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## Legislation

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Contents

### II *Non-legislative acts*

#### REGULATIONS

- ★ **Commission Implementing Regulation (EU) 2021/605 of 7 April 2021 laying down special control measures for African swine fever <sup>(1)</sup> ..... 1**
- ★ **Commission Implementing Regulation (EU) 2021/606 of 14 April 2021 amending Annex I, Annexes IV to XIII, and Annex XVI to Implementing Regulation (EU) 2021/405 as regards the entries of Belarus and of the United Kingdom and the Crown Dependencies of Guernsey, the Isle of Man and Jersey in the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption <sup>(1)</sup> ..... 65**
- ★ **Commission Implementing Regulation (EU) 2021/607 of 14 April 2021 imposing a definitive anti-dumping duty on imports of citric acid originating in the People's Republic of China as extended to imports of citric acid consigned from Malaysia, whether declared as originating in Malaysia or not, following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council ..... 73**
- ★ **Commission Implementing Regulation (EU) 2021/608 of 14 April 2021 amending Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council <sup>(1)</sup> ..... 119**

#### DECISIONS

- ★ **Commission Implementing Decision (EU) 2021/609 of 14 April 2021 amending Implementing Decision (EU) 2020/439 as regards harmonised standards on packaging for terminally sterilised medical devices and sterilisation of health care products ..... 150**

<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.

- ★ Commission Implementing Decision (EU) 2021/610 of 14 April 2021 amending Implementing Decision (EU) 2020/437 as regards harmonised standards on medical vehicles and their equipment, anaesthetic and respiratory equipment, biological evaluation of medical devices, packaging for terminally sterilised medical devices, sterilisation of health care products, clinical investigation of medical devices for human subjects, non-active surgical implants, medical devices utilising animal tissues and their derivatives, electroacoustics and medical electrical equipment ..... 153
  
  - ★ Commission Implementing Decision (EU) 2021/611 of 14 April 2021 amending Implementing Decision (EU) 2020/438 as regards harmonised standards on biological evaluation of medical devices, packaging for terminally sterilised medical devices, sterilisation of health care products and clinical investigation of medical devices for human subjects ..... 158
- 

**Corrigenda**

- ★ Corrigendum to Council Regulation (EU) No 509/2012 of 15 June 2012 amending Regulation (EU) No 36/2012 concerning restrictive measures in view of the situation in Syria (OJ L 156, 16.6.2012)..... 161

## II

(Non-legislative acts)

## REGULATIONS

**COMMISSION IMPLEMENTING REGULATION (EU) 2021/605****of 7 April 2021****laying down special control measures for African swine fever**

(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 71(3) thereof

Whereas:

- (1) African swine fever is an infectious viral disease affecting kept and wild porcine animals and can have a severe impact on the concerned animal population and the profitability of farming causing disturbance to movements of consignments of those animals and products thereof within the Union and exports to third countries. In the event of an outbreak of African swine fever, there is a risk that the disease agent may spread between establishments of kept porcine animals and in the metapopulations of wild porcine animals. The spread of the disease can significantly affect the productivity of the farming sector due to both direct and indirect losses.
- (2) Since 1978, the African swine fever virus has been present in Sardinia, Italy, and since 2014 there have been outbreaks of that disease in other Member States as well as in neighbouring third countries. Currently, African swine fever can be considered as endemic disease in the populations of porcine animals in a number of third countries bordering the Union and it represents a permanent threat for populations of porcine animals in the Union. The present African swine fever disease situation also poses a health risk for kept porcine animals in unaffected areas of the Member States currently concerned by the disease, as well as for kept porcine animals in other Member States, notably in view of movements of consignments of porcine animals and commodities from porcine animals.
- (3) Commission Implementing Decision 2014/709/EU <sup>(2)</sup> lays down animal health control measures in relation to African swine fever in the Member States and has been amended many times to take account mainly of developments in the epidemiological situation in the Union as regards that disease and new scientific evidence. It applies until 21 April 2021.

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

<sup>(2)</sup> Commission Implementing Decision 2014/709/EU of 9 October 2014 concerning animal health control measures relating to African swine fever in certain Member States and repealing Implementing Decision 2014/178/EU (OJ L 295, 11.10.2014, p. 63).

- (4) Regulation (EU) 2016/429 establishes a new legislative framework for the prevention and control of diseases, which are transmissible to animals or humans. African swine fever falls within the definition of a listed disease in that Regulation, and it is subject to the disease prevention and control rules laid down therein. In addition, Annex to Commission Implementing Regulation (EU) 2018/1882 <sup>(3)</sup> lists African swine fever as a Category A, D and E disease affecting Suidae, while Commission Delegated Regulation (EU) 2020/687 <sup>(4)</sup> supplements the rules for the control of category A, B and C diseases laid down in Regulation (EU) 2016/429, including disease control measures for African swine fever. Those three acts apply from 21 April 2021.
- (5) It is necessary to adapt the current Union control measures for African swine fever laid down in Implementing Decision 2014/709/EU to align them with the new legislative framework for animal health established by Regulation (EU) 2016/429, and in order to improve the control of that disease in the Union by simplifying the Union rules so to enable a more effective and rapid implementation of control measures. It is also necessary to align Union rules as much as possible with international standards, such as those set out in Chapter 15.1 'Infection with African swine fever virus' of the Terrestrial Animal Health Code of the World Organization for Animal Health <sup>(5)</sup> (OIE code). The control measures laid down in this Regulation should take account of the experience gained in the application of Implementing Decision 2014/709/EU.
- (6) The epidemiological situation of African swine fever in affected Member States and globally poses a high risk for the further spread of that disease in the Union. The general disease control measures laid down in Regulation (EU) 2016/429 and in Delegated Regulation (EU) 2020/687 do not cover all specific details and aspects in relation to the spread and the epidemiological situation of African swine fever. It is therefore appropriate to lay down in this Regulation special disease control measures for a limited period of time, under conditions appropriate to the epidemiological situation of African swine fever in the Union.
- (7) This Regulation should provide for a regionalisation approach, which should apply in addition to the disease control measures laid down in Regulation (EU) 2020/687 and list the restricted zones of Member States concerned by outbreaks of African swine fever or at risk due to their proximity to such outbreaks. Those restricted zones should be differentiated by the epidemiological situation of African swine fever and the level of risk and classed as restricted zones I, II and III, with restricted zone III listing the areas with the highest level of risk for the spread of that disease and the most dynamic disease situation in kept porcine animals. They should be listed in Annex I to this Regulation taking account of the information provided by the competent authority of the Member States concerned as regards the disease situation, scientifically based principles and criteria for geographically defining regionalisation due to African swine fever and Union's guidelines agreed with the Member States at the Standing Committee on Plants, Animals, Food and Feed and publicly available on Commissions website <sup>(6)</sup>, the level of risk for the spread of African swine fever and the overall epidemiological situation of African swine fever in the Member State concerned and in the neighbouring areas, where relevant.
- (8) Any amendments of the restricted zones I, II and III in Annex I to this Regulation should be based on similar considerations as were used for listing and should take account of international standards, such as Chapter 15.1 'Infection with African swine fever virus' of the OIE Code, such as indicating the absence of the disease for a period of at least 12 months in the zone or a country. In certain situations, taking account of the justification provided by the competent authority of the Member States concerned and scientifically based principles and criteria for geographically defining regionalisation due to African swine fever and guidelines available at Union level, that period should be reduced to three months.

<sup>(3)</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>(4)</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).

<sup>(5)</sup> <https://www.oie.int/en/standard-setting/terrestrial-code/access-online/>

<sup>(6)</sup> [https://ec.europa.eu/food/animals/animal-diseases/control-measures/asf\\_en](https://ec.europa.eu/food/animals/animal-diseases/control-measures/asf_en)

- (9) As regards risks for the spread of African swine fever, movements of consignments of porcine animals and different porcine commodities pose different levels of risk. As a general rule, movements of consignments of kept porcine animals, of germinal products and of animal by-products of porcine origin from restricted zones pose a higher level of risk in terms of exposure and consequences, than movements of consignments of products of animal origin, including in particular fresh meat and meat products, including casings, as indicated in the Scientific Opinion of the European Food Safety Authority on African Swine Fever, adopted on 11 March 2010 <sup>(7)</sup>. Therefore, movements of consignments of kept porcine animals, and various products of porcine origin from restricted zones II and III listed in Annex I to this Regulation should be prohibited in a manner proportionate to the risk involved and taking into account the rules laid down in Delegated Regulation (EU) 2020/687 and Commission Delegated Regulation (EU) 2020/2154 <sup>(8)</sup>.
- (10) The rules laid down in Commission Delegated Regulation (EU) 2020/686 <sup>(9)</sup> supplement Regulation (EU) 2016/429, as regards the approval of germinal product establishments, the registers of germinal product establishments to be kept by the competent authorities, the record-keeping obligations of operators, the traceability and animal health requirements, and animal health certification and notification requirements for movements within the Union of consignments of germinal products of certain kept terrestrial animals in order to prevent the spread of transmissible animal diseases within the Union by those products. This Regulation should refer to Delegated Regulation (EU) 2020/689 as regards the information required to be kept by the competent authority of approved germinal product establishments for porcine animals.
- (11) Regulation (EC) No 1069/2009 <sup>(10)</sup> lays down animal health rules for animal by-products in order to prevent and minimise risks to animal health arising from those by-products. In addition, Commission Regulation (EU) No 142/2011 <sup>(11)</sup> lays down certain animal health rules for animal by-products covered by Regulation (EC) No 1069/2009, including rules regarding the certification requirements for movements of consignments of those by-products in the Union. These legal acts do not cover all specific details and aspects in relation to risk of the spread of African swine fever through animal by-products obtained from porcine animals kept in restricted zones II and III and animal by-products obtained from wild porcine animals from restricted zones I, II and III. It is therefore appropriate to lay down in this Regulation special disease control measures related to animal by-products and their movements from restricted zones I, II and III.
- (12) In order to take account of the different levels of risk depending on the type of porcine commodities and the epidemiological situation in the Member States and the restricted zones concerned by the spread of African swine fever, this Regulation should provide for certain prohibitions on movements of different type of porcine commodities obtained from porcine animals kept in restricted zones I, II and III listed in the Annex I to this Regulation. In order to avoid unnecessary disturbances to trade, certain derogations from those prohibitions and specific conditions should be laid down in this Regulation. Those derogations should also take into account the general rules for the prevention and control of animal diseases already laid down in Regulation (EU) 2016/429 and in Delegated Regulation (EU) 2020/687 and the principles of the OIE Code as regards risk mitigation measures for African swine fever.

<sup>(7)</sup> The *EFSA Journal* 2010; 8(3):1556.

<sup>(8)</sup> Commission Delegated Regulation (EU) 2020/2154 of 14 October 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards animal health, certification and notification requirements for movements within the Union of products of animal origin from terrestrial animals (OJ L 431, 21.12.2020, p. 5).

<sup>(9)</sup> Commission Delegated Regulation (EU) 2020/686 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of germinal product establishments and the traceability and animal health requirements for movements within the Union of germinal products of certain kept terrestrial animals (OJ L 174, 3.6.2020, p. 1).

<sup>(10)</sup> Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

<sup>(11)</sup> Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

- (13) Movements of kept animals for immediate slaughter generally poses a lower risk for the spread of animal diseases than other types of movements of kept animals provided that risk mitigation measures are in place. It is therefore appropriate that the Member States concerned should be permitted exceptionally to grant derogations from certain prohibitions laid down in this Regulation for movements of consignments of kept porcine animals, from restricted zones II and III, for immediate slaughter to a slaughterhouse located outside of restricted zones I, II and III in the same Member State. Therefore, this Regulation should provide for specific conditions for those derogations to ensure that movements of consignments of kept porcine animals from restricted zones I, II and III do not pose a risk for the spread of African swine fever.
- (14) The derogations for movements of certain kept porcine animals from a restricted zone II to other restricted zones II or III of another Member State are justified provided that specific risk mitigating measures are applied. This requires the establishment of a safe channelling procedure under the strict control of the competent authorities of the Member State of dispatch, passage and destination.
- (15) Article 143 of Regulation (EU) 2016/429 provides that animal health certificates are to accompany the movements of animals, including kept porcine animals. Where derogations from the prohibition on movements of kept porcine animals from the restricted zones I, II and III are applied to consignments of kept porcine animals intended for intra-Union movements, those animal health certificates should include a reference to this Regulation, to ensure that adequate and accurate animal health information is provided in those animal health certificates. It is necessary to mitigate the risks arising from movements of consignments, and movements for private use, of fresh meat, meat products and any other products of animal origin obtained from wild porcine animals, bodies of wild porcine animals, which are intended for human consumption, and wild porcine animals from the restricted zones I, II and III within the same Member State concerned and to other Member States. Risks for the spread of disease should be reduced by prohibiting movements of those products and movements of wild porcine animals by operators as laid down in Article 101 of Commission Delegated Regulation (EU) 2020/688 <sup>(12)</sup> within and from Member States.
- (16) Article 167(1)(b)(i) and (ii) of Regulation (EU) 2016/429 provides that animal health certificates issued by the competent authority of the Member State of origin are to accompany consignments of products of animal origin, including those of porcine origin, that are allowed to be moved from a restricted zone established in accordance with Article 71(3) of that Regulation subject to certain disease control measures. Where this Implementing Regulation provides for derogations from prohibitions on movements of consignments of products of animal origin from the restricted zones I, II and III accompanying animal health certificates should include a reference to this Regulation, so as to ensure adequate and accurate health information in accordance with Delegated Regulation (EU) 2020/2154.
- (17) Movements of consignments of fresh or processed meat and meat products, including casings obtained from porcine animals kept in restricted zones I and II or kept outside restricted zones I, II and III and slaughtered in restricted zones I, II and III should be subject to less stringent certification requirements in order to avoid unnecessary and over burdensome trade limitations. It should be possible to authorise movements of relevant consignments within the territory of the same Member State and to other Member States based on the health or identification marks applied in establishments, provided that those establishments are designated in accordance with this Regulation. The competent authorities should only designate establishments, if kept porcine animals and products thereof that are eligible for movements outside restricted zones I, II and III are clearly separated from those animals and products that are not eligible for such authorised movements. The fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zone III, and the fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zone II, if the specific conditions for authorising movements of those consignments outside restricted zone II provided for in this Regulation are not met, should be marked with special health marks in accordance with this Regulation.

<sup>(12)</sup> Commission Delegated Regulation (EU) 2020/688 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs (OJ L 174, 3.6.2020, p. 140).

- (18) In addition, movements of consignments of fresh meat and meat products, including casings, from kept porcine animals from restricted zones III listed in Annex I to this Regulation, should be subject to more stringent conditions. In specific situations, fresh meat from kept porcine animals should be marked in accordance with the requirements for the marking of fresh meat from protection and surveillance zones set out in Annex IX to Delegated Regulation (EU) 2020/687 or the fresh meat and meat products, including casings, from kept porcine animals should be marked with special marks which cannot be confused with the health mark referred to in Article 48 of Regulation (EU) 2019/627 <sup>(13)</sup> or the identification mark provided for in Article 5(1)(b) of Regulation (EC) No 853/2004 <sup>(14)</sup>.
- (19) Article 15 of Regulation (EU) 2016/429 provides that appropriate steps are to be taken by the competent authority to inform the public of the nature of any risk from animals or products and the measures taken or planned to prevent or control that risk. This Regulation should provide for special information obligations concerning African swine fever that would address the risks posed by movements of consignments of infected animals, contaminated meat products and the illegal disposal of carcasses. It is therefore extremely important to prevent the diffusion of African swine fever related to human activity, and to ensure that information on the animal health control measures laid down in this Regulation, including restrictions on movements of kept porcine animals and relevant products are effectively brought to the attention of travellers, including travellers by road or railway. For that reason, Member States should ensure that passenger transport operators and postal services draw the attention of travellers, moving from the restricted zones I, II and III listed in Annex I to this Regulation, to the animal health control restrictions in place in those zones. Such information should be adapted to the level of risk for the spread of that disease. In addition, coordinated action by the competent authorities of the Member States concerned to combat the risk of the spread of African swine fever should ensure that information disseminated through specific public awareness campaigns is fit for purpose.
- (20) The experience gained in the fight against African swine fever in the Union shows that certain risk mitigation and reinforced biosecurity measures are necessary in order to prevent, control and eradicate that disease in establishments of kept porcine animals. These measures should be laid down in the Annex II to this Regulation and should cover establishments subject to derogations laid down for movements of consignments of porcine animals kept in the restricted zones I, II and III.
- (21) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (Withdrawal Agreement), and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, Regulation (EU) 2016/429, as well as the Commission acts based on it, apply to and in the United Kingdom in respect of Northern Ireland after the end of the transition period provided for in the Withdrawal Agreement. Therefore, references to Member States in this Regulation should include the United Kingdom in respect of Northern Ireland.
- (22) As Regulation (EU) 2016/429 applies with effect from 21 April 2021, this Regulation should also apply from that date.
- (23) This Regulation should continue to apply for the period of at least seven years taking into account Union's experience in the fight against African swine fever and the current epidemiological situation of this disease in Member States concerned. The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

<sup>(13)</sup> Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (OJ L 131, 17.5.2019, p. 51).

<sup>(14)</sup> Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.4.2004, p. 55).

HAS ADOPTED THIS REGULATION:

## CHAPTER I

### SUBJECT MATTER, SCOPE AND DEFINITIONS

#### Article 1

#### Subject matter and scope

1. This Regulation lays down rules on:

- (a) special disease control measures regarding African swine fever to be applied for a limited period of time by the Member States <sup>(15)</sup> which have restricted zones I, II or III listed in Annex I (the Member States concerned).

These special disease control measures apply to kept and wild porcine animals and to products obtained from porcine animals in addition to the measures applicable in the protection, surveillance, further restricted and the infected zones established by the competent authority of the Member State concerned in accordance with Articles 21(1) and 63 of Delegated Regulation (EU) 2020/687.

- (b) special disease control measures regarding African swine fever to be applied for a limited period of time by all Member States.

2. This Regulation applies to:

- (a) the movements of consignments of:

- (i) porcine animals kept in establishments located in restricted zones I, II and III outside those zones;
- (ii) germinal products, products of animal origin and animal by-products obtained from kept porcine animals referred to in point (a)(i);

- (b) the movements of:

- (i) consignments of wild porcine animals in all Member States;
- (ii) consignments and movements for private use by hunters of products of animal origin and animal by-products obtained from wild porcine in the restricted zones I, II and III or processed in establishments located in restricted zones I, II and III;

- (c) food business operators handling consignments referred to in points (a) and (b);

- (d) all Member States concerning awareness raising on African swine fever.

3. The rules referred to in paragraph 1 cover the following:

- (a) Chapter II lays down special rules for the establishment of restricted zones I, II and III in the event of an outbreak of African swine fever and the application of special disease control measures in all Member States;

- (b) Chapter III lays down special disease control measures applicable to consignments of porcine animals kept in restricted zones I, II and III and products obtained thereof in the Member States concerned;

- (c) Chapter IV lays down special risk-mitigating measures concerning African swine fever for food businesses in the Member States concerned;

- (d) Chapter V lays down special disease control measures applicable to wild porcine animals in the Member States;

- (e) Chapter VI lays down special information and training obligations in the Member States;

- (f) Chapter VII lays down final provisions.

<sup>(15)</sup> In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Regulation references to Member States include the United Kingdom in respect of Northern Ireland.



*Article 2***Definitions**

For the purposes of this Regulation, the definitions laid down in Delegated Regulation (EU) 2020/687 shall apply.

In addition, the following definitions shall apply:

- (a) 'porcine animal' means an animal of the species of ungulates of the family *Suidae* listed in Annex III to Regulation (EU) 2016/429;
- (b) 'germinal products' means porcine semen, oocytes and embryos obtained from kept porcine animals for artificial reproduction;
- (c) 'restricted zone I' means an area of a Member State listed in Part I of Annex I with a precise geographical delimitation subject to special disease control measures and bordering restricted zones II or III;
- (d) 'restricted zone II' means an area of a Member State listed in Part II of Annex I with a precise geographical delimitation subject to special disease control measures;
- (e) 'restricted zone III' means an area of a Member State listed in Part III of Annex I with a precise geographical delimitation subject to special disease control measures;
- (f) 'previously disease-free Member State' means a Member State, where African swine fever has not been confirmed in kept porcine animals during the previous period of 12 months;
- (g) 'Category 2 materials' means animal by-products referred to in Article 9 of Regulation (EC) No 1069/2009 obtained from kept porcine animals;
- (h) 'Category 3 materials' means animal by-products referred to in Article 10 of Regulation (EC) No 1069/2009 obtained from kept porcine animals.

## CHAPTER II

**SPECIAL RULES FOR THE ESTABLISHMENT OF RESTRICTED ZONES I, II AND III IN THE EVENT OF AN OUTBREAK OF AFRICAN SWINE FEVER AND THE APPLICATION OF SPECIAL DISEASE CONTROL MEASURES IN ALL MEMBER STATES***Article 3***Special rules for the establishment of restricted and infected zones in the event of an outbreak of African swine fever**

In the event of an outbreak of African swine fever in kept or wild porcine animals, the competent authority of the Member State shall establish either:

- (a) in case of an outbreak in kept porcine animals, a restricted zone in accordance with Article 21(1) of Delegated Regulation (EU) 2020/687 and under the conditions set out in that Article; or
- (b) in case of an outbreak in wild porcine animals, an infected zone in accordance with Article 63 of Delegated Regulation (EU) 2020/687.

*Article 4***Special rules for the establishment of an additional restricted zone in the event of an outbreak of African swine fever in kept or wild porcine animals**

1. In the event of an outbreak of African swine fever in kept or wild porcine animals the competent authority of the Member State may establish, on the basis of the criteria and principles for the geographical demarcation of restricted zones laid down in Article 64(1) of Regulation (EU) 2016/429, an additional restricted zone bordering the established restricted zone or infected zone referred to in Article 3 of this Regulation to demarcate those zones from non-restricted areas.

2. The competent authority of the Member State concerned shall ensure that the additional restricted zone referred to in paragraph 1 corresponds to the restricted zone I listed in Part I of Annex I in accordance with Article 5.

#### *Article 5*

### **Special rules for the listing of restricted zones I in the event of an outbreak of African swine fever in kept or wild porcine animals in an area of a Member State bordering an area where no outbreak of African swine fever has been officially confirmed**

1. Following an outbreak of African swine fever in kept or wild porcine animals in an area of the Member State, bordering an area where no outbreak of African swine fever has been officially confirmed in kept or wild porcine animals, that area where no outbreak has been confirmed shall be listed, where necessary, in Part I of Annex I as restricted zone I.

2. The competent authority of the Member State concerned shall ensure that after the listing of an area in Part I of Annex I as a restricted zone I, an additional restricted zone established in accordance with Article 64(1) of Regulation (EU) 2016/429 is adjusted without delay to comprise at least of the relevant restricted zone I listed in Annex I for that Member State.

3. The competent authority of the Member State shall establish without delay the relevant additional restricted zone in accordance with Article 64(1) of Regulation (EU) 2016/429, if the restricted zone I has been listed to in Annex I.

#### *Article 6*

### **Special rules for the listing of restricted zones II in the event of an outbreak of African swine fever in wild porcine animals in a Member State**

1. Following an outbreak of African swine fever in wild porcine animals in an area of a Member State, that area shall be listed as a restricted zone II in Part II of Annex I.

2. The competent authority of the Member State concerned shall ensure that the infected zone established in accordance with Article 63 of Delegated Regulation (EU) 2020/687 is adjusted without delay to comprise at least the relevant restricted zone II listed in Annex I to this Regulation for that Member State.

#### *Article 7*

### **Special rules for the listing of restricted zones III in the event of an outbreak of African swine fever in kept porcine animals in the Member State**

1. Following an outbreak of African swine fever in kept porcine animals in an area of a Member State, that area shall be listed as a restricted zone III in Part III of Annex I.

However, where only a first and single outbreak of African swine fever in kept porcine animals has been confirmed in an area of a previously disease-free Member State, that area shall not be listed as a restricted zone III in Part III of Annex I to this Regulation.

2. The competent authority of the Member State concerned shall ensure that the restricted zone established in accordance with Article 21(1) of Delegated Regulation (EU) 2020/687 is adjusted without delay to comprise at least the relevant restricted zone III listed in Annex I to this Regulation for that Member State.

#### *Article 8*

### **General application of special disease control measures in restricted zones I, II and III**

The Member States concerned shall apply the special disease control measures laid down in this Regulation in restricted zones I, II and III in addition to the disease control measures to be applied in accordance with Delegated Regulation (EU) 2020/687 in:

(a) restricted zones established in accordance with Article 21(1) of Delegated Regulation (EU) 2020/687;

(b) infected zones established in accordance with Articles 63 of Delegated Regulation (EU) 2020/687.

### CHAPTER III

#### **SPECIAL DISEASE CONTROL MEASURES APPLICABLE TO CONSIGNMENTS OF PORCINE ANIMALS KEPT IN RESTRICTED ZONES I, II AND III AND PRODUCTS OBTAINED THEREOF IN THE MEMBER STATES CONCERNED**

#### SECTION 1

##### ***Application of specific prohibitions on consignments of kept porcine animals and products thereof in the Member States concerned***

##### *Article 9*

##### **Specific prohibitions in relation to movements of consignments of porcine animals kept in restricted zones I, II and III outside those zones**

1. The competent authority of the Member State concerned shall prohibit movements of consignments of porcine animals kept in restricted zones I, II and III outside those zones.
2. The competent authority of the Member State concerned may decide that the prohibition provided for in paragraph 1 shall not apply to movements of consignments of porcine animals kept in restricted zone I to establishments located in other restricted zones I, II and III or outside those zones provided that the establishment of destination is located in the territory of the same Member State concerned.

##### *Article 10*

##### **Specific prohibitions in relation to movements of consignments of germinal products obtained from porcine animals kept in restricted zones II and III outside those zones**

The competent authority of the Member State concerned shall prohibit movements of consignments of germinal products obtained from porcine animals kept in restricted zones II and III outside those zones.

##### *Article 11*

##### **Specific prohibitions in relation to movements of consignments of animal by-products obtained from porcine animals kept in restricted zones II and III outside those zones**

1. The competent authority of the Member State concerned shall prohibit movements of consignments of animal by-products obtained from porcine animals kept in restricted zones II and III outside those zones.
2. The competent authority of the Member State concerned may decide that the prohibition provided for in paragraph 1 shall not apply to animal by-products obtained from porcine animals kept outside restricted zones II and III and slaughtered in slaughterhouses located in restricted zones II and III provided a clear separation of those animal by-products in establishments and during transport from animal by-products obtained from porcine animals kept in restricted zones II and III.

*Article 12***Specific prohibitions in relation to movements of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zones II and III outside those zones**

1. The competent authority of the Member State concerned shall prohibit movements of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zones II and III outside those zones.
2. The competent authority of the Member State concerned may decide that the prohibition provided for in paragraph 1 shall not apply to meat products, including casings, obtained from porcine animals kept in restricted zones II and III, which have undergone the relevant treatment in accordance with Annex VII to Delegated Regulation (EU) 2020/687, as regards African swine fever, in establishments designated in accordance with Article 41(1) of this Regulation.

*Article 13***General prohibitions in relation to movements of consignments of kept porcine animals and products thereof considered a risk of spread of African swine fever**

The competent authority of the Member State concerned may prohibit, within the territory of the same Member State, the movements of consignments of kept porcine animals and products obtained from kept porcine animals if the competent authority considers that there is a risk for the spread of African swine fever to, from or through those kept porcine animals or products thereof.

*SECTION 2****General and specific conditions for derogations authorising movements of consignments of porcine animals kept in restricted zones I, II and III outside those zones****Article 14***General conditions for derogations from specific prohibitions in relation to movements of consignments of porcine animals kept in restricted zones I, II and III outside those zones**

1. By way of derogation from the specific prohibitions provided for in Article 9(1), the competent authority of the Member State concerned may authorise movements of consignments of porcine animals kept in restricted zones I, II and III outside those zones in the cases covered by Articles 22, 23, 24, 25, 28 and 29 and under the specific conditions provided for in those Articles, and:
  - (a) the general conditions laid down Article 28(2) to (7) of Delegated Regulation (EU) 2020/687; and
  - (b) the additional general conditions concerning:
    - (i) movements of consignments of kept porcine animals from restricted zones I, II and III laid down in Article 15;
    - (ii) establishments for kept porcine animals located in restricted zones I, II and III laid down in Article 16;
    - (iii) the means of transport used for the transportation of kept porcine animals from restricted zones I, II and III laid down in Article 17.
2. Prior to granting authorisations provided for in Articles 22 to 25 and 28 to 30, the competent authority of the Member State concerned shall assess the risks deriving from such authorisations and that assessment must indicate that the risk of the spread of African swine fever is negligible.

3. The competent authority of the Member State concerned may decide that additional general conditions referred to in Articles 15 and 16 shall not apply to movements of consignments of porcine animals kept in slaughterhouses located in the restricted zones I, II and III provided that:

- (a) the kept porcine animals need to be moved to another slaughterhouse due to exceptional circumstances, such as a major breakdown in the slaughterhouse;
- (b) the slaughterhouse of destination is located either:
  - (i) in restricted zones I, II or III of the same Member State; or
  - (ii) in exceptional circumstances, such as the absence of the slaughterhouses referred to in point (b)(i), outside restricted zones I, II or III in the territory of the same Member State;
- (c) the movement is authorised by the competent authority of the Member State concerned.

#### Article 15

#### **Additional general conditions related to movements of consignments of porcine animals kept in restricted zones I, II and III outside those zones**

1. The competent authority of the Member State concerned shall authorise movements of porcine animals kept in restricted zones I, II and III outside those zones in the cases covered by Articles 22 to 25 and 28 to 30 under the specific conditions provided for in those Articles provided that:

- (a) the porcine animals have been kept in and have not been moved from the establishment of dispatch for a period of at least 30 days prior to the date of movement, or since birth, if they are younger than 30 days of age, and during that period no other kept porcine animals have been introduced from restricted zones II and III into either:
  - (i) that establishment; or
  - (ii) the epidemiological unit where the porcine animals to be moved were kept completely separated. The competent authority shall determine, after carrying out a risk assessment, the boundaries of such epidemiological unit confirming that the structure, size and distance between different epidemiological units and the operations being carried out ensure separate facilities for housing, keeping and feeding of kept porcine animals so that the African swine fever virus cannot spread from one epidemiological unit to another;
- (b) a clinical examination has been carried out on the porcine animals kept in the establishment of dispatch, including those animals to be moved or used for the collection of germinal products, with favourable results concerning African swine fever:
  - (i) by an official veterinarian;
  - (ii) within the period of last 24 hours prior to the time of movement of the consignment of porcine animals or prior to the time of the collection of germinal products; and
  - (iii) in accordance with Article 3(1) and (2) of Delegated Regulation (EU) 2020/687 and point A.1 of Annex I thereto.
- (c) if necessary, following the instructions of the competent authority, pathogen identification tests have been carried prior to the date of the movement of the consignment from the establishment of dispatch or prior to the date of the collection of germinal products:
  - (i) following the clinical examination referred to in point (b) for porcine animals kept in the establishment, including those animals to be moved or to be used for the collection of germinal products; and
  - (ii) in accordance with point A.2 of Annex I to Delegated Regulation (EU) 2020/687.

2. The competent authority of the Member State concerned shall obtain, where relevant, negative results of pathogen identification tests referred to in point (1)(c) before authorising the movement of consignment.

3. The competent authority of a Member State concerned may decide that, in the case of movements of consignments of kept porcine animals from establishments of dispatch located in restricted zones I and II outside those zones to establishments located within the same Member State concerned, the clinical examination referred to in paragraph (1)(b):

- (a) shall be carried out only for animals to be moved; or
- (b) does not have to be carried out, provided that:
  - (i) the establishment of dispatch have been visited by an official veterinarian with a frequency referred to in Article 16(a)(i) and with a favourable outcome of all the visits by an official veterinarian during a period of at least 12 months before the date of movement, indicating that:
    - biosecurity requirements referred to in Article 16(b) have been implemented in the establishment of dispatch;
    - a clinical examination with favourable results concerning African swine fever has been carried out by an official veterinarian during those visits on the porcine animals kept in the establishment of dispatch in accordance with Article 3(1) and (2) of Delegated Regulation (EU) 2020/687 and point A.1 of Annex I thereto;
  - (ii) the continuous surveillance referred to in Article 16(c) has been in place in the establishment of dispatch during a period of at least 12 months before the date of movement.

#### Article 16

#### **Additional general conditions related to establishments of kept porcine animals located in restricted zones I, II and III**

1. The competent authority of the Member State concerned shall only authorise movements of porcine animals kept in establishments located in restricted zones I, II and III outside those zones in the cases covered by Articles 22 to 25 and 28 to 30 and under the specific conditions provided for in those Articles provided that:

- (a) the establishment of dispatch has been visited by an official veterinarian at least once after the listing of the restricted zones I, II and III in Annex I to this Regulation or during a period of the last three months prior to the movement, and is subject to regular visits by official veterinarians as provided for in Article 26(2) of Delegated Regulation (EU) 2020/687 as follows:
  - (i) in the restricted zones I and II: at least twice a year, with an interval of at least four months between such visits;
  - (ii) in the restricted zone III: at least once every three months.

The competent authority may decide to carry out visits to the establishment in restricted zone III with a frequency referred to in paragraph (a)(i) based on the favourable outcome of the last visit after the listing of the restricted zones I, II and III in Annex I to this Regulation or during a period of the last three months prior to the movement indicating that the biosecurity requirements referred to in paragraph (b) are implemented and the continuous surveillance referred to in paragraph (c) is in place in that establishment.

- (b) the establishment of dispatch implements biosecurity requirements for African swine fever:
  - (i) in accordance with the reinforced biosecurity measures set out in Annex II; and
  - (ii) as established by the Member State concerned;
- (c) continuous surveillance by means of testing with pathogen identification tests for African swine fever is carried out in the establishment of dispatch:
  - (i) in accordance with Article 3(2) of Delegated Regulation (EU) 2020/687 and Annex I thereto;
  - (ii) with negative results each week on at least the first two dead kept porcine animals over the age of 60 days or, in the absence of such dead animals over the age of 60 days, on any dead kept porcine animals after weaning, in each epidemiological unit;
  - (iii) at least during the monitoring period for African swine fever set out in Annex II to Delegated Regulation (EU) 2020/687 before the movement of the consignment from the establishment of dispatch.

2. The competent authority of the Member State concerned may decide that the stock-proof fencing provided for in point (2)(h) of Annex II referred to in paragraph (1)(b)(i) of this Article shall not be required for establishments of kept porcine animals for a period of three months after a confirmation of a first outbreak of African swine fever in that Member State provided that:

- (a) the competent authority of the Member State has assessed the risks deriving from such decision and that assessment indicates that the risk of the spread of African swine fever is negligible;
- (b) an alternative system is in place ensuring that porcine animals kept in establishments are separated from wild porcine animals in Member States where the population of wild porcine animals is present;
- (c) kept porcine animals from those establishments are not moved to another Member States.

#### Article 17

### **Additional general conditions related to the means of transport used for the transportation of porcine animals kept in restricted zones I, II and III outside those zones**

The competent authority of the Member State concerned shall only authorise movements of consignments of porcine animals kept in restricted zones I, II and III outside those zones if the means of transport used for transportation of those consignments:

- (a) comply with requirements laid down in Article 24(1) of Delegated Regulation (EU) 2020/687; and
- (b) are cleaned and disinfected in accordance with Article 24(2) of Delegated Regulation (EU) 2020/687 under the control or supervision of the competent authority of the Member State concerned.

#### SECTION 3

### **Obligations on operators with regard to animal health certificates**

#### Article 18

### **Operators' obligations with regard to animal health certificates for movements of consignments of porcine animals kept in restricted zones I, II and III outside those zones**

Operators shall only move consignments of porcine animals kept in restricted zones I, II and III outside those zones within the Member State concerned or to another Member State in cases covered by Articles 22 to 25 and 28 to 30 if those consignments are accompanied by an animal health certificate as provided for in Article 143(1) of Regulation (EU) 2016/429 that contains at least one of the following attestations of compliance with the requirements provided for in this Regulation:

- (a) 'Porcine animals kept in restricted zone I in compliance with the special control measures relating to African swine fever laid down in Commission Implementing Regulation (EU) 2021/605.');
- (b) 'Porcine animals kept in restricted zone II in compliance with the special control measures relating to African swine fever laid down in Commission Implementing Regulation (EU) 2021/605.');
- (c) 'Porcine animals kept in restricted zone III in compliance with the special control measures relating to African swine fever laid down in Commission Implementing Regulation (EU) 2021/605.');

However, in the case of movements within the same Member State concerned, the competent authority may decide that an animal health certificate does not have to be issued as referred to in second subparagraph of Article 143(2) of Regulation (EU) 2016/429.

## Article 19

**Operators' obligations with regard to animal health certificates for movements of consignments of fresh meat and meat products, including casings, obtained from porcine animals from restricted zones I, II and III**

1. Operators shall only move consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zones I and II outside those zones within the same Member State concerned or to another Member State in cases covered by Articles 38 and 39, if those consignments are accompanied by an animal health certificate as provided for in Article 167(1) of Regulation (EU) 2016/429 that contains:

- (a) the information required in accordance with Article 3 of Delegated Regulation (EU) 2020/2154; and
- (b) at least one of the following attestations of compliance with the requirements provided for in this Regulation:
  - (i) 'Fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zone I in compliance with the special control measures relating to African swine fever laid down in Commission Implementing Regulation (EU) 2021/605.;
  - (ii) 'Fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zone II in compliance with the special control measures relating to African swine fever laid down in Commission Implementing Regulation (EU) 2021/605.'

