine procedure before entering the Union antigen, vaccine and diagnostic reagent banks.

*Article 11***Transitional measures**

The Union banks established before the date of application of this Regulation shall be maintained until the date of expiry of the relevant contracts under which those Union banks were established for the following commodities:

- (a) antigens of foot-and-mouth disease virus, established in accordance with Decision 91/666/EEC and with Article 80(1) of Directive 2003/85/EC;
- (b) vaccines against classical swine fever, established in accordance with Article 18(2) of Directive 2001/89/EC and with Decision 2007/682/EC;
- (c) vaccines against lumpy skin disease, established in accordance with Article 6(5) of Regulation (EU) No 652/2014;

- (d) vaccines against peste des petits ruminants, established in accordance with Article 6(5) of Regulation (EU) No 652/2014;
- (e) vaccines against sheep pox and goat pox, established in accordance with Article 6(5) of Regulation (EU) No 652/2014.

#### Article 12

#### **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*.

It shall apply from 1 May 2022.

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

Done at Brussels, 16 November 2021.

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

---

## ANNEX I

**CONDITIONS FOR THE SUPPLY AND STORAGE OF ANTIGENS, VACCINES AND DIAGNOSTIC REAGENTS AS REFERRED TO IN ARTICLE 6(1)**

1. Antigens, vaccines or diagnostic reagents shall be stored at the site and under the responsibility of the selected manufacturers referred to in Article 3(1) or Article 4(1) or the European Union reference laboratories referred to in Article 5.
2. In the case of vaccines produced and stored in the Union, the principles and guidelines of good manufacturing practice shall be maintained throughout the production process, as referred to in:

(a) Commission Directive 91/412/EEC <sup>(1)</sup>, or

(b) as of the date of their application, the implementing acts adopted pursuant to Article 93(2) of Regulation (EU) 2019/6 of the European Parliament and of the Council <sup>(2)</sup>.

The principles and guidelines of good manufacturing practice shall also be maintained during the storage and finishing, namely filling of vials with vaccine and finishing the process of packaging for distribution, of the vaccine reconstituted from the antigens in store.

3. The antigen or vaccine shall be produced and stored at least in accordance with the principles of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE), Edition 2021.
4. The vaccine must have a marketing authorisation granted by the Commission or by a competent authority in at least one Member State, as applicable, in accordance with:
  - (a) either Chapters 3 and 4 of Title III of Directive 2001/82/EC, or Chapter 1 of Title III of Regulation (EC) No 726/2004 of the European Parliament and of the Council <sup>(3)</sup>, respectively, or,
  - (b) as of 28 January 2022, Chapter III of Regulation (EU) 2019/6.

However, in the event of a serious epidemic, particularly caused by an emerging disease, where a marketing authorisation has not been granted for a vaccine in the Union, a marketing authorisation or other equivalent document granted in the country of production of that vaccine shall be made available by the manufacturer to the Commission.

---

---

<sup>(1)</sup> Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (OJ L 228, 17.8.1991, p. 70).

<sup>(2)</sup> Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

<sup>(3)</sup> Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

## ANNEX II

**ADDITIONAL CONDITIONS FOR THE SUPPLY AND STORAGE OF CONCENTRATED  
INACTIVATED ANTIGENS OF THE FOOT AND MOUTH DISEASE VIRUS AS REFERRED TO IN  
ARTICLE 6(2)**

1. Each antigen shall consist of a single homogeneous batch.
2. Each batch shall be split in order to permit its storage in separate storage capacities to prevent, in the case of technical problems, the deterioration or loss of the entire batch.
3. The vaccine produced from the antigens to be supplied shall comply with the position paper on requirements for vaccines against foot-and-mouth disease of the Committee for Medicinal Products for Veterinary use of the European Medicines Agency) <sup>(1)</sup>.
4. The antigens shall meet at least the requirements of the European Pharmacopoeia <sup>(2)</sup> and the relevant provisions of Chapter 3.1.8 'Foot and mouth disease (infection with foot and mouth disease virus)' of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE), Edition 2021.
5. If not otherwise specified in the documents referred to in point 4, the antigen shall be purified to remove non-structural proteins of the foot and mouth disease virus. The purification shall at least ensure that the residual content of non-structural proteins in vaccines reconstituted from such antigen does not induce detectable levels of antibodies against non-structural proteins in animals which had received one initial and one subsequent booster vaccination.
6. The vaccine reconstituted from the antigens stored in the Union antigen bank must have a marketing authorisation granted by the Commission or by a competent authority in at least one Member State, as applicable, in accordance with:
  - (a) either Chapters 3 and 4 of Title III of Directive 2001/82/EC, or Chapter 1 of Title III of Regulation (EC) No 726/2004, respectively, or,
  - (b) as of 28 January 2022, Chapter III of Regulation (EU) 2019/6.

In the absence of suitable vaccines against emerging strains of foot and mouth disease virus, a marketing authorisation may not be required for vaccines reconstituted from high and medium priority or new antigens produced under the same conditions and to the same quality standards as antigens that have a marketing authorisation.

7. Each dose of vaccine produced from antigens stored in the Union antigen bank shall have a potency of at least 6 PD<sub>50</sub> in cattle, and shall be suitable for the emergency vaccination of bovine, ovine, caprine and porcine animals, depending on the request by the Commission.

---

<sup>(1)</sup> European Medicines Agency (2004). Position paper on requirements for vaccines against foot-and-mouth disease, EMEA/CVMP/775/02-FINAL 01/12/2004.