2. Operators shall only move consignments of processed meat products, including casings, obtained from porcine animals kept in restricted zones I, II and III outside those zones within the same Member State concerned or to another Member State provided that:

- (a) products of animal origin have undergone the relevant risk-mitigating treatment set out in Annex VII to Delegated Regulation (EU) 2020/687;
- (b) those consignments are accompanied by an animal health certificate as provided for in Article 167(1) of Regulation (EU) 2016/429 that contains:
  - (i) the information required in accordance with Article 3 of Delegated Regulation (EU) 2020/2154; and
  - (ii) the following attestation of compliance with the requirements provided for in this Regulation:

'Processed meat products, including casings, obtained from porcine animals kept in restricted zones I, II and III in compliance with the special control measures relating to African swine fever laid down in Commission Implementing Regulation (EU) 2021/605.'

3. Operators shall only move consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in areas outside restricted zones I, II and III and slaughtered in slaughterhouses located in restricted zones I, II and III outside those zones within the same Member State concerned or to another Member State, if those consignments are accompanied by:

- (a) an animal health certificate as provided for in Article 167(1) of Regulation (EU) 2016/429 that contains the information required in accordance with Article 3 of Delegated Regulation (EU) 2020/2154; and
- (b) the following attestation of compliance with the requirements provided for in this Regulation:

'Fresh meat and meat products, including casings, obtained from porcine animals kept in areas outside restricted zones I, II and III and slaughtered in restricted zones I, II and III in compliance with the special control measures relating to African swine fever laid down in Commission Implementing Regulation (EU) 2021/605.'



4. Operators shall only move consignments of processed meat products, including casings, obtained from porcine animals kept in areas outside restricted zones I, II and III and processed in restricted zones I, II and III outside those zones within the same Member State concerned or to another Member State provided that:

- (a) products of animal origin have undergone the relevant risk-mitigating treatment set out in Annex VII to Delegated Regulation (EU) 2020/687;
- (b) those consignments are accompanied by an animal health certificate as provided for in Article 167(1) of Regulation (EU) 2016/429 that contains:
  - (i) the information required in accordance with Article 3 of Delegated Regulation (EU) 2020/2154; and
  - (ii) the following attestation of compliance with the requirements provided for in this Regulation:

‘Processed meat products, including casings, obtained from porcine animals kept in areas outside restricted zones I, II and III and processed in restricted zones I, II and III in compliance with the special control measures relating to African swine fever laid down in Commission Implementing Regulation (EU) 2021/605.’

5. In the cases of movements of consignments referred to in paragraphs 1, 2, 3 and 4 within the same Member State concerned, the competent authority may decide that an animal health certificate does not have to be issued as referred to in first subparagraph of Article 167(1) of Regulation (EU) 2016/429.

6. The competent authority of the Member State concerned may decide that a health mark or, where relevant, an identification mark provided for in point (b) of Article 5(1) of Regulation (EC) No 853/2004 applied on the fresh or processed meat, meat products, including casings, in establishments designated in accordance with Article 41(1) of this Regulation or establishments which handle fresh or processed meat, meat products, including casings, obtained from porcine animals kept in restricted zone I or areas outside restricted zones I, II and III, can substitute the animal health certificate for movements of the following consignments of:

- (a) the fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zones I and II outside those zones within the same Member State concerned or to another Member State, as laid down in paragraph 1;
- (b) the processed meat products, including casings, obtained from porcine animals kept in restricted zones I and II outside those zones within the same Member State concerned or to another Member State, as laid down in paragraph 2;
- (c) the fresh meat and meat products, including casings, obtained from porcine animals kept in areas outside restricted zones I, II and III and slaughtered in slaughterhouses located in restricted zones I, II and III outside those zones within the same Member State concerned or to another Member State, as laid down in paragraph 3;
- (d) the processed meat products, including casings, obtained from porcine animals kept in areas outside restricted zones I, II and III and processed in restricted zones I, II and III outside those zones within the same Member State concerned or to another Member State, as laid down in paragraph 4.

#### *Article 20*

#### **Operators’ obligations with regard to animal health certificates for movements of consignments of germinal products obtained from porcine animals kept in establishments located in restricted zones II and III outside those zones**

Operators shall only move consignments of germinal products obtained from porcine animals kept in restricted zones II and III outside those zones within the same Member State concerned or to another Member State in cases covered by Articles 31 and 32, if those consignments are accompanied by an animal health certificate as provided for in Article 161(1) of Regulation (EU) 2016/429 that contains at least one of the following attestations of compliance with the requirements provided for in this Regulation:

- (a) ‘Germinal products obtained from porcine animals kept in restricted zones II in compliance with the special control measures relating to African swine fever laid down in Commission Implementing Regulation (EU) 2021/605.’;

- (b) 'Germinal products obtained from porcine animals kept in restricted zone III in compliance with the special control measures relating to African swine fever laid down in Commission Implementing Regulation (EU) 2021/605.'

However, in the case of movements within the same Member State concerned, the competent authority may decide that an animal health certificate does not have to be issued as referred to in second subparagraph of Article 161(2) of Regulation (EU) 2016/429.

#### Article 21

### **Operators' obligations with regard to animal health certificates for movements of consignments of Category 2 and 3 materials obtained from porcine animals kept in restricted zones II and III outside those zones**

Operators shall only move consignments of Category 2 and 3 materials obtained from porcine animals kept in restricted zones II and III outside those zones within the same Member State concerned or to another Member State in cases covered by Articles 33 to 37, if those consignments are accompanied by:

- (a) the commercial document referred to in Chapter III of Annex VIII to Commission Regulation (EU) No 142/2011; and
- (b) an animal health certificate referred to in Article 22(5) of Regulation (EU) 2020/687;

However, in the case of movements within the same Member State concerned, the competent authority may decide that an animal health certificate shall not be issued as referred to in Article 22(6) of Regulation (EU) 2020/687.

#### SECTION 4

### ***Specific conditions for derogations authorising movements of consignments of porcine animals kept in restricted zone I outside that zone***

#### Article 22

### **Specific conditions for derogations authorising movements of consignments of porcine animals kept in restricted zone I outside that zone**

1. By way of derogation from the prohibition provided for in Article 9(1), the competent authority of the Member State concerned may authorise movements of consignments of porcine animals kept in restricted zone I outside that zone to:

- (a) an establishment located in the territory of the same Member State concerned:
  - (i) in another restricted zone I;
  - (ii) in restricted zones II and III;
  - (iii) outside the restricted zones I, II and III;
- (b) an establishment located in the territory of another Member State;
- (c) third countries.

2. The competent authority shall only grant the authorisations provided for in paragraph 1 subject to compliance with:

- (a) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687;
- (b) the additional general conditions laid down in Article 14(2) and Articles Article 15(1)(b)(c), (2) and (3), and Articles 16 and 17.

## SECTION 5

***Specific conditions for derogations authorising movements of consignments of porcine animals kept in restricted zone II outside that zone****Article 23***Specific conditions for derogations authorising movements of consignments of porcine animals kept in restricted zone II outside that zone in the territory of the same Member State concerned**

1. By way of derogation from the prohibition provided for in Article 9, the competent authority of the Member State concerned may authorise movements of consignments of porcine animals kept in restricted zone II outside that zone to an establishment located in the territory of the same Member State concerned:

- (a) in another restricted zone II;
- (b) in restricted zones I and III;
- (c) outside the restricted zones I, II and III.

2. The competent authority shall only grant the authorisations provided for in paragraph 1 subject to compliance with:

- (a) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687;
- (b) the additional general conditions laid down in Article 14(2) and Articles 15, 16 and 17.

3. The competent authority of the Member State concerned shall ensure that porcine animals subject to an authorised movement referred to in paragraph 1 remain in the establishment of destination for at least the monitoring period for African swine fever set out in Annex II to Delegated Regulation (EU) 2020/687.

*Article 24***Specific conditions for derogations authorising movements of consignments of porcine animals kept in restricted zone II outside that zone to a slaughterhouse located in the territory of the same Member State concerned for the purpose of immediate slaughter**

1. By way of derogation from the prohibition provided for in Article 9, the competent authority of the Member State concerned may authorise movements of consignments of porcine animals kept in restricted zone II outside that zone to a slaughterhouse located in the territory of the same Member State concerned, provided that:

- (a) the kept porcine animals are moved for the purpose of immediate slaughter;
- (b) the slaughterhouse of destination is designated in accordance with Article 41(1).

2. The competent authority shall only grant the authorisations provided for in paragraph 1 subject to compliance with:

- (a) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687;
- (b) the additional general conditions laid down in Article 14(2), Article 15(1)(b)(c), (2) and (3), and Articles 16 and 17.

*Article 25***Specific conditions for derogations authorising movements of consignments of porcine animals kept in restricted zone II outside that zone to restricted zones II or III in another Member State**

1. By way of derogation from the prohibition provided for in Article 9, the competent authority of the Member State concerned may authorise movements of consignments of porcine animals kept in restricted zone II outside that zone to an establishment located in restricted zone II or III in another Member State.

2. The competent authority shall only grant the authorisations provided for in paragraph 1 provided that:
  - (a) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687 are met;
  - (b) the additional general conditions laid down in Article 14(2) and Articles 15, 16 and 17 are met;
  - (c) a channelling procedure has been set up in accordance with Article 26;
  - (d) the kept porcine animals comply with any other additional appropriate guarantees related to African swine fever based on a positive outcome of a risk assessment of the measures against the spread of that disease:
    - (i) required by the competent authority of the establishment of dispatch;
    - (ii) approved by the competent authorities of the Member States of passage and of the establishment of destination, prior to the movement of the kept porcine animals;
  - (e) no outbreak of African swine fever has been officially confirmed in kept porcine animals in accordance with Article 11 of Delegated Regulation (EU) 2020/687 during a period of at least past 12 months in the establishment of dispatch;
  - (f) the operator has notified the competent authority in advance of the intention to move the consignment of kept porcine animals in accordance with point (b) of Article 152 of Regulation (EU) 2016/429 and Article 96 of Delegated Regulation (EU) 2020/688.
3. The competent authority of the establishment of dispatch shall:
  - (a) draw up a list of establishments that comply with the guarantees referred to in paragraph 2(d);
  - (b) immediately inform the Commission and the other Member States of the guarantees provided for in paragraph (2)(d) and of the approval by the competent authorities provided for in the paragraph 2(d)(ii).
4. The approval provided for in paragraph 2(d)(ii) and the obligation of immediate information provided for in paragraph 3(b) shall not be required when the establishment of dispatch, places of passage and the establishment of destination are all located in restricted zones I, II and III and those zones are continuous, thereby ensuring that the kept porcine animals are only moved through any of those restricted zones I, II and III in accordance with specific conditions provided for in Article 22(4) of Delegated Regulation (EU) 2020/687.

#### Article 26

#### **Specific channelling procedure for granting derogations for movements of consignments of porcine animals kept in restricted zone II outside that zone to restricted zones II or III in another Member State**

1. The competent authority of the Member State concerned shall set up a channelling procedure as provided for in Article 25(2)(c) for movements of consignments of porcine animals kept in restricted zone II outside that zone to an establishment located in restricted zones II or III in another Member State under the control of the competent authorities of:
  - (a) the establishment of dispatch;
  - (b) passage;
  - (c) the establishment of destination.
2. The competent authority of the establishment of dispatch shall:
  - (a) ensure that each means of transport used for movements referred to in paragraph 1 are:
    - (i) individually accompanied by a satellite navigation system to determine, transmit and record its real time location;
    - (ii) sealed by an official veterinarian immediately after the loading of the consignment of kept porcine animals; only an official veterinarian or enforcement authority of the Member State concerned, as agreed with the competent authority, may break the seal and replace it with a new one, where relevant.

- (b) inform in advance the competent authority of the place of the establishment of destination and, where relevant, the competent authority of the place of passage, of the intention to send the consignment of kept porcine animals;
- (c) set up a system whereby operators are required to immediately notify the competent authority of the place of the establishment of dispatch of any accident or breakdown of any means of transport used in the transportation of the consignment of kept porcine animals;
- (d) ensure the establishment of an emergency plan, the chain of command and the necessary arrangements for cooperation between the competent authorities referred to in paragraph 1(a), (b) and (c) in the event of possible accidents during the transport, any major breakdown or any fraudulent action by operators.

#### Article 27

### **Obligations on the competent authority of the Member State concerned of the place of the establishment of destinations for consignments of porcine animals kept in restricted zone II of another Member State**

The competent authority of the Member State concerned of the place of the establishment of destinations for consignments of porcine animals kept in restricted zone II of another Member State shall:

- (a) notify without undue delay the competent authority of the establishment of dispatch of the arrival of the consignment;
- (b) ensure that kept porcine animals either:
  - (i) remain in the establishment of destination for at least the monitoring period for African swine fever set out in Annex II to Delegated Regulation (EU) 2020/687; or
  - (ii) are moved directly to a slaughterhouse designated in accordance with Article 41(1) of this Regulation.

#### SECTION 6

### ***Specific conditions for derogations authorising movements of consignments of porcine animals kept in restricted zone III outside that zone***

#### Article 28

### **Specific conditions for derogations authorising movements of consignments of porcine animals kept in restricted zone III outside that zone to a restricted zone II in the same Member State concerned**

1. By way of derogation from the prohibition provided for in Article 9, in exceptional circumstances, where as a result of that prohibition animal welfare problems arise in an establishment where porcine animals are kept, the competent authority of the Member State concerned may authorise movements of porcine animals kept in restricted zone III outside that zone to an establishment located in restricted zone II in the territory of the same Member State provided that:

- (a) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687 are met;
- (b) the additional general conditions laid down in Article 14(2), Articles 15, 16 and 17 are met;
- (c) the establishment of destination belongs to the same supply chain and kept porcine animals are to be moved to complete the production cycle.

2. The competent authority of the Member State concerned shall ensure that kept porcine animals are not moved from the establishment of destination located in the restricted zone II during at least the monitoring period for African swine fever set out in Annex II to Delegated Regulation (EU) 2020/687.

*Article 29***Specific conditions for derogations authorising movements of consignments of porcine animals kept in restricted zone III outside that zone for immediate slaughter in the same Member State concerned**

1. By way of derogation from the prohibition provided for in Article 9, in exceptional circumstances, where as a result of prohibition referred to in Article 5(1) animal welfare problems arise in an establishment where porcine animals are kept, and in the case of logistic limitations in the slaughter capacity of the slaughterhouses located in the restricted zone III and designated in accordance with Article 41(1) or in the absence of the designated slaughterhouse in the restricted zone III, the competent authority of the Member State concerned may authorise for the purpose of immediate slaughter movements of porcine animals kept in restricted zone III outside that zone to a slaughterhouse designated in accordance with Article 41(1) in the same Member State as near as possible to the establishment of dispatch located:

- (a) in a restricted zone II;
- (b) in a restricted zone I, where it is not possible to slaughter the animals in the restricted zone II;
- (c) outside of restricted zones I, II and III, where it is not possible to slaughter the animals in the restricted zones III, II and I.

2. The competent authority of the Member State concerned shall only grant an authorisation provided for in paragraph 1 provided that:

- (a) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687 are met;
- (b) the additional general conditions laid down in Article 14(2) and Articles 15(1)(b)(c) and (2), 16 and 17 are met;

3. The competent authority of the Member State concerned shall ensure that:

- (a) the kept porcine animals are destined for immediate slaughter directly to a slaughterhouse designated in accordance with Article 41(1);
- (b) on arrival at the designated slaughterhouse, the porcine animals from restricted zone III are kept separately from other porcine animals and are slaughtered either:
  - (i) on a specific day when only porcine animals from restricted zone III are slaughtered; or
  - (ii) at the end of a slaughter day thereby ensuring that other kept porcine animals are not slaughtered thereafter;
- (c) after the slaughtering of the porcine animals from restricted zone III, and before the slaughtering of other kept porcine animals starts, the slaughterhouse must be cleaned and disinfected in accordance with the instructions of the competent authority of the Member State concerned.

4. The competent authority of the Member State concerned shall ensure that:

- (a) animal by-products obtained from porcine animals kept in restricted zone III and moved outside that zone are processed or disposed in accordance with Articles 33 and 36;
- (b) fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zone III and moved outside restricted zone III are processed and stored in accordance with Article 40.

## SECTION 7

***Specific conditions for derogations authorising movements of porcine animals kept in restricted zones I, II and III outside those zones to an animal by-products approved plant***

## Article 30

**Specific conditions for derogations authorising movements of consignments of porcine animals kept in restricted zones I, II and III to an animal by-products approved plant located outside restricted zones I, II and III situated within the same Member State concerned**

1. By way of derogation from the prohibitions provided for in Article 9, the competent authority of the Member State concerned may authorise movements of porcine animals kept in restricted zones I, II and III to an animal by-products approved plant located outside restricted zones I, II and III situated within the same Member State concerned in which:

- (a) the kept porcine animals are immediately killed; and
- (b) the resulting animal by-products are disposed in accordance with Regulation (EC) No 1069/2009.

2. The competent authority of the Member State concerned shall only grant an authorisation provided for in paragraph 1 provided that:

- (a) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687 are met;
- (b) the additional general conditions laid down in Articles 14(2) and 17 are met.

## SECTION 8

***Specific conditions for authorising movements of consignments of germinal products obtained from porcine animals kept in restricted zone II outside that zone***

## Article 31

**Specific conditions for derogations authorising movements of consignments of germinal products obtained from porcine animals kept in restricted zone II from that zone in the territory of the same Member State concerned**

By way of derogation from the prohibition provided for in Article 10, the competent authority of the Member State concerned may authorise movements of consignments of germinal products from germinal product establishment located in restricted zone II to another restricted zone II and restricted zones I and III or to areas outside restricted zones I, II and III in the territory of the same Member State provided that:

- (a) the germinal products were collected or produced, processed and stored in establishments and were obtained from kept porcine animals that comply with conditions laid down in Article 15(1)(b)(c) and (2) and Article 16;
- (b) the donor males and donor females of the porcine animals were kept at germinal product establishments where no other kept porcine animals were introduced from restricted zones II and III during a period of at least 30 days prior to the date of the collection or production of germinal products.

## Article 32

**Specific conditions for derogations authorising movements of consignments of germinal products obtained from porcine animals kept in restricted zone II from that zone to restricted zones II and III in another Member State**

1. By way of derogation from the prohibition provided for in Article 10, the competent authority of the Member State concerned may authorise movements of consignments of germinal products obtained from porcine animals kept in restricted zone II from an approved germinal product establishment located in restricted zone II to restricted zones II and III in the territory of another Member State concerned provided that:

- (a) the germinal products were collected or produced, processed and stored at germinal product establishments under the conditions laid down in Article 15(1)(b)(c) and (2) and Article 16;
- (b) the donor males and donor females of the porcine animals were kept in approved germinal product establishments where no other kept porcine animals were introduced from restricted zones II and III during a period of at least 30 days prior to the date of the collection or production of germinal products;
- (c) the consignments of germinal products comply with any other appropriate animal health guarantees based on a positive outcome of a risk assessment of measures against the spread of African swine fever:
  - (i) required by the competent authorities of the establishment of dispatch;
  - (ii) approved by the competent authority of the Member State of the establishment of destination, prior to the movement of the germinal products.

2. The competent authority of the Member State concerned shall:

- (a) draw up a list of approved germinal product establishments that comply with the conditions laid down in paragraph 1 and which are authorised for movements of germinal products from restricted zone II in that Member State concerned to restricted zones II and III in another Member State concerned; that list shall contain the information required to be kept by the competent authority of the Member State concerned on approved germinal product establishments for porcine animals as laid down in Article 7 of Delegated Regulation (EU) 2020/686;
- (b) make the list provided for in point (a) available to the public on its website and keep it up-to-date;
- (c) provide the Commission and the Member States with the link to the website referred to in paragraph (b).

## SECTION 9

**Specific conditions for derogations authorising movements of consignments of animal by-products obtained from porcine animals kept in restricted zones II and III outside those zones**

## Article 33

**Specific conditions for derogations authorising movements of consignments of animal by-products obtained from porcine animals kept in restricted zones II and III outside those zones within the same Member State for the purpose of processing or disposal**

1. By way of derogation from Article 11(1), the competent authority of the Member State concerned may authorise movements of consignments of animal by-products obtained from porcine animals kept in restricted zones II and III outside those zones to a plant or establishment approved by the competent authority for the purpose of processing, disposal as waste by incineration or disposal or recovery by co-incineration of animal by-products referred to in Article 24(1)(a), (b) and (c) of Regulation (EC) No 1069/2009, located outside restricted zones II or III situated within the same Member State provided that the means of transport are individually equipped with a satellite navigation system to determine, transmit and record its real time location.



2. The transport operator responsible for the movements of animal by-products referred to in paragraph 1 shall:
  - (a) enable the competent authority to control by means of a satellite navigation system the real time movement of the means of transport;
  - (b) keep the electronic records of that movement for a period of at least two months from the date of movement.
3. The competent authority may decide that the satellite navigation system referred to in paragraph 1 shall be replaced by an individual sealing of means of transport provided that:
  - (a) consignments of animal by-products obtained from porcine animals kept in restricted zones II and III are only moved within the same Member State for the uses referred to in paragraph 1;
  - (b) each means of transport is sealed by an official veterinarian immediately after the loading of the consignment of animal by-products; only an official veterinarian or enforcement authority of the Member State, as agreed with the competent authority, may break the seal and replace it with a new one, where relevant.

#### Article 34

##### **Specific conditions for derogations authorising movements of consignments of manure obtained from porcine animals kept in restricted zones II and III outside those zones within the same Member State**

1. By way of derogation from Article 11(1), the competent authority of the Member State concerned may authorise movements of consignments of manure, including litter and used bedding, obtained from porcine animals kept in restricted zones II and III to a landfill located outside those zones within the same Member State in accordance with the specific conditions laid down in Article 51 of Delegated Regulation (EU) 2020/687.
2. By way of derogation from Article 11(1), the competent authority of the Member State concerned may authorise movements of consignments of manure, including litter and used bedding, obtained from porcine animals kept in restricted zone II for processing or disposal in accordance with Regulation (EC) No 1069/2009 in a plant approved for those purposes within the territory of the same Member State.
3. The transport operator responsible for the movements of consignments of manure, including litter and used bedding, referred to in paragraphs 1 and 2 shall:
  - (a) enable the competent authority to control by means of a satellite navigation system the real time movement of the means of transport;
  - (b) keep the electronic records of that movement for a period of at least two months from the date of movement.
4. The competent authority may decide that the satellite navigation system referred to in paragraph 3(a) shall be replaced by an individual sealing of means of transport provided that each means of transport is sealed by an official veterinarian immediately after the loading of the consignment of manure, including litter and used bedding, referred to in paragraphs 1 and 2.

Only an official veterinarian or enforcement authority of the Member State, as agreed with the competent authority, may break the seal and replace it with a new one, where relevant.

#### Article 35

##### **Specific conditions for authorising movements of consignments of Category 3 materials obtained from porcine animals kept in restricted zones II outside those zones within the same Member State for the purpose of the processing of animal by-products referred to in Article 24(1)(a), (e) and (g) of Regulation (EC) No 1069/2009**

1. By way of derogation from Article 11(1), the competent authority of the Member State concerned may authorise movements of consignments of Category 3 materials obtained from porcine animals kept in restricted zone II outside that zone to a plant or establishment approved by the competent authority for the purposes of further processing into

processed feed, for the manufacturing of processed pet food, derived products intended for uses outside the feed chain, or transformation of animal by-products into biogas or compost as referred to in Article 24(1)(a), (e) and (g) of Regulation (EC) No 1069/2009 located outside the restricted zone II situated within the same Member States provided that:

- (a) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687 are met;
- (b) the additional general conditions laid down in Articles 14(2) are met;
- (c) the Category 3 materials originate from kept porcine animals and establishments that comply with the general conditions laid down in Articles 15(1)(b)(c), (2) and (3) and Article 16;
- (d) the Category 3 materials are obtained from porcine animals kept in restricted zone II and slaughtered either:
  - (i) in restricted zone II of:
    - the same Member State concerned; or
    - another Member State concerned in accordance with Article 25;
  - or
  - (ii) outside restricted zone II situated in the same Member State concerned in accordance with Article 24;
- (e) the means of transport is individually equipped with a satellite navigation system to determine, transmit and record its real time location;
- (f) the consignments of Category 3 materials are moved from the slaughterhouse designated in accordance with Article 41(1) directly to:
  - (i) a processing plant for the processing of derived products referred to in Annex X to Regulation (EU) No 142/2011;
  - (ii) a pet food plant approved for the production of processed pet food referred to in point 3(a) and (b)(i) to (iii) of Chapter II of Annex XIII to Regulation (EU) No 142/2011;
  - (iii) a biogas or a compost plant approved for the transformation of animal by-products into compost or biogas in accordance with the standard transformation parameters referred to in Section 1 of Chapter III of Annex V to Regulation (EU) No 142/2011; or
  - (iv) a processing plant for the processing of derived products referred to in Annex XIII to Regulation (EU) No 142/2011.

2. The transport operator responsible for the movements of consignments of Category 3 materials shall:

- (a) enable the competent authority to control by means of a satellite navigation system the real time movement of the means of transport;
- (b) keep the electronic records of that movement for a period of at least two months from the date of movement.

3. The competent authority may decide that the satellite navigation system referred to in paragraph 1(e) shall be replaced by an individual sealing of means of transport provided that:

- (a) the Category 3 materials are:
  - (i) obtained from porcine animals kept in restricted zones II;
  - (ii) only moved within the same Member State for the uses referred to in paragraph 1;
- (b) each means of transport is sealed by an official veterinarian immediately after the loading of the consignment of Category 3 materials; only an official veterinarian or enforcement authority of the Member State, as agreed with the competent authority, may break the seal and replace it with a new one, where relevant.

*Article 36***Specific conditions for derogations authorising movements of consignments of Category 2 materials obtained from porcine animals kept in restricted zones II and III outside those zones for the purpose of processing and disposal in another Member States**

1. By way of derogation from Article 11(1), the competent authority of the Member State concerned may authorise movements of consignments of animal by-products of Category 2 materials obtained from porcine animals kept in restricted zones II and III to a processing plant to be processed by methods 1 to 5, as set out in Chapter III of Annex IV to Regulation (EU) No 142/2011, or to an incineration or co-incineration plant, as referred to in Article 24(1)(a),(b) and (c) of Regulation (EC) No 1069/2009, located in another Member States, provided that:

- (a) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687 are met;
- (b) the additional general conditions laid down in Articles 14(2) are met;
- (c) the means of transport is individually equipped with a satellite navigation system to determine, transmit and record its real time location;

2. The transport operator responsible for movements of consignments of Category 2 materials shall:

- (a) enable the competent authority to control by means of a satellite navigation system the real time movement of the means of transport; and
- (b) keep the electronic records of that movement for a period of at least two months from the date of movement.

3. The competent authorities of the Member States of dispatch and of destination of the consignment of Category 2 materials shall ensure the controls of that consignment in accordance with Article 48(1) and (3) of Regulation (EC) No 1069/2009.

*Article 37***Specific conditions for derogations authorising movements of consignments of Category 3 materials obtained from porcine animals kept in restricted zone II outside that zone for further processing or transformation in another Member States**

1. By way of derogation from Article 11(1), the competent authority of the Member State concerned may authorise movements of consignments of Category 3 materials obtained from porcine animals kept in restricted zone II outside that zone to a plant or establishment approved by the competent authority for the processing of Category 3 materials into processed feed, processed pet food, derived products intended for uses outside the feed chain, or the transformation of Category 3 materials into biogas or compost as referred to in Article 24(1)(a), (e) and (g) of Regulation (EC) No 1069/2009, located in another Member States, provided that:

- (a) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687 are met;
- (b) the additional general conditions laid down in Article 14(2) are met;
- (c) the Category 3 materials originate from kept porcine animals and establishments that comply with the general conditions laid down in Articles 15(1)(b)(c), (2) and (3), and Article 16;
- (d) the Category 3 materials are obtained from porcine animals kept in restricted zone II and slaughtered either:
  - (i) in restricted zone II of:
    - the same Member State concerned; or
    - another Member State concerned in accordance with Article 25;

or

- (ii) outside restricted zone II situated in the same Member State concerned in accordance with Article 24;
  - (e) the means of transport is individually equipped with a satellite navigation system to determine, transmit and record its real time location;
  - (f) the animal by-products are moved directly from the slaughterhouse designated in accordance with Article 41(1) to:
    - (i) a processing plant for the processing of derived products referred to in Annexes X and XIII to Regulation (EU) No 142/2011;
    - (ii) a pet food plant approved for the production of processed pet food referred to in point 3(b)(i)(ii) and (iii) of Chapter II of Annex XIII to Regulation (EU) No 142/2011;
    - (iii) a biogas or a compost plant approved for transformation of animal by-products into compost or biogas in accordance with the standard transformation parameters referred to in Section 1 of Chapter III of Annex V to Regulation (EU) No 142/2011.
2. The transport operator responsible for movements of consignments of Category 3 materials shall:
- (a) enable the competent authority to control by means of a satellite navigation system the real time movement of the means of transport; and
  - (b) keep the electronic records of the movement for a period of at least two months from the date of movement.

#### SECTION 10

#### ***Specific conditions for derogations authorising movements of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zones II and III outside those zones***

#### Article 38

#### **Specific conditions for authorising movements of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zone II outside that zone in the territory of the same Member State concerned**

1. By way of derogation from prohibitions provided for in Article 12, the competent authority of the Member State concerned may authorise movements of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zone II outside that zone in the territory of the same Member State concerned, provided that:
- (a) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687 are met;
  - (b) the fresh meat and meat products, including casings, are obtained from porcine animals kept in establishments that comply with the additional general conditions laid down in Article 14(2), Article 15(1)(b)(c), (2) and (3), and Article 16;
  - (c) the fresh meat and meat products, including casings, have been produced in establishments designated in accordance with Article 41(1).
2. By way of derogation from prohibitions provided for in Article 12, if conditions laid down in paragraph 1 are not met, the competent authority of the Member State concerned may authorise movements of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zone II outside that zone in the territory of the same Member State concerned, provided that:
- (a) the fresh meat and meat products, including casings, have been produced in establishments designated in accordance with Article 41(1);

- (b) the fresh meat and meat products, including casings, either
- (i) in the case of fresh meat only, are marked and moved in accordance with the specific conditions for authorising movements of fresh meat obtained from kept animals of listed species from certain establishments laid down in Article 33(2) of Delegated Regulation (EU) 2020/687 to a processing establishment to undergo one of the relevant risk-mitigating treatments set out in Annex VII thereto;
- or
- (ii) have been marked in accordance with Article 44 with a special health mark or, where relevant, an identification mark that is not oval and cannot be confused with the health or identification mark as referred to in points (a) and (b) of Article 5(1) of Regulation (EC) No 853/2004; and
  - (iii) are only intended for movement within the same Member State concerned.

#### Article 39

#### **Specific conditions for derogations authorising movements of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zone II outside that zone to other Member States and to third countries**

By way of derogation from prohibitions provided for in Article 12, the competent authority of the Member State concerned may authorise movements of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zone II outside that zone to other Member States and to third countries, provided that:

- (a) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687 are met;
- (b) the additional general conditions laid down in Article 14(2) are met;
- (c) the fresh meat and meat products, including casings, are obtained from porcine animals kept in establishments that comply with the general conditions laid down in Articles 15 and 16;
- (d) the fresh meat and meat products, including casings, have been produced in establishments designated in accordance with Article 41(1).

#### Article 40

#### **Specific conditions for derogations authorising movements of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zone III to other restricted zones I, II and III or areas outside restricted zones I, II and III in the territory of the same Member State**

By way of derogation from prohibitions provided for in Article 12, the competent authority of the Member State concerned may authorise movements of consignments of fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zone III to other restricted zones I, II and III or areas outside restricted zones I, II and III in the territory of the same Member State, provided that:

- (a) the general conditions laid down in Article 28(2) to (7) of Delegated Regulation (EU) 2020/687 are met;
- (b) the additional general conditions laid down in Article 14(2) are met;
- (c) the fresh meat and meat products, including casings, are obtained from porcine animals:
  - (i) kept in establishments that comply with the general conditions laid down in Articles 15 and 16; and
  - (ii) slaughtered:
    - within the same restricted zone III; or
    - outside restricted zone III, after the authorised movement in accordance with Article 29;

- (d) the fresh meat and meat products, including casings, have been produced in establishments designated in accordance with Article 41(1); and either
- (i) in the case of fresh meat only, are marked and moved in accordance with the specific conditions for authorising movements of fresh meat obtained from kept animals of listed species from certain establishments laid down in Article 33(2) of Delegated Regulation (EU) 2020/687 to a processing establishment to undergo one of the relevant risk-mitigating treatments set out in Annex VII thereto;
- or
- (ii) have been marked in accordance with Article 44 with a special health mark or, where relevant, an identification mark that is not oval and cannot be confused with the health or identification mark as referred to in points (a) and (b) of Article 5(1) of Regulation (EC) No 853/2004; and
  - (iii) are only intended for movement within the same Member State concerned.

#### CHAPTER IV

### SPECIAL RISK-MITIGATING MEASURES CONCERNING AFRICAN SWINE FEVER FOR FOOD BUSINESSES IN THE MEMBER STATES CONCERNED

#### Article 41

#### **Special designation of slaughterhouses, cutting plants, cold stores, meat processing and game handling establishments**

1. The competent authority of the Member State concerned shall, following an application by a food business operator, designate establishments for:
- (a) the immediate slaughter of kept porcine animals from restricted zones II and III:
    - (i) within those restricted zones II and III;
    - (ii) outside those restricted zones II and III, as referred to in Articles 24 and 29;
  - (b) the cutting, processing and storage of the fresh meat and meat products, including casings, from porcine animals kept in restricted zones II and III as referred to in Articles 38, 39 and 40;
  - (c) the preparation of game meat as referred to in point 1(1.18) of Annex I to Regulation (EC) No 853/2004 and the processing and storage of the fresh meat and meat products from wild porcine animals obtained in restricted zones I, II and III as provided for in Articles 48 and 49 of this Regulation;
  - (d) the preparation of game meat as referred to in point 1(1.18) of Annex I to Regulation (EC) No 853/2004 and the processing and storage of the fresh meat and meat products from wild porcine animals, if those establishments are located in restricted zones I, II and III as provided for in Articles 48 and 49 of this Regulation.
2. The competent authority may decide that the designation referred to in paragraph 1 shall not be required for establishments processing, cutting and storing fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zones II and III and from wild porcine animals obtained in the restricted zones I, II and III, and establishment referred to in paragraph 1(d), provided that:
- (a) the fresh meat and meat products, including casings, of porcine origin are marked with a special health mark or, where relevant, an identification mark referred to in Article 44 in those establishment;
  - (b) the fresh meat and meat products, including casings, of porcine origin from those establishment are only intended for the same Member State concerned;
  - (c) animal by-products of porcine origin from those establishments are only processed or disposed of in accordance with Article 33 within the same Member State.

3. The competent authority of the Member State concerned shall:
  - (a) provide the Commission and other Member States with a link to the website of the competent authority with a list of designated establishments and their activities referred to in paragraph 1;
  - (b) keep the list provided for in paragraph (a) updated.

#### Article 42

##### **Special conditions for the designation of establishments for the immediate slaughter of porcine animals kept in restricted zone II and III**

The competent authority of the Member State concerned shall only designate establishments for the immediate slaughter of porcine animals kept in restricted zone II and III, provided that:

- (a) the slaughtering of porcine animals kept outside restricted zones II and III and of porcine animals kept in the restricted zones II and III that are subject to authorised movements provided for in Articles 24 and 29 and the production and storage of products thereof are carried out separately from the slaughtering of porcine animals kept in restricted zones I, II and III and from the production and storage of products thereof that do not comply with relevant:
  - (i) additional general conditions laid down in Articles 15, 16 and 17; and
  - (ii) specific conditions provided for in Articles 24 and 29;
- (b) the operator of the establishment has in place documented instructions or procedures approved by the competent authority of the Member State concerned to ensure that the conditions laid down in paragraph (a) are met.

#### Article 43

##### **Special conditions for the designation of establishments for cutting, processing and storing of the fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zones II and III**

The competent authority of the Member State concerned shall only designate establishments for the cutting, processing and storing of the fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zones II and III subject to authorised movement provided for in Articles 38, 39 and 40, provided that:

- (a) the cutting, processing and storing of the fresh meat and meat products, including casings, obtained from porcine animals kept outside restricted zones II and III and from porcine animals kept in restricted zones II and III are carried out separately from fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zones II and III that do not comply with:
  - (i) additional general conditions laid down in Articles 15, 16 and 17; and
  - (ii) specific conditions provided for in Articles 38, 39 and 40;
- (b) the operator of the establishment has in place documented instructions or procedures approved by the competent authority of the Member State concerned to ensure that the conditions laid down in paragraph (a) are met.

#### Article 44

##### **Special health or identification marks**

The competent authority of the Member States concerned shall ensure that the following products of animal origin are marked with a special health mark or, where relevant, an identification mark that is not oval and cannot be confused with the health mark or identification mark provided for in Article 5(1) of Regulation (EC) No 853/2004:

- (a) the fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zone III, as laid down in Article 40(d)(ii);

- (b) the fresh meat and meat products, including casings, obtained from porcine animals kept in restricted zone II, if the specific conditions for authorising movements of those consignments outside restricted zone II provided for in Article 38(1) are not met, as laid down in accordance with Article 38(2)(b)(ii);
- (c) the fresh meat and meat products from wild porcine animals moved within restricted zone I or outside that zone from the establishment designated in accordance with Article 41(1), as laid down in the first indent of Article 49(1)(c)(iii).