<sup>(2)</sup> <https://www.edqm.eu/en>

**COMMISSION IMPLEMENTING REGULATION (EU) 2022/140****of 16 November 2021****laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to the Union antigen, vaccine and diagnostic reagent banks****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') <sup>(1)</sup>, and in particular Article 50(1) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down rules for the prevention and control of diseases which are transmissible to animals or humans, including rules for the establishment and management of the Union antigen, vaccine and diagnostic reagent banks. In accordance with Article 48(1) of that Regulation, the Commission may establish and be responsible for managing the Union antigen, vaccine and diagnostic reagent banks for the storage and replacement of stocks of antigens, vaccines, vaccine master seed-stocks and diagnostic reagents for the listed diseases referred to in Article 9(1), point (a) thereof, in respect of which vaccination is not prohibited by a delegated act adopted pursuant to Article 47 thereof. The establishment of Union antigen, vaccine and diagnostic reagent banks would promote attainment of the Union's animal health objectives by permitting a quick and effective response when the resources of those banks are required in the event of the occurrence of a category A disease, as defined and categorised in Commission Implementing Regulation (EU) 2018/1882 <sup>(2)</sup>, and would represent an efficient use of limited resources.
- (2) In addition, Article 47(1) of Regulation (EU) 2016/429 empowers the Commission to adopt delegated acts laying down rules concerning the use of veterinary medicinal products, including vaccines, for the purpose of the prevention and control of listed diseases in terrestrial animals. When Member States allow the use of vaccines in kept and wild terrestrial animals against category A diseases, taking into consideration the criteria set out in Article 46(2) of Regulation (EU) 2016/429, they are also required to take into account the rules laid down in those delegated acts.
- (3) In accordance with Article 48(3) of Regulation (EU) 2016/429, the Commission has adopted Delegated Regulation (EU) 2022/139 <sup>(3)</sup> that supplements Regulation (EU) 2016/429, as regards rules for the management, storage and replacement of stocks of antigens, vaccines and, where relevant, other biological products in the Union antigen, vaccine and diagnostic reagent banks. It also lays down biosecurity, biosafety and bio-containment requirements for the operation of those banks.

<sup>(1)</sup> OJ L 84, 31.3.2016, p. 1.

<sup>(2)</sup> Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

<sup>(3)</sup> Commission Delegated Regulation (EU) 2022/139 of 16 November 2021 supplementing Regulation (EU) 2016/429 of the European Parliament and the Council as regards the management, storage and replacement of stocks of the Union antigen, vaccine and diagnostic reagent banks and the biosecurity, biosafety and bio-containment requirements for the operation of those banks (See page 1 of this Official Journal).

- (4) This Regulation should lay down the necessary implementing rules to be applied in tandem with the rules laid down in Part III of Regulation (EU) 2016/429 and Delegated Regulation (EU) 2022/139 for the management, storage and replacement of stocks of antigens, vaccines and diagnostic reagents in Union antigen, vaccine and diagnostic reagent banks, and also biosecurity, biosafety and bio-containment requirements for the operation of those banks.
- (5) This Regulation should lay down the necessary requirements concerning the types, strains and quantities of the biological products to be included in the Union antigen, vaccine and diagnostic reagent banks. It should also lay down the necessary requirements concerning the supply, storage and replacement of biological products in the Union antigen, vaccine and diagnostic reagent banks, as well as in relation to the formulation of antigens of the foot and mouth disease virus stored in the Union antigen banks into vaccines.
- (6) Member States should have access to the Union antigen, vaccine and diagnostic reagent banks. In addition, the Commission should be able to supply or lend antigens, vaccines or diagnostic reagents from the Union antigen, vaccine and diagnostic reagent banks to third countries or territories. Therefore, it is necessary to lay down in this Regulation the procedural and technical requirements for requesting access to the Union antigen, vaccine and diagnostic reagent banks.
- (7) As Delegated Regulation (EU) 2022/139 applies from 1 May 2022, this Regulation should also apply from that date.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

### **Subject matter and scope**

This Regulation lays down rules for the Union antigen, vaccine and diagnostic reagent banks, specifying:

- (a) the biological products to be included in the Union antigen, vaccine and diagnostic reagent banks, and the category A diseases for which they may be intended;
- (b) the requirements concerning types, strains and quantities of the biological products to be included in the Union antigen, vaccine and diagnostic reagent banks;
- (c) the additional requirements concerning the supply and storage of antigens and vaccines to be included in the Union antigen, vaccine and diagnostic reagent banks;
- (d) the requirements concerning the formulation of antigens of the foot and mouth disease virus stored in the Union antigen banks into vaccines, and the labelling of ready-to-use vaccines;
- (e) the procedures for the release and delivery of vaccines from the Union antigen, vaccine and diagnostic reagent banks;
- (f) the requirements concerning the replacement of antigens, vaccines and diagnostic reagents in the Union antigen, vaccine and diagnostic reagent banks;
- (g) the procedural and technical requirements for requesting access to the Union antigen, vaccine and diagnostic reagent banks.

#### *Article 2*

### **Definitions**

For the purpose of this Regulation, the definitions in Article 2 of Delegated Regulation (EU) 2022/139 shall apply.

*Article 3***Biological products to be included in the Union antigen, vaccine and diagnostic reagent banks for certain category A diseases**

1. The Commission shall include in the Union antigen, vaccine and diagnostic reagent banks the biological products listed in column 2 of the table in Annex I ('the table') for the category A diseases listed in column 1 of the table.
2. The Commission shall maintain in the Union antigen, vaccine and diagnostic reagent banks the types and strains of the biological products listed in column 3 of the table and the quantities of biological products listed in column 4 of the table, and take account of the validity period of the biological products indicated in column 5 thereof.

*Article 4***Additional requirements concerning the supply and storage of antigens and vaccines**

1. The Commission shall arrange independent testing of the potency and innocuity of the vaccines supplied and stored in the Union vaccine banks and of the vaccines reconstituted from antigens stored in the Union antigen banks.
2. The contracted manufacturer shall comply with the additional requirements concerning the storage of antigens of the foot and mouth disease virus and vaccines against category A diseases set out in Annex II.

*Article 5***Requirements concerning the formulation of antigens of the foot and mouth disease virus into vaccines and the labelling of the ready-to-use vaccine**

1. In the case of an emergency and with due regard to the epidemiological situation in the Union or in third countries or territories where it is in the interest of the Union, the Commission shall request the contracted manufacturer, in writing, for a formulation of antigens of the foot and mouth disease virus stored in the Union antigen banks into vaccines and the bottling, labelling and temporary storage of the necessary quantities of those vaccines.
2. The contracted manufacturer shall comply with the request referred to in paragraph 1 of this Article and the requirements concerning the formulation of antigens of the foot and mouth disease virus into vaccines and the labelling of the ready to use vaccines set out in Annex III.

*Article 6***Procedures for the release and delivery of vaccines**

1. When required, the Commission shall request the contracted manufacturer, in writing, for a delivery of the vaccines stored in the Union vaccine banks or of the formulated vaccines referred to in Article 5(1).
2. The contracted manufacturer shall comply with the request referred to in paragraph 1 of this Article and the procedures for the release and delivery of the formulated vaccines referred to in Article 5(1) set out in Annex IV.
3. The contracted manufacturer shall comply with the procedures for the delivery of vaccines stored in the Union vaccine banks set out in Annex V.

*Article 7***Requirements concerning the replacement of antigens, vaccines and diagnostic reagents**

Following the use of any antigen, vaccine or diagnostic reagent from the Union antigen, vaccine and diagnostic reagent banks, the Commission shall ensure that the used antigen, vaccine or diagnostic reagent is replaced, if necessary, by its equivalent, as soon as possible and with due regard to the epidemiological situation.

*Article 8***Procedural and technical requirements for requesting access to the antigens, vaccines and diagnostic reagents from the Union antigen, vaccine and diagnostic reagent banks**

1. The Commission shall grant Member States access to the Union antigen, vaccine and diagnostic reagent banks upon their written request.
2. The Commission shall, within the limits of availability of stocks of the Union antigen, vaccine and diagnostic reagent banks, immediately arrange for the shipment of the required quantities and types of vaccines or diagnostic reagents, taking into account the criteria laid down in Article 49(2) of Regulation (EU) 2016/429 and the additional criteria for the distribution of the required quantities and types of vaccines set out in Annex VI to this Regulation.
3. Member States that maintain national antigen, vaccine and diagnostic reagent banks or Member States that are associated to an international antigen and vaccine bank shall have the same rights and obligations with regard to the Union antigen, vaccine and diagnostic reagent banks as other Member States that do not have a national antigen, vaccine and diagnostic reagent bank or access to an international antigen and vaccine bank.
4. Where it is in the interest of the Union, the Commission may supply or lend, following their request, to third countries or territories, antigens, vaccines or diagnostic reagents from the Union antigen, vaccine and diagnostic reagent banks.
5. Access of third countries and territories to the Union antigen, vaccine and diagnostic reagent banks shall be granted under detailed conditions agreed between the Commission and the third country or territory concerned.

*Article 9***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*.

It shall apply from 1 May 2022.

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

Done at Brussels, 16 November 2021.

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

**Biological products to be included in the Union antigen, vaccine and diagnostic reagent banks as referred to in Article 3**

| Name of category A disease                         | Biological product | Type and/or strain of biological product                                                                | Number of doses                                                                                   | Validity period of biological product |
|----------------------------------------------------|--------------------|---------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------|---------------------------------------|
| 1                                                  | 2                  | 3                                                                                                       | 4                                                                                                 | 5                                     |
| Foot and mouth disease                             | antigen            | inactivated<br>various strains representing all seven sero-<br>types: O, A, Asia 1, C, SAT1, SAT2, SAT3 | at least 1 000 000 and up to 5 000 000 for<br>each selected antigen, depending on the<br>priority | at least 60 months                    |
| Classical swine fever                              | vaccine            | live attenuated                                                                                         | at least 1 000 000                                                                                | at least 24 months                    |
| Infection with lumpy skin disease virus            | vaccine            | live attenuated or inactivated                                                                          | at least 250 000                                                                                  | at least 20 months                    |
| Infection with peste des petits ruminants<br>virus | vaccine            | live attenuated or inactivated                                                                          | at least 250 000                                                                                  | at least 20 months                    |
| Sheep pox and goat pox                             | vaccine            | live attenuated or inactivated                                                                          | at least 250 000                                                                                  | at least 20 months                    |

## ANNEX II

**Additional requirements concerning the storage of antigens and vaccines as referred to in Article 4(2)****A. Antigens of the foot and mouth disease virus**

1. Antigens of the foot and mouth disease virus shall be stored in an establishment which is specifically designed for the storage of deep-frozen antigens, meeting the principles and guidelines of good manufacturing practice for veterinary medicinal products, in accordance with Commission Directive 91/412/EEC <sup>(1)</sup>, and as of the date of their application, implementing acts adopted pursuant to Article 93(2) of Regulation (EU) 2019/6 of the European Parliament and of the Council <sup>(2)</sup>, including regular checks and where necessary adjustments of the temperature regime. The antigens shall be stored at or below  $-70^{\circ}\text{C}$ .
2. The contracted manufacturer shall respect the technical requirements referred to in the specific monograph 'Foot-and-mouth disease (ruminants) vaccine (inactivated)' (number 63) of the European Pharmacopoeia in use, and in particular the technical requirements concerning safety, innocuity and sterility of the vaccines.
3. The contracted manufacturer shall report to the Commission, without delay and in any event within a period of seven days from the date of any exceptional event relating to the storage of the antigens and liable to deteriorate the antigens.
4. The contracted manufacturer shall produce a detailed annual report on the quantities and subtypes of antigens stored in the Union antigen, vaccine and diagnostic reagent banks and on the results of stability tests carried out on those antigens.
5. Small aliquots of 20 x 4,5 ml antigen samples for each of the antigen batches manufactured and supplied to the Union bank for antigens of the foot and mouth disease virus shall be stored for in-house monitoring purposes by the contracted manufacturer. The antigen samples shall be made available to the Commission if requested and be supplied either as the purified antigen or as formulated trial blends of vaccines ( $> 6\text{PD}_{50}$ ) throughout the validity period for the relevant antigen.
6. After the end of the validity period for the antigens, and until their destruction and safe disposal or buy-back is completed, the antigens shall remain the property of the Commission and may be stored at the Commission's expense for a period not exceeding 12 months for possible formulation of antigens into vaccines.

**B. Vaccines**

1. The vaccines shall be stored under conditions ensuring that their efficacy, safety, innocuity and sterility throughout their storage period is maintained.
2. In the case of any changing condition ('an incident') in storage that may alter the efficacy, safety, innocuity and sterility of the vaccines, the contracted manufacturer shall perform all necessary testing of the vaccines to verify their conformity with the conditions specified in the contract. The contracted manufacturer shall inform the Commission immediately about the time and conditions of such an incident as well as about the tests that will be performed upon the stored vaccines and the time required for their completion. The results of such tests shall be reported, in the form of a written report, to the Commission within a period of 2 weeks following the date of their completion.
3. The contracted manufacturer shall produce a detailed annual report on the quantities and types of vaccines stored in the Union vaccine bank and the results of stability tests carried out.