#### CHAPTER V

#### SPECIAL DISEASE CONTROL MEASURES APPLICABLE TO WILD PORCINE ANIMALS IN THE MEMBER STATES

##### Article 45

##### **Specific prohibitions in relation to the movements of wild porcine animals**

The competent authorities of all Member States shall prohibit movements of wild porcine animals by operators as provided for in Article 101 of Delegated Regulation (EU) 2020/688:

- (a) within the whole territory of the Member State;
- (b) from the whole territory of the Member State to:
  - (i) other Member States; and
  - (ii) third countries.

##### Article 46

##### **Specific prohibitions in relation to movements within restricted zones I, II and III and from those zones of fresh meat, meat products and any other products of animal origin, animal by-products and derived products obtained from wild porcine animals and bodies of wild porcine animals, which are intended for human consumption**

1. The competent authorities of the Member States concerned shall prohibit movements within and from restricted zones I, II and III of consignments of fresh meat, meat products and any other products of animal origin, animal by-products and derived products obtained from wild porcine animals and bodies of wild porcine animals, which are intended for human consumption.
2. The competent authorities of the Member States concerned shall prohibit movements within restricted zones I, II and III and from those zones of fresh meat, meat products and any other products of animal origin, animal by-products and derived products obtained from wild porcine animals and bodies of wild porcine animals, which are intended for human consumption:
  - (a) for private domestic use;
  - (b) linked to the activities of hunters who supply small quantities of wild porcine game or wild game meat of porcine origin directly to the final consumer or to local retail establishments directly supplying the final consumer, as provided for in Article 1(3)(e) of Regulation (EC) No 853/2004.

##### Article 47

##### **General prohibitions in relation to movements of consignments of products obtained from wild porcine animals and bodies of wild porcine animals, which are intended for human consumption, considering a risk for the spread of African swine fever**

The competent authority of the Member State concerned may prohibit within the territory of the same Member State the movements of fresh meat, meat products and any other products obtained from wild porcine animals and bodies of wild porcine animals, which are intended for human consumption, if the competent authority considers that there is a risk for the spread of African swine fever to, from or through those wild porcine animals or products thereof.



*Article 48***Specific conditions for derogations authorising movements within restricted zones I, II and III and from those zones of consignments of processed meat products obtained from wild porcine animals**

1. By way of derogation from the prohibition provided for in Article 46(1), the competent authority of the Member State concerned may authorise movements within restricted zones I, II and III and from those zones of consignments of processed meat products obtained from wild porcine animals from establishment located in restricted zones I, II and III to:

- (a) other restricted zones I, II and III situated in the same Member State concerned;
- (b) areas outside restricted zones I, II and III of the same Member State concerned; and
- (c) to other Member States and to third countries.

2. The competent authority of the Member State concerned shall only authorise movements of consignments of processed meat products obtained from wild porcine animals from establishments located in restricted zone I, II and III referred to in paragraph 1 provided that:

- (a) pathogen identification tests for African swine fever have been carried out for each wild porcine animal used for the production and processing of meat products in restricted zone I, II and III;
- (b) the competent authority obtained negative results of the pathogen identification tests for African swine fever referred to in point (a) before the treatment referred to in point (c)(ii);
- (c) meat products from wild porcine animals:
  - (i) were produced, processed and stored in establishments designated in accordance with Article 41(1); and
  - (ii) have undergone the relevant risk-mitigating treatment for products of animal origin from restricted zones in accordance with Annex VII to Delegated Regulation (EU) 2020/687, as regards African swine fever.

*Article 49***Specific conditions for derogations authorising movements within restricted zones I, II and III and from restricted zone I of fresh meat, meat products and any other products of animal origin obtained from wild porcine animals and bodies of wild porcine animals, which are intended for human consumption**

1. By way of derogation from the prohibitions provided for in Article 46(1) and (2), the competent authority of the Member State concerned may authorise movements within restricted zone I and from that zone of the fresh meat, meat products and any other products of animal origin obtained from wild porcine animals and bodies of wild porcine animals, which are intended for human consumption, to other restricted zones I, II and III or to areas outside restricted zones I, II and III of the same Member State, provided that:

- (a) pathogen identification tests for African swine fever have been carried out for every relevant wild porcine animal before the movement of the fresh meat, meat products and any other products of animal origin from that wild porcine animals;
- (b) the competent authority of the Member State concerned obtained negative results for the pathogen identification tests for African swine fever referred to in point (a) before the movement;
- (c) the fresh meat, meat products and any other products of animal origin from wild porcine animals and bodies of wild porcine animals, which are intended for human consumption, are moved within or outside restricted zone I within the same Member State:
  - (i) for private domestic use; or
  - (ii) linked to the activities of hunters who supply small quantities of wild porcine game or wild game meat of porcine origin directly to the final consumer or to local retail establishments directly supplying the final consumer, as provided for in Article 1(3)(e) of Regulation (EC) No 853/2004; or

(iii) from the establishment designated in accordance with Article 41(1) where the fresh meat and meat products have been marked either:

— with a special health or identification mark in accordance with point (c) of Article 44;

or

— in accordance with Article 33(2) of Delegated Regulation (EU) 2020/687 and are moved to a processing establishment to undergo one of the relevant risk-mitigating treatments set out in Annex VII thereto.

2. By way of derogation from the prohibitions provided for in Article 46(2), the competent authority of the Member State concerned may authorise movements of the fresh meat, meat products and any other products of animal origin from wild porcine animals and bodies of wild porcine animals, which are intended for human consumption, within restricted zones II and III of the same Member State, provided that:

(a) pathogen identification tests for African swine fever have been carried out for every relevant wild porcine animal before the movement of the fresh meat, meat products and any other products of animal origin from that wild porcine or body of that wild porcine animal, which is intended for human consumption;

(b) the competent authority of the Member State concerned obtained negative results for the pathogen identification tests for African swine fever referred to in point (a) before the movement;

(c) the fresh meat, meat products and any other products of animal origin from wild porcine animals and bodies of wild porcine animals, which are intended for human consumption, are moved within restricted zones II and III within the same Member State for:

(i) private domestic use;

or

(ii) in accordance with Article 33(2) of Delegated Regulation (EU) 2020/687 are moved to a processing establishment to undergo one of the relevant risk-mitigating treatments set out in Annex VII thereto.

#### Article 50

#### **Operators' obligations with regard to animal health certificates for consignments of fresh meat, meat products and any other products of animal origin, obtained from wild porcine animals and bodies of wild porcine animals, which are intended for human consumption, for movements outside restricted zones I, II and III**

Operators shall only move outside restricted zones I, II and III the consignments of fresh meat, meat products, and any other products of animal origin obtained from wild porcine animals and bodies of wild porcine animals, which are intended for human consumption:

(a) in cases covered by Articles 48 and 49; and

(b) if those consignments are accompanied by an animal health certificate as provided for in Article 167(1) of Regulation (EU) 2016/429 that contains:

(i) the information required in accordance with Article 3 of Delegated Regulation (EU) 2020/2154; and

(ii) at least one of the following attestations of compliance with the requirements provided for in this Regulation:

— 'Fresh meat and meat products, and any other products of animal origin, from restricted zone I obtained from wild porcine animals in compliance with the special control measures relating to African swine fever laid down in Commission Implementing Regulation (EU) 2021/605.:'

— 'Bodies of wild porcine animals, which are intended for human consumption, from restricted zone I in compliance with the special control measures relating to African swine fever laid down in Commission Implementing Regulation (EU) 2021/605.:'

- ‘Processed meat products from restricted zones I, II and III obtained from wild porcine animals in compliance with the special control measures relating to African swine fever laid down in Commission Implementing Regulation (EU) 2021/605.’.

However, in the case of movement within the same Member State concerned, the competent authority may decide that an animal health certificate does not have to be issued as referred to in first subparagraph of Article 167(1) of Regulation (EU) 2016/429.

#### Article 51

##### **Specific conditions for authorising movements within restricted zones I, II and III and outside those zones of consignments of animal by products and derived products from wild porcine animals**

1. By way of derogation from prohibitions laid down in Article 46, the competent authority of the Member State concerned may authorise movements within restricted zones I, II and III and outside those zones of consignments of derived products obtained from wild porcine animals to other restricted zones I, II and III or to areas outside restricted zones I, II and III of the same Member State and to other Member States provided that they have been subjected to a treatment which ensures that the derived products pose no risks as regards African swine fever.
2. By way of derogation from prohibitions laid down in Article 46(1), the competent authority of the Member State concerned may authorise movements within restricted zones I, II and III and outside those zones of consignments of animal by-products from wild porcine animals to other restricted zones I, II and III and to areas outside restricted zones I, II and III of the same Member State provided that:
  - (a) the animal by-products are collected, transported and disposed of in accordance with Regulation (EC) No 1069/2009;
  - (b) for the movements outside restricted zones I, II and III, the means of transport are individually equipped with a satellite navigation system to determine, transmit and record its real time location. The transport operator shall enable the competent authority to control the real time movement of the means of transport and keep the electronic records of the movement for a period of at least two months from the time of the movement of the consignment.

#### Article 52

##### **Operators' obligations with regard to animal health certificates for movements of consignments of animal by-products from wild porcine animals outside restricted zones I, II and III in the territory of the same Member State concerned**

Operators shall only move consignments of animal by-products from wild porcine animals outside restricted zones I, II and III within the same Member State concerned in case referred to in Article 51(2), if those consignments are accompanied by:

- (a) a commercial document referred to in Chapter III of Annex VIII to Commission Regulation (EU) No 142/2011; and
- (b) an animal health certificate referred to in Article 22(5) of Regulation (EU) 2020/687;

However, the competent authority of the Member State concerned may decide that an animal health certificate shall not be issued as referred to in Article 22(6) of Regulation (EU) 2020/687.

## CHAPTER VI

**SPECIAL INFORMATION AND TRAINING OBLIGATIONS IN THE MEMBER STATES***Article 53***Special information obligations of the Member States concerned**

1. The Member States concerned shall ensure that at least railway, coach, airport and port operators, travel agencies, hunting trip organisers and postal services operators are required to draw the attention of their customers to the special disease control measures laid down in this Regulation, by providing information at least on the main prohibitions laid down in Articles 9, 11, 12, 45 and 46 to travellers moving from restricted zones I, II and III and customers of postal services in an appropriate way.

For that purpose, the Member States concerned shall organise and carry out regular public awareness campaigns to promote and spread information on the special disease control measures laid down in this Regulation.

2. The Member States concerned shall inform the Commission and the other Member States in the framework of the Standing Committee on Plants, Animals, Food and Feed, of the following:

- (a) changes in the epidemiological situation as regards African swine fever in their territory;
- (b) results of surveillance for African swine fever carried out in restricted zones I, II and III and areas outside restricted zones I, II and III in kept and wild porcine animals;
- (c) other measures and initiatives taken to prevent, control and eradicate African swine fever.

*Article 54***Special trainings obligations of the Member States concerned**

The Member States concerned shall organise and carry out regularly or at appropriate intervals specific trainings about the risks of African swine fever and possible prevention, control and eradication measures for at least the following targeted groups:

- (a) veterinarians;
- (b) farmers keeping porcine animals;
- (c) hunters.

*Article 55***Special information obligations of all Member States**

1. All Member States shall ensure that:

- (a) on major land infrastructure routes, such as international communication roads and railway, and related land transport networks, appropriate information on the risks of the transmission of African swine fever and on the special disease control measures laid down in this Regulation are brought to the attention of travellers:
  - (i) in a visible and prominent manner;
  - (ii) presented in a way that is easily understood by travellers coming from, and going to:
    - the restricted zones I, II and III; or
    - third countries at risk of the spread of African swine fever;
- (b) the necessary measures are in place to raise awareness among stakeholders active in the kept porcine animals sector including small-size establishments of the risks for the introduction of the African swine fever virus and to provide them with the most appropriate information on reinforced biosecurity measures for establishments of kept porcine animals located in the restricted zones I, II and III as provided for in Annex II, in particular the measures to be enforced in restricted zones I, II and III, by the means best suited to bringing such information to their attention.

2. All Member States shall raise awareness on African swine fever among:
- (a) the public as provided for in Article 15 of Regulation (EU) 2016/429;
  - (b) veterinarians, farmers and hunters and provide them with the most appropriate information on risk mitigation and reinforced biosecurity measures as provided for in:
    - (i) Annex II to this Regulation;
    - (ii) Union's guidelines on African swine fever as agreed with the Member States at the Standing Committee on Plants, Animals, Food and Feed;
    - (iii) available scientific evidence provided by the European food safety authority;
    - (iv) the Terrestrial Animal Health Code of the World Organisation for Animal Health.

#### CHAPTER VII

#### FINAL PROVISIONS

#### Article 56

#### **Entry into force and application**

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

It shall apply from 21 April 2021 to 20 April 2028.

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

Done at Brussels, 7 April 2021.

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

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## ANNEX I

## RESTRICTED ZONES

## PART I

**1. Estonia**

The following restricted zones I in Estonia:

- Hiiu maakond.

**2. Hungary**

The following restricted zones I in Hungary:

- Békés megye 950950, 950960, 950970, 951950, 952050, 952750, 952850, 952950, 953050, 953150, 953650, 953660, 953750, 953850, 953960, 954250, 954260, 954350, 954450, 954550, 954650, 954750, 954850, 954860, 954950, 955050, 955150, 955250, 955260, 955270, 955350, 955450, 955510, 955650, 955750, 955760, 955850, 955950, 956050, 956060, 956150 és 956160 kódszámú vadgazdálkodási egységeinek teljes területe,
- Bács-Kiskun megye 600150, 600850, 601550, 601650, 601660, 601750, 601850, 601950, 602050, 603250, 603750 és 603850 kódszámú vadgazdálkodási egységeinek teljes területe,
- Budapest 1 kódszámú, vadgazdálkodási tevékenységre nem alkalmas területe,
- Csongrád-Csanád megye 800150, 800160, 800250, 802220, 802260, 802310 és 802450 kódszámú vadgazdálkodási egységeinek teljes területe,
- Fejér megye 400150, 400250, 400351, 400352, 400450, 400550, 401150, 401250, 401350, 402050, 402350, 402360, 402850, 402950, 403050, 403250, 403350, 403450, 403550, 403650, 403750, 403950, 403960, 403970, 404570, 404650, 404750, 404850, 404950, 404960, 405050, 405750, 405850, 405950, 406050, 406150, 406550, 406650 és 406750 kódszámú vadgazdálkodási egységeinek teljes területe,
- Jász-Nagykun-Szolnok megye 750150, 750160, 750260, 750350, 750450, 750460, 754450, 754550, 754560, 754570, 754650, 754750, 754950, 755050, 755150, 755250, 755350 és 755450 kódszámú vadgazdálkodási egységeinek teljes területe,
- Komárom-Esztergom megye 250150, 250250, 250350, 250450, 250460, 250550, 250650, 250750, 250850, 250950, 251050, 251150, 251250, 251350, 251360, 251450, 251550, 251650, 251750, 251850, 252150 és 252250, kódszámú vadgazdálkodási egységeinek teljes területe,
- Pest megye 571550, 572150, 572250, 572350, 572550, 572650, 572750, 572850, 572950, 573150, 573250, 573260, 573350, 573360, 573450, 573850, 573950, 573960, 574050, 574150, 574350, 574360, 574550, 574650, 574750, 574850, 574860, 574950, 575050, 575150, 575250, 575350, 575550, 575650, 575750, 575850, 575950, 576050, 576150, 576250, 576350, 576450, 576650, 576750, 576850, 576950, 577050, 577150, 577350, 577450, 577650, 577850, 577950, 578050, 578150, 578250, 578350, 578360, 578450, 578550, 578560, 578650, 578850, 578950, 579050, 579150, 579250, 579350, 579450, 579460, 579550, 579650, 579750, 580250 és 580450 kódszámú vadgazdálkodási egységeinek teljes területe.

**3. Latvia**

The following restricted zones I in Latvia:

- Pāvilostas novada Vērgales pagasts,
- Stopiņu novada daļa, kas atrodas uz rietumiem no autoceļa V36, P4 un P5, Acones ielas, Dauguļupes ielas un Dauguļupītes,
- Grobiņas novads,
- Rucavas novada Dunikas pagasts.

**4. Lithuania**

The following restricted zones I in Lithuania:

- Klaipėdos rajono savivaldybė: Agluonėnų, Dovių, Gargždų, Priekulės, Vėžaičių, Kretingalės ir Dauparų-Kvietinių seniūnijos,
- Palangos miesto savivaldybė.

## 5. Poland

The following restricted zones I in Poland:

w województwie warmińsko-mazurskim:

- gminy Wielbark i Rozogi w powiecie szczycieńskim,
- gminy Janowiec Kościelny, Janowo i część gminy Kozłowo położona na południe od linii wyznaczonej przez linię kolejową w powiecie nidzickim,
- gminy Iłowo – Osada, Lidzbark, Płońnica, Rybno, miasto Działdowo, część gminy wiejskiej Działdowo położona na południe od linii wyznaczonej przez linię kolejową biegnącą od wschodniej do zachodniej granicy gminy w powiecie działdowskim,
- gminy Kisielice, Susz, miasto Iława i część gminy wiejskiej Iława położona na zachód od linii wyznaczonej przez drogę nr 521 biegnącą od zachodniej granicy gminy do zachodniej granicy miasta Iława oraz na zachód od linii wyznaczonej przez drogę biegnącą od południowej granicy gminy miasta Iława przez miejscowość Katarzynki do południowej granicy gminy w powiecie iławskim,
- powiat nowomiejski.

w województwie podlaskim:

- gminy Wysokie Mazowieckie z miastem Wysokie Mazowieckie, Czyżew i część gminy Kulesze Kościelne położona na południe od linii wyznaczonej przez linię kolejową w powiecie wysokomazowieckim,
- gminy Miastkowo, Nowogród, Śniadowo i Zbójna w powiecie łomżyńskim,
- gminy Szumowo, Zambrów z miastem Zambrów i część gminy Kołaki Kościelne położona na południe od linii wyznaczonej przez linię kolejową w powiecie zambrowskim,

w województwie mazowieckim:

- powiat ostrołęcki,
- powiat miejski Ostrołęka,
- gminy Bielsk, Brudzeń Duży, Drobin, Gąbin, Łąck, Nowy Duninów, Radzanowo, Słupno i Stara Biała w powiecie płockim,
- powiat miejski Płock,
- powiat sierpecki,
- powiat żuromiński,
- gminy Andrzejewo, Brok, Stary Lubotyń, Szulborze Wielkie, Wąsewo, Ostrów Mazowiecka z miastem Ostrów Mazowiecka, część gminy Małkinia Górna położona na północ od rzeki Brok w powiecie ostrowskim,
- gminy Dzierzgowo, Lipowiec Kościelny, miasto Mława, Radzanów, Szreńsk, Szydłowo i Wieczfnia Kościelna, w powiecie mławskim,
- powiat przasnyski,
- powiat makowski,
- gminy Gzy, Obryte, Zatory, Pułtusk i część gminy Winnica położona na wschód od linii wyznaczonej przez drogę łączącą miejscowości Bielany, Winnica i Pokrzywnica w powiecie pułtuskim,
- gminy wyszkowski,
- gminy Jadów, Strachówka i Tłuszcz w powiecie wołomińskim,
- gminy Korytnica, Liw, Łochów, Miedzna, Sadowne, Stoczek i miasto Węgrów w powiecie węgrowskim,
- gminy Kowala, Wierzbica, część gminy Wolanów położona na południe od linii wyznaczonej przez drogę nr 12 w powiecie radomskim,
- powiat miejski Radom,

- gminy Jastrząb, Mirów, Orońsko w powiecie szydłowieckim,
- powiat gostyniński,

w województwie podkarpackim:

- gminy Pruchnik, Rokietnica, Roźwienica, w powiecie jarosławskim,
- gminy Fredropol, Krasiczyn, Krzywca, Medyka, Orły, Żurawica, Przemysł w powiecie przemyskim,
- powiat miejski Przemysł,
- gminy Gać, Jawornik Polski, Kańczuga, część gminy wiejskiej Przeworsk położona na zachód od miasta Przeworsk i na zachód od linii wyznaczonej przez autostradę A4 biegnącą od granicy z gminą Tryńcza do granicy miasta Przeworsk, część gminy Zarzecze położona na zachód od linii wyznaczonej przez drogę nr 1594R biegnącą od północnej granicy gminy do miejscowości Zarzecze oraz na południe od linii wyznaczonej przez drogi nr 1617R oraz 1619R biegnącą do południowej granicy gminy w powiecie przeworskim,
- powiat łańcucki,
- gminy Trzebownik, Głogów Małopolski i część gminy Sokołów Małopolski położona na południe od linii wyznaczonej przez drogę nr 875 w powiecie rzeszowskim,
- gminy Dzikowiec, Kolbuszowa, Niwiska i Raniszów w powiecie kolbuszowskim,
- gminy Borowa, Czermin, Gawłuszowice, Mielec z miastem Mielec, Padew Narodowa, Przeclaw, Tuszów Narodowy w powiecie mieleckim,

w województwie świętokrzyskim:

- powiat opatowski,
- powiat sandomierski,
- gminy Bogoria, Łubnice, Oleśnica, Osiek, Połaniec, Rytwiany i Staszów w powiecie staszowskim,
- gminy Bliżyn, Skarżysko – Kamienna, Suchedniów i Skarżysko Kościelne w powiecie skarżyskim,
- gmina Wąchock, część gminy Brody położona na zachód od linii wyznaczonej przez drogę nr 9 oraz na południowy – zachód od linii wyznaczonej przez drogi: nr 0618T biegnącą od północnej granicy gminy do skrzyżowania w miejscowości Lipie, drogę biegnącą od miejscowości Lipie do wschodniej granicy gminy oraz na północ od drogi nr 42 i część gminy Mirzec położona na zachód od linii wyznaczonej przez drogę nr 744 biegnącą od południowej granicy gminy do miejscowości Tychów Stary a następnie przez drogę nr 0566T biegnącą od miejscowości Tychów Stary w kierunku północno – wschodnim do granicy gminy w powiecie starachowickim,
- powiat ostrowiecki,
- gminy Falków, Ruda Maleniecka, Radoszyce, Smyków, część gminy Końskie położona na zachód od linii kolejowej, część gminy Stąporków położona na południe od linii kolejowej w powiecie koneckim,
- gminy Mniów i Zagnańsk w powiecie kieleckim,

w województwie łódzkim:

- gminy Łyszkowice, Kocierzew Południowy, Kiernoza, Chąsno, Nieborów, część gminy wiejskiej Łowicz położona na północ od linii wyznaczonej przez drogę nr 92 biegnącej od granicy miasta Łowicz do zachodniej granicy gminy oraz część gminy wiejskiej Łowicz położona na wschód od granicy miasta Łowicz i na północ od granicy gminy Nieborów w powiecie łowickim,
- gminy Cieladz, Rawa Mazowiecka z miastem Rawa Mazowiecka w powiecie rawskim,
- gminy Bolimów, Głuchów, Godzianów, Lipce Reymontowskie, Maków, Nowy Kawęczyn, Skierniewice, Słupia w powiecie skierniewickim,
- powiat miejski Skierniewice,



- gminy Mniszków, Paradyż, Sławno i Żarnów w powiecie opoczyńskim,
  - gminy Czerniewice, Inowłódz, Lubochnia, Rzeczyca, Tomaszów Mazowiecki z miastem Tomaszów Mazowiecki i Żelechlinek w powiecie tomaszowskim,
  - gmina Aleksandrów w powiecie piotrkowskim,
- w województwie pomorskim:
- gminy Ostaszewo, miasto Krynica Morska oraz część gminy Nowy Dwór Gdański położona na południowy – zachód od linii wyznaczonej przez drogę nr 55 biegnącą od południowej granicy gminy do skrzyżowania z drogą nr 7, następnie przez drogę nr 7 i S7 biegnącą do zachodniej granicy gminy w powiecie nowodworskim,
  - gminy Lichnowy, Miłoradz, Nowy Staw, Malbork z miastem Malbork w powiecie malborskim,
  - gminy Mikołajki Pomorskie, Stary Targ i Sztum w powiecie sztumskim,
  - powiat gdański,
  - Miasto Gdańsk,
  - powiat tczewski,
  - powiat kwidzyński,
- w województwie lubuskim:
- gminy Przytoczna, Pszczew, Skwierzyna i część gminy Trzciel położona na północ od linii wyznaczonej przez drogę nr 92 w powiecie międzyrzeckim,
  - gminy Lubniewice i Krzeszyce w powiecie sulęcińskim,
  - gminy Bogdaniec, Deszczno, Lubiszyn i część gminy Witnica położona na północny – wschód od drogi biegnącej od zachodniej granicy gminy od miejscowości Krześnica, przez miejscowości Kamień Wielki – Mościce -Witnica – Kłopotowo do południowej granicy gminy w powiecie gorzowskim,
- w województwie dolnośląskim:
- gminy Bolesławiec z miastem Bolesławiec, Gromadka i Osiecznica w powiecie bolesławieckim,
  - gmina Węgliniec w powiecie zgorzeleckim,
  - gmina Chocianów i część gminy Przemków położona na południe od linii wyznaczonej przez drogę nr 12 w powiecie polkowickim,
  - gmina Jemielno, Niechlów i Góra w powiecie górowskim,
  - gmina Rudna i Lubin z miastem Lubin w powiecie lubińskim,
- w województwie wielkopolskim:
- gminy Krzemieniewo, Rydzyna, część gminy Świąciechowa położona na południe od linii wyznaczonej przez drogę nr 12 w powiecie leszczyńskim,
  - część gminy Kwilcz położona na południe od linii wyznaczonej przez drogę nr 24, część gminy Międzychód położona na południe od linii wyznaczonej przez drogę nr 24 w powiecie międzychodzkiem,
  - gminy Lwówek, Kuślin, Opalenica, część gminy Miedzichowo położona na północ od linii wyznaczonej przez drogę nr 92, część gminy Nowy Tomyśl położona na wschód od linii wyznaczonej przez drogę nr 305 w powiecie nowotomyskim,
  - gminy Granowo, Grodzisk Wielkopolski i część gminy Kamieniec położona na wschód od linii wyznaczonej przez drogę nr 308 w powiecie grodziskim,
  - gmina Czempień, miasto Kościan, część gminy wiejskiej Kościan położona na północny – zachód od linii wyznaczonej przez drogę nr 5 oraz na wschód od linii wyznaczonej przez kanał Obry, część gminy Krzywiń położona na wschód od linii wyznaczonej przez kanał Obry w powiecie kościańskim,
  - powiat miejski Poznań,

- gminy Buk, Dopiewo, Komorniki, Tarnowo Podgórne, Stęszew, Swarzędz, Pobiedziska, Czerwonak, Mosina, miasto Luboń, miasto Puszczykowo i część gminy Kórnik położona na zachód od linii wyznaczonych przez drogi: nr S11 biegnącą od północnej granicy gminy do skrzyżowania z drogą nr 434 i drogę nr 434 biegnącą od tego skrzyżowania do południowej granicy gminy, część gminy Rokietnica położona na południowy zachód od linii kolejowej biegnącej od północnej granicy gminy w miejscowości Krzyszkowo do południowej granicy gminy w miejscowości Kiekrz oraz część gminy wiejskiej Murowana Goślina położona na południe od linii kolejowej biegnącej od północnej granicy miasta Murowana Goślina do północno-wschodniej granicy gminy w powiecie poznańskim,
  - gmina Kiszkowo i część gminy Kłecko położona na zachód od rzeki Mała Wełna w powiecie gnieźnieńskim,
  - gminy Lubasz, Czarnków z miastem Czarnków, część gminy Połajewo na położona na północ od drogi łączącej miejscowości Chraplewo, Tarnówko-Boruszyn, Krosin, Jakubowo, Połajewo – ul. Ryczywolska do północno-wschodniej granicy gminy oraz część gminy Wieleń położona na południe od linii kolejowej biegnącej od wschodniej granicy gminy przez miasto Wieleń i miejscowość Herbutowo do zachodniej granicy gminy w powiecie czarnkowsko-trzcianeckim,
  - gminy Duszniki, Kaźmierz, Pniewy, Ostroróg, Wronki, miasto Szamotuły i część gminy Szamotuły położona na zachód od zachodniej granicy miasta Szamotuły i na południe od linii kolejowej biegnącej od południowej granicy miasta Szamotuły, do południowo-wschodniej granicy gminy oraz część gminy Obrzycko położona na zachód od drogi nr 185 łączącej miejscowości Gaj Mały, Słopanowo i Obrzycko do północnej granicy miasta Obrzycko, a następnie na zachód od drogi przebiegającej przez miejscowość Chraplewo w powiecie szamotulskim,
  - gmina Budzyń w powiecie chodzieskim,
  - gminy Mieścisko, Skoki i Wągrowiec z miastem Wągrowiec w powiecie wągrowieckim,
  - gmina Dobrzyca i część gminy Gizalki położona na północ od linii wyznaczonej przez drogę nr 443 w powiecie pleszewskim,
  - gmina Zagórów w powiecie słupeckim,
  - gmina Pyzdry w powiecie wrzesińskim,
  - gminy Kotlin, Żerków i część gminy Jarocin położona na wschód od linii wyznaczonej przez drogi nr S11 i 15 w powiecie jarocińskim,
  - gmina Rozdrażew, część gminy Koźmin Wielkopolski położona na wschód od linii wyznaczonej przez drogę nr 15, część gminy Krotoszyn położona na wschód od linii wyznaczonej przez drogę nr 15 oraz na wschód od granic miasta Krotoszyn w powiecie krotoszyńskim,
  - gminy Nowe Skalmierzyce, Raszków, Ostrów Wielkopolski z miastem Ostrów Wielkopolski w powiecie ostrowskim,
  - powiat miejski Kalisz,
  - gminy Ceków – Kolonia, Godziesze Wielkie, Koźminek, Lisków, Mycielin, Opatówek, Szczytniki w powiecie kaliskim,
  - gmina Malanów i część gminy Tuliszków położona na zachód od linii wyznaczonej przez drogę nr 72 w powiecie tureckim,
  - gminy Rychwał, Rzgów, część gminy Grodziec położona na północ od linii wyznaczonej przez drogę nr 443, część gminy Stare Miasto położona na południe od linii wyznaczonej przez autostradę nr A2 w powiecie konińskim,
- w województwie zachodniopomorskim:
- część gminy Dębno położona na wschód od linii wyznaczonej przez drogę nr 126 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 23 w miejscowości Dębno, następnie na wschód od linii wyznaczonej przez drogę nr 23 do skrzyżowania z ul. Jana Pawła II w miejscowości Cychry, następnie na północ od ul. Jana Pawła II do skrzyżowania z ul. Ogrodową i dalej na północ od linii wyznaczonej przez ul. Ogrodową, której przedłużenie biegnie do wschodniej granicy gminy w powiecie myśliborskim,

- gminy Chojna, Trzcińsko – Zdrój oraz część gminy Cedynia położona na północ od linii wyznaczonej przez drogę nr 124 biegnącą od zachodniej granicy gminy do miasta Cedynia, a następnie na północ od linii wyznaczonej przez drogę nr 125 biegnącą od miasta Cedynia do wschodniej granicy gminy w powiecie gryfińskim.

## 6. Slovakia

The following restricted zones I in Slovakia:

- the whole district of Vranov nad Topľou, except municipalities included in part II,
- the whole district of Humenné,
- the whole district of Snina,
- the whole district of Medzilaborce
- the whole district of Stropkov
- the whole district of Svidník, except municipalities included in part II,
- the whole district of Stará Ľubovňa, except municipalities included in part II,
- the whole district of Kežmarok,
- the whole district of Poprad,
- in the district of Rožňava, the whole municipalities of Dobšiná, Vlachovo, Gočovo, Kobeliarovo, Markuška, Kocel'ovce, Vyšná Slaná Rejdová, Čierna Lehota, Slavošovce, Rochovce, Brdárka, Hanková, Slavoška, Dedinky, Stratená,
- the whole district of Revúca, except municipalities included in part II,
- in the district of Michalovce, the whole municipality of Strážske,
- in the district of Rimavská Sobota, municipalities located south of the road No 526 not included in part II,
- the whole district of Lučenec, except municipalities included in part II,
- the whole district of Veľký Krtíš, except municipalities included in part II,
- in the district of Zvolen, the whole municipality of Lešť,
- in the district of Detva, the whole municipality of Horný Tisovník.

## 7. Greece

The following restricted zones I in Greece:

- in the regional unit of Drama:
  - the community departments of Sidironero and Skaloti and the municipal departments of Livadero and Ksiropotamo (in Drama municipality),
  - the municipal department of Paranesti (in Paranesti municipality),
  - the municipal departments of Kokkinogeia, Mikropoli, Panorama, Pyrgoi (in Prosotsani municipality),
  - the municipal departments of Kato Nevrokopi, Chrysokefalo, Achladea, Vathytopos, Volakas, Granitis, Dasotos, Eksohi, Katafyto, Lefkogeia, Mikrokleisoura, Mikromilea, Ochyro, Pagoneri, Perithorio, Kato Vrontou and Potamoi (in Kato Nevrokopi municipality),
- in the regional unit of Xanthi:
  - the municipal departments of Kimmerion, Stavroupoli, Gerakas, Dafnonas, Komnina, Kariofyto and Neochori (in Xanthi municipality),
  - the community departments of Satres, Thermes, Kotyli, and the municipal departments of Myki, Echinis and Oraio and (in Myki municipality),
  - the community department of Selero and the municipal department of Sounio (in Avdira municipality),
- in the regional unit of Rodopi:
  - the municipal departments of Komotini, Anthochorio, Gratini, Thrylorio, Kalhas, Karydia, Kikidio, Kosmio, Pandrosos, Aigeiros, Kallisti, Meleti, Neo Sidirochori and Mega Doukato (in Komotini municipality),

- the municipal departments of Ipio, Arriana, Darmeni, Archontika, Fillyra, Ano Drosini, Aratos and the Community Departments Kehros and Organi (in Arriana municipality),
- the municipal departments of Iasmos, Sostis, Asomatoi, Polyanthos and Amvrosia and the community department of Amaxades (in Iasmos municipality),
- the municipal department of Amaranta (in Maroneia Sapon municipality),
- in the regional unit of Evros:
  - the municipal departments of Kyriaki, Mandra, Mavroklisi, Mikro Dereio, Protokklisi, Roussa, Goniko, Geriko, Sidirochori, Megalo Derio, Sidiro, Giannouli, Agriani and Petrolofos (in Soufli municipality),
  - the municipal departments of Dikaia, Arzos, Elaia, Therapio, Komara, Marasia, Ormenio, Pentalofos, Petrota, Plati, Ptelea, Kyprinos, Zoni, Fulakio, Spilaio, Nea Vyssa, Kavili, Kastanies, Rizia, Sterna, Ampelakia, Valtos, Megali Doxipara, Neochori and Chandras (in Orestiada municipality),
  - the municipal departments of Asvestades, Ellinochori, Karoti, Koufovouno, Kiani, Mani, Sitochori, Alepochori, Asproneri, Metaxades, Vrysika, Doksa, Elafoxori, Ladi, Paliouri and Poimeniko (in Didymoteixo municipality),
- in the regional unit of Serres:
  - the municipal departments of Kerkini, Livadia, Makrynitsa, Neochori, Platanakia, Petritsi, Akritochori, Vyroneia, Gonimo, Mandraki, Megalochori, Rodopoli, Ano Poroia, Katw Poroia, Sidirokastro, Vamvakophyto, Promahonas, Kamaroto, Strymonochori, Charopo, Kastanousi and Chortero and the community departments of Achladochori, Agkistro and Kapnophyto (in Sintiki municipality),
  - the municipal departments of Serres, Elaionas and Oinoussa and the community departments of Orini and Ano Vrontou (in Serres municipality),
  - the municipal departments of Dasochoriou, Irakleia, Valtero, Karperi, Koimisi, Lithotopos, Limnochori, Podismeno and Chrysochorafa (in Irakleia municipality).