<sup>(1)</sup> Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products (OJ L 228, 17.8.1991, p. 70).

<sup>(2)</sup> Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

4. The contracted manufacturer shall guarantee that the vaccines from each vaccine batch in the Union vaccine bank are regularly tested for their potency and sterility throughout their storage period and report the results of these tests to the Commission.
-

## ANNEX III

**Requirements concerning the formulation of antigens of the foot and mouth disease virus into vaccines and the labelling of the ready-to-use vaccine as referred to in Article 5**

1. The formulation of the antigen(s) into vaccines shall be performed as follows:
  - (a) as regards those for immediate supply: the contracted manufacturer shall formulate, bottle and label a minimum of 300 000 doses and a maximum of 2 000 000 doses of finished vaccine  $\text{Al(OH)}_3$ /Saponin and/or DOE) per formulation site during the period of 6 working days following the date of notice of the request for delivery by the Commission; or
  - (b) as regards those for urgent but not immediate supply: the contracted manufacturer shall formulate, bottle and label a minimum of 300 000 doses up to a maximum of 2 000 000 doses of finished vaccine  $\text{Al(OH)}_3$ /Saponin and/or DOE) per formulation site during a period of between 7 to 15 working days following the date of notice of the request for delivery by the Commission.
2. The biggest requisition may be up to 5 million doses of each of the 4 different antigens from the stock of antigens in the Union antigen, vaccine and diagnostic reagent banks formulated into 5 million doses of a tetravalent vaccine.
3. The minimum potency of vaccines formulated from the stocks of antigens in the Union antigen, vaccine and diagnostic reagent banks shall be at least 6  $\text{PD}_{50}$ .
4. The bottling, labelling and distribution of the vaccine shall be carried out taking into account the specific needs of the area where vaccination is to be carried out.
5. The labelling of the ready-to-use vaccine shall be in accordance with the marketing authorisation for  $\text{Al(OH)}_3$ /Saponin and/or DOE vaccine adjuvants adapted in accordance with the contract referred to in Article 3(1) or 4(1) of Delegated Regulation (EU) 2022/139.
6. The boxes containing the vaccines shall have the following label in A4 format:



**VACCINES DONATED**

**BY THE**

**EUROPEAN UNION**

---

## ANNEX IV

**Procedures for the release and delivery of vaccines formulated from the antigens of the foot and mouth disease virus as referred to in Article 6(2)**

1. Following notice of the request for delivery by the Commission, the contracted manufacturer shall comply with the following deadlines for delivery:
  - (a) for urgent but not immediate supply: a period of 7 to 15 working days for formulation, bottling and labelling, plus 3 working days for delivery;
  - (b) for immediate supply: a period of 6 working days for formulation, bottling and labelling, plus 3 working days for delivery;
  - (c) in cases of extreme urgency: the contracted manufacturer shall deliver quicker than at the deadlines referred to in points (a) and (b), subject to the necessary documentation, such as an Early Release Certificate or an introduction permit granted by the Member State, third country or territory of destination, being provided and subject to any enforced delays caused by or restrictions imposed by the shipping company.

The contracted manufacturer shall take the necessary steps to facilitate the sourcing of any permit or licence required for performance of the contract under the laws and regulations in force at the place where the contract referred to in Article 3(1) or 4(1) of Delegated Regulation (EU) 2022/139 is to be executed.

However, the contracted manufacturer shall not be held responsible for obtaining documents that are dependent on other legal entities and authorities which do not exercise direct control over or influence him/her.

2. For the shipment to the destination the vaccines shall be packaged in insulated cardboard boxes containing 6 cool-packs per standard sized box (45x42x45 cm) or equivalent. This combination must ensure cold-chain conditions for up to 72 hours.

Where specifically requested by the Commission, the contracted manufacturer shall furnish the shipment of vaccines with WHO approved vaccine cold-chain monitors <sup>(1)</sup> in each standard box of vaccines. The vaccine cold-chain monitor card must have a time-temperature indicator with the threshold response temperatures of +10 °C and +34 °C. The vaccine cold-chain monitor card must show a blue colouration of the indicator if the temperature has been exceeded during transport or storage.

---

<sup>(1)</sup> WHO, World Health Organisation, 'Temperature monitors for vaccines and the cold chain', document WHO/V&B/99.15 (1999).

## ANNEX V

**Procedures for the delivery of vaccines stored in the Union vaccine banks as referred to in Article 6(3)**

1. Delivery of the vaccines from the site of their storage shall be within a period of 3 to 15 working days following notice of the request for delivery by the Commission, depending on the urgency.
2. The bottling, labelling and distribution of the vaccine shall be carried out taking into account the specific needs of the area where vaccination is to be carried out.
3. The boxes containing the vaccines shall have the following label in A4 format:



**VACCINES DONATED**

**BY THE**

**EUROPEAN UNION**

\_\_\_\_\_

## ANNEX VI

**Additional criteria for the distribution of the required quantities and types of vaccines as referred to in Article 8(2)**

1. A requesting Member State, third country or territory may receive not more than half of the stocks of an antigen, vaccine or diagnostic reagent available in the Union antigen, vaccine and diagnostic reagent bank.
  2. In addition to the condition laid down in point 1, the following shall be taken into account:
    - (a) the time needed for the contracted manufacturer to produce and to replenish the Union antigen, vaccine and diagnostic reagent bank with the equivalent type and quantity of antigen, vaccine or diagnostic reagent; and
    - (b) the availability of the antigen, vaccine or diagnostic reagent on the market.
-