## 8. Germany

The following restricted zones I in Germany:

Bundesland Brandenburg:

- Landkreis Dahme-Spreewald:
  - Gemeinde Alt Zauche-Wußwerk,
  - Gemeinde Byhleguhre-Byhlen,
  - Gemeinde Märkische Heide,
  - Gemeinde Neu Zauche,
  - Gemeinde Schwielochsee mit den Gemarkungen Groß Liebitz, Gühlen, Mochow und Siegadel,
  - Gemeinde Spreewaldheide,
  - Gemeinde Straupitz,
- Landkreis Märkisch-Oderland:
  - Gemeinde Neuhardenberg,
  - Gemeinde Gusow-Platkow,
  - Gemeinde Lietzen,
  - Gemeinde Falkenhagen (Mark),
  - Gemeinde Zeschdorf,
  - Gemeinde Treplin,
  - Gemeinde Lebus mit den Gemarkungen Wüste-Kunersdorf, Wulkow bei Booßen, Schönfließ, Mallnow – westlich der Bahnstrecke RB 60,
  - Gemeinde Fichtenhöhe – westlich der Bahnstrecke RB 60,
  - Gemeinde Lindendorf – westlich der Bahnstrecke RB 60,

- Gemeinde Vierlinden – westlich der Bahnstrecke RB 60,
- Gemeinde Müncheberg mit den Gemarkungen Trebnitz und Jahnsfelde,
- Gemeinde Letschin mit den Gemarkungen Steintoch, Neu Rosenthal, Letschin, Kiehnwerder, Sietzing, Kienitz, Wilhelmsaue, Posedin, Solikante, Klein Neuendorf, Neubarnim, Ortwig, Groß Neuendorf, Ortwig Graben, Mehrin-Graben und Zelliner Loose,
- Gemeinde Seelow – westlich der Bahnstrecke RB 60,
- Landkreis Oder-Spree:
  - Gemeinde Storkow (Mark),
  - Gemeinde Wendisch Rietz,
  - Gemeinde Reichenwalde,
  - Gemeinde Diensdorf-Radlow,
  - Gemeinde Bad Saarow,
- Gemeinde Rietz-Neuendorf mit den Gemarkungen Buckow, Glienicke, Behrendorf, Ahrendorf, Herzberg, Görzig, Pfaffendorf, Sauen, Wilmersdorf (G), Neubrück, Drahendorf, Alt Golm,
- Gemeinde Tauche mit den Gemarkungen Briescht, Kossenblatt, Werder, Görsdorf (B), Giesendorf, Wiesendorf, Wulfersdorf, Falkenberg (T), Lindenberg,
- Gemeinde Steinhöfel mit den Gemarkungen Demnitz, Steinhöfel, Hasenfelde, Ahrendorf, Heinersdorf, Tempelberg,
- Gemeinde Langewahl,
- Gemeinde Berkenbrück,
- Gemeinde Briesen (Mark),
- Gemeinde Jacobsdorf,
- Landkreis Spree-Neiße:
  - Gemeinde Jänschwalde,
  - Gemeinde Peitz,
  - Gemeinde Tauer,
  - Gemeinde Turnow-Preilack,
  - Gemeinde Drachhausen,
  - Gemeinde Schmogrow-Fehrow,
  - Gemeinde Drehnow,
  - Gemeinde Guben mit der Gemarkung Schlagsdorf,
  - Gemeinde Schenkendöbern mit den Gemarkungen Grabko, Kerkwitz, Groß Gastrose,
  - Gemeinde Teichland,
  - Gemeinde Dissen-Striesow,
  - Gemeinde Heinersbrück,
  - Gemeinde Briesen,
  - Gemeinde Forst,
  - Gemeinde Wiesengrund,
  - Gemeinde Groß Schacksdorf-Simmersdorf,
  - Gemeinde Neiße-Malxetal,
  - Gemeinde Jämlitz-Klein Düben,
  - Gemeinde Tschernitz,
  - Gemeinde Döbern,
  - Gemeinde Felixsee,

- Gemeinde Spremberg mit den Gemarkungen Lieskau, Schönheide, Graustein, Türkendorf, Groß Luja, Wadelsdorf, Hornow,
  - Gemeinde Neuhausen/Spree mit den Gemarkungen Kathlow, Haasow,
  - Stadt Cottbus mit den Gemarkungen Dissenchen, Döbbrick, Merzdorf, Saspow, Schmellwitz, Sielow, Willmersdorf,
  - kreisfreie Stadt Frankfurt (Oder),
- Bundesland Sachsen:
- Landkreis Görlitz:
  - Landkreis Görlitz nördlich der Bundesautobahn 4 sofern nicht bereits Teil des gefährdeten Gebietes.

## PART II

**1. Bulgaria**

The following restricted zones II in Bulgaria:

- the whole region of Haskovo,
- the whole region of Yambol,
- the whole region of Stara Zagora,
- the whole region of Pernik,
- the whole region of Kyustendil,
- the whole region of Plovdiv,
- the whole region of Pazardzhik,
- the whole region of Smolyan,
- the whole region of Burgas excluding the areas in Part III.

**2. Estonia**

The following restricted zones II in Estonia:

- Eesti Vabariik (välja arvatud Hiiu maakond).

**3. Hungary**

The following restricted zones II in Hungary:

- Békés megye 950150, 950250, 950350, 950450, 950550, 950650, 950660, 950750, 950850, 950860, 951050, 951150, 951250, 951260, 951350, 951450, 951460, 951550, 951650, 951750, 952150, 952250, 952350, 952450, 952550, 952650, 953250, 953260, 953270, 953350, 953450, 953550, 953560, 953950, 954050, 954060, 954150, 956250, 956350, 956450, 956550, 956650 és 956750 kódszámú vadgazdálkodási egységeinek teljes területe,
- Borsod-Abaúj-Zemplén megye valamennyi vadgazdálkodási egységének teljes területe,
- Fejér megye 403150, 403160, 403260, 404250, 404550, 404560, 405450, 405550, 405650, 406450 és 407050 kódszámú vadgazdálkodási egységeinek teljes területe,
- Hajdú-Bihar megye valamennyi vadgazdálkodási egységének teljes területe,
- Heves megye valamennyi vadgazdálkodási egységének teljes területe,
- Jász-Nagykun-Szolnok megye 750250, 750550, 750650, 750750, 750850, 750970, 750980, 751050, 751150, 751160, 751250, 751260, 751350, 751360, 751450, 751460, 751470, 751550, 751650, 751750, 751850, 751950, 752150, 752250, 752350, 752450, 752460, 752550, 752560, 752650, 752750, 752850, 752950, 753060, 753070, 753150, 753250, 753310, 753450, 753550, 753650, 753660, 753750, 753850, 753950, 753960, 754050, 754150, 754250, 754360, 754370, 754850, 755550, 755650 és 755750 kódszámú vadgazdálkodási egységeinek teljes területe,
- Komárom-Esztergom megye: 251950, 252050, 252350, 252450, 252460, 252550, 252650, 252750, 252850, 252860, 252950, 252960, 253050, 253150, 253250, 253350, 253450 és 253550 kódszámú vadgazdálkodási egységeinek teljes területe,
- Nógrád megye valamennyi vadgazdálkodási egységeinek teljes területe,

- Pest megye 570150, 570250, 570350, 570450, 570550, 570650, 570750, 570850, 570950, 571050, 571150, 571250, 571350, 571650, 571750, 571760, 571850, 571950, 572050, 573550, 573650, 574250, 577250, 580050 és 580150 kódszámú vadgazdálkodási egységeinek teljes területe,
- Szabolcs-Szatmár-Bereg megye valamennyi vadgazdálkodási egységének teljes területe.

#### 4. Latvia

The following restricted zones II in Latvia:

- Ādažu novads,
- Aizputes novada Aizputes, Cīravas un Lažas pagasts, Kalvenes pagasta daļa uz rietumiem no ceļa pie Vārtājas upes līdz autoceļam A9, uz dienvidiem no autoceļa A9, uz rietumiem no autoceļa V1200, Kazdangas pagasta daļa uz rietumiem no ceļa V1200, P115, P117, V1296, Aizputes pilsēta,
- Aglonas novads,
- Aizkraukles novads,
- Aknīstes novads,
- Alojas novads,
- Alsungas novads,
- Alūksnes novads,
- Amatas novads,
- Apes novads,
- Auces novads,
- Babītes novads,
- Baldones novads,
- Baltinavas novads,
- Balvu novads,
- Bauskas novads,
- Beverīnas novads,
- Brocēnu novads,
- Burtnieku novads,
- Carnikavas novads,
- Cēsu novads
- Cesvaines novads,
- Ciblas novads,
- Dagdas novads,
- Daugavpils novads,
- Dobeles novads,
- Dundagas novads,
- Durbes novads,
- Engures novads,
- Ērgļu novads,
- Garkalnes novads,
- Gulbenes novads,
- Iecavas novads,
- Ikšķiles novads,
- Ilūkstes novads,
- Inčukalna novads,

- Jaunjelgavas novads,
- Jaunpiebalgas novads,
- Jaunpils novads,
- Jēkabpils novads,
- Jelgavas novads,
- Kandavas novads,
- Kārsavas novads,
- Ķeguma novads,
- Ķekavas novads,
- Kocēnu novads,
- Kokneses novads,
- Krāslavas novads,
- Krimuldas novads,
- Krustpils novads,
- Kuldīgas novada, Laidu pagasta daļa uz ziemeļiem no autoceļa V1296, Padures, Rumbas, Rendas, Kabiles, Vārmes, Pelču, Ēdoles, Īvandes, Kurmāles, Turlavas, Gudenieku un Snēpeles pagasts, Kuldīgas pilsēta,
- Lielvārdes novads,
- Līgatnes novads,
- Limbažu novads,
- Līvānu novads,
- Lubānas novads,
- Ludzas novads,
- Madonas novads,
- Mālpils novads,
- Mārupes novads,
- Mazsalacas novads,
- Mērsraga novads,
- Naukšēnu novads,
- Neretas novads,
- Ogres novads,
- Olaines novads,
- Ozolnieku novads,
- Pārgaujas novads,
- Pāvilostas novada Sakas pagasts, Pāvilostas pilsēta,
- Pļaviņu novads,
- Preiļu novads,
- Priekules novads,
- Priekuļu novads,
- Raunas novads,
- republikas pilsēta Daugavpils,
- republikas pilsēta Jelgava,
- republikas pilsēta Jēkabpils,
- republikas pilsēta Jūrmala,
- republikas pilsēta Rēzekne,



- republikas pilsēta Valmiera,
- Rēzeknes novads,
- Riebiņu novads,
- Rojas novads,
- Ropažu novads,
- Rugāju novads,
- Rundāles novads,
- Rūjienas novads,
- Salacgrīvas novads,
- Salas novads,
- Salaspils novads,
- Saldus novads,
- Saulkrastu novads,
- Sējas novads,
- Siguldas novads,
- Skrīveru novads,
- Skrundas novada Raņķu pagasta daļa uz ziemeļiem no autoceļa V1272 līdz robežai ar Ventas upi, Skrundas pagasta daļa no Skrundas uz ziemeļiem no autoceļa A9 un austrumiem no Ventas upes,
- Smiltenes novads,
- Stopiņu novada daļa, kas atrodas uz austrumiem no autoceļa V36, P4 un P5, Acones ielas, Dauguļupes ielas un Dauguļupītes,
- Strenču novads,
- Talsu novads,
- Tērvetes novads,
- Tukuma novads,
- Vaiņodes novada Vaiņodes pagasts un Embūtes pagasta daļa uz dienvidiem autoceļa P116, P106,
- Valkas novads,
- Varakļānu novads,
- Vārkavas novads,
- Vecpiebalgas novads,
- Vecumnieku novads,
- Ventspils novads,
- Viesītes novads,
- Viļakas novads,
- Viļānu novads,
- Zilupes novads.

## 5. Lithuania

The following restricted zones II in Lithuania:

- Alytaus miesto savivaldybė,
- Alytaus rajono savivaldybė,
- Anykščių rajono savivaldybė,
- Akmenės rajono savivaldybė,
- Birštono savivaldybė,

- Biržų miesto savivaldybė,
- Biržų rajono savivaldybė,
- Druskininkų savivaldybė,
- Elektrėnų savivaldybė,
- Ignalinos rajono savivaldybė,
- Jonavos rajono savivaldybė,
- Joniškio rajono savivaldybė,
- Jurbarko rajono savivaldybė: Eržvilko, Girdžių, Jurbarko miesto, Jurbarkų, Raudonės, Šimkaičių, Skirsnemunės, Smalininkų, Veliuonos ir Viešvilės seniūnijos,
- Kaišiadorių rajono savivaldybė,
- Kalvarijos savivaldybė,
- Kauno miesto savivaldybė,
- Kauno rajono savivaldybė: Akademijos, Alšėnų, Batniavos, Ežerėlio, Domeikavos, Garliavos, Garliavos apylinkių, Karmėlavos, Kulautuvos, Lapių, Linksmakalnio, Neveronių, Raudondvario, Ringaudų, Rokų, Samylų, Taurakiemio, Vandžiogalos, Užliedžių, Vilkijos, ir Zapyškio seniūnijos, Babtų seniūnijos dalis į rytus nuo kelio A1, ir Vilkijos apylinkių seniūnijos dalis į vakarus nuo kelio Nr. 1907,
- Kazlų rūdos savivaldybė,
- Kelmės rajono savivaldybė,
- Kėdainių rajono savivaldybė: Dotnuvos, Gudžiūnų, Kėdainių miesto, Krakių, Pelėdnagių, Surviliškio, Šėtos, Truskavos, Vilainių ir Josvainių seniūnijos dalis į šiaurę ir rytus nuo kelio Nr. 229 ir Nr. 2032,
- Klaipėdos rajono savivaldybė: Judrėnų, Endriejavo ir Veiviržėnų seniūnijos,
- Kupiškio rajono savivaldybė,
- Kretingos rajono savivaldybė,
- Lazdijų rajono savivaldybė,
- Marijampolės savivaldybė,
- Mažeikių rajono savivaldybė,
- Molėtų rajono savivaldybė,
- Pagėgių savivaldybė,
- Pakruojo rajono savivaldybė,
- Panevėžio rajono savivaldybė,
- Panevėžio miesto savivaldybė,
- Pasvalio rajono savivaldybė,
- Radviliškio rajono savivaldybė,
- Rietavo savivaldybė,
- Prienų rajono savivaldybė,
- Plungės rajono savivaldybė: Žlibinų, Stalgėnų, Nausodžio, Plungės miesto, Šateikių ir Kulių seniūnijos,
- Raseinių rajono savivaldybė: Betygalos, Girkalnio, Kalnujų, Nemakščių, Pagojukų, Paliepių, Raseinių miesto, Raseinių, Šiluvos, Viduklės seniūnijos,
- Rokiškio rajono savivaldybė,
- Skuodo rajono savivaldybės: Aleksandrijos, Ylakių, Lenkimų, Mosėdžio, Skuodo ir Skuodo miesto seniūnijos,
- Šakių rajono savivaldybė,
- Šalčininkų rajono savivaldybė,
- Šiaulių miesto savivaldybė,

- Šiaulių rajono savivaldybė,
- Šilutės rajono savivaldybė,
- Širvintų rajono savivaldybė,
- Šilalės rajono savivaldybė,
- Švenčionių rajono savivaldybė,
- Tauragės rajono savivaldybė,
- Telšių rajono savivaldybė,
- Trakų rajono savivaldybė,
- Ukmergės rajono savivaldybė,
- Utenos rajono savivaldybė,
- Varėnos rajono savivaldybė,
- Vilniaus miesto savivaldybė,
- Vilniaus rajono savivaldybė,
- Vilkaviškio rajono savivaldybė,
- Visagino savivaldybė,
- Zarasų rajono savivaldybė.

## 6. Poland

The following restricted zones II in Poland:

w województwie warmińsko-mazurskim:

- gminy Kalinowo, Stare Juchy, Prostki oraz gmina wiejska Elk w powiecie elckim,
- powiat elbląski,
- powiat miejski Elbląg,
- powiat gołdapski,
- powiat piski,
- gminy Górowo Iławeckie z miastem Górowo Iławeckie i Sępólno w powiecie bartoszyckim,
- gminy Biskupiec, Kolno, część gminy Olsztynek położona na południe od linii wyznaczonej przez drogę nr S51 biegnącą od wschodniej granicy gminy do miejscowości Ameryka oraz na zachód od linii wyznaczonej przez drogę biegnącą od skrzyżowania z drogą S51 do północnej granicy gminy, łączącej miejscowości Mańki – Myncyny – Ameryka w powiecie olsztyńskim,
- gminy Dąbrówno, Grunwald, część gminy Małdyty położona na zachód od linii wyznaczonej przez drogę nr S7, część gminy Miłomłyn położona na zachód od linii wyznaczonej przez drogę nr S7, część gminy wiejskiej Ostróda położona na zachód od linii wyznaczonej przez drogę nr S7 oraz na południe od drogi nr 16, część miasta Ostróda położona na zachód od linii wyznaczonej przez drogę nr S7 w powiecie ostródzkim,
- powiat giżycki,
- powiat braniewski,
- powiat kętrzyński,
- gminy Lubomino i Orneta w powiecie lidzbarskim,
- gmina Nidzica i część gminy Kozłowo położona na północ od linii wyznaczonej przez linię kolejową w powiecie nidzickim,
- gminy Dźwierzuty, Jedwabno, Pasym, Szczytno i miasto Szczytno i Świątajno w powiecie szczywieńskim,

- powiat mrągowski,
- gminy Lubawa, miasto Lubawa, Zalewo i część gminy wiejskiej Iława położona na wschód od linii wyznaczonej przez drogę nr 521 biegnącą od zachodniej granicy gminy do zachodniej granicy miasta Iława oraz na wschód od linii wyznaczonej przez drogę biegnącą od południowej granicy gminy miasta Iława przez miejscowość Katarzynki do południowej granicy gminy w powiecie iławskim,
- powiat węgorszewski,
- część gminy wiejskiej Działdowo położona na północ od linii wyznaczonej przez linię kolejowe biegnące od wschodniej do zachodniej granicy gminy w powiecie działdowskim,

w województwie podlaskim:

- powiat bielski,
- powiat grajewski,
- powiat moniecki,
- powiat sejneński,
- gminy Łomża, Piątnica, Jedwabne, Przytuły i Wizna w powiecie łomżyńskim,
- powiat miejski Łomża,
- powiat siemiatycki,
- powiat hajnowski,
- gminy Ciechanowiec, Klukowo, Szepietowo, Kobylin-Borzymy, Nowe Piekuty, Sokoły i część gminy Kulesze Kościelne położona na północ od linii wyznaczonej przez linię kolejową w powiecie wysokomazowieckim,
- gmina Rutki i część gminy Kołaki Kościelne położona na północ od linii wyznaczonej przez linię kolejową w powiecie zambrowskim,
- powiat kolneński z miastem Kolno,
- powiat białostocki,
- gminy Filipów, Jeleniewo, Przerośl, Raczki, Rutka-Tartak, Suwałki, Szypliszki Wizajny oraz część gminy Bakalarzewo położona na północ od linii wyznaczonej przez drogę 653 biegnącej od zachodniej granicy gminy do skrzyżowania z drogą 1122B oraz na wschód od linii wyznaczonej przez drogę nr 1122B biegnącą od drogi 653 w kierunku południowym do skrzyżowania z drogą 1124B i następnie na północny – wschód od drogi nr 1124B biegnącej od skrzyżowania z drogą 1122B do granicy z gminą Raczki w powiecie suwalskim,
- powiat miejski Suwałki,
- powiat augustowski,
- powiat sokólski,
- powiat miejski Białystok,

w województwie mazowieckim:

- powiat siedlecki,
- powiat miejski Siedlce,
- gminy Bielany, Ceranów, Jabłonna Lacka, Kosów Lacki, Repki, Sabnie, Sterdyń i gmina wiejska Sokółów Podlaski w powiecie sokołowskim,
- gminy Grębków i Wierzbno w powiecie węgrowskim,
- powiat łosicki,
- powiat ciechanowski,
- powiat sochaczewski,
- gminy Policzna, Przyłęk, Tczów i Zwoleń w powiecie zwoleńskim,

- powiat kozienicki,
  - gminy Chotcza i Solec nad Wisłą w powiecie lipskim,
  - gminy Gózd, Jastrzębia, Jedlnia Letnisko, Pionki z miastem Pionki, Skaryszew, Jedlińsk, Przytyk, Zakrzew, część gminy Iłża położona na zachód od linii wyznaczonej przez drogę nr 9, część gminy Wolanów położona na północ od drogi nr 12 w powiecie radomskim,
  - gminy Bodzanów, Bulkowo, Starożreby, Słubice, Wyszogród i Mała Wieś w powiecie plockim,
  - powiat nowodworski,
  - powiat płoński,
  - gminy Pokrzywnica, Świercze i część gminy Winnica położona na zachód od linii wyznaczonej przez drogę łączącą miejscowości Bielany, Winnica i Pokrzywnica w powiecie pułtuskim,
  - gminy Dębówka, Klembów, Poświętne, Radzymin, Wołomin, miasto Kobyłka, miasto Marki, miasto Ząbki, miasto Zielonka w powiecie wołomińskim,
  - gminy Borowie, Garwolin z miastem Garwolin, Miastków Kościelny, Parysów, Pilawa, część gminy Wilga położona na północ od linii wyznaczonej przez rzekę Wilga biegnącą od wschodniej granicy gminy do ujścia do rzeki Wisły, część gminy Górzno położona na północ od linii wyznaczonej przez drogę łączącą miejscowości Łąki i Górzno biegnącą od wschodniej granicy gminy, następnie od miejscowości Górzno na północ od drogi nr 1328W biegnącej do drogi nr 17, a następnie na północ od linii wyznaczonej przez drogę biegnącą od drogi nr 17 do zachodniej granicy gminy przez miejscowości Józefów i Kobyła Wola w powiecie garwolińskim,
  - gminy Boguty – Pianki, Zaręby Kościelne, Nur i część gminy Małkinia Górna położona na południe od rzeki Brok w powiecie ostrowskim,
  - gminy Stupsk, Wiśniewo i Strzegowo w powiecie mławskim,
  - gminy Chlewiska i Szydłowiec w powiecie szydłowieckim,
  - powiat miński,
  - powiat otwocki,
  - powiat warszawski zachodni,
  - powiat legionowski,
  - powiat piaseczyński,
  - powiat pruszkowski,
  - powiat grójecki,
  - powiat grodziski,
  - powiat zyrardowski,
  - powiat białobrzegi,
  - powiat przysuski,
  - powiat miejski Warszawa,
- w województwie lubelskim:
- powiat bialski,
  - powiat miejski Biała Podlaska,
  - gminy Batorz, Godziszów, Janów Lubelski, Modliborzyce i Potok Wielki w powiecie janowskim,
  - gminy Janowiec, Kazimierz Dolny, Końskowola, Kurów, Markuszów, Nałęczów, Puławy z miastem Puławy, Wąwolnica i Żyrzyn w powiecie puławskim,
  - gminy Nowodwór, miasto Dęblin i część gminy Ryki położona na południe od linii wyznaczonej przez linię kolejową powiecie ryckim,

- gminy Adamów, Krzywda, Stoczek Łukowski z miastem Stoczek Łukowski, Wola Mysłowska, Trzebieszów, Stanin, Wojcieszków, gmina wiejska Łuków i miasto Łuków w powiecie łukowskim,
  - powiat lubelski,
  - powiat miejski Lublin,
  - gminy Niedźwiada, Ostrów Lubelski, Serniki i Uścimów w powiecie lubartowskim,
  - powiat łęczyński,
  - powiat świdnicki,
  - gminy Fajslawice, Gorzków, Izbica, Krasnystaw z miastem Krasnystaw, Kraśniczyn, Łopiennik Górny, Siennica Różana i część gminy Żółkiewka położona na północ od linii wyznaczonej przez drogę nr 842 w powiecie krasnostawskim,
  - gminy Chełm, Ruda – Huta, Sawin, Rejowiec, Rejowiec Fabryczny z miastem Rejowiec Fabryczny, Siedliszcze, Wierzbica, część gminy Dorohusk położona na północ od linii wyznaczonej przez linię kolejową, część gminy Wojsławice położona na zachód od linii wyznaczonej przez drogę 1839L, część gminy Leśniowice położona na zachód od linii wyznaczonej przez drogę 1839L w powiecie chełmskim,
  - powiat miejski Chełm,
  - powiat kraśnicki,
  - powiat opolski,
  - powiat parczewski,
  - powiat włodawski,
  - powiat radzyński,
- w województwie podkarpackim:
- powiat stalowowolski,
  - gminy Oleszyce, Lubaczów z miastem Lubaczów, Wielkie Oczy w powiecie lubaczowskim,
  - część gminy Kamień położona na zachód od linii wyznaczonej przez drogę nr 19, część gminy Sokołów Małopolski położona na północ od linii wyznaczonej przez drogę nr 875 w powiecie rzeszowskim,
  - gminy Cmolas i Majdan Królewski w powiecie kolbuszowskim,
  - gminy Grodzisko Dolne, część gminy wiejskiej Leżajsk położona na południe od miasta Leżajsk oraz na zachód od linii wyznaczonej przez rzekę San, w powiecie leżańskim,
  - gmina Jarocin, część gminy Harasiuki położona na północ od linii wyznaczonej przez drogę nr 1048 R, część gminy Ulanów położona na północ od linii wyznaczonej przez rzekę Tanew, część gminy Nisko położona na zachód od linii wyznaczonej przez drogę nr 19 oraz na północ od linii wyznaczonej przez linię kolejową biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 19, część gminy Jeżowe położona na zachód od linii wyznaczonej przez drogę nr 19 w powiecie niżańskim,
  - powiat tarnobrzeski,
- w województwie pomorskim:
- gminy Dzierżgoń i Stary Dzierżgoń w powiecie sztumskim,
  - gmina Stare Pole w powiecie malborskim,
  - gminy Stegny, Sztutowo i część gminy Nowy Dwór Gdański położona na północny – wschód od linii wyznaczonej przez drogę nr 55 biegnącą od południowej granicy gminy do skrzyżowania z drogą nr 7, następnie przez drogę nr 7 i S7 biegnącą do zachodniej granicy gminy w powiecie nowodworskim,
- w województwie świętokrzyskim:
- gmina Tarłów i część gminy Ożarów położona na północ od linii wyznaczonej przez drogę nr 74 w powiecie opatowskim,

- część gminy Brody położona na zachód od linii kolejowej biegnącej od miejscowości Marcule i od północnej granicy gminy przez miejscowości Klepacze i Karczma Kunowska do południowej granicy gminy oraz na wschód od linii wyznaczonej przez drogę nr 9 i na północny – wschód od linii wyznaczonej przez drogę nr 0618T biegnącą od północnej granicy gminy do skrzyżowania w miejscowości Lipie oraz przez drogę biegnącą od miejscowości Lipie do wschodniej granicy gminy i część gminy Mirzec położona na wschód od linii wyznaczonej przez drogę nr 744 biegnącą od południowej granicy gminy do miejscowości Tychów Stary a następnie przez drogę nr 0566T biegnącą od miejscowości Tychów Stary w kierunku północno – wschodnim do granicy gminy w powiecie starachowickim,
- gmina Gowarczów, część gminy Końskie położona na wschód od linii kolejowej, część gminy Stąporków położona na północ od linii kolejowej w powiecie koneckim,

w województwie lubuskim:

- powiat wschowski,
- gmina Kostrzyn nad Odrą i część gminy Witnica położona na południowy zachód od drogi biegnącej od zachodniej granicy gminy od miejscowości Krześnica, przez miejscowości Kamień Wielki – Mościce – Witnica – Kłopotowo do południowej granicy gminy w powiecie gorzowskim,
- gminy Gubin z miastem Gubin, Maszewo i część gminy Bytnica położona na zachód od linii wyznaczonej przez drogę nr 1157F w powiecie krośnieńskim,
- powiat ślubicki,
- gminy Słońsk, Sulęcín i Torzym w powiecie sulęcińskim,
- gminy Bledzew i Międzyrzecz w powiecie międzyrzeckim,
- gminy Kolsko, część gminy Kozuchów położona na południe od linii wyznaczonej przez drogę nr 283 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 290 i na południe od linii wyznaczonej przez drogę nr 290 biegnącej od miasta Mirocín Dolny do zachodniej granicy gminy, część gminy Bytom Odrzański położona na północny zachód od linii wyznaczonej przez drogi nr 293 i 326, część gminy Nowe Miasteczko położona na zachód od linii wyznaczonych przez drogi 293 i 328, część gminy Siedlisko położona na północny zachód od linii wyznaczonej przez drogę biegnącą od rzeki Odry przy południowe granicy gminy do drogi nr 326 łączącej się z drogą nr 325 biegnącą w kierunku miejscowości Różanówka do skrzyżowania z drogą nr 321 biegnącą od tego skrzyżowania w kierunku miejscowości Bielawy, a następnie przedłużoną przez drogę przeciwpożarową biegnącą od drogi nr 321 w miejscowości Bielawy do granicy gminy w powiecie nowosolskim,
- gminy Nowogród Bobrzański, Trzebiechów część gminy Bojadła położona na północ od linii wyznaczonej przez drogę nr 278 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 282 i na północ od linii wyznaczonej przez drogę nr 282 biegnącej od miasta Bojadła do zachodniej granicy gminy i część gminy Sulechów położona na wschód od linii wyznaczonej przez drogę nr S3 w powiecie zielonogórskim,
- powiat żarski,
- gminy Brzeźnica, Iłowa, Małomice, Szprotawa, Wymiarki, Żagań, miasto Żagań, miasto Gozdnicza, część gminy Niegosławice położona na zachód od linii wyznaczonej przez drogę nr 328 w powiecie żagańskim,
- gminy Lubrza, Łągów i Świebodzin w powiecie świebodzińskim,

w województwie dolnośląskim:

- gmina Pęcław, część gminy Kotla położona na północ od linii wyznaczonej przez rzekę Krzycki Rów, część gminy wiejskiej Głogów położona na wschód od linii wyznaczonej przez drogi nr 12, 319 oraz 329, część miasta Głogów położona na wschód od linii wyznaczonej przez drogę nr 12 w powiecie głogowskim,
- gminy Grębocice i Polkowice w powiecie polkowickim,

w województwie wielkopolskim:

- gminy Przemęt i Wolsztyn w powiecie wolsztyńskim,

- gmina Wielichowo część gminy Kamieniec położona na zachód od linii wyznaczonej przez drogę nr 308 i część gminy Rakoniewice położona na zachód od linii wyznaczonej przez drogę nr 305 w powiecie grodziskim,
- gminy Lipno, Osieczna, Wijewo, Włoszakowice i część gminy Świąciechowa położona na północ od linii wyznaczonej przez drogę nr 12 w powiecie leszczyńskim,
- gmina Śmigiel, część gminy wiejskiej Kościan położona na południowy – wschód od linii wyznaczonej przez drogę nr 5 oraz na zachód od linii wyznaczonej przez kanał Obry, część gminy Krzywiń położona na zachód od linii wyznaczonej przez kanał Obry w powiecie kościańskim,
- powiat miejski Leszno,
- powiat obornicki,
- część gminy Połajewo na położona na południe od drogi łączącej miejscowości Chraplewo, Tarnówko-Boruszyn, Krosin, Jakubowo, Połajewo – ul. Ryczywolska do północno-wschodniej granicy gminy w powiecie czarnkowsko-trzcianeckim,
- gmina Suchy Las, część gminy wiejskiej Murowana Goślina położona na północ od linii kolejowej biegnącej od północnej granicy miasta Murowana Goślina do północno-wschodniej granicy gminy oraz część gminy Rokietnica położona na północ i na wschód od linii kolejowej biegnącej od północnej granicy gminy w miejscowości Krzyszkowo do południowej granicy gminy w miejscowości Kiekrz w powiecie poznańskim,
- część gminy Szamotuły położona na wschód od wschodniej granicy miasta Szamotuły i na północ od linii kolejowej biegnącej od południowej granicy miasta Szamotuły do południowo-wschodniej granicy gminy oraz część gminy Obrzycko położona na wschód od drogi nr 185 łączącej miejscowości Gaj Mały, Słopanowo i Obrzycko do północnej granicy miasta Obrzycko, a następnie na wschód od drogi przebiegającej przez miejscowość Chraplewo w powiecie szamotulskim.

w województwie łódzkim:

- gminy Białaczów, Drzewica, Opoczno i Poświętne w powiecie opoczyńskim,
- gminy Biała Rawska, Regnów i Sadkowiec w powiecie rawskim,
- gmina Kowiesy w powiecie skierniewickim,

w województwie zachodniopomorskim:

- gmina Boleszkowice i część gminy Dębno położona na zachód od linii wyznaczonej przez drogę nr 126 biegnącą od zachodniej granicy gminy do skrzyżowania z drogą nr 23 w miejscowości Dębno, następnie na zachód od linii wyznaczonej przez drogę nr 23 do skrzyżowania z ul. Jana Pawła II w miejscowości Cychry, następnie na południe od ul. Jana Pawła II do skrzyżowania z ul. Ogrodową i dalej na południe od linii wyznaczonej przez ul. Ogrodową, której przedłużenie biegnie do wschodniej granicy gminy w powiecie myśliborskim,
- gminy Mieszkowice, Moryń, część gminy Cedynia położona na południe od linii wyznaczonej przez drogę nr 124 biegnącą od zachodniej granicy gminy do miasta Cedynia, a następnie na południe od linii wyznaczonej przez drogę nr 125 biegnącą od miasta Cedynia do wschodniej granicy gminy w powiecie gryfińskim.

## 7. Slovakia

The following restricted zones II in Slovakia:

- the whole district of Gelnica,
- the whole district of Spišská Nová Ves,
- the whole district of Levoča,
- in the district of Michalovce, the whole municipalities of the district not included in Part I,
- the whole district of Košice-okolie,
- the whole district of Rožnava, except the municipalities included in Part I,
- the whole city of Košice,
- the whole district of Sobrance,



- in the district of Vranov nad Topľou, the whole municipalities of Zámutov, Rudlov, Jusková Voľa, Banské, Cabov, Davidov, Kamenná Poruba, Večec, Čaklov, Sol', Komárany, Čičava, Nižný Kručov, Vranov nad Topľou, Sačurov, Sečovská Polianka, Dlhé Klčovo, Nižný Hrušov, Poša, Nižný Hrabovec, Hencovce, Kučín, Majerovce, Sedliská, Kladzany and Tovarnianska Polianka, Herrmanovce nad Topľou, Petrovce, Pavlovce, Hanušovce nad Topľou, Medzianky, Radvanovce, Babie, Vlača, Ďurd'oš, Prosačov, Remeniny, Skrabské, Bystré, Petkovce, Michalok, Vyšný Žipov, Čierne nad Topľou, Zlatník, Hlinné, Jastrabie nad Topľou, Merník,
- the whole district of Prešov,
- in the whole district of Sabinov,
- in the district of Svidník, the whole municipalities of Dukovce, Želmanovce, Kuková, Kalnište, Lužany pri Ondave, Lúčka, Giraltovce, Kračúnovce, Železník, Kobylince, Mičakovce,
- the whole district of Bardejov,
- in the district of Stará Ľubovňa, the whole municipalities of Kyjov, Pusté Pole, Šarišské Jastrabie, Čirč, Ruská Voľa nad Popradom, Obručné, Vislanka, Ďurková, Plaveč, Ľubotín, Orlov,
- in the district of Revúca, the whole municipalities of Gemer, Tornaľa, Žiar, Gemerská Ves, Levkuška, Otročok, Polina, Rašice, Licince, Leváre, Držkovce, Chvalová, Sekerešovo, Višňové, Gemerské Teplice, Gemerský Sad, Hucín, Jelšava, Nadraž, Prihradzany, Šivetice, Kameňany,
- in the district of Rimavská Sobota, the whole municipalities of Abovce, Barca, Bátka, Cakov, Chanava, Dulovo, Figa, Gemerské Michalovce, Hubovo, Ivanice, Kaloša, Kesovce, Král', Lenartovce, Lenka, Neporadza, Orávka, Radnovce, Rakytník, Riečka, Rimavská Seč, Rumince, Stránska, Uzovská Panica, Valice, Vieska nad Blhom, Vlkyňa, Vyšné Valice, Včelince, Zádor, Číž, Štrkovec Tomášovce, Žíp, Španie Pole, Hostišovce, Budikovany, Teplý Vrch, Veľký Blh, Janice, Chrámec, Orávka, Martinová, Bottovo, Dubovec, Šimonovce, Širkovce Drňa, Hostice, Gemerské Dechtáre, Jestice, Petrovce, Dubno, Gemerský Jablonec,
- in the district of Veľký Krtíš, the whole municipalities of Luboriečka, Muľa, Dolná Strehová, Závada, Pravica, Chrtány, Senné, Brusník, Horná Strehová, Slovenské Kľačany, Vieska, Veľký Lom, Suché Brezovo, Horné Strháre, Dolné Strháre, Modrý Kameň, Veľký Krtíš, Veľké Zlievce, Malé Zlievce, Veľké Stračiny, Malé Stračiny, Bušince, Čeláre, Gabušovce, Zombor, Olováry, Malý Krtíš, Nová Ves
- in the district of Lučenec the whole municipalities of Kalonda, Panické Dravce, Halič, Mašková, Lehôtka, Ľuboreč, Jelšovec, Veľká nad Ipľom, Trenč, Rapovce, Mučín, Lipovany.