**COMMISSION REGULATION (EU) 2022/141****of 21 January 2022****amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sodium carbonates (E 500) and potassium carbonates (E 501) in unprocessed cephalopods****(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 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives <sup>(1)</sup>, and in particular Article 10(3) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in food and their conditions of use.
- (2) That list may be updated in accordance with the common procedure referred to in Article 3(1) of Regulation (EC) No 1331/2008 of the European Parliament and of the Council <sup>(2)</sup>, either on the initiative of the Commission or following an application by a Member State or by an interested party.
- (3) Pursuant to Annex II to Regulation (EC) No 1333/2008, sodium carbonates (E 500) and potassium carbonates (E 501) are authorised for use as food additives in a wide variety of foods at *quantum satis* levels. Among others, they are authorised for use in food category 9.2. 'Processed fish and fishery products including molluscs and crustaceans'.
- (4) On 9 September 2020, the Commission received an application for the authorisation of the use of sodium carbonates (E 500) and potassium carbonates (E 501) in unprocessed cephalopods.
- (5) Carbonates have similar effect as phosphoric acid — phosphates — di-, tri- and polyphosphates (E 338-452), currently authorized in frozen and deep-frozen molluscs and crustaceans, as regard the appearance of cephalopods. The manufacturing process for cephalopods involves an immersion treatment in baths containing a dissolution of salt, citrates and carbonates at a maximum concentration of 3 % to regulate the acidity of the bath for 2-3 days. The result being hydration, a change in the consistency and texture of the product as well as keeping the colour. After steaming, cephalopods treated with carbonates and citrates have better organoleptic properties such as softer flesh, better taste and lighter colour than cephalopods treated only with citrates. It results from the sensorial evaluation performed by the applicant that the proposed use of sodium carbonates (E 500) and potassium carbonates (E 501) as acidity regulators in alternative to phosphates, improves the organoleptic properties of cephalopods and consumer's perception of it.
- (6) Pursuant to Article 3(2) of Regulation (EC) No 1331/2008, the Commission has to seek the opinion of the European Food Safety Authority ('the Authority') in order to update the Union list of food additives set out in Annex II to Regulation (EC) No 1333/2008, except where the update in question is not liable to have an effect on human health.
- (7) The safety of sodium carbonate (E 500) and potassium carbonate (E 501) was evaluated in 1990 by the Scientific Committee for Food, which established its Acceptable daily intake (ADI) as 'not specified' <sup>(3)</sup>. The term 'not specified' means that, on the basis of the available toxicological, biochemical and clinical data, the total daily intake of the substance, arising from its natural occurrence and its present use or uses in food at the levels necessary to

<sup>(1)</sup> OJ L 354, 31.12.2008, p. 16.

<sup>(2)</sup> Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (OJ L 354, 31.12.2008, p. 1).

<sup>(3)</sup> Reports of the Scientific Committee for Food, Twenty-fifth series, 1991, p. 13 ([https://ec.europa.eu/food/system/files/2020-12/sci-com\\_scf\\_reports\\_25.pdf](https://ec.europa.eu/food/system/files/2020-12/sci-com_scf_reports_25.pdf)).

achieve the desired technological effect, does not present a hazard to health. In view of that and in the absence of specific priorities for the re-evaluation of sodium carbonates (E 500) and potassium carbonates (E 501) under the programme for the re-evaluation of food additives laid down in Commission Regulation (EU) No 257/2010 <sup>(4)</sup>, the Commission considers that the authorisation of use of sodium carbonates (E 500) and potassium carbonates (E 501) as acidity regulators on unprocessed cephalopods constitutes an update of that list which is not liable to have an effect on human health and therefore it is not necessary to seek the opinion of the Authority.

- (8) Thus, it is appropriate to authorise the use of sodium carbonates (E 500) and potassium carbonates (E 501) as acidity regulators in the food category '09.1.2 'Unprocessed molluscs and crustaceans' in Annex II to Regulation (EC) No 1333/2008 at *quantum satis* for cephalopods. For the reasons of the restriction of use of phosphates to frozen and deep-frozen molluscs and crustaceans, the use of sodium carbonates (E 500) and potassium carbonates (E 501) in alternative to phosphates in unprocessed cephalopods should be restricted to frozen and deep-frozen cephalopods not treated with phosphoric acid — phosphates — di-, tri- and polyphosphates (E 338-452).
- (9) Annex II to Regulation (EC) No 1333/2008 should therefore be amended accordingly.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with the Annex to this 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*.

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

Done at Brussels, 21 January 2022.

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

---

<sup>(4)</sup> Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (OJ L 80, 26.3.2010, p. 19).

## ANNEX

Part E of Annex II to Regulation (EC) No 1333/2008 is amended as follows:

- (i) in food category 09.1.2 'Unprocessed molluscs and crustaceans' the following entries are inserted after the entry for E 385, Calcium disodium ethylene diamine tetra-acetate (Calcium disodium EDTA):

|       |                      |                      |      |                                          |
|-------|----------------------|----------------------|------|------------------------------------------|
| E 500 | Sodium carbonates    | <i>quantum satis</i> | (95) | only frozen and deep-frozen cephalopods  |
| E 501 | Potassium carbonates | <i>quantum satis</i> | (95) | only frozen and deep-frozen cephalopods' |

- (ii) the following footnote (95) is added after footnote (90):

'(95): may not be used in combination with Phosphoric acid — phosphates — di-, tri- and polyphosphates (E 338-452)'

---

# DECISIONS

## COMMISSION IMPLEMENTING DECISION (EU) 2022/142

of 31 January 2022

**amending Implementing Decision (EU) 2019/1741 as regards the reporting on production volume and correcting that Implementing Decision**

*(notified under document C(2022) 451)*

**(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 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC <sup>(1)</sup>, and in particular Article 7(2) thereof,

Whereas:

- (1) Commission Implementing Decision (EU) 2019/1741 <sup>(2)</sup> sets out the format and frequency of the annual reporting of data on releases of pollutants to air, water and land and on off-site waste transfers.
- (2) It follows from Implementing Decision (EU) 2019/1741 that the Member States are required to report data on production volume for each facility concerned with regard to sectors where the Commission has established units and metrics for reporting.
- (3) In order to improve the effectiveness of the European Pollutant Release and Transfer Register (E-PRTR) as a comprehensive source of environmental information and the use of reported data for benchmarking the environmental performance of industrial facilities, there is a need for mandatory reporting on production volume for each facility concerned and, consequently, for establishing the units and metrics to be used for such reporting and for setting out in further detail the format for the reporting on production volume.
- (4) It is appropriate to provide sufficient time for the operators of concerned facilities and Member States' competent authorities to take the measures necessary to enable the reporting of production volume in accordance with the new format. The requirement to report such data should therefore apply from the reporting year 2023.
- (5) Table notes (9) and (10) in the Annex to Implementing Decision (EU) 2019/1741 refer to table note (7) of that Annex, which concerns the mandatory nature and date of application of the reporting on production volume, whereas they should have referred to table note (8) of that Annex, which concerns the publication of individual data points.
- (6) Implementing Decision (EU) 2019/1741 should therefore be amended and corrected accordingly.

<sup>(1)</sup> OJ L 33, 4.2.2006, p. 1.

<sup>(2)</sup> Commission Implementing Decision (EU) 2019/1741 of 23 September 2019 establishing the format and frequency of data to be made available by the Member States for the purposes of reporting under Regulation (EC) No 166/2006 of the European Parliament and of the Council concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (OJ L 267, 21.10.2019, p. 3).

- (7) These efforts will feed into the outlook and foresight dimension of the Zero Pollution Monitoring Framework under the EU's Action Plan 'Towards a Zero Pollution for Air, Water and Soil' <sup>(3)</sup>, thus helping anticipate policy challenges and identify the most effective and preventive solutions.
- (8) The measures provided for in this Decision are in accordance with the opinion of the committee established by Article 19(1) of Regulation (EC) No 166/2006,

HAS ADOPTED THIS DECISION:

*Article 1*

**Amendments to Implementing Decision (EU) 2019/1741**

Article 1, third subparagraph, is replaced by the following:

'The administrative information set out in Sections 1 to 4 of the Annex shall be submitted to the Commission, at the latest, by 30 September of the following reporting year. By derogation, the Administrative Information set out in fields 2.12, 2.13 and 2.14 shall be submitted to the Commission, at the latest, by 30 November of the following reporting year.'

The Annex is amended in accordance with the Annex to this Decision.

*Article 2*

**Corrections to Implementing Decision (EU) 2019/1741**

In the Annex, in the text of table notes (9) and (10), 'No 7' is replaced by 'No 8'.

This Decision is addressed to the Member States.

Done at Brussels, 31 January 2022.

*For the Commission*  
Virginijus SINKEVIČIUS  
*Member of the Commission*

---

<sup>(3)</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions – Pathway to a Healthy Planet for All EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil' (COM/2021/400 final).

## ANNEX

The Annex is amended as follows:

- (1) after the title, the following text is inserted:

‘Part 1

Administrative and thematic information’;

- (2) the text of table note (7) is replaced by the following:

‘(7) Optional for the 2019, 2020, 2021 and 2022 reporting years. From the reporting year 2023, the production volume of each facility shall be reported in accordance with the rules set out in Part 2.’;

- (3) the following Part 2 is added:

‘Part 2

Establishing the units and metrics to be reported by Member States under field 2.12 “Production volume”

## 1. Definitions

For the purposes of this Part, the following definitions shall apply:

- (1) “tonnes of products/extracted material” means, unless otherwise stated, the weight of the stated metric, including any inherent moisture content of the products or extracted material, but excluding any product packaging/containment;
- (2) “tonnes of products as oil equivalents” means the output of a facility expressed as the amount of energy released by burning 1 tonne of crude oil, considering that the energy content of a tonne of crude oil is 42 gigajoules;
- (3) “gigajoules of useful energy output” means the energy effectively converted into electricity or heat expressed in gigajoules and served to the grid or the final user;
- (4) “tonnes of incoming waste” means the weight of all incoming waste, within a calendar year, to a facility that is further dealt within the defined recovery or disposal activity performed by the same facility and which excludes waste quantities transferred to other facilities without treatment;
- (5) “cubic metres of incoming waste-water” means the volume of water that enters the treatment operations of the relevant waste-water treatment facility;
- (6) “tonnes of organic solvent” means the weight of the total amount of solvents consumed in the operations performed within the facility;
- (7) “tonnes of paint used and/or removed” means the weight of the paint consumed, the best estimate of the paint removed, or, when performing painting and removal activities within the same facility, the sum of both;
- (8) “number of livestock units (LSU)” means the conversion rates in Annex II of Commission Implementing Regulation (EU) No 808/2014 of 17 July 2014 laying down rules for the application of Regulation (EU) No 1305/2013 of the European Parliament and of the Council on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) <sup>(1)</sup>; the livestock units for animals not covered explicitly by this Regulation should be based on scientific evidence e.g. broilers 0,007 LSU, ostriches 0,350 LSU.

## 2. General rules

- (a) Unless otherwise stated, the data on production volume shall cover total viable outputs from a facility and shall include the sum of all outputs during the year that are sold, stored on-site, and used on-site for further processing. The sum of outputs that are spoiled, rejected or off-specification shall be excluded.

---

<sup>(1)</sup> Commission Implementing Regulation (EU) No 808/2014 of 17 July 2014 laying down rules for the application of Regulation (EU) No 1305/2013 of the European Parliament and of the Council on support for rural development by the European Agricultural Fund for Rural Development (EAFRD) (OJ L 227, 31.7.2014, p. 18).

- (b) The production volume field 2.12 of Part 1 has a multiplicity of “one to many”. The reporting on production volume shall cover activities performed in the facility and that are reported to the EU Registry on Industrial Sites <sup>(2)</sup> with reference to the relevant facility. The reporting shall cover at least one activity.
- (c) Where possible, the data on production volume shall be reported in accordance with the Prodcom methodology for national statistics on the production of manufactured goods and with the methodology laid down in Regulation (EU) 2019/2152 of the European parliament and of the Council <sup>(3)</sup>.
- (d) The following data shall be reported under field 2.12 of Part 1:
- (i) quantity expressed in the unit/metric set out in point 3;
  - (ii) comments (optional).