## 8. Germany

The following restricted zones II in Germany:

Bundesland Brandenburg:

- Landkreis Oder-Spree:
- Gemeinde Grunow-Dammendorf,
- Gemeinde Mixdorf
- Gemeinde Schlaubetal,
- Gemeinde Neuzelle,
- Gemeinde Neißemünde,
- Gemeinde Lawitz,
- Gemeinde Eisenhüttenstadt,
- Gemeinde Vogelsang,
- Gemeinde Ziltendorf,
- Gemeinde Wiesenau,
- Gemeinde Friedland,

- Gemeinde Siehdichum
- Gemeinde Müllrose,
- Gemeinde Groß Lindow,
- Gemeinde Brieskow-Finkenheerd,
- Gemeinde Ragow-Merz,
- Gemeinde Beeskow,
- Gemeinde Rietz-Neuendorf mit den Gemarkungen Groß Rietz und Birkholz,
- Gemeinde Tauche mit den Gemarkungen Stremmen, Ranzig, Trebatsch, Sabrodt, Sawall, Mitweide und Tauche,
- Landkreis Dahme-Spreewald:
  - Gemeinde Jamlitz,
  - Gemeinde Lieberose,
  - Gemeinde Schwielochsee mit den Gemarkungen Goyatz, Jessern, Lamsfeld, Ressen, Speichrow und Zaue,
- Landkreis Spree-Neiße:
  - Gemeinde Schenkendöbern mit den Gemarkungen Stakow, Reicherskreuz, Groß Drewitz, Sembten, Lauschütz, Krayne, Lübbinchen, Grano, Pinnow, Bärenklau, Schenkendöbern und Atterwasch,
  - Gemeinde Guben mit den Gemarkungen Bresinchen, Guben und Deulowitz,
- Landkreis Märkisch-Oderland:
  - Gemeinde Zechin,
  - Gemeinde Bleyen-Genschmar,
  - Gemeinde Golzow,
  - Gemeinde Küstriner Vorland,
  - Gemeinde Alt Tucheband,
  - Gemeinde Reitwein,
  - Gemeinde Podelzig,
  - Gemeinde Letschin mit der Gemarkung Sophienthal,
  - Gemeinde Seelow – östlich der Bahnstrecke RB 60,
  - Gemeinde Vierlinden – östlich der Bahnstrecke RB 60,
  - Gemeinde Lindendorf – östlich der Bahnstrecke RB 60,
  - Gemeinde Fichtenhöhe – östlich der Bahnstrecke RB 60,
  - Gemeinde Lebus mit den Gemarkungen Lebus und Mallnow – östlich der Bahnstrecke RB 60,
- Bundesland Sachsen:
  - Landkreis Görlitz:
    - Gemeinde Bad Muskau,
    - Gemeinde Krauschwitz i.d. O.L. östlich der Linie: Straßenzug B115/B156 nördlicher Teil (Jämlitzer Weg) bis Abzweig Forstweg, weiter entlang des Wildzaunes: Forstweg – Bautzener Straße – Waldstück „Drachenberge“ – S126 bis B115,
    - Gemeinde Hähnichen östlich der B115,
    - Gemeinde Horka nördlich der Bahnstrecke DB6207 'Roßlau (Elbe) – Horka – Grenze DE/PL',
    - Gemeinde Neißeau nördlich der Bahnstrecke DB6207 'Roßlau (Elbe) – Horka – Grenze DE/PL',
    - Gemeinde Niesky östlich der B115 und nördlich der Bahnstrecke DB6207 'Roßlau (Elbe) – Horka – Grenze DE/PL',

- Gemeinde Rietschen östlich der B115,
- Gemeinde Rothenburg/O.L. nördlich der Bahnstrecke DB6207 'Roßlau (Elbe) – Horka – Grenze DE/PL',
- Gemeinde Weißkeißel östlich der B115 sowie Gebiet westlich der B115 und nördlich der S126 (Friedhof).

## PART III

**1. Bulgaria**

The following restricted zones III in Bulgaria:

- the whole region of Blagoevgrad,
- the whole region of Dobrich,
- the whole region of Gabrovo,
- the whole region of Kardzhali,
- the whole region of Lovech,
- the whole region of Montana,
- the whole region of Pleven,
- the whole region of Razgrad,
- the whole region of Ruse,
- the whole region of Shumen,
- the whole region of Silistra,
- the whole region of Sliven,
- the whole region of Sofia city,
- the whole region of Sofia Province,
- the whole region of Targovishte,
- the whole region of Vidin,
- the whole region of Varna,
- the whole region of Veliko Tarnovo,
- the whole region of Vratza,
- in Burgas region:
  - the whole municipality of Burgas,
  - the whole municipality of Kameno,
  - the whole municipality of Malko Tarnovo,
  - the whole municipality of Primorsko,
  - the whole municipality of Sozopol,
  - the whole municipality of Sredets,
  - the whole municipality of Tsarevo,
  - the whole municipality of Sungurlare,
  - the whole municipality of Ruen,
  - the whole municipality of Aytos.

**2. Latvia**

The following restricted zones III in Latvia:

- Aizputes novada Kalvenes pagasta daļa uz austrumiem no ceļa pie Vārtājas upes līdz autoceļam A9, uz ziemeļiem no autoceļa A9, uz austrumiem no autoceļa V1200, Kazdangas pagasta daļa uz austrumiem no ceļa V1200, P115, P117, V1296,

- Kuldīgas novada, Laidu pagasta daļa uz dienvidiem no autoceļa V1296,
- Skrundas novada Rudbāržu, Nīkrāces pagasts, Raņķu pagasta daļa uz dienvidiem no autoceļa V1272 līdz robežai ar Ventas upi, Skrundas pagasts (izņemot pagasta daļa no Skrundas uz ziemeļiem no autoceļa A9 un austrumiem no Ventas upes), Skrundas pilsēta,
- Vaiņodes novada Embūtes pagasta daļa uz ziemeļiem autoceļa P116, P106.

### 3. Lithuania

The following restricted zones III in Lithuania:

- Jurbarko rajono savivaldybė: Seredžiaus ir Juodaičių seniūnijos,
- Kauno rajono savivaldybė: Čekiškės seniūnija, Babtų seniūnijos dalis į vakarus nuo kelio A1 ir Vilkijos apylinkių seniūnijos dalis į rytus nuo kelio Nr. 1907,
- Kėdainių rajono savivaldybė: Pernaravos seniūnija ir Josvainių seniūnijos pietvakarinė dalis tarp kelio Nr. 229 ir Nr. 2032,
- Plungės rajono savivaldybė: Alsėdžių, Babrungo, Paukštakių, Platelių ir Žemaičių Kalvarijos seniūnijos,
- Raseinių rajono savivaldybė: Ariogalos ir Ariogalos miesto seniūnijos,
- Skuodo rajono savivaldybės: Barstyčių, Notėnų ir Šačių seniūnijos.

### 4. Poland

The following restricted zones III in Poland:

w województwie warmińsko-mazurskim:

- gminy Bisztynek i Bartoszyce z miastem Bartoszyce w powiecie bartoszyckim,
- gminy Kiwity i Lidzbark Warmiński z miastem Lidzbark Warmiński w powiecie lidzbarskim,
- gminy Łukta, Morąg, Miłakowo, część gminy Małydy położona na wschód od linii wyznaczonej przez drogę nr S7, część gminy Miłomłyn położona na wschód od linii wyznaczonej przez drogę nr S7, część gminy wiejskiej Ostróda położona na wschód od linii wyznaczonej przez drogę nr S7 oraz na północ od drogi nr 16, część miasta Ostróda położona na wschód od linii wyznaczonej przez drogę nr w powiecie ostródzkim,
- powiat olecki,
- gminy Barczewo, Gietrzwałd, Jeziorany, Jonkowo, Dywity, Dobre Miasto, Purda, Stawiguda, Świątki, część gminy Olsztynek położona na północ od linii wyznaczonej przez drogę nr S51 biegnącą od wschodniej granicy gminy do miejscowości Ameryka oraz na wschód od linii wyznaczonej przez drogę biegnącą od skrzyżowania z drogą S51 do północnej granicy gminy, łączącej miejscowości Mańki – Mycyny – Ameryka w powiecie olsztyńskim,
- powiat miejski Olsztyn,

w województwie podlaskim:

- część gminy Bakałarzewo położona na południe od linii wyznaczonej przez drogę 653 biegnącej od zachodniej granicy gminy do skrzyżowania z drogą 1122B oraz na zachód od linii wyznaczonej przez drogę nr 1122B biegnącą od drogi 653 w kierunku południowym do skrzyżowania z drogą 1124B i następnie na południowy – zachód od drogi nr 1124B biegnącej od skrzyżowania z drogą 1122B do granicy z gminą Raczki w powiecie suwalskim,

w województwie mazowieckim:

- gminy Łaskarzew z miastem Łaskarzew, Maciejowice, Sobolew, Trojanów, Żelechów, część gminy Wilga położona na południe od linii wyznaczonej przez rzekę Wilga biegnącą od wschodniej granicy gminy do ujścia do rzeki Wisły, część gminy Górzno położona na południe od linii wyznaczonej przez drogę łączącą miejscowości Łąki i Górzno biegnącą od wschodniej granicy gminy, następnie od miejscowości Górzno na południe od drogi nr 1328W biegnącej od drogi nr 17, a następnie na południe od linii wyznaczonej przez drogę biegnącą od drogi nr 17 do zachodniej granicy gminy przez miejscowości Józefów i Kobyła Wola w powiecie garwolińskim,

- część gminy Iłża położona na wschód od linii wyznaczonej przez drogę nr 9 w powiecie radomskim,
  - gmina Kazanów w powiecie zwoleńskim,
  - gminy Ciepeliów, Lipsko, Rzecznów i Sienno w powiecie lipskim,
- w województwie lubelskim:
- powiat tomaszowski,
  - gminy Białopole, Dubienka, Kamień, Żmudź, część gminy Dorohusk położona na południe od linii wyznaczonej przez linię kolejową, część gminy Wojsławice położona na wschód od linii wyznaczonej przez drogę 1839L, część gminy Leśniowice położona na wschód od linii wyznaczonej przez drogę 1839L w powiecie chełmskim,
  - gmina Rudnik i część gminy Żółkiewka położona na południe od linii wyznaczonej przez drogę nr 842 w powiecie krasnostawskim,
  - powiat zamojski,
  - powiat miejski Zamość,
  - powiat biłgorajski,
  - powiat hrubieszowski,
  - gminy Dzwola i Chrzanów w powiecie janowskim,
  - gmina Serokomla w powiecie łukowskim,
  - gminy Abramów, Kamionka, Michów, Lubartów z miastem Lubartów, Firlej, Jeziorzany, Kock, Ostrówek w powiecie lubartowskim,
  - gminy Kłoczew, Stężycza, Ułęż i część gminy Ryki położona na północ od linii wyznaczonej przez linię kolejową w powiecie ryckim,
  - gmina Baranów w powiecie puławskim,
- w województwie podkarpackim:
- gminy Cieszanów, Horyniec – Zdrój, Narol i Stary Dzików w powiecie lubaczowskim,
  - gminy Kuryłówka, Nowa Sarzyna, miasto Leżajsk, część gminy wiejskiej Leżajsk położona na północ od miasta Leżajsk oraz część gminy wiejskiej Leżajsk położona na wschód od linii wyznaczonej przez rzekę San, w powiecie leżajskim,
  - gminy Krzeszów, Rudnik nad Sanem, część gminy Harasiuki położona na południe od linii wyznaczonej przez drogę nr 1048 R, część gminy Ulanów położona na południe od linii wyznaczonej przez rzekę Tanew, część gminy Nisko położona na wschód od linii wyznaczonej przez drogę nr 19 oraz na południe od linii wyznaczonej przez linię kolejową biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 19, część gminy Jeżowe położona na wschód od linii wyznaczonej przez drogę nr 19 w powiecie niżańskim,
  - gminy Chłopice, Jarosław z miastem Jarosław, Laszki, Wiązownica, Pawłosiów, Radymno z miastem Radymno, w powiecie jarosławskim,
  - gmina Stubno w powiecie przemyskim,
  - część gminy Kamień położona na wschód od linii wyznaczonej przez drogę nr 19 w powiecie rzeszowskim,
  - gminy Adamówka, Sieniawa, Tryńcza, miasto Przeworsk, część gminy wiejskiej Przeworsk położona na wschód od miasta Przeworsk i na wschód od linii wyznaczonej przez autostradę A4 biegnącą od granicy z gminą Tryńcza do granicy miasta Przeworsk, część gminy Zarzecze położona na wschód od linii wyznaczonej przez drogę nr 1594R biegnącą od północnej granicy gminy do miejscowości Zarzecze oraz na północ od linii wyznaczonej przez drogi nr 1617R oraz 1619R biegnącą do południowej granicy gminy w powiecie przeworskim,

w województwie lubuskim:

- gminy Nowa Sól i miasto Nowa Sól, Otyń oraz część gminy Kozuchów położona na północ od linii wyznaczonej przez drogę nr 283 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 290 i na północ od linii wyznaczonej przez drogę nr 290 biegnącej od miasta Mirocin Dolny do zachodniej granicy gminy, część gminy Bytom Odrzański położona na południowy wschód od linii wyznaczonej przez drogi nr 293 i 326, część gminy Nowe Miasteczko położona na wschód od linii wyznaczonych przez drogi 293 i 328, część gminy Siedlisko położona na południowy wschód od linii wyznaczonej przez drogę biegnącą od rzeki Odry przy południowe granicy gminy do drogi nr 326 łączącej się z drogą nr 325 biegnącą w kierunku miejscowości Różanówka do skrzyżowania z drogą nr 321 biegnącą od tego skrzyżowania w kierunku miejscowości Bielawy, a następnie przedłużoną przez drogę przeciwpożarową biegnącą od drogi nr 321 w miejscowości Bielawy do granicy gminy w powiecie nowosolskim,
- gminy Babimost, Czerwieńsk, Kargowa, Świdnica, Zabór, część gminy Bojadła położona na południe od linii wyznaczonej przez drogę nr 278 biegnącą od wschodniej granicy gminy do skrzyżowania z drogą nr 282 i na południe od linii wyznaczonej przez drogę nr 282 biegnącej od miasta Bojadła do zachodniej granicy gminy i część gminy Sulechów położona na zachód od linii wyznaczonej przez drogę nr S3 w powiecie zielonogórskim,
- część gminy Niegosławice położona na wschód od linii wyznaczonej przez drogę nr 328 w powiecie żagańskim,
- powiat miejski Zielona Góra,
- gminy Skąpe, Szczaniec i Zbąszynek w powiecie świebodzińskim,
- gminy Bobrowice, Dąbie, Krosno Odrzańskie i część gminy Bytnica położona na wschód od linii wyznaczonej przez drogę nr 1157F w powiecie krośnieńskim,
- część gminy Trzciel położona na południe od linii wyznaczonej przez drogę nr 92 w powiecie międzyrzeckim,

w województwie wielkopolskim:

- gmina Zbąszyń, część gminy Miedzichowo położona na południe od linii wyznaczonej przez drogę nr 92, część gminy Nowy Tomyśl położona na zachód od linii wyznaczonej przez drogę nr 305 w powiecie nowotomyskim,
- gmina Siedlec w powiecie wolsztyńskim,
- część gminy Rakoniewice położona na wschód od linii wyznaczonej przez drogę nr 305 w powiecie grodziskim,
- gminy Chocz, Czermin, Gołuchów, Pleszew i część gminy Gizałki położona na południe od linii wyznaczonej przez drogę nr 443 w powiecie pleszewskim,
- część gminy Grodziec położona na południe od linii wyznaczonej przez drogę nr 443 w powiecie konińskim,
- gminy Blizanów, Stawiszyn, Żelazków w powiecie kaliskim,

w województwie dolnośląskim:

- gminy Jerzmanowa, Żukowice, część gminy Kotła położona na południe od linii wyznaczonej przez rzekę Krzycki Rów, część gminy wiejskiej Głogów położona na zachód od linii wyznaczonej przez drogi nr 12, 319 oraz 329, część miasta Głogów położona na zachód od linii wyznaczonej przez drogę nr 12 w powiecie głogowskim,
- gminy Gaworzycze, Radwanice i część gminy Przemków położona na północ od linii wyznaczonej przez drogę nr 12 w powiecie polkowickim,

w województwie świętokrzyskim:

- część gminy Brody położona na wschód od linii kolejowej biegnącej od miejscowości Marcule i od północnej granicy gminy przez miejscowości Klepacze i Karczma Kunowska do południowej granicy gminy w powiecie starachowickim.

## 5. Romania

The following restricted zones III in Romania:

- Zona oraşului Bucureşti,
- Judeţul Constanţa,
- Judeţul Satu Mare,
- Judeţul Tulcea,
- Judeţul Bacău,
- Judeţul Bihor,
- Judeţul Bistriţa Năsăud,
- Judeţul Brăila,
- Judeţul Buzău,
- Judeţul Călăraşi,
- Judeţul Dâmboviţa,
- Judeţul Galaţi,
- Judeţul Giurgiu,
- Judeţul Ialomiţa,
- Judeţul Ilfov,
- Judeţul Prahova,
- Judeţul Sălaj,
- Judeţul Suceava
- Judeţul Vaslui,
- Judeţul Vrancea,
- Judeţul Teleorman,
- Judeţul Mehedinţi,
- Judeţul Gorj,
- Judeţul Argeş,
- Judeţul Olt,
- Judeţul Dolj,
- Judeţul Arad,
- Judeţul Timiş,
- Judeţul Covasna,
- Judeţul Braşov,
- Judeţul Botoşani,
- Judeţul Vâlcea,
- Judeţul Iaşi,
- Judeţul Hunedoara,
- Judeţul Alba,
- Judeţul Sibiu,
- Judeţul Caraş-Severin,
- Judeţul Neamţ,
- Judeţul Harghita,
- Judeţul Mureş,
- Judeţul Cluj,
- Judeţul Maramureş.

**6. Slovakia**

The following restricted zones III in Slovakia:

- the whole district of Trebišov.

**7. Italy**

The following restricted zones III in Italy:

tutto il territorio della Sardegna.

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## ANNEX II

**REINFORCED BIOSECURITY MEASURES FOR ESTABLISHMENTS OF KEPT PORCINE ANIMALS LOCATED IN RESTRICTED ZONES I, II AND III**

(as referred to in Article 16(1)(b)(i))

1. The following reinforced biosecurity measures, as referred to in Article 16(1)(b)(i) shall apply to establishments of kept porcine animals located in restricted zones I, II and III situated in the Member States concerned in the case of authorised movements of consignments of:
  - (a) porcine animals kept in restricted zones I, II and III outside those zones as provided for in Articles 22, 23, 24, 25, 28 and 29;
  - (b) germinal products obtained from porcine animals kept in restricted zone II outside that zone as provided for in Articles 31 and 32;
  - (c) animal by-products obtained from porcine animals kept in restricted zone II outside that zone as provided for in Articles 35 and 37;
  - (d) fresh meat, meat products, including casings, obtained from porcine animals kept in restricted zones II and III outside those zones as provided for in Articles 38, 39 and 40.
  
2. The operators of establishments of kept porcine animals located in restricted zones I, II and III situated in the Member States concerned in the case of authorised movements outside those zones shall ensure that the following reinforced biosecurity measures are applied in establishments of kept porcine animals:
  - (a) there must be no direct or indirect contact between kept porcine animals and at least:
    - (i) other kept porcine animals from other establishments;
    - (ii) wild porcine animals;
  - (b) appropriate hygienic measures such as a change of clothes and footwear on entering and leaving the premises where porcine animals are kept;
  - (c) washing and disinfection of hands and disinfection of footwear at the entrance to the premises where porcine animals are kept;
  - (d) the absence of any contact with kept porcine animals for a period of at least 48 hours after any hunting activity related to wild porcine animals or any other contact with wild porcine animals;
  - (e) a prohibition on unauthorized persons or means of transport entering the establishment, including the premises, where porcine animals are kept;
  - (f) adequate record-keeping of persons and means of transport accessing the establishment where the porcine animals are kept;
  - (g) the premises and buildings of the establishment where porcine animals are kept must:
    - (i) be built in such a way that no other animals can enter the premises and buildings or have contact with the kept porcine animals or their feed and bedding material;
    - (ii) allow for the washing and disinfection of hands;
    - (iii) allow for the cleaning and disinfection of the premises;
    - (iv) have appropriate changing facilities for footwear and clothes at the entrance to the premises where porcine animals are kept;
  - (h) stock-proof fencing of at least the premises where the porcine animals are kept and buildings where feed and bedding are kept;
  - (i) a biosecurity plan approved by the competent authority of the Member State concerned taking account of the profile of the establishment and national legislation must be in place; that biosecurity plan shall at least include:
    - (i) the establishment of the 'clean' and 'dirty' areas for personnel appropriate to the farm typology, such as changing rooms, shower, dining room;
    - (ii) the setting up and the review, when applicable, of the logistical arrangements for the entry of new kept porcine animals into the establishment;

- (iii) the procedures for the cleaning and disinfection of the facilities, transport, equipment and personnel hygiene;
  - (iv) rules on food for personnel on site and a prohibition on the keeping of porcine animals by the personnel, where relevant and if applicable;
  - (v) dedicated recurrent awareness programme for personnel on the establishment;
  - (vi) the setting up and the review, when applicable, of logistical arrangements in order to ensure a proper separation between different epidemiological units and to avoid porcine animals being in contact, directly or indirectly, with animal by-products and other units;
  - (vii) the procedures and instructions for enforcement of biosecurity requirements during the construction or repair of the premises or buildings;
  - (viii) internal audit or self-evaluation for enforcing the biosecurity measures.
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**COMMISSION IMPLEMENTING REGULATION (EU) 2021/606**  
**of 14 April 2021**

**amending Annex I, Annexes IV to XIII, and Annex XVI to Implementing Regulation (EU) 2021/405 as regards the entries of Belarus and of the United Kingdom and the Crown Dependencies of Guernsey, the Isle of Man and Jersey in the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption**

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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) <sup>(1)</sup>, and in particular Article 127(2) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) 2019/625 <sup>(2)</sup> supplements Regulation (EU) 2017/625 as regards the conditions for the entry into the Union of consignments of certain animals and goods intended for human consumption from third countries or regions thereof, in order to ensure that they comply with the applicable requirements established in the rules on food safety referred to in Article 1(2)(a) of Regulation (EU) 2017/625 or with requirements recognised to be at least equivalent. Those conditions include the identification of the animals and goods intended for human consumption which can only enter the Union from third countries or regions listed in accordance with Article 126(2)(a) of Regulation (EU) 2017/625.
- (2) Commission Regulations (EC) No 798/2008 <sup>(3)</sup>, (EC) No 119/2009 <sup>(4)</sup>, (EU) No 206/2010 <sup>(5)</sup> and (EU) No 605/2010 <sup>(6)</sup>, which are repealed as from 21 April 2021 by Commission Delegated Regulation (EU) 2020/692 <sup>(7)</sup>, and Commission Implementing Regulation (EU) 2019/626 <sup>(8)</sup>, which is repealed as from 21 April 2021 by Commission Implementing

<sup>(1)</sup> OJ L 95, 7.4.2017, p. 1.

<sup>(2)</sup> Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (OJ L 131, 17.5.2019, p. 18).

<sup>(3)</sup> Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements (OJ L 226, 23.8.2008, p. 1).

<sup>(4)</sup> Commission Regulation (EC) No 119/2009 of 9 February 2009 laying down a list of third countries or parts thereof, for imports into, or transit through, the Community of meat of wild leporidae, of certain wild land mammals and of farmed rabbits and the veterinary certification requirements (OJ L 39, 10.2.2009, p. 12).

<sup>(5)</sup> Commission Regulation (EU) No 206/2010 of 12 March 2010 laying down lists of third countries, territories or parts thereof authorised for the introduction into the European Union of certain animals and fresh meat and the veterinary certification requirements (OJ L 73, 20.3.2010, p. 1).

<sup>(6)</sup> Commission Regulation (EU) No 605/2010 of 2 July 2010 laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk and dairy products, colostrum and colostrum-based products intended for human consumption (OJ L 175, 10.7.2010, p. 1).

<sup>(7)</sup> Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

<sup>(8)</sup> Commission Implementing Regulation (EU) 2019/626 of 5 March 2019 concerning lists of third countries or regions thereof authorised for the entry into the European Union of certain animals and goods intended for human consumption, amending Implementing Regulation (EU) 2016/759 as regards these lists (OJ L 131, 17.5.2019, p. 31).

Regulation (EU) 2021/405 <sup>(9)</sup>, lay down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods. Implementing Regulation (EU) 2021/405, which applies from 21 April 2021, replaces the lists concerning food safety requirements in Commission Regulations (EC) No 798/2008, (EC) No 119/2009, (EU) No 206/2010 and (EU) No 605/2010, as well as in Implementing Regulation (EU) 2019/626.

- (3) Belarus is included in the list of third countries from which entry into the Union is permitted of fishery products other than bivalve molluscs, echinoderms, tunicates and marine gastropods set out in Annex II to Implementing Regulation (EU) 2019/626, and has a residue monitoring plan for aquaculture approved in accordance with Article 1 of Commission Decision 2011/163/EU <sup>(10)</sup>. There is therefore appropriate evidence and guarantees to ensure that Belarus fulfils the requirements of points (a) to (f) of Article 4 of Delegated Regulation (EU) 2019/625 for the entry into the Union of fishery products, including those from aquaculture, other than bivalve molluscs, echinoderms, tunicates and marine gastropods. The remark 'only wild catch' currently associated with Belarus in the list set out in Annex IX to Implementing Regulation (EU) 2021/405 should be removed in order to authorise the entry into the Union of fishery products from aquaculture from that third country.
- (4) Regulations (EC) No 798/2008, (EC) No 119/2009, (EU) No 206/2010 and (EU) No 605/2010 and Implementing Regulation (EU) 2019/626 were amended as regards the entries of the United Kingdom and the Crown Dependencies of Guernsey, the Isle of Man and Jersey in the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption by Commission Implementing Regulations (EU) 2020/2205 <sup>(11)</sup>, (EU) 2020/2206 <sup>(12)</sup>, (EU) 2020/2204 <sup>(13)</sup>, (EU) 2020/2207 <sup>(14)</sup> and (EU) 2020/2209 <sup>(15)</sup>, respectively.
- (5) Implementing Regulation (EU) 2021/405 did not include the United Kingdom and the Crown Dependencies of Guernsey, the Isle of Man and Jersey in those lists. That Implementing Regulation should therefore be amended to include those entries.
- (6) The United Kingdom has provided appropriate evidence and guarantees to ensure that the animals and goods authorised for entry into the Union from the United Kingdom and the Crown Dependencies of Guernsey, the Isle of Man and Jersey comply with the requirements laid down in points (a) to (e) of Article 4 of Delegated Regulation (EU) 2019/625.

<sup>(9)</sup> Commission Implementing Regulation (EU) 2021/405 of 24 March 2021 laying down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 118).

<sup>(10)</sup> Commission Decision 2011/163/EU of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (OJ L 70, 17.3.2011, p. 40).

<sup>(11)</sup> Commission Implementing Regulation (EU) 2020/2205 of 22 December 2020 amending Annex I to Regulation (EC) No 798/2008 as regards the entries for the United Kingdom and the Crown Dependency of Guernsey in the list of third countries, territories, zones or compartments from which consignments of poultry and poultry products may be introduced into or transit through the Union (OJ L 438, 28.12.2020, p. 11).

<sup>(12)</sup> Commission Implementing Regulation (EU) 2020/2206 of 22 December 2020 amending Annex I to Regulation (EC) No 119/2009 as regards the entry for the United Kingdom in the list of third countries or parts thereof authorised for the introduction into the Union of consignments of meat of wild leporidae, of certain wild land mammals and of farmed rabbits (OJ L 438, 28.12.2020, p. 15).

<sup>(13)</sup> Commission Implementing Regulation (EU) 2020/2204 of 22 December 2020 amending Annexes I and II to Regulation (EU) No 206/2010 as regards the entries for the United Kingdom and the Crown Dependencies in the lists of third countries, territories or parts thereof authorised for the introduction into the Union of certain animals and fresh meat (OJ L 438, 28.12.2020, p. 7).

<sup>(14)</sup> Commission Implementing Regulation (EU) 2020/2207 of 22 December 2020 amending Annex I to Regulation (EU) No 605/2010 as regards the entries for the United Kingdom and the Crown Dependencies in the list of third countries or parts thereof authorised for the introduction into the Union of raw milk, dairy products, colostrum and colostrum-based products intended for human consumption (OJ L 438, 28.12.2020, p. 18).

<sup>(15)</sup> Commission Implementing Regulation (EU) 2020/2209 of 22 December 2020 amending Annexes I, II and III to Implementing Regulation (EU) 2019/626 as regards the entries of the United Kingdom and the Crown Dependencies in the list of third countries or regions thereof authorised for the entry into the European Union of certain animals and goods intended for human consumption (OJ L 438, 28.12.2020, p. 24).

- (7) Point (f) of Article 4 of Delegated Regulation (EU) 2019/625 provides that the existence, implementation and communication of a residues control programme approved by the Commission, when applicable, is a further requirement for the inclusion of third countries or regions thereof in the list referred to in Article 126(2)(a) of Regulation (EU) 2017/625. The list of third countries whose residue monitoring plans have been approved is set out in the Annex to Decision 2011/163/EU, which has been amended as regards the approval of residue monitoring plans submitted by the United Kingdom and the Crown Dependencies of Guernsey, the Isle of Man and Jersey by Commission Implementing Decision (EU) 2020/2218 <sup>(16)</sup>.
- (8) Taking into account the evidence and guarantees provided by the United Kingdom, that third country and the Crown Dependencies of Guernsey, the Isle of Man and Jersey should be included in Annex I, Annexes IV to XIII, and Annex XVI to Implementing Regulation (EU) 2021/405, without prejudice to the application of Union law to and in the United Kingdom in respect of Northern Ireland in accordance with Article 5(4) of the Protocol on Ireland/Northern Ireland to the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community in conjunction with Annex 2 to that Protocol. A re-assessment of compliance with the requirements laid down in points (a) to (f) of Article 4 of Delegated Regulation (EU) 2019/625 is not necessary.
- (9) Annex I, Annexes IV to XIII, and Annex XVI to Implementing Regulation (EU) 2021/405 should therefore be amended accordingly.
- (10) As Implementing Regulation (EU) 2021/405 applies from 21 April 2021, this Regulation should apply from the same date.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

#### *Article 1*

Annex I, Annexes IV to XIII, and Annex XVI to Implementing Regulation (EU) 2021/405 are amended in accordance with the Annex to this Regulation.

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<sup>(16)</sup> Commission Implementing Decision (EU) 2020/2218 of 22 December 2020 amending the Annex to Decision 2011/163/EU as regards the approval of residue monitoring plans submitted by the United Kingdom and the Crown Dependencies (OJ L 438, 28.12.2020, p. 63).

*Article 2*

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

It shall apply from 21 April 2021.

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

Done at Brussels, 14 April 2021.

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

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## ANNEX

Annex I, Annexes IV to XIII, and Annex XVI to Implementing Regulation (EU) 2021/405 are amended as follows:

- (1) in Annex I, the following entry is inserted between the entries for Switzerland and New Zealand:

'GB	United Kingdom (*)	
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(\*) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex references to the United Kingdom do not include Northern Ireland.;

- (2) in Annex IV, the following entry is inserted between the entries for Switzerland and Japan:

'GB	United Kingdom (*)	
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(\*) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex references to the United Kingdom do not include Northern Ireland.;

- (3) in Annex V, the following entry is inserted between the entries for China and North Macedonia:

'GB	United Kingdom (*)	
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(\*) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex references to the United Kingdom do not include Northern Ireland.;

- (4) in Annex VI, the following entry is inserted between the entries for Canada and Greenland:

'GB	United Kingdom (*)	
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(\*) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex references to the United Kingdom do not include Northern Ireland.;

- (5) in Annex VII, the following entry is inserted between the entries for China and Greenland:

'GB	United Kingdom (*)	A	A	A	A	A
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(\*) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex references to the United Kingdom do not include Northern Ireland.;

- (6) Annex VIII is amended as follows:

- (a) the following entries are inserted between the entries for Chile and Greenland:

'GB	United Kingdom (*)	
GG	Guernsey	Only wild catch

(\*) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex references to the United Kingdom do not include Northern Ireland.;

- (b) the following entries are inserted between the entries for Greenland and Jamaica:

'IM	Isle of Man	
JE	Jersey	Only wild catch'

- (7) Annex IX is amended as follows:

- (a) the entry for Belarus is replaced by the following:

'BY	Belarus'	
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- (b) the following entry is inserted between the entries for Gabon and Grenada:

'GB	United Kingdom (*)	
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(\*) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex references to the United Kingdom do not include Northern Ireland.;

- (c) the following entry is inserted between the entries for Georgia and Ghana:

'GG	Guernsey	Only wild catch'
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- (d) the following entry is inserted between the entries for Israel and India:

'IM	Isle of Man'	
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- (e) the following entry is inserted between the entries for Iran and Jamaica:

'JE	Jersey	Only wild catch'
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- (8) in Annex X, the following entries are inserted between the entries for Switzerland and Japan:

'GB	United Kingdom (*)	
GG	Guernsey	
IM	Isle of Man	
JE	Jersey	

(\*) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex references to the United Kingdom do not include Northern Ireland.;

- (9) Annex XI is amended as follows:

- (a) the following entries are inserted between the entries for Egypt and Ghana:

'GB	United Kingdom (*)	
GG	Guernsey	

(\*) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex references to the United Kingdom do not include Northern Ireland.;

- (b) the following entry is inserted between the entries for Indonesia and India:

'IM	Isle of Man'	
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- (c) the following entry is inserted between the entries for India and Morocco:

'JE	Jersey'	
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(10) Annex XII is amended as follows:

(a) the following entries are inserted between the entries for Falkland Islands and Greenland:

'GB	United Kingdom (*)	
GG	Guernsey	

(\*) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex references to the United Kingdom do not include Northern Ireland.;

(b) the following entry is inserted between the entries for Israel and India:

'IM	Isle of Man'	
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(c) the following entry is inserted between the entries for India and Japan:

'JE	Jersey'	
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(11) in Annex XIII, the following entries are inserted between the entries for China and Greenland:

'GB	United Kingdom (*)	
GG	Guernsey	

(\*) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex references to the United Kingdom do not include Northern Ireland.;

(12) in Annex XVI, the following entries are inserted between the entries for Switzerland and Israel:

'GB	United Kingdom (*)	BPP, DOC, HEP	BPP, DOC, HEP
GG	Guernsey	BPP	BPP

(\*) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex references to the United Kingdom do not include Northern Ireland.;

**COMMISSION IMPLEMENTING REGULATION (EU) 2021/607****of 14 April 2021****imposing a definitive anti-dumping duty on imports of citric acid originating in the People's Republic of China as extended to imports of citric acid consigned from Malaysia, whether declared as originating in Malaysia or not, following an expiry review pursuant to Article 11(2) of Regulation (EU) 2016/1036 of the European Parliament and of the Council**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/1036 of the European Parliament and of the Council of 8 June 2016 on protection against dumped imports from countries not members of the European Union <sup>(1)</sup> ('the basic Regulation'), and in particular Article 11(2) thereof,

Whereas:

**1. PROCEDURE****1.1. Previous investigations and measures in force**

- (1) By Regulation (EC) No 1193/2008 <sup>(2)</sup> the Council imposed anti-dumping duties on imports of citric acid, originating in the People's Republic of China ('PRC', 'China or the 'country concerned') ('the original measures'). The investigation that led to the imposition of the original measures will be referred to as 'the original investigation'. The measures took the form of an *ad valorem* duty ranging from 6,6 % to 42,7 %.
- (2) By Decision 2008/899/EC <sup>(3)</sup> the European Commission ('the Commission'), accepted price undertakings offered by six Chinese exporting producers (including a group of exporting producers) together with the China Chamber of Commerce of Metals, Minerals & Chemicals Importers & Exporters ('CCCMC'). The producers were Anhui BBKA Biochemical Co., Ltd. (now COFCO Bio-Chemical Energy (Yushu) Co., Ltd.); Laiwu Taihe Biochemistry Co., Ltd.; RZBC Co., Ltd. and RZBC (Juxian) Co., Ltd.; TTCA Co., Ltd.; Weifang Ensign Industry Co., Ltd. and Yixing Union Biochemical Co., Ltd. (now Jiangsu Guoxin Union Energy Co., Ltd.).
- (3) By Decision 2012/501/EU <sup>(4)</sup> the Commission withdrew the undertaking offered by one exporting producer, i.e. Laiwu Taihe Biochemistry Co. Ltd. ('Laiwu Taihe').
- (4) By Regulation (EU) 2015/82 <sup>(5)</sup> the Commission re-imposed the definitive anti-dumping measures on imports of citric acid originating in the PRC following an expiry review, (the 'previous expiry review').
- (5) By Regulation (EU) 2016/32 <sup>(6)</sup>, the Commission extended the measures on imports of citric acid originating in China to imports of citric acid consigned from Malaysia, whether declared as originating in Malaysia or not.
- (6) By Regulation (EU) 2016/704 <sup>(7)</sup>, the Commission withdrew the undertaking from two more companies based on findings of breaches of the undertaking and its impracticability, both of which justified the withdrawal of the acceptance of the undertaking.
- (7) By Regulation (EU) 2018/1236 <sup>(8)</sup>, the Commission terminated the investigation concerning the possible circumvention on imports of citric acid originating in China by imports of citric acid consigned from Cambodia, whether declared as originating in Cambodia or not.

<sup>(1)</sup> OJ L 176, 30.6.2016, p. 21.<sup>(2)</sup> OJ L 323, 3.12.2008, p. 1.<sup>(3)</sup> OJ L 323, 3.12.2008, p. 62.<sup>(4)</sup> OJ L 244, 8.9.2012, p. 27.<sup>(5)</sup> OJ L 15, 22.1.2015, p. 8.<sup>(6)</sup> OJ L 10, 15.1.2016, p. 3.<sup>(7)</sup> OJ L 122, 12.5.2016, p. 19.<sup>(8)</sup> OJ L 231, 14.9.2018, p. 20.

- (8) The anti-dumping duties currently in force range from 15,3 % to 42,7 % on imports from the cooperating exporting producers and a duty rate of 42,7 % applies to imports from all other companies.

#### 1.2. Request for an expiry review

- (9) Following the publication of a notice of impending expiry <sup>(9)</sup>, the Commission received a request for a review pursuant to Article 11(2) of the basic Regulation.
- (10) The request for review was lodged on 21 October 2019 by N.V. Citrique Belge S.A. and Jungbunzlauer Austria AG (‘the applicants’) on behalf of Union producers representing 100 % of the total Union production of citric acid. The request for review was based on the grounds that the expiry of the measures would likely result in continuation of dumping and recurrence of injury to the Union industry.

#### 1.3. Initiation of an expiry review

- (11) Having determined that sufficient evidence existed for the initiation of an expiry review, and after consulting the Committee established by Article 15(1) of the basic Regulation, the Commission initiated an expiry review regarding imports of citric acid originating in China pursuant to Article 11(2) of the basic Regulation. On 20 January 2020, the Commission published a Notice of Initiation in the *Official Journal of the European Union* <sup>(10)</sup> (‘the Notice of Initiation’).

#### 1.4. Review investigation period and period considered

- (12) The investigation of continuation or recurrence of dumping covered the period from 1 January 2019 to 31 December 2019 (‘review investigation period’ or ‘RIP’). The examination of trends relevant for the assessment of the likelihood of a continuation or recurrence of injury covered the period from 1 January 2016 to the end of the review investigation period (‘the period considered’).

#### 1.5. Interested parties

- (13) In the Notice of Initiation, the Commission invited interested parties to contact it in order to participate in the investigation. In addition, the Commission specifically informed the applicants, the known exporting producers, the Chinese authorities, known importers and users about the initiation of the review and invited them to participate.
- (14) Interested parties also had an opportunity to comment on the initiation of the expiry review and to request a hearing with the Commission and/or the Hearing Officer in trade proceedings.

#### 1.6. Sampling

- (15) In the Notice of Initiation, the Commission stated that it might sample the interested parties in accordance with Article 17 of the basic Regulation.

##### 1.6.1. No sampling of Union producers

- (16) In the Notice of Initiation, the Commission stated that the two known Union producers, N.V. Citrique Belge S.A. and Jungbunzlauer Austria AG, had to submit the completed questionnaire within 37 days of the date of publication of the Notice of Initiation. The Commission also invited other Union producers and representative associations, if any, to make themselves known and request a questionnaire. No other Union producer or representative association came forward.

<sup>(9)</sup> OJ C 165, 14.5.2019, p. 3.

<sup>(10)</sup> Notice of initiation of an expiry review of the anti-dumping measures applicable to imports of citric acid originating in the People’s Republic of China (OJ C 18, 20.1.2020, p. 3).

### 1.6.2. *Sampling of importers*

- (17) To decide whether sampling was necessary and, if so, to select a sample, the Commission asked unrelated importers to provide the information specified in the Notice of Initiation.
- (18) One unrelated importer provided the requested information and agreed to be included in the sample. In view of the low number of replies, the Commission decided that sampling was not necessary.

### 1.6.3. *Sampling of exporting producers in China*

- (19) To decide whether sampling was necessary and, if so, to select a sample, the Commission asked all exporting producers in China to provide the information specified in the Notice of Initiation. In addition, it asked the mission of the People's Republic of China to the European Union to identify and/or contact other exporting producers, if any, that could be interested in participating in the investigation.
- (20) Four exporting producers in the country concerned provided the requested information and agreed to be included in the sample. In view of the low number of replies, the Commission decided that sampling was not necessary.
- (21) Overall, the cooperation of Chinese exporting producers was insufficient. In fact, Laiwu Taihe, the biggest exporting producer accounting for over 53 % of exports from China to the Union, did not cooperate in the present expiry review. The Commission instead used the data of the four cooperating exporting producers.

## 1.7. **Replies to the questionnaire**

- (22) At the initiation, the Commission made the questionnaires for the Union producers, importers, users, and exporting producers in China available in the file for inspection by interested parties and on DG Trade's website<sup>(11)</sup>. In addition, the Commission sent a questionnaire concerning the existence of significant distortions within the meaning of Article 2(6a)(b) of the basic Regulation in China to the Government of the People's Republic of China ("GOC").
- (23) The Commission received questionnaire replies from the applicants, one importer, four users, and four exporting producers. The GOC did not reply to the questionnaire concerning the existence of significant distortions in China.

## 1.8. **Verification**

- (24) Due to the outbreak of the COVID-19 pandemic and the consequent measures taken to deal with the outbreak as detailed in a notice published to the case file ('the COVID-19 Notice'<sup>(12)</sup>), the Commission could not carry out verification visits pursuant to Article 16 of the basic Regulation at the premises of the entities which submitted the questionnaire replies.
- (25) Instead the Commission remotely cross-checked all the information deemed necessary for its determinations. The Commission carried out remote cross-checks of the following companies/parties:

Union producers:

- S.A. Citrique Belge N.V., Tienen, Belgium,
- Jungbunzlauer Austria AG, Vienna, Austria and Jungbunzlauer Ladenburg GmbH, Ladenburg, Germany;

Users:

- Reckitt Benckiser (ENA) BV, Schiphol, the Netherlands,
- Henkel AG & Co. KGaA, Düsseldorf, Germany;

<sup>(11)</sup> Link to the case-specific website: [https://trade.ec.europa.eu/tdi/case\\_details.cfm?id=2432](https://trade.ec.europa.eu/tdi/case_details.cfm?id=2432)

<sup>(12)</sup> Notice available on the case file under number t20.002450.

Exporting producers in China:

- COFCO Bio-Chemical Energy (Yushu) Co. Ltd., Changchun, Jilin Province, People's Republic of China,
- Jiangsu Guoxin Union Energy Co., Ltd., Yixing, Jiangsu Province, People's Republic of China,
- RZBC Group, Rizhao, Shandong Province, People's Republic of China,
- Weifang Ensign Industry Co., Ltd., Weifang, Shandong Province, People's Republic of China.

### 1.9. Procedure for the determination of the normal value under Article 2(6a) of the basic Regulation

- (26) In view of the sufficient evidence available at the initiation of the investigation pointing to the existence of significant distortions in China within the meaning of point (b) of Article 2(6a) of the basic Regulation, the Commission considered it appropriate to initiate the investigation having regard to Article 2(6a) of the basic Regulation.
- (27) Consequently, in order to collect the necessary data for the eventual application of Article 2(6a) of the basic Regulation, in the Notice of Initiation the Commission invited all exporting producers in China to provide the information requested in Annex III to the Notice of the Initiation regarding the inputs used for producing citric acid. Four Chinese exporting producers submitted the relevant information.
- (28) In order to obtain information it deemed necessary for its investigation with regard to the alleged significant distortions within the meaning of point (b) of Article 2(6a) of the basic Regulation, the Commission also sent a questionnaire to the GOC. The GOC, however, did not reply to that questionnaire. Subsequently, the Commission informed the GOC that it would use facts available within the meaning of Article 18 of the basic Regulation for the determination of the existence of the significant distortions in China.
- (29) In the Notice of Initiation, the Commission also invited all interested parties to make their views known, submit information and provide supporting evidence regarding the appropriateness of the application of Article 2(6a) of the basic Regulation within 37 days of the date of publication of the Notice of Initiation in the *Official Journal of the European Union*. In reaction to the Notice of Initiation, CCCMC made comments on the existence of significant distortions. These comments were analysed in detail below under point 3.2.
- (30) In the Notice of Initiation, the Commission also specified that, in view of the evidence available, it might need to select an appropriate representative country pursuant to Article 2(6a)(a), first indent of the basic Regulation for the purpose of determining the normal value based on undistorted prices or benchmarks.
- (31) On 5 March 2020, the Commission published a first note to the file on the sources for the determination of the normal value ('the Note of 5 March 2020') seeking the views of the interested parties on the relevant sources that the Commission might use for the determination of the normal value, in accordance with Article 2(6a)(e) second paragraph of the basic Regulation <sup>(13)</sup>. In that note, the Commission provided a list of all factors of production such as materials, energy and labour used in the production of the product under review by the exporting producers. In addition, based on the criteria guiding the choice of undistorted prices or benchmarks, the Commission identified at that stage Brazil, Colombia and Thailand as possible representative countries. On 13 March 2020, upon the request of CCCMC, the Commission disclosed Annex IV to the Note of 5 March 2020, containing the publicly available Global Trade Atlas ('GTA') <sup>(14)</sup> data that the Commission services proposed to use for the input materials and by-products listed in the Note of 5 March 2020.
- (32) The Commission gave all interested parties the opportunity to comment. The Commission received comments from four Chinese exporting producers, from CCCMC and the applicants. The GOC did not provide any comments.

<sup>(13)</sup> Notice available on the case file under number t20.002149.

<sup>(14)</sup> Trade information database provided by IHS Markit, <https://ihsmarkit.com/products.html>

- (33) The Commission addressed the comments received on the Note of 5 March in the Second Note on the Sources for the Determination of the Normal Value of 30 November 2020 ('the Note of 30 November 2020')<sup>(15)</sup>. The Commission also established a provisional list of factors of production and concluded that, at that stage, it intended to use Colombia as the representative country under Article 2(6a)(a), first indent of the basic Regulation. The Commission invited interested parties to comment and it received comments from the applicants and CCCMC. These comments were analysed in detail below under points 3.3. and 3.4.

## 2. PRODUCT UNDER REVIEW AND LIKE PRODUCT

### 2.1. Product under review

- (34) The product subject to this review is the same as in the original investigation and previous expiry review, namely citric acid and trisodium citrate dihydrate, currently falling under CN codes 2918 14 00 and ex 2918 15 00 (TARIC code 2918 15 00 11 and 2918 15 00 19) ('the product under review').
- (35) Citric acid is used as an acidulant and pH regulator in a wide range of applications, for example home care detergents, beverages, food, cosmetics and pharmaceuticals. Its main raw materials are sugar/molasses, tapioca, corn or glucose (obtained from cereals) and different agents for the submerged microbial fermentation of carbohydrates.

### 2.2. Like product

- (36) As established in the original investigation as well as in the previous expiry review, this expiry review investigation confirmed that the following products have the same basic physical, chemical and technical characteristics as well as the same basic uses:
- the product under review originating in the country concerned,
  - the product produced and sold on the domestic market of the country concerned, and
  - the product produced and sold in the Union by the Union industry.
- (37) Those products were therefore considered to be like products within the meaning of Article 1(4) of the basic Regulation.

### 2.3. Claims regarding product scope

- (38) The Commission did not receive claims regarding the product scope. CCCMC noted in its comments on initiation that the product under review as defined in the Notice of Initiation covers the product types subject to the original measures as well as the types covered by the first expiry review.

## 3. DUMPING

### 3.1. Preliminary remarks

- (39) In accordance with Article 11(2) of the basic Regulation, the Commission examined whether the expiry of the measures in force would be likely to lead to a continuation or recurrence of dumping from China.
- (40) The total declared production capacity of the cooperating exporting producers amounted roughly to 72 % of the total estimated Chinese production capacity. Given the low level of cooperation, the Commission applied Article 18 and based its findings on the Chinese market of citric acid including production, capacity and spare capacity, on facts available.
- (41) The findings in relation to the likelihood of continuation of dumping set out below were based in particular on the information contained in the request for review, the statistics based on the data reported to the Commission by the Member States in accordance with Article 14(6) of the basic Regulation ('Article 14(6) database'), as well as the sampling replies provided at the time of initiation and the questionnaire replies. In addition, the Commission used other sources of publicly available information such as the GTA and the Orbis Bureau van Dijk<sup>(16)</sup> ('Orbis') databases.

<sup>(15)</sup> Notice available on the case file under number t20.007937.

<sup>(16)</sup> Company financial database provided by Bureau van Dijk, [www.bvdinfo.com](http://www.bvdinfo.com)

### 3.2. Normal value

- (42) According to Article 2(1) of the basic Regulation, 'the normal value shall normally be based on the prices paid or payable, in the ordinary course of trade, by independent customers in the exporting country'.
- (43) However, Article 2(6a)(a) of the basic Regulation stipulates that in case it is determined that it is not appropriate to use domestic prices and costs in the exporting country due to the existence in that country of significant distortions within the meaning of point (b), the normal value shall be constructed exclusively on the basis of costs of production and sale reflecting undistorted prices or benchmarks, and shall include an undistorted and reasonable amount of administrative, selling and general costs and for profits.
- (44) As further explained below, the Commission concluded in the present investigation that, based on the evidence available and in view of the lack of cooperation of the GOC, the application of Article 2(6a) of the basic Regulation was appropriate.

#### 3.2.1. Existence of significant distortions

##### 3.2.1.1. Introduction

- (45) Article 2(6a)(b) of the basic Regulation defines 'significant distortions are those distortions which occur when reported prices or costs, including the costs of raw materials and energy, are not the result of free market forces as they are affected by substantial government intervention. In assessing the existence of significant distortions regard shall be had, inter alia, to the potential impact of one or more of the following elements:
- 'the market in question being served to a significant extent by enterprises which operate under the ownership, control or policy supervision or guidance of the authorities of the exporting country,
  - state presence in firms allowing the state to interfere with respect to prices or costs,
  - public policies or measures discriminating in favour of domestic suppliers or otherwise influencing free market forces,
  - the lack, discriminatory application or inadequate enforcement of bankruptcy, corporate or property laws,
  - wage costs being distorted,
  - access to finance granted by institutions which implement public policy objectives or otherwise not acting independently of the state'.
- (46) According to Article 2(6a)(b) of the basic Regulation, the assessment of the existence of significant distortions within the meaning of Article 2(6a)(a) shall take into account, amongst others, the non-exhaustive list of elements in the former provision. Pursuant to Article 2(6a)(b) of the basic Regulation, in assessing the existence of significant distortions, regard shall be had to the potential impact of one or more of these elements on prices and costs in the exporting country of the product under review. Indeed, as that list is non-cumulative, not all the elements need to be given regard to for a finding of significant distortions. Moreover, the same factual circumstances may be used to demonstrate the existence of one or more of the elements of the list. However, any conclusion on significant distortions within the meaning of Article 2(6a)(a) must be made on the basis of all the evidence at hand. The overall assessment on the existence of distortions may also take into account the general context and situation in the exporting country, in particular where the fundamental elements of the exporting country's economic and administrative set-up provides the government with substantial powers to intervene in the economy in such a way that prices and costs are not the result of the free development of market forces.
- (47) Article 2(6a)(c) of the basic Regulation provides that '[w]here the Commission has well-founded indications of the possible existence of significant distortions as referred to in point (b) in a certain country or a certain sector in that country, and where appropriate for the effective application of this Regulation, the Commission shall produce, make public and regularly update a report describing the market circumstances referred to in point (b) in that country or sector'.



- (48) Pursuant to this provision, the Commission has issued a country report concerning China (hereinafter 'the Report' or 'the China report') <sup>(17)</sup>, showing the existence of substantial government intervention at many levels of the economy, including specific distortions in many key factors of production (such as land, energy, capital, raw materials and labour) as well as in specific sectors (such as steel and chemicals). Interested parties were invited to rebut, comment or supplement the evidence contained in the investigation file at the time of initiation. The Report was placed in the investigation file at the initiation stage.
- (49) The review request submitted by the applicant, on top of reiterating the findings made in the Report, particularly in the chemical sector, contained additional information on the previous US anti-dumping proceedings concerning citric acid and in particular the findings in the most recent proceeding, as published in the Issues and Decision Memorandum for the Final Results of Countervailing Duty Administrative Review: Citric Acid and Certain Citrate Salts, 7 December 2015. In particular, the applicant referred to the findings concerning: policy lending (loans made available to the citric acid industry by state-owned banks with interest rates below the commercial rates); reduced income taxes (citric acid industry benefitting from reduced income taxes and claiming tax credits on the purchase of domestic equipment); cheaper access to auxiliary raw materials, especially chemicals, including sulphuric acid, caustic soda, steam coal, calcium carbonate or lime; land (findings on land use rights obtained for less than adequate remuneration); electricity (finding of the US Department of Commerce that the investigated company was provided with electricity for less than adequate remuneration) as well as subsidies in the form of direct transfer of funds and an environmental tax offset.
- (50) As indicated in recitals (23) and (28) respectively, the GOC did not comment or provide evidence supporting or rebutting the existing evidence on the case file, including the Report and the additional evidence provided by the applicant, on the existence of significant distortions and/or on the appropriateness of the application of Article 2(6a) of the basic Regulation in the case at hand.
- (51) Comments in this regard were received in response to the initiation of the case from CCCMC on behalf CCCMC cooperating member producers.
- (52) First, CCCMC argued that Article 2(6a) of the basic Regulation is inconsistent with WTO law. First, CCCMC claimed that the WTO Anti-Dumping Agreement ('ADA') does not recognise the concept of significant distortions in Article 2.2 ADA, which only allows the construction of the normal value if there are no sales in the ordinary course of trade. CCCMC observed that this Article does not mention significant distortions allowing for the construction of normal value. Second, CCCMC claimed that even if the concept of significant distortions were in accordance with WTO law, the constructed value would need to be calculated in accordance with Article 2.2.1.1 ADA and its interpretation by the WTO Appellate Body in *EU – Biodiesel* (DS478). Third, CCCMC submitted that even though the concept of 'ordinary course of trade' is not explicitly defined in the ADA, Article 2.2.1 provides that sales of a product can be treated as not being in the ordinary course of trade and disregarded 'only if [...] such sales are made within an extended period of time in substantial quantities and are at prices which do not provide for the recovery of all costs [...]'. Fourth, the ADA requires that the normal value must be determined based on the sales prices or costs that reflect the price or cost level in the country of origin. Therefore, the constructed price based on the representative country cannot reflect the price and cost level in the exporting country. According to CCCMC, there is no provision in the WTO law allowing for the use of data from a third country.
- (53) The Commission considered that the provision of Article 2(6a) is fully consistent with the European Union's WTO obligations and the jurisprudence cited by CCCMC. It is the Commission's view that, in accordance with the opinion of the WTO Panel and the Appellate Body in *EU – Biodiesel* (DS473), the provisions of the basic Regulation that apply generally with respect to all WTO Members, in particular Article 2(5), second subparagraph, permit the use of data from a third country, duly adjusted when such adjustment is necessary and substantiated. The existence of significant distortions renders costs and prices in the exporting country inappropriate for the construction of

<sup>(17)</sup> Commission Staff Working Document on Significant Distortions in the Economy of the People's Republic of China for the purposes of Trade Defence Investigations, 20 December 2017, SWD(2017) 483 final/2 (hereafter 'Report').

normal value. In these circumstances, this provision envisages the construction of costs of production and sale on the basis of undistorted prices or benchmarks, including those in an appropriate representative country with a similar level of development as the exporting country. Therefore, the Commission rejected this claim.

- (54) Second, CCCMC submitted that in the case at hand there is no proof of significant distortions. First, CCCMC submitted that the applicants did not provide sufficient evidence of the existence of significant distortions warranting an initiation in accordance with Article 5(3) of the basic Regulation, in particular because the evidence was very general and not specific to the citric acid industry. Second, the Report was published in December 2017, while the RIP in this investigation covered 2019. Therefore, the evidence collected in the Report was outdated and did not reflect the situation of the citric acid industry in the case at hand. Third, in *US – Countervailing Measures (China)* (Article 21.5) (DS437), the Appellate Body found that ‘the existence of price distortion resulting from government intervention has to be established and adequately explained’ and that ‘the determination [...] must be made on a case-by-case basis’. Therefore, CCCMC submitted that the Report was an inadequate source to use as evidence in the citric acid industry, as it describes distortions in the broader chemical industry sector. Fourth, CCCMC argued that the US anti-dumping proceedings mentioned by the applicants are irrelevant in this case, as they concern findings made before the RIP.
- (55) In response, the Commission recalled that point 4.1 of the Notice of Initiation referred to a number of elements in the Chinese citric acid market, to substantiate that the market was affected by the distortions in the Chinese raw materials, petrochemical and chemical sectors. The Commission considered that the evidence listed in the Notice of Initiation was sufficient to warrant initiation of an investigation on the basis of Article 2(6a) of the basic Regulation. Furthermore, while the findings in the dumping investigations conducted by the authorities of other countries do not automatically constitute evidence of distortions in EU anti-dumping investigations, they may contain relevant probative elements to illustrate that there are certain abnormalities in the relevant market of the exporting country, as was the case in this instance with regard to the Chinese citric acid industry.
- (56) Regarding the argument that the Report was outdated, the Commission recalled that so far no evidence was provided showing that the report is outdated. On the contrary, the Commission noted in particular that the main policy documents and evidence contained in the report, including the relevant five-year plans and legislation applicable to the product under review were still relevant during the RIP, and that neither CCCMC nor other parties have proven that this was no longer the case.
- (57) The Commission further recalled that *US – Countervailing Measures (China)* (DS437) did not concern the application of Article 2(6a) of the basic Regulation, which is the relevant legal basis for the determination of normal value in this investigation. That dispute concerned a different factual situation, and concerned the interpretation of the WTO Agreement on Subsidies and Countervailing Measures, not the ADA. In any event, as explained in recitals (49) and (55) above, the evidence put forward clearly related to the Chinese citric acid market and thus to the product under investigation in the case at hand. Therefore, this claim was rejected.
- (58) Regarding the last argument of CCCMC that the findings in the US anti-dumping proceedings were irrelevant in this case, the Commission observes that the evidence listed in the Notice of Initiation by the applicant included also other findings apart from the results of US investigations, particularly a number of evidence based on the Report. This evidence was deemed sufficient to warrant initiation of an investigation on the basis of Article 2(6a) of the basic Regulation. Whereas the US investigation took place before the RIP, the comments provided by the applicants on initiation served as additional supporting indication of irregularities on the Chinese market.
- (59) Furthermore, CCCMC submitted comments on the First Note on the Sources for Determination of Normal Value. In this submission, CCCMC first reiterated its comments made on initiation. Second, it asserted that according to Article 2(6a)(a) of the basic Regulation, only those costs of production and sales which were proven to be distorted should be replaced by undistorted prices or benchmarks. Specifically, CCCMC commented that the applicants failed to prove that the labour costs in China were distorted, hence the Commission should have used the effective labour costs as reported by the exporting producers. CCCMC stated that it was unreasonable to replace the labour costs

with those in a third country, because they were influenced by several factors, such as the supply and demand relationship in the market concerned, the degree of automation in the production and the commodity price level in the region where the producers were located. CCCMC added that the labour costs varied not only between different countries but also between different Chinese producers. Moreover, CCCMC commented that the energy costs varied according to several factors, including the type of energy and its availability in the area, the technology of energy generation, the relationship between supply and demand, etc. Therefore, the prices of energy in one country cannot reflect the price level of energy under normal market condition in another country.

- (60) The Commission noted that once it is determined that due to the existence of significant distortions for the exporting country in accordance with Article 2(6a)(b), it is not appropriate to use domestic prices and costs in the exporting country, the Commission may construct normal using undistorted prices or benchmarks in an appropriate representative country for each exporting producer according to Article 2(6a)(a). Article 2(6a)(a) allows the use of domestic costs only if they are positively established not to be distorted. However, individual labour and energy costs and/or other input costs of production and sale of the product under review could not be established to be undistorted in light of the evidence available. As evidenced in Sections 3.2.1.1 to 3.2.1.9, the Commission has established the existence of significant distortions in the citric acid industry, and there was no positive evidence of the factors of production of individual exporting producers being undistorted.
- (61) In any event, the calculation of the labour and energy costs were based on the respective amount of labour and energy used in the manufacturing process as declared by the exporting producers. Hence, the amount of labour and energy corresponded to the real use of these factors by Chinese producers, whereas only the cost of labour and energy were replaced by the undistorted value from the representative country. While it may be true that the labour and energy costs can vary to some degree between different geographical areas, the Commission uses only costs which are not subject to distortions in an appropriate representative country in accordance with Article 2(6a)(a). The Commission published two notes to the file on the factors of production allowing the parties ample opportunities to comment, including by pointing to any possible abnormalities or other considerations potentially affecting them in the representative country or countries. In this context, interested parties have not questioned the level of labour and/or energy costs in the appropriate representative country set out in the Note of 30 November 2020. Therefore these claims were dismissed.
- (62) Third, CCCMC commented that according to Article 2(6a)(a) of the basic Regulation, the assessment concerning the existence of significant distortions should be done for each exporting producer separately. Therefore, the Commission had the obligation to analyse the situation of each sampled Chinese producer and decide whether any of the factors of costs of production and sales are distorted for each of them.
- (63) The Commission noted that the existence of significant distortions giving rise to the application of Article 2(6a) of the basic Regulation is established on a country-wide level, thus applying to all exporting producers in that country, as is the case here. In any event, as mentioned at recital (60), the same provision of the basic Regulation provides that domestic costs can be used if they are established not to be affected by significant distortions, in which cases they are used for the calculation of normal value. Therefore this claim was dismissed.
- (64) In separate submissions, exporting producers Weifang Ensign Industry, RZBC and Jiangsu Guoxin Union Energy reiterated the claims made by CCCMC on the first note. Furthermore, in a submission by COFCO Bio-Chemical Energy (Yushu), this exporting producer commented that application of Article 2(6a) of the basic Regulation goes against the provision of Article 2.2 of the ADA.
- (65) The Commission noted that the issue of the compatibility of Article 2(6a) with WTO law was already explained in recital (53) above.
- (66) After disclosure, a set of comments on the existence of significant distortions was submitted by CCCMC and by Weifang Ensign Industry, RZBC and Jiangsu Guoxin Union Energy ('the three exporting producers').

- (67) First, CCCMC and the three exporting producers reiterated the claim that Article 2(6a) of the basic Regulation is incompatible with Articles 2.2.1.1 and 2.2 ADA and with the findings made in the following WTO cases: EU – Biodiesel (Argentina) (Panel and AB findings), EU-Biodiesel (Indonesia) (Panel findings), Ukraine – Ammonium Nitrate (Panel and AB findings), Australia – Copy Paper (Panel findings) and EU – Cost Adjustment Methodologies (Panel findings). These parties specifically refer to the findings in the latter Panel report, namely that the alleged Russian government intervention/market distortion did not constitute an adequate basis to conclude that the records of the exporting producers did not reasonably reflect the costs associated with the production and sale of the product concerned.
- (68) The Commission recalled that none of the above quoted WTO cases concerned the application of Article 2(6a) of the basic Regulation and the conditions for its application. Furthermore, the underlying factual situations in those cases are all different from the underlying situation and criteria giving rise to the application of the methodology under this provision of the basic Regulation. As for the WTO dispute EU – Cost Adjustment Methodologies, the Commission recalled that both the EU and Russia appealed the findings of the Panel, which are therefore not final and therefore, according to standing WTO case-law, have no legal status in the GATT or WTO system since they have not been endorsed through decisions by the Contracting Parties to GATT or WTO Members. In any event, the Panel Report specifically considered the provisions in Article 2(6a) of the basic Regulation to be outside the scope of the dispute. The Panel found that these provisions are of a different essence and have different legal implications from the provisions under Article 2(5) of the basic Regulation, which were the object of that dispute and the Article 2(6a) provisions did not replace the latter when they were introduced <sup>(18)</sup>. Therefore, the findings made in the above mentioned cases have no relevance for the application of Article 2(6a), which is a new provision and was never subject to any WTO proceedings, and does not replace Article 2(5) and/or Article 2(3). These findings therefore have no significance for assessing the compatibility of Article 2(6a) with the relevant WTO rules. For these reasons, this claim was rejected.
- (69) Second, CCCMC and the three exporting producers submitted that in spite of the WTO findings referenced at recital (67) constituting an integral part of the EU findings on normal value under Article 2(6a) of the basic Regulation, the disclosure did not indicate any reasoning of how this provision was in line with the provisions in Article 2.2.1.1 ADA and the corresponding provisions of Article 2(5) of the basic Regulation. Nor did it indicate any linkage between Article 2(6a) and a potential ‘particular market situation’ as referenced in Article 2.2 ADA and the corresponding provisions of Article 2(3) of basic Regulation. Furthermore, CCCMC and the three exporting producers claimed the Commission failed to provide an explanation on how the Commission’s use of third country data would be justified by Article 2(5) second subparagraph of the basic Regulation. Therefore, CCCMC and the three exporting producers claimed that the Commission failed to explain the legal consistency of Article 2(6a) with the cited WTO jurisprudence.
- (70) The Commission first recalled that the provisions of Article 2(5) and Article 2(3) of the basic Regulation apply to anti-dumping investigations provided the relevant conditions of these respective provisions are met. By contrast, the provisions of Article 2(6a) concern the specific case of investigations of products originating from countries in which the existence of significant distortions was confirmed, and where the existence of significant distortions renders the domestic costs and prices not appropriate for the purpose of the calculation of normal value. The procedure applied under Article 2(6a) of the basic Regulation and the substance of the assessment are therefore different from those under Articles 2(3) and 2(5) of the basic Regulation. In their claim, CCCMC and the three exporting producers assume that the provisions in Article 2(6a) are necessarily linked to the provisions in Article 2(5) and 2(3) of the basic Regulation, and claim as a result that the Commission should legally justify the application of the methodology under Article 2(6a) under Articles 2(5) and/or 2(3) of the basic Regulation. This assumption by the CCCMC and the three exporting producers was purely speculative, because Article 2(6a) of the basic Regulation provides that once the relevant conditions for its application are met, then the methodology under this article must be applied. There are no requirements in this provision to conduct any supplementary legal analysis under Articles 2(3) and/or 2(5) of the basic Regulation, let alone their underlying jurisprudence, as CCCME and the three exporting producers wrongly assert. These provisions are separate from each other. Therefore, this claim was rejected.

<sup>(18)</sup> WTO DS 494, EU – Cost Adjustment Methodologies, paragraphs 7.76, 7.80 and 7.81.

- (71) Third, CCCMC and the three exporting producers claimed that the findings of the Panel in EU – Cost Adjustment Methodologies concerning the application of Article 2(5) of the basic Regulation apply also to Article 2(6a). Furthermore, CCCMC and the three exporting producers submitted that the disclosure made no reference to adjustments made to Colombian data in order to reflect costs of production in China, which would be a required step under Article 2.2 ADA, which envisages an adjustment of any third country data used by the investigating authority necessary to reflect the costs of production in the country of origin.
- (72) The Commission noted in response that, as already explained in recitals (68) and (70), the findings made in the WTO investigations to date, including the EU – Cost Adjustment Methodologies, did not specifically concern the application of Article 2(6a) of the basic Regulation but of Article 2(5) of the basic Regulation. Most importantly, the findings in that dispute are not final as both the EU and Russia have appealed them and therefore, according to standing WTO case-law, have no legal status in the GATT or WTO system since they have not been endorsed through decisions by the Contracting Parties to GATT or WTO Members. Moreover, that Panel report specifically stated that the respective provisions are not of the same essence and have different legal implications than Article 2(6a). Equally important, as explained in recital (53) and further discussed in recital (74) below, the relevant WTO jurisprudence does allow the use of data from a third country, where justified. With regard to the Colombian data, CCCMC and the three exporting producers are once again basing their claim on a mixing of the provisions in Article 2(6a) of the basic Regulation, with Article 2(3) of the basic Regulation. As explained in detail below at Sections 3.3 through 3.8 of this Regulation and in the specific disclosures, the Commission has used the relevant data in Colombia (or from other sources for certain factors of production) fully in line with the provisions of Article 2(6a) of the basic Regulation. Certain adjustments have been made to the relevant value to arrive at undistorted prices or benchmarks to construct normal value. Therefore this claim was rejected.
- (73) Fourth, CCCMC and the three exporting producers submitted that the Commission's disclosed finding of likelihood of continuation of dumping in recitals 170-186 of the Disclosure and its intention to maintain the existing measures was not legitimate in light of the Panel's findings in EU – Cost Adjustment Methodologies concerning the application of Article 11(3) of the ADA. CCCMC and the three exporting producers urged the Commission to explain and justify in detail its legal claim in recital 53 of the Disclosure that the methodology based on Article 2(6a) of the basic Regulation is consistent with the applicable ADA provisions and jurisprudence.
- (74) Once again, the Commission highlights that the findings of this WTO Panel report are not final as they have been appealed by both the EU and Russia, and therefore, according to standing WTO case-law, have no legal status in the GATT or WTO system since they have not been endorsed through decisions by the Contracting Parties to GATT or WTO Members. Furthermore, the Panel explicitly ruled that Article 2(6a) was outside its terms of reference given the provision's different essence and legal implications as compared to Article 2(5). Furthermore, as explained in recital (53), the Commission considered that according to the findings made in the WTO case *EU – Biodiesel* (DS473), the provisions of the basic Regulation that apply generally with respect to all WTO Members, in particular Article 2(5), second subparagraph, permit the use of data from a third country, duly adjusted when such adjustment is necessary and substantiated. Since there are no specific findings made by the WTO Dispute Settlement Body concerning the provisions under Article 2(6a), the Commission considered that if the findings made in the *EU-Biodiesel* (DS473) case are considered relevant in the different context and situation falling under Article 2(6a) of the basic anti-dumping Regulation, they would in any event be fully consistent with the possibility to use out-of-country data to source undistorted values in an appropriate representative country. Therefore this argument was rejected.
- (75) Fifth, CCCMC and the three exporting producers submitted that since the expiry of the WTO Chinese Accession Protocol in December 2016, there is no legal basis in the WTO to apply a normal value calculation outside the framework of the WTO ADA. Therefore, the EU is bound by its international obligations to strictly adhere to the provisions of Article 2 ADA bearing on the determination of normal value.

- (76) The Commission recalled at the outset that in anti-dumping proceedings concerning products from China, the parts of Section 15 of China's Accession Protocol to the WTO that have not expired continue to apply when determining normal value, both with respect to the market economy standard and with respect to the use of a methodology that is not based on a strict comparison with Chinese prices or costs. Furthermore, the Commission recalled that Article 2(6a) of the basic Regulation was introduced by Regulation (EU) 2017/2321 of the European Parliament and of the Council <sup>(19)</sup> referring to Article 207(2) of the Treaty on the Functioning of the European Union as its legal basis. As also clarified at recital (53), the provisions of Article 2(6a) are fully consistent with the EU's international obligations, including the relevant WTO rules. Since the Commission has concluded in Section 3.2.1 that it is appropriate to apply Article 2(6a) of the basic Regulation in this investigation and this provision is fully consistent with WTO rules, this claim was rejected.
- (77) Sixth, CCCMC and the three exporting producers stated that the findings in the investigation were based broadly on the 2017 Commission Report which relates not to the citric acid sector specifically but rather more generally to the broader chemical sector, to upstream raw material markets and/or to elements of the Chinese economy and Chinese government policies which clearly are not specific to the citric acid sector. In this regard, CCCMC and the three exporting producers observed that according to the WTO Appellate Body findings in *US – Countervailing Measures*, the Commission is required to conduct a case-by-case determination of any distortions. CCCMC and the three exporting producers added that they did not agree with the Commission's statement that those findings are irrelevant to this case because they concern the WTO Agreement on Subsidies and Countervailing Measures ('ASCM'). The CCCMC and the three exporting producers emphasised that those findings are relevant also in the case at hand.
- (78) The Commission recalled that under the ASCM, the context of the distortions are addressed from the specific point of view of the subsidisation they give rise to in favour of the exporting producers. The consequence of these proceedings is the application of a countervailing duty specifically calculated on the basis of the amount of injurious subsidisation found by an investigating authority. By contrast, in the anti-dumping context under Article 2(6a) of the basic Regulation, the analysis is not focused on whether these distortions amount to a countervailable subsidy and meet the relevant conditions, but whether they are significant within the meaning of Article 2(6a)(b) and thus justify the application of the methodology for the calculation of normal value foreseen by this provision. The underlying legal order, situations and context are different, serve different purposes, and give rise to different legal consequences. Hence, the Commission maintained its view that the findings in the above mentioned case are not relevant to the current investigation and thus rejected this claim.
- (79) With regard to the argument that the 2017 Commission Report does not include a specific chapter on citric acid, the Commission noted that the existence of the significant distortions giving rise to the application of Article 2(6a) of the basic Regulation is not linked to the existence of a specific sectoral chapter covering the product under investigation. The Report describes different types of distortions present in the PRC which are cross-cutting and applicable throughout the Chinese economy and affect the prices and/or the raw materials and costs of production of the product under investigation. Furthermore, the Report is not the only source of evidence used by the Commission for its determination, as there are additional probatory elements used for this purpose. As explained in Sections 3.2.1.2 to 3.2.1.9 below, the citric acid industry is subject to a number of governmental interventions described in the Report (coverage by the Five-Year Plans and other documents, raw material distortions, financial distortions etc.), which are explicitly listed and referenced in this Regulation. In addition, recitals (94), (97), (100) and (101) of this Regulation have also detailed a number of distortions applicable to the citric acid sector and/or to its raw materials and its inputs beyond the significant distortions already contained in the Report. The market circumstances and the underlying policies and plans giving rise to the significant distortions are still applicable to the citric acid sector and that of its costs of production, despite the Report being released in December 2017. No party submitted any evidence to the contrary. Therefore, this argument was dismissed.

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<sup>(19)</sup> OJ L 338, 19.12.2017, p. 1.