### 3. Units and metrics

| Activity                                      |                                                                                                                                                                       | Unit/metric                           |
|-----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------|
| <b>1. Energy sector</b>                       |                                                                                                                                                                       |                                       |
| <b>1(a)</b>                                   | Mineral oil and gas refineries                                                                                                                                        | Tonnes of products as oil equivalents |
| <b>1(b)</b>                                   | Installations for gasification and liquefaction                                                                                                                       | Tonnes of products as oil equivalents |
| <b>1(c)</b>                                   | Thermal power stations and other combustion installations                                                                                                             | Gigajoules of useful energy output    |
| <b>1(d)</b>                                   | Coke ovens                                                                                                                                                            | Tonnes of products as oil equivalents |
| <b>1(e)</b>                                   | Coal rolling mills                                                                                                                                                    | Tonnes of products as oil equivalents |
| <b>1(f)</b>                                   | Installations for manufacture of coal products and solid smokeless fuel                                                                                               | Tonnes of products as oil equivalents |
| <b>2. Production and processing of metals</b> |                                                                                                                                                                       |                                       |
| <b>2(a)</b>                                   | Metal ore (including sulphide ore) roasting or sintering installations                                                                                                | Tonnes of products                    |
| <b>2(b)</b>                                   | Installations for the production of pig iron or steel (primary or secondary melting) including continuous casting                                                     | Tonnes of products                    |
| <b>2(c)(i)</b>                                | Installations for the processing of ferrous metals: Hot-rolling mills                                                                                                 | Tonnes of products                    |
| <b>2(c)(ii)</b>                               | Installations for the processing of ferrous metals: Smitheries with hammers                                                                                           | Tonnes of products                    |
| <b>2(c)(iii)</b>                              | Installations for the processing of ferrous metals: Application of protective fused metal coats                                                                       | Tonnes of products                    |
| <b>2(d)</b>                                   | Ferrous metal foundries                                                                                                                                               | Tonnes of products                    |
| <b>2(e)(i)</b>                                | Installations: For the production of non-ferrous crude metals from ore, concentrates or secondary raw materials by metallurgical, chemical, or electrolytic processes | Tonnes of products                    |
| <b>2(e)(ii)</b>                               | Installations: For the smelting, including the alloying, of non-ferrous metals, including recovered products (refining, foundry casting, etc.                         | Tonnes of products                    |

<sup>(2)</sup> <https://cdr.eionet.europa.eu/help/euregistry>

<sup>(3)</sup> Regulation (EU) 2019/2152 of the European Parliament and of the Council of 27 November 2019 on European business statistics, repealing 10 legal acts in the field of business statistics (OJ L 327, 17.12.2019, p. 1). ‘PRODUCTION COMMUNAUTAIRE’ (Community Production). See <https://ec.europa.eu/eurostat/web/prodcom/overview>

|      |                                                                                                               |                                                    |
|------|---------------------------------------------------------------------------------------------------------------|----------------------------------------------------|
| 2(f) | Installations for surface treatment of metals and plastic materials using an electrolytic or chemical process | Tonnes of the surface treatment substances (input) |
|------|---------------------------------------------------------------------------------------------------------------|----------------------------------------------------|

### 3. Mineral industry

|           |                                                                                                                                                        |                              |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| 3(a)      | Underground mining and related operations                                                                                                              | Tonnes of extracted material |
| 3(b)      | Opencast mining and quarrying                                                                                                                          | Tonnes of extracted material |
| 3(c)(i)   | Installations for the production of: Cement clinker in rotary kilns                                                                                    | Tonnes of products           |
| 3(c)(ii)  | Installations for the production of: Lime in rotary kilns                                                                                              | Tonnes of products           |
| 3(c)(iii) | Installations for the production of: Cement clinker or lime in other furnaces                                                                          | Tonnes of products           |
| 3(d)      | Installations for the production of asbestos and the manufacture of asbestos-based products                                                            | Tonnes of products           |
| 3(e)      | Installations for the manufacture of glass, including glass fibre                                                                                      | Tonnes of products           |
| 3(f)      | Installations for melting mineral substances, including the production of mineral fibres                                                               | Tonnes of products           |
| 3(g)      | Installations for the manufacture of ceramic products by firing, in particular roofing tiles, bricks, refractory bricks, tiles, stoneware or porcelain | Tonnes of products           |

### 4. Chemical industry

|           |                                                                                                                                                                                                                                                 |                    |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| 4(a)(i)   | Chemical installations for the production on an industrial scale of basic organic chemicals, such as: Simple hydrocarbons (linear or cyclic, saturated, or unsaturated, aliphatic, or aromatic)                                                 | Tonnes of products |
| 4(a)(ii)  | Chemical installations for the production on an industrial scale of basic organic chemicals, such as: Oxygen-containing hydrocarbons such as alcohols, aldehydes, ketones, carboxylic acids, esters, acetates, ethers, peroxides, epoxy resins  | Tonnes of products |
| 4(a)(iii) | Chemical installations for the production on an industrial scale of basic organic chemicals, such as: Sulphurous hydrocarbons                                                                                                                   | Tonnes of products |
| 4(a)(iv)  | Chemical installations for the production on an industrial scale of basic organic chemicals, such as: Nitrogenous hydrocarbons such as amines, amides, nitrous compounds, nitro compounds or nitrate compounds, nitriles, cyanates, isocyanates | Tonnes of products |
| 4(a)(v)   | Chemical installations for the production on an industrial scale of basic organic chemicals, such as: Phosphorus- containing hydrocarbons                                                                                                       | Tonnes of products |
| 4(a)(vi)  | Chemical installations for the production on an industrial scale of basic organic chemicals, such as: Halogenic hydrocarbons                                                                                                                    | Tonnes of products |
| 4(a)(vii) | Chemical installations for the production on an industrial scale of basic organic chemicals, such as: Organometallic compounds                                                                                                                  | Tonnes of products |