- (80) Seventh, CCCMC and the three exporting producers argued that while the Commission mentioned various guiding governmental concepts and implementing provisions which allow for and may even expressly mandate government interventions in the economy, the Commission failed to demonstrate the existence of actual distortions as a consequence thereof. CCCMC and the three exporting producers added that pursuant to the Appellate Body findings in US – Countervailing Measures ‘the existence of price distortion resulting from government intervention has to be established and adequately explained’ and that ‘the determination must be made on a case-by-case basis.’ CCCMC and the three exporting producers further argued that the Commission’s price distortion analysis must be made on an individual producer by producer and cost by cost basis, because any actual exercise of governmental intervention may take place, for example, at different levels of government and with regard to different regions within the country, thus not affecting all producers of the product under investigation in all parts of the country in the same way.
- (81) The Commission recalled that Article 2(6a)(b) states that, when assessing the existence of significant distortions, the Commission must consider the ‘potential impact’ of the elements listed in that Article. The findings in Sections 3.2.1.2 to 3.2.1.9 of this Regulation show that the Chinese citric acid producers do have preferential access to state financing and that there are countrywide distortions with regard to all six elements pointing to distortions, as listed in Article 2(6a)(b). Therefore, the presence of such distortions in the sector is relevant for the assessment of the existence of distortions under Article 2(6a)(b). The Commission further recalled that regardless of the exporting producers actually being affected by direct state intervention, such as the receipt of subsidies, their suppliers or other actors involved in the upstream or downstream markets of the production of the product concerned are likely to have been affected by state intervention, such as preferential access to finance, which is an additional indicator that prices or costs are not the result of free market forces. With regard to the reference to the WTO findings in US – Countervailing measures, as explained at recitals (57) and (78), the Commission reiterates that they are not relevant in the context of this investigation as they concern the anti-subsidy instrument, and in any event do not alter the findings of the existence of significant distortions under Article 2(6a) of the basic Regulation. Therefore, this claim was dismissed.
- (82) Lastly, CCCMC and the three exporting producers submitted that the Disclosure consistently failed, both with regard to its references to general government policies or plans and with regard to alleged government intervention in the citric acid sector specifically, to cite instances of actual government intervention in the operations of the Chinese citric acid producers with the result of distorting these producers’ prices. As an example, CCCMC and the three exporting producers quoted the governmental plan mentioned in recital (76) of the Disclosure encouraging the citric acid producers to create larger enterprises by means of mergers and reorganisations. CCCMC and the three exporting producers claimed that the mentioned plan relates only to certain provinces, regions or areas of production, meaning that even the encouragement is not comprehensively extended to all producers across China, which again would justify a producer-by-producer analysis and disclosure. Furthermore, CCCMC and the three exporting producers added that simple ‘encouragement’ does not in fact equate to actual intervention to require mergers/reorganisations and the Commission failed to provide examples of actual intervention. Finally, CCCMC and the three exporting producers submitted that the same document included other measures, such as, the application of environmental protection standards, clean production verification efforts and comprehensive improvements of energy conservation and emissions reduction, reduction of energy and water consumption, and promotion of clean production and recycling. All of these measures would reasonably be more efficient to apply if production units are larger, as encouraged.
- (83) The Commission recalled that the governmental ‘encouragement’ of certain actions, such as mergers and reorganisations to create larger conglomerates, are not just empty declarations and recommendations, but that there are actual financial incentives supporting the recommendations made by the government in the official plans (see Section 3.2.1.8 and recital (110) in particular). Even if, based on its plan, the Chinese government would not force or oblige the companies to group into larger entities, *quod non*, there are in any event certain financial benefits or favourable lending conditions available to the enterprises deciding to follow the plan’s recommendations, hence the free market forces which would steer the companies in the absence of such plans are distorted. In any event, the analysis and findings in Sections 3.2.1.2 to 3.2.1.9 of this Regulation clearly show the existence of significant distortions in the citric acid sector, and the fact that they are likely to affect the suppliers of raw materials to the producers of the product concerned.

- (84) The Commission thus proceeded to examine whether it was appropriate or not to use domestic prices and costs in China, due to the existence of significant distortions within the meaning of point (b) of Article 2(6a) of the basic Regulation. The Commission did so on the basis of the evidence available on the file, including the evidence contained in the Report, which relies on publicly available sources. That analysis covered the examination of the substantial government interventions in the Chinese economy in general, but also the specific market situation in the relevant sector including the product under review. On this basis these claims were rejected.

#### 3.2.1.2. Significant distortions affecting the domestic prices and costs in China

- (85) The Chinese economic system is based on the concept of a 'socialist market economy'. That concept is enshrined in the Chinese Constitution and determines the economic governance of China. The core principle is the 'socialist public ownership of the means of production, namely, ownership by the whole people and collective ownership by the working people'. The State-owned economy is the 'leading force of the national economy' and the State has the mandate 'to ensure its consolidation and growth' <sup>(20)</sup>. Consequently, the overall setup of the Chinese economy not only allows for substantial government interventions into the economy, but such interventions are expressly mandated. The notion of supremacy of public ownership over the private one permeates the entire legal system and is emphasized as a general principle in all central pieces of legislation. The Chinese property law is a prime example: it refers to China being in the primary stage of socialism and entrusts the State with upholding the basic economic system under which public ownership plays a dominant role. Other forms of ownership are tolerated, with the law permitting them to develop side by side with State ownership <sup>(21)</sup>.
- (86) In addition, under Chinese law, the socialist market economy is developed under the leadership of the Chinese Communist Party ('CCP'). The structures of the Chinese State and of the CCP are intertwined at every level (legal, institutional, personal), forming a superstructure in which the roles of CCP and the State are indistinguishable. Following an amendment of the Chinese Constitution in March 2018, the leading role of the CCP was given an even greater prominence by being reaffirmed in the text of Article 1 of the Constitution. Following the already existing first sentence of the provision: '[t]he socialist system is the basic system of the People's Republic of China' a new second sentence was inserted which reads: '[t]he defining feature of socialism with Chinese characteristics is the leadership of the Communist Party of China.' <sup>(22)</sup> This illustrates the unquestioned and ever growing control of the CCP over the economic system of China. This leadership and control is inherent to the Chinese system and goes well beyond the situation customary in other countries where the government exercises general macroeconomic control within the boundaries of which free market forces are at play.
- (87) The Chinese State engages in an interventionist economic policy in pursuance of goals, which coincide with the political agenda set by the CCP rather than reflecting the prevailing economic conditions in a free market <sup>(23)</sup>. The interventionist economic tools deployed by the Chinese authorities are manifold, including the system of industrial planning, the financial system, as well as the level of the regulatory environment.
- (88) First, on the level of overall administrative control, the direction of the Chinese economy is governed by a complex system of industrial planning which affects all economic activities within the country. The totality of these plans covers a comprehensive and complex matrix of sectors and crosscutting policies and is present on all levels of government. Plans at provincial level are detailed while national plans set broader targets. Plans also specify the means in order to support the relevant industries/sectors as well as the timeframes in which the objectives need to be achieved. Some plans still contain explicit output targets while this was a regular feature in previous planning cycles. Under the plans, individual industrial sectors and/or projects are being singled out as (positive or negative) priorities in line with the government priorities and specific development goals are attributed to them (industrial upgrade, international expansion, etc.). The economic operators, private and State-owned alike, must effectively

<sup>(20)</sup> Report – Chapter 2, p. 6-7.

<sup>(21)</sup> Report – Chapter 2, p. 10.

<sup>(22)</sup> Available at [http://www.fdi.gov.cn/1800000121\\_39\\_4866\\_0\\_7.html](http://www.fdi.gov.cn/1800000121_39_4866_0_7.html) (last viewed 15 July 2019).

<sup>(23)</sup> Report – Chapter 2, p. 20-21.



adjust their business activities according to the realities imposed by the planning system. This is not only because of the binding nature of the plans but also because the relevant Chinese authorities at all levels of government adhere to the system of plans and use their vested powers accordingly, thereby inducing the economic operators to comply with the priorities set out in the plans (see also Section 3.2.1.5 below) <sup>(24)</sup>.

- (89) Second, on the level of allocation of financial resources, the financial system of China is dominated by the State-owned commercial banks. Those banks, when setting up and implementing their lending policy need to align themselves with the government's industrial policy objectives rather than primarily assessing the economic merits of a given project (see also Section 3.2.1.8 below) <sup>(25)</sup>. The same applies to the other components of the Chinese financial system, such as the stock markets, bond markets, private equity markets etc. Also these parts of the financial sector other than the banking sector are institutionally and operationally set up in a manner not geared towards maximizing the efficient functioning of the financial markets but towards ensuring control and allowing intervention by the State and the CCP <sup>(26)</sup>.
- (90) Third, on the level of regulatory environment, the interventions by the State into the economy take a number of forms. For instance, the public procurement rules are regularly used in pursuit of policy goals other than economic efficiency, thereby undermining market based principles in the area. The applicable legislation specifically provides that public procurement shall be conducted in order to facilitate the achievement of goals designated by State policies. However, the nature of these goals remains undefined, thereby leaving a broad margin of appreciation to the decision-making bodies <sup>(27)</sup>. Similarly, in the area of investment, the GOC maintains significant control and influence over destination and magnitude of both State and private investment. Investment screening as well as various incentives, restrictions, and prohibitions related to investment are used by authorities as an important tool for supporting industrial policy goals, such as maintaining State control over key sectors or bolstering domestic industry <sup>(28)</sup>.
- (91) In sum, the Chinese economic model is based on certain basic axioms, which provide for and encourage manifold government interventions. Such substantial government interventions are at odds with the free play of market forces, resulting in distorting the effective allocation of resources in line with market principles <sup>(29)</sup>.

3.2.1.3. Significant distortions according to Article 2(6a)(b), first indent of the basic Regulation: the market in question being served to a significant extent by enterprises which operate under the ownership, control or policy supervision or guidance of the authorities of the exporting country.

- (92) In China, enterprises operating under the ownership, control and/or policy supervision or guidance by the State represent an essential part of the economy.
- (93) The GOC and the CCP maintain structures that ensure their continued influence over enterprises, and in particular State-owned enterprises (SOEs). The State (and in many aspects also the CCP) not only actively formulates and oversees the implementation of general economic policies by individual SOEs, but it also claims its rights to participate in operational decision making in SOEs. This is typically done through the rotation of cadres between government authorities and SOEs, through the presence of party members on SOEs executive bodies and of party cells in companies (see also Section 3.2.1.4), as well as through the shaping of the corporate structure of the SOE sector <sup>(30)</sup>. In exchange, SOEs enjoy a particular status within the Chinese economy, which entails a number of

<sup>(24)</sup> Report – Chapter 3, p. 41, 73-74.

<sup>(25)</sup> Report – Chapter 6, p. 120-121.

<sup>(26)</sup> Report – Chapter 6, p. 122-135.

<sup>(27)</sup> Report – Chapter 7, p. 167-168.

<sup>(28)</sup> Report – Chapter 8, p. 169-170, 200-201.

<sup>(29)</sup> Report – Chapter 2, p. 15-16, Report – Chapter 4, p. 50, p. 84, Report – Chapter 5, p. 108-9.

<sup>(30)</sup> Report – Chapter 3, p. 22-24 and Chapter 5, p. 97-108.

economic benefits, in particular shielding from competition and preferential access to relevant inputs, including finance <sup>(31)</sup>. The elements that point to the existence of government control over enterprises in the citric acid sector is further developed in Section 3.2.1.4 below.

- (94) Specifically in the citric acid sector, a certain degree of ownership by the GOC is evident. The investigation showed that at least three of the exporting producers, COFCO, Jiangsu Guoxin Union Energy and Laiwu Taihe, are SOEs. Furthermore, according to the Grain and Oil Processing 13<sup>th</sup> Five-Year Plan, the citric acid industry is encouraged to create larger enterprises by the means of mergers and reorganisations <sup>(32)</sup>. This encouragement is evidence of involvement by the government in industry affairs.
- (95) With the high level of government intervention in the citric acid industry and the prevalence of SOEs this sector, even privately owned producers are prevented from operating under market conditions. Indeed, both publicly and privately owned enterprises in the citric acid sector are subject to policy supervision and guidance as further set out in Section 3.2.1.5 below.

#### 3.2.1.4. Significant distortions according to Article 2(6a)(b), second indent of the basic Regulation: State presence in firms allowing the state to interfere with respect to prices or costs

- (96) Apart from exercising control over the economy by means of ownership of SOEs and other tools, the GOC is in a position to interfere with prices and costs through State presence in firms. While the right to appoint and to remove key management personnel in SOEs by the relevant State authorities, as provided for in the Chinese legislation, can be considered to reflect the corresponding ownership rights <sup>(33)</sup>, CCP cells in enterprises, state owned and private alike, represent another important channel through which the State can interfere with business decisions. According to Chinese company law, a CCP organisation is to be established in every company (with at least three CCP members as specified in the CCP Constitution <sup>(34)</sup>) and the company shall provide the necessary conditions for the activities of the party organisation. In the past, this requirement appears not to always have been followed or to have been strictly enforced. However, since at least 2016 the CCP has reinforced its claims to control business decisions in SOEs as a matter of political principle. The CCP is also reported to have exercised pressure on private companies to put 'patriotism' first and to follow party discipline <sup>(35)</sup>. In 2017, it was reported that party cells existed in 70 % of some 1,86 million privately owned companies, with growing pressure for CCP organisations to have a final say over the business decisions within their respective companies <sup>(36)</sup>. These rules are of general application throughout the Chinese economy, across all sectors, including to the producers of citric acid and the suppliers of their inputs.
- (97) Specifically in the citric acid sector, as already pointed out, some producers are owned by the State. Furthermore, the investigation revealed that five of the citric acid producers, including Cofco, Weifang Ensign, RZBC, Jiangsu Guoxin and Laiwu Taihe Biochemistry have CCP links among the senior management as well as party building activities.
- (98) The State's presence and intervention in the financial markets (see also Section 3.2.1.8 below) as well as in the provision of raw materials and inputs further have an additional distorting effect on the market <sup>(37)</sup>. Thus, the State presence in firms, including SOEs, in the citric acid and other sectors (such as the financial and input sectors) allow the GOC to interfere with respect to prices and costs.

<sup>(31)</sup> Report – Chapter 5, p. 104-9.

<sup>(32)</sup> See Grain and Oil Processing 13th Five-Year Plan, Section IV.2.1, available online at [http://www.gov.cn/xinwen/2017-01/03/content\\_5155835.htm](http://www.gov.cn/xinwen/2017-01/03/content_5155835.htm) (last accessed 21 December 2020).

<sup>(33)</sup> Report – Chapter 5, p. 100-1.

<sup>(34)</sup> Report – Chapter 2, p. 26.

<sup>(35)</sup> Report – Chapter 2, p. 31-2.

<sup>(36)</sup> Available at <https://www.reuters.com/article/us-china-congress-companies-idUSKCN1B40JU> (last viewed 15 July 2019).

<sup>(37)</sup> Report – Chapters 14.1 to 14.3.

3.2.1.5. Significant distortions according to Article 2(6a)(b), third indent of the basic Regulation: public policies or measures discriminating in favour of domestic suppliers or otherwise influencing free market forces

- (99) The direction of the Chinese economy is to a significant degree determined by an elaborate system of planning which sets out priorities and prescribes the goals the central and local governments must focus on. Relevant plans exist on all levels of government and cover virtually all economic sectors. The objectives set by the planning instruments are of binding nature and the authorities at each administrative level monitor the implementation of the plans by the corresponding lower level of government. Overall, the system of planning in China results in resources being driven to sectors designated as strategic or otherwise politically important by the government, rather than being allocated in line with market forces <sup>(38)</sup>.
- (100) While the citric acid industry in itself is not a key industry in China, the raw materials used in the production of citric acid are heavily regulated in China. The main raw material, corn, is subject to intensive regulation.
- (101) China holds large amounts of corn stockpiles allowing the government to artificially lower or raise the prices of this commodity by purchasing or selling large amounts of corn on the market. Even though China started tackling the problem of excessive corn reserves in 2016, it still holds very large stockpiles, which have a distortive effect on prices <sup>(39)</sup>. Furthermore, the government is controlling the various aspects of the entire corn value chain, including subsidies on the production of corn <sup>(40)</sup> and supervision of the processing: '[a]ll local authorities shall expand the monitoring and analysis of the corn supply and demand in the relevant areas, strengthen the supervision of the building phase and post-building phase of corn deep processing projects, foster the balance of corn supply and demand and ensure national food security' <sup>(41)</sup>. There are also investment control measures in place in the PRC: '[t]he filing for building corn deep processing projects shall be subject to harmonized management in accordance with the State Council Order No 673' <sup>(42)</sup>. This involvement of the government in the entire value chain has, at least potentially, a distortive effect on prices.
- (102) In sum, the GOC has measures in place to induce operators to comply with the public policy objectives to support encouraged industries, including the production of corn; corn being the main raw material used in the manufacturing of citric acid. Such measures impede market forces from operating freely.

3.2.1.6. Significant distortions according to Article 2(6a)(b), fourth indent of the basic Regulation: the lack, discriminatory application or inadequate enforcement of bankruptcy, corporate or property laws

- (103) According to the information on file, the Chinese bankruptcy system delivers inadequately on its own main objectives, such as the fair settlement of claims and debts and the safeguarding of the lawful rights and interests of creditors and debtors. This appears to be rooted in the fact that while the Chinese bankruptcy law formally rests on principles that are similar to those applied in corresponding laws in countries other than China, the Chinese system is characterised by systematic under-enforcement. The number of bankruptcies remains notoriously low in relation to the size of the country's economy, not least because the insolvency proceedings suffer from a number of shortcomings, which effectively function as a disincentive for bankruptcy filings. Moreover, the role of the State in the insolvency proceedings remains strong and active, often having a direct influence on the outcome of the proceedings <sup>(43)</sup>.
- (104) In addition, the shortcomings of the system of property rights are particularly obvious in relation to ownership of land and land-use rights in China <sup>(44)</sup>. All land is owned by the Chinese State (collectively owned rural land and State-owned urban land). Its allocation remains solely dependent on the State. There are legal provisions that aim at

<sup>(38)</sup> Report – Chapter 4, p. 41-42, 83.

<sup>(39)</sup> Report – Chapter 12, p. 319.

<sup>(40)</sup> Information on subsidies available on the Ministry of Agriculture website: [http://www.moa.gov.cn/gk/zcfg/qnhnzc/201904/t20190416\\_6179338.htm](http://www.moa.gov.cn/gk/zcfg/qnhnzc/201904/t20190416_6179338.htm)

<sup>(41)</sup> See NDRC Notice 2017/627 repealing the 'NDRC Notice on Matters Concerning the Management of Corn Deep Processing Projects', available at: [https://www.ndrc.gov.cn/fggz/cyfz/zcyfz/201704/t20170417\\_1149901.html](https://www.ndrc.gov.cn/fggz/cyfz/zcyfz/201704/t20170417_1149901.html)

<sup>(42)</sup> Ibid.

<sup>(43)</sup> Report – Chapter 6, p. 138-149.

<sup>(44)</sup> Report – Chapter 9, p. 216.

allocating land use rights in a transparent manner and at market prices, for instance by introducing bidding procedures. However, these provisions are regularly not respected, with certain buyers obtaining their land for free or below market rates <sup>(45)</sup>. Moreover, authorities often pursue specific political goals, including the implementation of the economic plans, when allocating land <sup>(46)</sup>.

- (105) The Commission preliminarily concluded that the Chinese bankruptcy, corporate and property laws do not work properly, thus generating distortions by maintaining insolvent firms afloat and through the allocation of land use rights in China. Like other sectors in the Chinese economy, the producers of citric acid are subject to these laws, and are thus subject to the top-down distortions arising from their discriminatory application or inadequate enforcement. The present investigation revealed nothing that would call those findings into question.
- (106) In light of the above, the Commission concluded that there was discriminatory application or inadequate enforcement of bankruptcy and property laws in the citric acid sector, including with respect to the product under review.

#### 3.2.1.7. Significant distortions according to Article 2(6a)(b), fifth indent of the basic Regulation: wage costs being distorted

- (107) A system of market-based wages cannot fully develop in China as workers and employers are impeded in their rights to collectively organise. China has not ratified a number of essential conventions of the International Labour Organisation ('ILO'), in particular those on freedom of association and on collective bargaining <sup>(47)</sup>. Under national law, only one trade union organisation is active. However, this organisation lacks independence from State authorities and its engagement in collective bargaining and protection of workers' rights remains rudimentary <sup>(48)</sup>. Moreover, the mobility of the Chinese workforce is restricted by the household registration system, which limits access to the full range of social security and other benefits to local residents of a given administrative area. This typically results in workers who are not in possession of the local residence registration finding themselves in a vulnerable employment position and receiving lower income than the holders of the residence registration <sup>(49)</sup>. Those findings lead to the distortion of wage costs in China.
- (108) No evidence was submitted to the effect that the citric acid sector is not subject to the Chinese labour law system described above. The citric acid sector is thus affected by the distortions of wage costs both directly (when producing the product under review or the main raw material for its production) as well as indirectly (when having access to capital or inputs from companies subject to the same labour system in China).

#### 3.2.1.8. Significant distortions according to Article 2(6a)(b), sixth indent of the basic Regulation: access to finance granted by institutions which implement public policy objectives or are otherwise not acting independently of the State

- (109) Access to capital for corporate actors in China is subject to various distortions.
- (110) First, the Chinese financial system is characterised by the strong position of State-owned banks <sup>(50)</sup>, which, when granting access to finance, take into consideration criteria other than the economic viability of a project. Similarly to non-financial SOEs, the banks remain connected to the State not only through ownership but also via personal relations (the top executives of large State-owned financial institutions are ultimately appointed by the CCP) <sup>(51)</sup> and, again just like non-financial SOEs, the banks regularly implement public policies designed by the government. In doing so, the banks comply with an explicit legal obligation to conduct their business in accordance with the needs

<sup>(45)</sup> Report – Chapter 9, p. 213-215.

<sup>(46)</sup> Report – Chapter 9, p. 209-211.

<sup>(47)</sup> Report – Chapter 13, p. 332-337.

<sup>(48)</sup> Report – Chapter 13, p. 336.

<sup>(49)</sup> Report – Chapter 13, p. 337-341.

<sup>(50)</sup> Report – Chapter 6, p. 114-117.

<sup>(51)</sup> Report – Chapter 6, p. 119.

of the national economic and social development and under the guidance of the industrial policies of the State <sup>(52)</sup>. This is compounded by additional existing rules, which direct finances into sectors designated by the government as encouraged or otherwise important <sup>(53)</sup>.

- (111) While it is acknowledged that various legal provisions refer to the need to respect normal banking behaviour and prudential rules such as the need to examine the creditworthiness of the borrower, the overwhelming evidence, including findings made in trade defence investigations, suggests that these provisions play only a secondary role in the application of the various legal instruments.
- (112) Furthermore, bond and credit ratings are often distorted for a variety of reasons including the fact that the risk assessment is influenced by the firm's strategic importance to the GOC and the strength of any implicit guarantee by the government. Estimates strongly suggest that Chinese credit ratings systematically correspond to lower international ratings <sup>(54)</sup>.
- (113) This is compounded by additional existing rules, which direct finances into sectors designated by the government as encouraged or otherwise important <sup>(55)</sup>. This results in a bias in favour of lending to SOEs, large well-connected private firms and firms in key industrial sectors, which implies that the availability and cost of capital is not equal for all players on the market.
- (114) Secondly, borrowing costs have been kept artificially low to stimulate investment growth. This has led to the excessive use of capital investment with ever lower returns on investment. This is illustrated by the recent growth in corporate leverage in the state sector despite a sharp fall in profitability, which suggests that the mechanisms at work in the banking system do not follow normal commercial responses.
- (115) Thirdly, although nominal interest rate liberalization was achieved in October 2015, price signals are still not the result of free market forces, but are influenced by government induced distortions. Indeed, the share of lending at or below the benchmark rate still represents 45 % of all lending and recourse to targeted credit appears to have been stepped up, since this share has increased markedly since 2015 in spite of worsening economic conditions. Artificially low interest rates result in under-pricing, and consequently, the excessive utilization of capital.
- (116) Overall credit growth in China indicates a worsening efficiency of capital allocation without any signs of credit tightening that would be expected in an undistorted market environment. As a result, non-performing loans have increased rapidly in recent years. Faced with a situation of increasing debt-at-risk, the GOC has opted to avoid defaults. Consequently, bad debt issues have been handled by rolling over debt, thus creating so called 'zombie' companies, or by transferring the ownership of the debt (e.g. via mergers or debt-to-equity swaps), without necessarily removing the overall debt problem or addressing its root causes.
- (117) In essence, despite the recent steps that have been taken to liberalize the market, the corporate credit system in China is affected by significant distortions resulting from the continuing pervasive role of the state in the capital markets.
- (118) No evidence was submitted to the effect that the citric acid sector, and/or the suppliers of this sector, would be exempted from the above-described government intervention in the financial system. Therefore, the substantial government intervention in the financial system leads to the market conditions being severely affected at all levels.

<sup>(52)</sup> Report – Chapter 6, p. 120.

<sup>(53)</sup> Report – Chapter 6, p. 121-122, 126-128, 133-135.

<sup>(54)</sup> See IMF Working Paper 'Resolving China's Corporate Debt Problem', by Wojciech Maliszewski, Serkan Arslanalp, John Caparuso, José Garrido, Si Guo, Joong Shik Kang, W. Raphael Lam, T. Daniel Law, Wei Liao, Nadia Rendak, Philippe Wingender, Jianguan, October 2016, WP/16/203.

<sup>(55)</sup> Report – Chapter 6, p. 121-122, 126-128, 133-135.

#### 3.2.1.9. Systemic nature of the distortions described

- (119) The Commission noted that the distortions described in the Report are characteristic for the Chinese economy. The evidence available shows that the facts and features of the Chinese system as described above in Sections 3.2.1.1 to 3.2.1.5 as well as in Part A of the Report apply throughout the country and across the sectors of the economy. The same holds true for the description of the factors of production as set out above in Sections 3.2.1.6 to 3.2.1.8 above and in Part B of the Report.
- (120) The Commission recalled that in order to produce citric acid, a broad range of inputs is needed, including corn, dried sweet potatoes, sulphuric acid, hydrochloric acid, coal etc. According to evidence on the file, most of the sampled exporting producers sourced all their inputs in China, and the imported inputs constitute a negligible proportion of the raw materials of those exporting producers who source some inputs abroad. When the producers of citric acid purchase or contract for these inputs, the prices they pay (and which are recorded as their costs) are clearly exposed to the same systemic distortions mentioned above. For instance, suppliers of inputs employ labour that is subject to distortions. They may have borrowed funds that are subject to the distortions in the financial sector. In addition, they are subject to the planning system that applies across all levels of government and sectors.
- (121) As a consequence, not only are the domestic sales prices of citric acid not appropriate for use within the meaning of Article 2(6a)(a) of the basic Regulation, all the input costs (including raw materials, energy, land, financing, labour, etc.) are affected because their price formation is affected by substantial government intervention, as described in Parts A and B of the Report. Indeed, the government interventions described in relation to the allocation of capital, land, labour, energy and raw materials are present throughout China. This means, for instance, that any input produced in China, even if it combines several factors of production, is exposed to significant distortions. The same applies to the input of the input, and so on. No evidence or argument to the contrary has been adduced by the GOC or the exporting producers in the present investigation.

#### 3.2.1.10. Conclusion

- (122) The analysis set out in Sections 3.2.1.2 to 3.2.1.9, which includes an examination of all the available evidence relating to Chinese intervention in its economy in general as well as in the citric acid sector (including the product under review) showed that prices and costs of the product under review, including the costs of raw materials, energy and labour, are not the result of free market forces because they are affected by substantial government intervention within the meaning of Article 2(6a)(b) of the basic Regulation, as shown by the actual or potential impact of one or more of the relevant elements listed therein. On that basis, and in the absence of any cooperation from the GOC, the Commission concluded that it is not appropriate to use domestic prices and costs to establish normal value in this case.
- (123) Consequently, the Commission proceeded to construct the normal value exclusively on the basis of costs of production and sale reflecting undistorted prices or benchmarks, that is, in this case, on the basis of corresponding costs of production and sale in an appropriate representative country, in accordance with Article 2(6a)(a) of the basic Regulation, as discussed in the following section.

### 3.3. Representative country

- (124) In accordance with Article 2(6a)(a) of the basic Regulation, the Commission chose an appropriate representative country to determine undistorted prices or benchmarks for the costs of production and sale of the product under review on the basis of the following criteria:
- A level of economic development similar to China. For this purpose, the Commission considered countries with a gross national income similar to China on the basis of the database of the World Bank,
  - Production of the product under review in that country,

- Availability of relevant public data in that country, and
  - Where there is more than one possible representative country, preference would be given, where appropriate, to a country with an adequate level of social and environmental protection.
- (125) The Commission published two notes to the file on the sources for the determination of the normal value and on the representative country on this basis.
- (126) In the Note of 5 March 2020, the Commission provided detailed information concerning the criteria above and identified Brazil, Colombia and Thailand as potential appropriate representative countries. The Commission also identified the producers of the product under review in the potential appropriate representative countries for which it found publically available financial data.
- (127) The Commission invited interested parties to submit comments in this regard. The Commission received comments concerning various aspects of the selection of the representative country from CCCMC, the four cooperating exporting producers and from the Union industry.
- (128) In their submissions of 23 March 2020, CCCMC and the four Chinese exporting producers indicated that Brazil would be the best representative country. First, based on the database of the World Bank, Brazil's gross national income ('GNI') is the closest to that of China, whilst the GNI of Colombia and Thailand is much lower. Also, the two companies in Brazil identified as producers of citric acid were profitable in recent years. In addition, Brazil has an adequate level of social and environmental protection. At the same time, CCCMC and the cooperating exporting producers expressed their opposition to the choice of Colombia as the appropriate representative country. They claimed that some of the import data of Colombia concerning certain factors of production was not available or representative. They also argued that Colombia's import prices of some of the key raw materials (i.e. sulphuric acid, hydrochloric acid and raw coal) were substantially and unreasonably higher than those of the other potential representative countries and thus should not be regarded as undistorted prices that could be used to construct the normal value of citric acid.
- (129) CCCMC and the cooperating exporting producers also submitted that Thailand was not an appropriate representative country as two of the three identified producers of citric acid were unprofitable in 2018 and the third one was mainly focused on export markets.
- (130) In their submission, the Union industry considered that Colombia was the most appropriate choice for determining undistorted costs. They stressed that the financial data of the companies in Thailand was not audited, which greatly reduced their value in terms of reliability. In addition, they claimed that two of the three identified producers in Thailand were majority-owned by Chinese companies or by the Chinese State and that they were export-oriented. As regards Brazil, the Union industry argued that the two Brazilian companies belonged to groups and the influence of group on the financial data appeared to be difficult to assess, and these companies also sold a diverse range of products.
- (131) The Commission, after analysing in detail the above arguments, published a second Note on 30 November 2020 addressing all these comments on the basis of the criteria listed above and informing interested parties of its preliminary conclusions. The Commission stated in this Note that it intended to use Colombia as appropriate representative country if the existence of significant distortions would be confirmed. The Commission further indicated that for the calculation of normal value it may also use appropriate undistorted international prices, costs or benchmarks, and for undistorted selling, general and administrative costs ('SG&A') and profits it may consider all the suitable alternatives available in accordance with Article 2(6a)(a) of the basic Regulation. In particular, as the only Colombian company producing the product under review had low profitability in 2018 and was loss-making in 2017 – similar to the situation for the producers in Thailand and Brazil, the Commission would consider more recent data if available and if they would show a reasonable level of SG&A and profitability. The Commission invited interested parties to comment.
- (132) The Commission received comments from CCCMC and the Union producers regarding the Note of 30 November 2020.

- (133) In its submission of 9 December 2020, CCCMC maintained that Colombia was not an appropriate representative country and Brazil should be selected as the appropriate country instead. It argued that lower corn import prices in Brazil were due to the advantages of transportation distances and quantity rather than any distortion. They further argued that if Brazilian import prices could not be used, international prices should be used instead of excluding Brazil altogether from the choice of representative country. CCCMC also maintained that Colombia was not an appropriate representative country as the identified producer had unreasonable operating expenses.
- (134) The Union industry maintained that Colombia was the most appropriate representative country. Given that the Colombian company producing the product under review was loss-making or had low profitability in 2018 and also in 2019, for which data became available in the meantime, one of the Union producers identified a number of companies producing a product similar to the product under review. In particular, the Union producer focused on companies manufacturing ingredients for the beverage, cleaning, food, health and pharmaceutical industry in Colombia whose financial data showed a reasonable level of SG&A and profits in line with the provisions of the basic Regulation.
- (135) The Commission considered carefully all the arguments raised by all the parties. With regard to Thailand, the Commission agreed with CCCMC and the Union producer that it is not an appropriate representative country as producers of the product under review are loss-making and/or are subsidiaries of Chinese companies plus export restrictions exist for certain factors of production. In addition, the companies manufacturing the product under review did not show a reasonable level of SG&A and profits. Therefore, Thailand was dismissed.
- (136) The Commission thus focused its analysis on Brazil and Colombia. The Commission first analysed whether there were export restrictions or other distortions concerning the main factors of production. The main factor of production of the product under review is corn, accounting for more than 70 % of the total cost of input materials for the exporting producers. The Commission noted that the quantity of imports of corn into Brazil accounted for only 1,5 million tonnes, compared to Brazilian domestic corn production of over 100 million tonnes <sup>(56)</sup>. CCCMC contested the fact that these import quantities of corn into Brazil are low. However, when compared to the size of the Brazilian production, these import quantities only account for 1,5 % of production. Given this very limited import quantity relative to the large domestic production, the Commission also checked the import prices into Brazil and noted that they differed significantly from the international corn prices. In its comments to the Note of 30 November, CCCMC contested that prices differed significantly and asked for additional information on the price comparison. The 2019 average international corn price referenced by the Commission in the Note of 30 November amounted to EUR 151/tonne on a FOB basis according to IndexMundi <sup>(57)</sup>, while the average GTA import price of corn into Brazil amounted to only EUR 116/tonne on a FOB basis. This figure clearly shows that the import prices into Brazil were significantly lower than the international price index.
- (137) In addition, CCCMC argued that corn import prices were lower in Brazil than in Colombia due to lower transport costs as imports into Brazil were mainly made from neighbouring countries like Argentina and Paraguay, whereas Colombia imports corn predominantly from the US and Argentina. This allegation was not substantiated, as CCCMC did not show the actual origin and port of entry in the respective countries, nor did it show the incidence of transport costs of corn into the respective countries. Therefore, this argument was dismissed.
- (138) CCCMC also submitted that Chinese producers purchase a large quantity of their corn domestically. Therefore, it claimed that the import price of Brazil would better reflect the situation of the Chinese producers' purchases of corn. The Commission noted that this argument does not have any bearing on the fact that the import quantities into Brazil are objectively low as compared to the size of the domestic production, thus undermining the representa-

<sup>(56)</sup> <https://www.indexmundi.com/agriculture/?commodity=corn>

<sup>(57)</sup> <https://www.indexmundi.com/commodities/?commodity=corn&months=60&currency=eur>



tiveness of the corn import price into Brazil. This argument also does not detract from the conclusion that import prices into Brazil differ significantly from international corn prices, which is probably due to the low level of imports and the significant size of domestic production. Therefore, this argument was dismissed.

- (139) CCCMC further argued that, even if the import prices of corn into Brazil could not be used because they were unrepresentative, *quod non*, Brazil should still be selected as the representative country, and an appropriate undistorted international price for corn should be applied instead of the import prices into Brazil.
- (140) In response, the Commission noted that, as explained further in this section, it considered Colombia as an appropriate representative country in this investigation on the basis of the relevant elements listed in the basic Regulation, including the availability of more appropriate financial data for producers of products similar to citric acid as compared to Brazil. As concerns the Colombian import quantities and prices of corn, according to IndexMundi the total domestic corn production in Colombia amounts to 1,5 million tonnes whereas, according to GTA data, corn imports are around 5,5 million tonnes, thus accounting for 365 % of production. This comparison shows that the import quantities into Colombia seem to be representative taking into account the size of the domestic production, unlike Brazil. As for corn prices, the average GTA corn import price into Colombia for 2019 was 174 EUR/tonne on a CIF basis, much closer to and in line with the average international corn price of 151 EUR/tonne on a FOB basis, taking into account that the international import price on a CIF basis would be higher. Since Colombia is considered an appropriate representative country in other respects, as further detailed below; the corn import prices into Colombia are largely in line with the international corn prices; and there is no evidence of any distortion affecting corn prices in Colombia; there is no reason to select Brazil as an appropriate representative country and use an international benchmark instead of the import prices into the appropriate representative country as prescribed by Article 2(6a)(a), 2nd subparagraph, first dash.
- (141) With regard to the remaining factors of production, export restrictions for certain factors of production exist in Brazil (export licensing requirement for lime) and Thailand (export licensing requirement for gypsum), while none exist in Colombia, as confirmed by the relevant OECD List <sup>(58)</sup>. While these factors have a much more limited weight in the cost of production of certain exporting producers and did not apply to all exporting producers, this was another relevant element in the choice of the appropriate representative country.
- (142) For the choice of the appropriate representative country, the Commission also looked at the availability of public financial data for producers of the product under review in Thailand, Brazil, and Colombia in line with the basic Regulation.
- (143) Because Thailand was not considered a suitable representative country, as explained in recital (117), the Commission focused its comparative analysis on Brazil and Colombia.
- (144) With regard to Brazil and Colombia, the Commission indicated in the Note of 5 March the companies producing citric acid in those countries. At that time, there were no producers with reasonable profits in either Brazil or Colombia for 2018.
- (145) In the Note of 30 November 2020, the Commission stated that the Colombian company Sucroal SA, for which SG&A and profit data were publicly available, was an appropriate representative company as it produces the product under review and a product range closer to citric acid. At the same time, Sucroal SA showed a low level of profitability in 2018 and was loss making in 2017.
- (146) The situation was similar in Brazil, where the Brazilian company for which financial data was publicly available, a large conglomerate producing a wider range of products including citric acid, showed a low profitability for 2018. The Commission flagged in the Note of 30 November 2020 that if more recent data for the year 2019 would

<sup>(58)</sup> [https://qdd.oecd.org/subject.aspx?Subject=ExportRestrictions\\_IndustrialRawMaterials](https://qdd.oecd.org/subject.aspx?Subject=ExportRestrictions_IndustrialRawMaterials)

become available, the Commission may use this data if they showed a reasonable level of SG&A and profitability, or, if this were not the case, the Commission would consider all the suitable alternatives available.