|                   |                                                                                                                                                                                                                                                                                               |                    |
|-------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| <b>4(a)(viii)</b> | Chemical installations for the production on an industrial scale of basic organic chemicals, such as: Basic plastic materials (polymers, synthetic fibres, and cellulose-based fibres)                                                                                                        | Tonnes of products |
| <b>4(a)(ix)</b>   | Chemical installations for the production on an industrial scale of basic organic chemicals, such as: Synthetic rubbers                                                                                                                                                                       | Tonnes of products |
| <b>4(a)(x)</b>    | Chemical installations for the production on an industrial scale of basic organic chemicals, such as: Dyes and pigments                                                                                                                                                                       | Tonnes of products |
| <b>4(a)(xi)</b>   | Chemical installations for the production on an industrial scale of basic organic chemicals, such as: Surface-active agents and surfactants                                                                                                                                                   | Tonnes of products |
| <b>4(b)(i)</b>    | Chemical installations for the production on an industrial scale of basic inorganic chemicals, such as: Gases, such as ammonia, chlorine or hydrogen chloride, fluorine or hydrogen fluoride, carbon oxides, sulphur compounds, nitrogen oxides, hydrogen, sulphur dioxide, carbonyl chloride | Tonnes of products |
| <b>4(b)(ii)</b>   | Chemical installations for the production on an industrial scale of basic inorganic chemicals, such as: Acids, such as chromic acid, hydrofluoric acid, phosphoric acid, nitric acid, hydrochloric acid, sulphuric acid, oleum, sulphurous acids                                              | Tonnes of products |
| <b>4(b)(iii)</b>  | Chemical installations for the production on an industrial scale of basic inorganic chemicals, such as: Bases, such as ammonium hydroxide, potassium hydroxide, sodium hydroxide                                                                                                              | Tonnes of products |
| <b>4(b)(iv)</b>   | Chemical installations for the production on an industrial scale of basic inorganic chemicals, such as: Salts, such as ammonium chloride, potassium chlorate, potassium carbonate, sodium carbonate, perborate, silver nitrate                                                                | Tonnes of products |
| <b>4(b)(v)</b>    | Chemical installations for the production on an industrial scale of basic inorganic chemicals, such as: Non-metals, metal oxides or other inorganic compounds such as calcium carbide, silicon, silicon carbide                                                                               | Tonnes of products |
| <b>4(c)</b>       | Chemical installations for the production on an industrial scale of phosphorous-, nitrogen- or potassium-based fertilisers (simple or compound fertilisers)                                                                                                                                   | Tonnes of products |
| <b>4(d)</b>       | Chemical installations for the production on an industrial scale of basic plant health products and of biocides                                                                                                                                                                               | Tonnes of products |
| <b>4(e)</b>       | Installations using a chemical or biological process for the production on an industrial scale of basic pharmaceutical products                                                                                                                                                               | Tonnes of products |
| <b>4(f)</b>       | Installations for the production on an industrial scale of explosives and pyrotechnic products                                                                                                                                                                                                | Tonnes of products |

## 5. Waste and wastewater management

|             |                                                                                                                                                                                               |                          |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|
| <b>5(a)</b> | Installations for the recovery or disposal of hazardous waste                                                                                                                                 | Tonnes of incoming waste |
| <b>5(b)</b> | Installations for the incineration of non- hazardous waste in the scope of Directive 2000/76/EC of the European Parliament and of the Council of 4 December 2000 on the incineration of waste | Tonnes of incoming waste |

|             |                                                                                                                                                                                                                                                                                                        |                                      |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| <b>5(c)</b> | Installations for the disposal of non-hazardous waste                                                                                                                                                                                                                                                  | Tonnes of incoming waste             |
| <b>5(d)</b> | Landfills (excluding landfills of inert waste and landfills, which were definitively closed before 16 July 2001 or for which the after-care phase required by the competent authorities according to Article 13 of Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste has expired) | Tonnes of incoming waste             |
| <b>5(e)</b> | Installations for the disposal or recycling of animal carcasses and animal waste                                                                                                                                                                                                                       | Tonnes of incoming waste             |
| <b>5(f)</b> | Urban waste-water treatment plants                                                                                                                                                                                                                                                                     | Cubic metres of incoming waste-water |
| <b>5(g)</b> | Independently operated industrial waste-water treatment plants which serve one or more activities of this Annex                                                                                                                                                                                        | Cubic metres of incoming waste-water |

#### **6. Paper and wood production and processing**

|             |                                                                                                                                     |                    |
|-------------|-------------------------------------------------------------------------------------------------------------------------------------|--------------------|
| <b>6(a)</b> | Industrial plants for the production of pulp from timber or similar fibrous materials                                               | Tonnes of products |
| <b>6(b)</b> | Industrial plants for the production of paper and board and other primary wood products (such as chipboard, fibreboard and plywood) | Tonnes of products |
| <b>6(c)</b> | Industrial plants for the preservation of wood and wood products with chemicals                                                     | Tonnes of products |

#### **7. Intensive livestock production and aquaculture**

|                  |                                                                                                                |                           |
|------------------|----------------------------------------------------------------------------------------------------------------|---------------------------|
| <b>7(a)(i)</b>   | Installations for the intensive rearing of poultry or pigs: With 40 000 places for poultry                     | Number of livestock units |
| <b>7(a)(ii)</b>  | Installations for the intensive rearing of poultry or pigs: With 2 000 places for production pigs (over 30 kg) | Number of livestock units |
| <b>7(a)(iii)</b> | Installations for the intensive rearing of poultry or pigs: With 750 places for sows                           | Number of livestock units |
| <b>7(b)</b>      | Intensive aquaculture                                                                                          | Tonnes of products        |

#### **8. Animal and vegetable products from the food and beverage sector**

|                 |                                                                                                                                 |                    |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------|--------------------|
| <b>8(a)</b>     | Slaughterhouses                                                                                                                 | Tonnes of products |
| <b>8(b)(i)</b>  | Treatment and processing intended for the production of food and beverage products from: Animal raw materials (other than milk) | Tonnes of products |
| <b>8(b)(ii)</b> | Treatment and processing intended for the production of food and beverage products from: Vegetable raw materials                | Tonnes of products |
| <b>8(c)</b>     | Treatment and processing of milk                                                                                                | Tonnes of products |

#### **9. Other activities**

|             |                                                                                                                     |                    |
|-------------|---------------------------------------------------------------------------------------------------------------------|--------------------|
| <b>9(a)</b> | Plants for the pre-treatment (operations such as washing, bleaching, mercerisation) or dyeing of fibres or textiles | Tonnes of products |
| <b>9(b)</b> | Plants for the tanning of hides and skins                                                                           | Tonnes of products |

|             |                                                                                                                                                                                                                          |                                      |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| <b>9(c)</b> | Installations for the surface treatment of substances, objects or products using organic solvents, in particular for dressing, printing, coating, degreasing, waterproofing, sizing, painting, cleaning, or impregnating | Tonnes of organic solvent (input)    |
| <b>9(d)</b> | Installations for the production of carbon (hard-burnt coal) or electro-graphite by means of incineration or graphitisation                                                                                              | Tonnes of products                   |
| <b>9(e)</b> | Installations for the building of, and painting or removal of paint from ships                                                                                                                                           | Tonnes of paint used and/or removed' |



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



Publications Office  
of the European Union  
L-2985 Luxembourg  
LUXEMBOURG

EN