- (147) Following the publication of this Note of 30 November 2020, the 2019 data for Sucroal SA became available in Orbis. As Sucroal SA incurred a loss in 2019, the financial data for this company could not be considered appropriate for establishing an undistorted level of SG&A and profits.
- (148) The Commission therefore considered suitable alternatives. In particular, in situations where no producer of the product under review in a potential representative country shows a reasonable level of SG&A and profits, the Commission may consider producers of a product in the same general category and/or sector of the product under review with publically available financial data showing a reasonable level of SG&A and profits.
- (149) CCCMC submitted that since Sucroal SA showed losses for the year 2019, Colombia should not be considered as an appropriate representative country and Brazil should be used instead. CCCMC noted that the identified producer Cargill Agricola was again profitable in 2019 and hence its SG&A and profit were appropriate for the needs of the investigation. However, the Commission noted that Cargill Agricola's profit amounted to less than one percent of its turnover in 2019, and was therefore even lower than its profit in 2018. This low level of profit was at a similar level as for Sucroal SA in the same year and not considered reasonable. Therefore, this argument was dismissed.
- (150) In its two sets of comments, the Union industry suggested to use the data from companies in the same country, manufacturing the same category of goods or being in the same manufacturing sector as the product under review. The category of manufacturers of ingredients for the beverage, cleaning, food, health and pharmaceutical industry in Colombia was suggested together with a list of eleven companies in the same sector.
- (151) Considering all the facts of the investigation and the comments received, the Commission searched the Orbis database for the NAICS code 325998 (All Other Miscellaneous Chemical Product and Preparation Manufacturing). This is the same code used by both Cargill Agricola SA and Sucroal SA. As a result of this search, there was a far higher number of companies showing a reasonable level of profits in Colombia as compared to Brazil, showing that the availability of public financial data was also representative and reliable in Colombia. Furthermore, in order to narrow down the result of this search to those companies producing a product similar to citric acid, the Commission analysed in detail the activity and production of all the profitable Colombian companies. Using the description of their business activity available in Orbis, the Commission finally identified seven companies in Colombia producing products in a close category of products to citric acid. The SG&A and profit of those companies was considered reliable. By comparison, the Commission noted that in Brazil there were no companies in the same field of activity with publicly available 2019 financial data in Orbis.
- (152) The Colombian companies identified by the Commission in this way matched the companies identified by the Union industry as suitable companies in the same general category and/or sector of the product under review. The Union industry suggested in addition to those seven companies four other companies in Colombia, for which, however, the financial data or activity description was not readily available in Orbis. Therefore those companies were not taken into account for establishing the SG&A and profit.
- (153) Based on all the above elements, and in particular the available financial data and the representativeness of the import price for corn representing the major factor of production, the Commission therefore concluded that Colombia was the appropriate representative country for the calculation of the normal value in this investigation.
- (154) Following disclosure, CCCMC and three cooperating exporting producers questioned the Commission's choice of Colombia as an appropriate representative country. They repeated the aforementioned claim that the choice of Colombia was not reasonable given the fact that the sole Colombian citric acid producer was not profitable during

the review investigation period whereas a Brazilian producer was. They also repeated the aforementioned claim that corn prices in Brazil were not distorted. Given that these claims had already been addressed at recitals (136) and (149) of this Regulation and that no new evidence was provided in this regard, the claims were dismissed.

- (155) The aforementioned parties further claimed that the Commission used SG&A and profitability data from Colombian companies in other product sectors without proving that these companies have the same level of SG&A and profit as the producers of citric acid.
- (156) In line with Article 2(6a) of the basic Regulation, the normal value shall be constructed on the basis of costs of production and sale reflecting undistorted prices or benchmarks when the presence of significant distortions is confirmed. The constructed normal value shall include an undistorted and reasonable amount for SG&A and for profits. Given that the SG&A and profit of the Colombian company Sucroal SA could not be used for the reasons explained in recitals (145) and (147), the Commission used data for the closest sector including the product under investigation, where the aforementioned cost elements were considered undistorted and reasonable. No evidence has been provided to dispute this conclusion, and in particular that the level of SG&A and profits of the Colombian companies in the closest sector to citric acid were not reasonable according to Article 2(6a)(a) of the basic Regulation.
- (157) The Commission noted further that, contrary to the Union Industry, CCCMC and the cooperating exporting producers did not provide or suggest a list of manufacturers in the same potential representative country, manufacturing the same or similar category of goods or being in the same or similar manufacturing sector as the product under review, whose financial data the Commission could use.
- (158) Therefore, and for the reasons set out in recital (151), the Commission considered the financial data from the seven companies that it identified in Colombia producing products in a close category of products to citric acid to be a reasonable proxy for undistorted SG&A and profit to be used in the construction of the normal value in the investigation. The claim from CCCMC and three cooperating exporting producers was therefore dismissed.

#### **3.4. Sources used to establish undistorted costs**

- (159) On the basis of the information submitted by the interested parties and other relevant information available in the file, the Commission established a list of factors of production and sources such as materials, energy and labour used in the production of the product under review by the exporting producers.
- (160) The Commission also identified the sources to be used in order to construct the normal value in accordance with Article 2(6a)(a) of the basic Regulation (GTA, national statistics, etc.). In the same note, the Commission identified the Harmonised System (HS) codes of factors of production which, based on information provided by the interested parties, were initially considered to be used for the GTA analysis.
- (161) In the Note of 30 November 2020, the Commission confirmed that it would use GTA data to establish the undistorted cost of the factors of production, including raw materials.

#### **3.5. Sources used for electricity, water and labour costs**

##### *3.5.1. Electricity*

- (162) For electricity, the Commission used the readily available price from Enel, the major electricity supplier in Colombia. This source provides a single average price of electricity per month.

### 3.5.2. Water

- (163) The water tariff was readily available from the company Acueducto, which is responsible for water supply, sewage collection and treatment in Bogota. The information enabled the identification of tariffs applicable to industrial users in the review investigation period.

### 3.5.3. Labour

- (164) The Commission used ILO statistics to determine the wages in Colombia <sup>(59)</sup>. These provide information on monthly wages of employees in the manufacturing sector and average weekly hours worked in Colombia in 2019.
- (165) The Commission received no comments on the sources used for establishing the undistorted cost of electricity, water and labour and therefore used those sources to establish the normal value.

## 3.6. Sources used for SG&A and profit

- (166) According to Article 2(6a)(a) of the basic Regulation, the constructed normal value should include an undistorted and reasonable amount for SG&A and for profits. In addition, a value for manufacturing overhead costs had to be established to cover costs not included in the factors of production.
- (167) In order to establish an undistorted value of SG&A and profits, the Commission used the proportion of the cost of manufacturing that SG&A and profits represent in the representative companies in Colombia as explained in Section 3.3.
- (168) The resulting values expressed as a percentage of revenues amounted to 14,2 % for profit and 17 % for SG&A.

## 3.7. Raw materials

- (169) For all raw materials and auxiliary materials, the Commission relied on import prices into the representative country. The import price into the representative country was determined as a weighted average of unit prices of imports from all third countries excluding China. The Commission decided to exclude imports from China into the representative country due to the existence of significant distortions in accordance with Article 2(6a)(b) of the basic Regulation. Given that there is no evidence showing that the same distortions do not equally affect products intended for export, the Commission considered that the same distortions affected these prices. Similarly, imports into the representative country from non-WTO members listed in Annex 1 of Regulation (EU) 2015/755 of the European Parliament and of the Council <sup>(60)</sup> were also excluded.
- (170) In order to establish the undistorted price of raw materials, as provided by Article 2(6a)(a), first indent of the basic Regulation, the Commission applied the relevant import duties of the representative country. At a later stage, during the individual dumping margin calculations, the Commission added company specific domestic transport costs to the import price. The domestic transport costs for all raw materials were based on the verified data provided by the cooperating exporting producers.
- (171) For raw materials with negligible impact in terms of costs, which the companies did not report in Annex III of the Notice of Initiation, such costs were included in the manufacturing overheads as explained in Section 3.8. The factors of production expressed as overheads are listed in the company-specific disclosures.

<sup>(59)</sup> [https://www.ilo.org/ilostat/faces/oracle/webcenter/portalapp/pagehierarchy/Page21.jspx?\\_afLoop=2007202804813928&\\_afWindowMode=0&\\_afWindowId=ejmnga3iz\\_63#!%40%40%3F\\_afWindowId%3Dejmnga3iz\\_63%26\\_afLoop%3D2007202804813928%26\\_afWindowMode%3D0%26\\_adf.ctrl-state%3Dejmnga3iz\\_119](https://www.ilo.org/ilostat/faces/oracle/webcenter/portalapp/pagehierarchy/Page21.jspx?_afLoop=2007202804813928&_afWindowMode=0&_afWindowId=ejmnga3iz_63#!%40%40%3F_afWindowId%3Dejmnga3iz_63%26_afLoop%3D2007202804813928%26_afWindowMode%3D0%26_adf.ctrl-state%3Dejmnga3iz_119)

<sup>(60)</sup> OJ L 123, 19.5.2015, p. 33. Article 2(7) of the basic Regulation considered that domestic prices in those countries cannot be used for the purpose of determining normal value and, in any event, such import data was negligible.

- (172) The Union industry noted in its comments of 16 March 2020 that for some raw materials, either no average import values existed or that the average values concerned small quantities and were therefore unreliable or that other reasons existed which led to doubts about their reliability. They suggested that the values from statistics for the region or as published by market surveys from providers such as ArgusMedia, AgroChart or IntraTec should be used in these cases.
- (173) The Union industry reiterated in its comments of 11 December 2020 that in the case of Colombia, the costs for the production figures could be determined with the data for imports and available public data for the prices of electricity, water and the public data on labour costs. They stressed that some of the average import values for less important cost factors appeared to be high and suggested that these be replaced with data from specialised data service providers.
- (174) In its submission of 23 March 2020, CCCMC commented that some of the import prices for certain key materials like coal, sulphuric acid and hydrochloric acid in Colombia were abnormally high and therefore not representative. They also claimed that there were major differences between the disclosed import prices of Colombia, Thailand and Brazil and that import prices varied significantly even for the same material imported by the same country, which might be due to quality differences within the same HS code. CCCMC called on the Commission to identify the reason for these differences and to address them. The Commission considered this argument and, wherever justified, replaced unrepresentative import prices by reliable sources as detailed in Table A below.
- (175) CCCMC also argued that since certain of the raw materials used for the production of the product under review are purchased domestically in China, it is unreasonable to simply use the import prices of a specific third country, as these latter prices are likely to include higher shipping/delivery costs than those of domestically purchased raw materials. This is especially the case for dangerous chemicals like sulphuric acid and hydrochloric acid for which special vehicles are used for delivery. Therefore CCCMC considered that due adjustments must be made to ensure a fair comparison.
- (176) Concerning this argument, the Commission noted that, for the reasons set out in Section 3.2.1 above, it applies Article 2(6a) of the basic Regulation in the present expiry review. Therefore, the Commission is looking for undistorted costs in an appropriate representative country to ensure that the applied cost is not affected by distortions and is based on readily available data. In the absence of any information of possible distortions on the market of the representative country with respect to those dangerous chemicals and in the absence of data provided by CCCMC to substantiate its claim concerning high transport costs, the import values of the representative country are considered to fulfil the criteria of Article 2(6a) of the basic Regulation and to provide a reasonable estimate of the price in the representative country, including the transport costs. Additionally, because the imported inputs compete on the domestic market of the representative country in terms of prices, the Commission considered them a reliable proxy.
- (177) The Commission consequently used the GTA import prices into Colombia. Where those prices were not representative or otherwise unreliable, international benchmarks were sought. Where those were not available, reliable prices from other sources were used, as detailed in table A below.
- (178) Considering all the information submitted by interested parties and collected during the remote cross-checks, the following factors of production and tariff codes used in Brazil, Colombia or Thailand, where applicable, have been identified:

Table A

Factor of production	Tariff Code	Source of import data that the Commission intends to use	Unit of measurement
<b>Raw materials/Consumables</b>			
Corn	1005 90 11 00	GTA Colombia <sup>(61)</sup>	KG
Dried sweet potatoes	0714 20 90 00	GTA Colombia	KG

<sup>(61)</sup> Available at: <http://www.gtis.com/gta/>

Factor of production	Tariff Code	Source of import data that the Commission intends to use	Unit of measurement
Sodium chloride/edible salt	2501 00 91 00/ 2501 00 10 00, 2501 00 20 00, 2501 00 92 00, 2501 00 99 00	GTA Colombia	KG
Sulphuric acid	2807 00 10	GTA Brazil	KG
Sulphur/liquid sulphur	2503 00 00 00	GTA Colombia	KG
Hydrochloric acid	2806 10 20	GTA Brazil	KG
Activated carbon	3802 10 00 00	GTA Colombia	KG
Limestone powder/flour	2521 00 00	GTA Brazil	KG
Defoamer	3402 20 00 00/ 3402 90 90 00	GTA Colombia	KG
Diatomite	2512 00 00 00/ 3802 90 10 00	GTA Colombia	KG
Perlite	2530 10 00 00	GTA Colombia	KG
Amylase (Glucoamylase)/Saccharifying enzyme	3507 90 90 00	GTA Colombia	KG
Calcium	2805 12 00	GTA Brazil	KG
Caustic soda (Sodium hydroxide)	2815 11 00 00/ 2815 12 00 00	GTA Colombia	KG
Liquid alkali	2815 12 00 00	GTA Colombia	KG
Hydrogen peroxide	2847 00 00 00	GTA Colombia	KG
Flour (wheat or meslin)	1101 00 00 00	GTA Colombia	KG
Wood flour	4405 00 00 00	GTA Colombia	M <sup>3</sup>
Calcium oxide	2825 90 40 00	GTA Colombia	KG
Quicklime	2522 10 00 00	GTA Colombia	KG
Bran from corn	2302 10 00 00	GTA Colombia	KG
Corn steep liquor	1901 90 10 00	GTA Colombia	KG
Calcium carbonate/Calcite	2836 50 00 00	GTA Colombia	KG
Activated clay	3802 90 10 00	GTA Colombia	KG
Filter aid (perlite)	2530 10 00 00	GTA Colombia	KG
Sodium diacetate	2915 29 20 00	GTA Colombia	KG
Citric acid	2918 14 00 00	GTA Colombia	KG
Sodium citrate	2918 15 30 00	GTA Colombia	KG
Corrosion and scale inhibitor	2921 59	GTA Brazil	KG
Raw coal/Slime	2701 19 00	GTA Brazil	KG
Diesel	2710 19 21 00	GTA Colombia	M <sup>3</sup>
Packing – Film bag	3923 29 90 00	GTA Colombia	Piece
Packing – Soft tray	3923 90 00 00	GTA Colombia	Piece
Packing – Pallet	4421 99 90 00	GTA Colombia	Piece

Factor of production	Tariff Code	Source of import data that the Commission intends to use	Unit of measurement
Packing – Paper box	4819 20 00 00	GTA Colombia	Piece
Packing – Paper bag	4819 30 10 00	GTA Colombia	Piece
Packing – Paper bag	4819 40 00 00	GTA Colombia	Piece
Packing – Woven bag	6305 33 10 00	GTA Colombia	Piece
Packing – Heavy film bag	3920 10 00 00	GTA Colombia	Piece
<b>By-product/waste</b>			
Gas	2705 00 00 00	GTA Colombia	KG
High protein scrap/Corn starch residue	2303 10 00 00	GTA Colombia	KG
Corn feed	2303 30 00 00	GTA Colombia	KG
Calcium sulphate	2833 29 90 00	GTA Colombia	KG
Other residual products of the chemical industries (Granular sludge)	3825 90 00	GTA Brazil	KG
Corn germ oil/Corn oil	1518 00 90 00/ 1515 29 00 00	GTA Colombia	KG
Corn grits/Corn starch residue	2303 10 00 00	GTA Colombia	KG
Wheat gluten flour	1109 00 00 00	GTA Colombia	KG
Mycelium (animal feed preparation)	2309 90 90 00	GTA Colombia	KG
Germ of cereals	1104 30 00 00	GTA Colombia	KG
Calcite stone powder	2836 50 00 00	GTA Colombia	KG
Gypsum	2520 10 00 00	GTA Colombia	KG
Ash, slag	2621 90 00 00	GTA Colombia	KG
Corn germ oil extraction residue	2306 90 10/90	GTA Thailand	KG
Corn gluten meal/powder	2302 10 00 00	GTA Brazil	KG
Protein powder granules (corn residue)	2302 10 00 00	GTA Brazil	KG
Protein filter cake (corn residue)	2302 10 00 00	GTA Brazil	KG
Sprayed corn husk	2302 10 00 00	GTA Brazil	KG

### 3.8. Calculation of the Normal Value

- (179) In order to establish the normal value, the Commission took the following steps.
- (180) First, the Commission established the undistorted costs of manufacturing (covering the consumption of raw materials, labour and energy). It applied the undistorted unit costs based on the sources listed above to the actual consumption of the individual factors of production of the sampled exporting producers.
- (181) Second, to arrive at the undistorted costs of production, the Commission added manufacturing overheads. Manufacturing overheads incurred by the cooperating exporting producers were increased by the costs of raw materials and auxiliary materials referred to in recital (171) and subsequently expressed as a share of the costs of manufacturing actually incurred by each of the exporting producers. This percentage was applied to the undistorted costs of manufacturing.

- (182) Finally, the Commission applied the SG&A and the weighted average profit of seven representative Colombian producers of ingredients for the beverage, cleaning, food, health and pharmaceutical industry to the above calculation.
- (183) When expressed as a percentage of the costs of manufacturing, these amount to 24,82 % for SG&A and 20,72 % for profit. When expressed as a percentage of revenues, the same amounts to 17 % for SG&A and 14,2 % for profit.
- (184) On that basis, the Commission constructed the normal value per product type on an ex-works basis in accordance with Article 2(6a)(a) of the basic Regulation. The Commission constructed the normal value per product type for each of the four cooperating exporting producers.

### 3.9. Export price

- (185) The cooperating exporting producers exported to the Union directly to independent customers. Therefore, the export price was the price actually paid or payable for the product under review when sold for export to the Union, in accordance with Article 2(8) of the basic Regulation.

### 3.10. Comparison

- (186) The Commission compared the normal value and the export price of the cooperating exporting producer on an ex-works basis.
- (187) Where justified by the need to ensure a fair comparison, the Commission adjusted the normal value and/or the export price for differences affecting prices and price comparability, in accordance with Article 2(10) of the basic Regulation. On this basis, allowances for transport, insurance, handling, loading and ancillary costs, packing, credit costs, bank charges and commissions have been made where applicable and justified.

### 3.11. Dumping margins for the cooperating exporting producers

- (188) For the cooperating exporting producers, the Commission compared the weighted average normal value of each type of the like product with the weighted average export price of the corresponding type of the product under review, in accordance with Article 2(11) and (12) of the basic Regulation.
- (189) On this basis, the weighted average dumping margins expressed as a percentage of the CIF Union frontier price, duty unpaid, are 42 % for Weifang Ensign Industry Co., Ltd and 144 % for COFCO Bio-Chemical Energy (Yushu) Co. Ltd. No dumping was calculated for RZBC Group (RZBC (Juxian) Co., Ltd. and related trader RZBC Imp. & Exp. Co., Ltd.), nor for Jiangsu Guoxin Union Energy Co. Ltd, which are subject to price undertakings as explained in recital (191).

### 3.12. Dumping margins for the non-cooperating exporting producers

- (190) The Commission also established the average dumping margin for the non-cooperating exporting producers. On the basis of the facts available, in accordance with Article 18 of the basic Regulation, the highest dumping margin of the cooperating producers was used, not least given the significantly lower level of export prices by non-cooperating companies.

### 3.13. Conclusion on continuation of dumping

- (191) Altogether, a majority of Chinese exports to the EU (between 70 to 90 %) were made at significantly dumped prices during the review investigation period. The remaining Chinese exports were made by the two cooperating exporting producers for which no dumping was established. These two exporting producers are subject to price undertakings and their exports to the Union were made at the minimum import price. Their export prices to the Union were thus considered to be influenced by the undertakings and therefore not reliable enough to be used for the determination whether dumping will continue in the context of this expiry review.



- (192) In sum, dumping has continued for the vast majority of Chinese exports to the Union. The Commission therefore concluded that dumping continued during the review investigation period.

#### 4. LIKELIHOOD OF CONTINUATION OF DUMPING

- (193) Further to the finding of the existence of dumping during the review investigation period, the Commission investigated the likelihood of continuation of dumping should the measures be repealed in accordance with Article 11(2) of the basic Regulation. The following additional elements were analysed: the production capacity and spare capacity in the country concerned, the attractiveness of the Union market; the relation between export prices to third countries and the price level in the Union; and circumvention practices.
- (194) As mentioned above, only four Chinese exporting producers came forward. Therefore, the information available to the Commission on production and spare capacity from Chinese exporting producers was limited.
- (195) For this reason, most of the findings set out below concerning the continuation or the recurrence of dumping had to be based on other sources, namely Eurostat and GTA databases and the information submitted by the Union industry in the review request. The analysis of that information revealed the following.

##### 4.1. Production capacity and spare capacity in the country concerned

- (196) Based solely on the questionnaire replies of the cooperating exporting producers, the investigation revealed spare production capacities of around 129 000 tonnes, which accounts for 20 to 40 % of EU demand. In the RIP, total Chinese production capacity is estimated to be three to four times higher than the total EU consumption.
- (197) Domestic Chinese demand was estimated to be around 465 000 tonnes – less than 24 % of the country's production capacity. In addition, planned further increases in capacity indicate that the latter will reach the level of total world consumption in 2021 <sup>(62)</sup> – further exacerbating existing Chinese overcapacity. These new capacities will in all likelihood translate into even higher pressure to export, not least in view of the gap between capacity and the aforementioned levels of domestic demand. It is highly unlikely that Chinese domestic consumption would increase to the extent to be able to absorb existing capacity, let alone the increased one. In addition, the presence of measures already in place in a number of other markets makes it highly likely that there would be significant increase of dumped imports if the measures in the Union are repealed.

##### 4.2. Attractiveness of the Union market

- (198) The attractiveness of the Union market for Chinese exports was apparent given the continuing and massive presence even with measures – reaching 30 % to 50 % of the Union market share.
- (199) The attractiveness of the Union market was further underlined by the fact that a Chinese investor is building a new plant with a capacity of up to 60 000 tonnes in the Union <sup>(63)</sup>.
- (200) In addition, Chinese exports to other important markets such as the US, Brazil, Colombia, India or Thailand were constrained by the existence of trade defence measures.
- (201) The attractiveness of the Union market was further confirmed by the price elements hereunder.

##### 4.3. Relation between export prices to third countries and the price level in the Union

- (202) Export prices to third countries by the four cooperating companies were 20 to 40 % lower than the export prices to the Union, again underlining its attractiveness.

<sup>(62)</sup> The Commission made the information concerning level of capacities in China, together with source materials, available in the file for inspection by interested parties on 7 June 2020, save No t20.004035.

<sup>(63)</sup> China-CEE Institute: 'China and Hungary: 70 years of bilateral relations in a changing world', December 2019, p. 75.

#### 4.4. Circumvention practices

- (203) Circumvention practices via Malaysia, which led to the imposition of anti-circumvention duties in January 2016 referred to in recital (5), further underlined the attractiveness of the Union market for Chinese exports.

#### 4.5. Likely prices and dumping margins should measures be repealed

- (204) As explained above, dumping has continued for a large majority of Chinese exports.
- (205) In addition, all indications were that sales would take place at dumped levels should measures expire.
- (206) First, the fact that all companies with undertakings sold precisely at the undertaking's minimum import price, indicated that the undertaking was acting as a price floor. In the absence of such a floor, and faced with competition by other Chinese exports priced in the range of 30 to 40 % lower than those in the undertaking, firms would have to sell at that lower price range to stay in the market. This would in all likelihood lead to higher dumping margins for all companies subject to the undertaking.
- (207) Second, circumvention could be considered as an additional factor indicating the exporters' interest in entering the Union market and their inability to compete on the Union market at non-dumped levels. There was also a pattern of unfair pricing behaviour by Chinese firms when they export to other markets, as shown by high number of trade defence measures against citric acid in third countries mentioned in recital (200).
- (208) Third, export prices to third countries by the four cooperating companies were much lower than those to the Union, indicating the likelihood of a further drop in export prices and thus of a further increase in dumping margins should measures expire.

#### 4.6. Conclusion

- (209) Should measures expire, the above analysis revealed the continuation of dumping and the strong likelihood of an increase in the dumping margins, with an even more prominent presence of imports into the attractive Union market.
- (210) Following disclosure, CCCMC and three cooperating exporting producers questioned the findings on spare capacity. They claimed that based on the Commission's own calculations spare capacities went down from 192 000 tonnes in 2015 (the previous review) to 129 000 tonnes in the RIP, thus contradicting the finding of ever-larger spare production capacity translating into higher pressure to export. The Commission noted that it assessed the spare capacities based on data from the cooperating exporting producers. These cooperating exporting producers are different from the cooperating exporting producers in the previous review. For this reason, the comparison by CCCMC and the three cooperating exporting producers is flawed. In any event, 129 000 tonnes still represent a massive overcapacity. The claim was therefore dismissed.
- (211) Following disclosure, CCCMC and three cooperating exporting producers contended that the Commission had not verified the reliability and accuracy of claimed evidence on planned capacity increases submitted by the Union industry. The Commission noted that it has carefully reviewed the submissions of both the Union industry and CCCMC in this respect and its review has not brought to light any elements that might alter its findings as established in recital (197).
- (212) Following disclosure, CCCMC and three cooperating exporting producers claimed that the conclusion of the Commission that export prices to the Union would drop to third country levels in the absence of new measures, is total speculation. They also claimed that the Commission had provided no quantification or analysis with regard to its conclusion that exports from the PRC would likely increase and occur at higher dumping margins in the absence of measures. Finally, they claimed that the Commission did not present a sound economic reasoning of why Chinese exporting producers would drop substantially their prices to the Union in the absence of renewed measures.

- (213) In response, the Commission noted that the investigation clearly established that dumping continues even based on export prices that are propped up by the MIP of the undertakings. Prices of exporting producers not subject to undertakings were significantly lower, clearly indicating that prices would be likely to drop in the absence of undertakings. In addition, the Commission found export prices to the Union to be significantly higher than export prices to other markets for all exporting producers subject to undertakings, indicating that the Union market would attract an increase in imports. These elements, together with the significant spare capacity in the PRC, clearly supported the finding that exports to the Union would likely continue to occur at dumped prices and at increased volumes if the measures were repealed.

## 5. INJURY

### 5.1. Definition of the Union industry and Union production

- (214) The like product was manufactured by two producers in the Union during the RIP. The two producers constitute the 'Union industry' within the meaning of Article 4(1) of the basic Regulation.
- (215) With regard to the fact that only two producers constitute the Union industry, the Commission, presented some of the figures in this Regulation using ranges and/or indexes in accordance with Article 19 of the basic Regulation in order to protect confidential information.
- (216) The total Union production during the review investigation period was established within the range of 300 000 to 350 000 tonnes. The Commission established the figure on the basis of questionnaire replies of the two Union producers.

### 5.2. Union consumption

- (217) The Commission established the free market Union consumption on the basis of the free market sales of the Union industry on the Union market and imports from the PRC and other third countries, as indicated in the questionnaire replies and import statistics based on 14(6) database.
- (218) Free market union consumption developed as follows:

Table 1

#### Union consumption (tonnes)

	2016	2017	2018	Review investigation period
Total union consumption	500 000 - 550 000	535 000 – 585 000	535 000 – 585 000	515 000 - 565 000
<i>Index</i>	100	107	107	103

Source: Questionnaire replies and the 14(6) database

- (219) The Union consumption initially increased by 7 %, with a peak of consumption in 2017 and 2018. Between 2018 and the review investigation period, the consumption somewhat decreased, but remained 3 % higher than at the beginning of the period considered.
- (220) The reason for the increase of consumption of citric acid was the increase in consumption of products using the product under review in various industries such as food, household detergents, pharmaceutical and cosmetics. In addition, the legislation requiring substitution of phosphates in household cleaning detergents added to the increase of consumption of the product under review, as citric acid is one of the more suitable substitute of phosphates in these applications.

### 5.3. Imports from the country concerned

#### 5.3.1. Volume and market share of the imports from the country concerned

- (221) The Commission established the volume of imports on the basis of the 14(6) database. The market share of the imports was established on the basis of the 14(6) database and questionnaire replies of the Union industry.
- (222) Imports from the country concerned developed as follows:

Table 2

#### Import volume (tonnes) and market share

	2016	2017	2018	Review investigation period
Volume of imports from China	207 295	190 750	223 185	205 595
<i>Index</i>	100	92	108	99
Market share (%)	40 – 45	34 – 39	40 – 45	38 – 43
<i>Index</i>	100	86	100	96

Source: Questionnaire replies and the 14(6) database

- (223) The volume of imports from China was significant throughout the period considered, remaining almost at the same level in the review investigation period compared to 2016. The lower imports in 2017 and higher imports of 2018 are linked to the fact that citric acid is a product transported in large quantities, and such a large quantity entered the Union market in January 2018 and was hence attributed to the 2018 imports (imports of January 2018 are around 50 % higher than December 2017). Overall, the import volumes from China were stable.
- (224) The market share of imports of citric acid from China was significant and remained largely in the 40 % range, with a small decline of 1,4 percentage points over the period considered. As imports from other countries also declined, as described in recital (234) to (235), the Commission observed that the increased demand during the period considered was satisfied by the increase of production of the Union industry.

#### 5.3.2. Prices of the imports from the country concerned and price undercutting

- (225) The Commission established the prices of imports on the basis of the 14(6) database. The average price of imports from the country concerned developed as follows:

Table 3

#### Import prices (EUR/tonne)

	2016	2017	2018	Review investigation period
China	736,7	773,8	738,2	701,9
<i>Index</i>	100	105	100	95

Source: 14(6) database

- (226) The price of citric acid imported from China was stable during the period considered. Overall, the price of Chinese citric acid decreased by 5 % compared to 2016. Import prices from China remained substantially lower compared to Union prices, as reflected in Table 8.
- (227) The increase of import prices in 2017 can be linked with the increase of consumption, which, as explained in recital (219), was particularly high in 2017, due to the legislative change described in recital (220) concerning phosphates. This increase of demand triggered an increase in import prices. Prices then fell back in 2018 and 2019 as demand adjusted.
- (228) The Commission determined the price undercutting during the review investigation period by comparing:
- the weighted average sales prices per product type of the Union producers charged to unrelated customers on the Union market, adjusted to an ex-works level; and
  - the corresponding weighted average prices per product type of the imports from the cooperating Chinese producers to the first independent customer on the Union market, established on a Cost, insurance, freight (CIF) basis, including the anti-dumping duty, with appropriate adjustments for customs duties and post-importation costs.
- (229) Two levels of undercutting margins are shown below, the first covers the cooperating exporting producers not subject to the undertaking mentioned in recital (189). The second level also includes the three cooperators which were subject to the undertaking. A distinction is made because the prices of the companies subject to the undertaking were influenced by the terms of the undertaking.
- (230) For non-cooperating exporting producers, price undercutting could not be established using prices per product type, as this information was not available. Therefore, price undercutting was established by comparing overall weighted average sales prices both for the Union producers and for the non-cooperating Chinese exporting producers.
- (231) The price comparisons were made on a type-by-type basis for transactions at the same level of trade, duly adjusted where necessary, and after deduction of rebates and discounts. The results of the comparisons were expressed as a percentage of the Union producers' turnover during the review investigation period. They showed a weighted average undercutting margin for exporting producers not subject to the undertakings of more than 19 %, and for exporting producers subject to the undertaking of more than 10 %.

#### 5.4. Imports from third countries other than China

- (232) The imports of citric acid from third countries other than China came mainly from Cambodia, Colombia and Thailand.
- (233) The (aggregated) volume of imports as well as the market share and price trends for imports of citric acid from other third countries developed as follows:

Table 4

#### Imports from third countries

Country		2016	2017	2018	Review investigation period
Thailand	Volume (tonnes)	19 410	20 163	13 203	13 305
	<i>Index</i>	100	104	68	69
	Market share (%)	< 5	< 5	< 5	< 5
	Average price (EUR)	817	887	847	784
	<i>Index</i>	100	109	104	96

Other third countries	Volume (tonnes)	10 331	18 612	7 909	7 194
	<i>Index</i>	100	180	77	70
	Market share (%)	< 5	< 5	< 5	< 5
	Average price (EUR)	1 094	1 001	1 251	1 265
	<i>Index</i>	100	92	114	116
Total of all third countries	Volume (tonnes)	29 741	38 775	21 112	20 500
	<i>Index</i>	100	130	71	69
	Market share (%)	5-10	5-10	< 5	< 5
	Average price (EUR)	913	942	998	952
	<i>Index</i>	100	103	109	104

Source: The 14(6) database

- (234) The largest volumes of imports of citric acid from third countries other than China throughout the period considered came from Thailand. Imports from Thailand decreased by 31 % during the period considered. In every year of the period considered, the prices followed the trend of price evolution of Chinese imports, but were 11 % to 15 % higher.
- (235) Imports of citric acid from all third countries fell by 30 % over the period considered. Their prices were also higher compared to prices of imports from China.

## 5.5. Economic situation of the Union industry

### 5.5.1. General remarks

- (236) The assessment of the economic situation of the Union industry included an evaluation of all economic indicators having a bearing on the state of the Union industry during the period considered.

### 5.5.2. Production, production capacity and capacity utilisation

- (237) The total Union production, production capacity and capacity utilisation developed as follows over the period considered:

Table 5

### Union production volume, production capacity and capacity utilisation

	2016	2017	2018	Review investigation period
Production volume (tonnes)	300 000 – 350 000	342 000 – 392 000	339 000 – 389 000	327 000 – 377 000
<i>Index</i>	100	114	113	109
Production capacity (tonnes)	350 000 – 400 000	381 000 – 431 000	395 000 – 445 000	395 000 – 445 000
<i>Index</i>	100	109	113	113

Capacity utilisation (%)	90 – 100	90 – 100	90 – 100	87 – 97
<i>Index</i>	100	105	100	97

Source: Questionnaire replies

- (238) The production volume increased by 9 % during the period considered and the peak of the production was reached in 2017 (when it was by 14 % higher than in 2016). The trend of production volume of the Union industry largely follows the trend of the Union consumption.
- (239) Production capacity has increased steadily during the period considered and compared with 2016 it was by 13 % higher in the review investigation period.
- (240) Capacity utilisation fluctuated during the period considered, reaching the lowest level during the review investigation period, at 3 % below the level of 2016.

#### 5.5.3. Sales volume and market share

- (241) The Union industry's sales volume and market share developed as follows over the period considered:

Table 6

#### Union sales volume and market share

	2016	2017	2018	Review investigation period
Total sales volume on the Union market (tonnes)	250 000 – 300 000	292 000 – 342 000	280 000 – 330 000	275 000 – 325 000
<i>Index</i>	100	117	112	110
Captive market sales	0 – 5 000	0 – 5 000	0 – 5 000	0 – 5 000
Free market sales	245 000 – 300 000	287 000 – 342 000	275 000 – 330 000	270 000 – 325 000
<i>Index</i>	100	116	112	110
Market share of free market sales (%)	50 – 60	54 – 64	52 – 62	54 – 64
<i>Index</i>	100	109	104	107

Source: Questionnaire replies

- (242) Captive market sales, linked mainly to the production of specialties and special salts which use citric acid as an input material, were at a small level of below 5 000 tonnes in each year of the period considered and therefore had no noticeable influence on the Union industry's situation, including its market shares.
- (243) The sales developed similarly to the trend of production and increased by 10 % during the period considered, being at the highest level in 2017.
- (244) The market share of the Union industry was between 50 % and 64 % in each year of the period considered. It increased in the review investigation period by around 4 percentage points.

#### 5.5.4. Employment and productivity

- (245) Employment and productivity developed in the Union over the period considered as follows:

Table 7

**Employment and productivity in the Union**

	2016	2017	2018	Review investigation period
Number of employees	600 – 650	624 – 674	642 – 692	642 – 792
<i>Index</i>	100	104	107	107
Productivity (unit/employee)	500 – 550	550 – 600	530 – 580	510 – 560
<i>Index</i>	100	110	106	102

Source: Questionnaire responses

- (246) The number of employees expressed in full time equivalent increased by around 7 % during the period considered to reach a level of over 640 employees in the review investigation period.
- (247) Productivity increased only slightly during the period considered by around 2 %. In this respect, the productivity is expressed as number of tonnes per number of employees (full time equivalents) during the year.

#### 5.5.5. Magnitude of the dumping margin and recovery from past dumping

- (248) The impact of the actual dumping margins on the Union industry was mitigated by the undertaking applicable to the price level of large Chinese exporting producers, which acted as a floor for the relevant Chinese export prices.
- (249) It can therefore be concluded that the Union industry has recovered from the injury caused by the past dumping of Chinese exporting producers. During the period considered, the recovery process of the Union industry continued as demonstrated by a favourable trend of the main injury indicators.

#### 5.5.6. Prices and factors affecting prices

- (250) The weighted average unit sales prices of the Union producers to unrelated customers in the Union developed over the period considered as follows:

Table 8

**Sales prices in the Union**

	2016	2017	2018	Review investigation period
Average unit sales price on the free market (EUR/tonne)	1 000 – 1 100	980 – 1 080	1 010 – 1 110	1 010 – 1 110
<i>Index</i>	100	98	101	101
Unit cost of production (EUR/tonne)	800 – 900	760 – 860	824 – 924	840 – 940
<i>Index</i>	100	95	103	105

Source: Questionnaire responses



- (251) The weighted average unit sales prices of the Union producers to unrelated customers in the Union was very stable and increased only by 1 % during the period considered.
- (252) The unit cost of production fluctuated during the period considered to reach a 5 % higher level in the review investigation period compared to 2016. The increase of costs combined with only a small increase in sales prices resulted in a decrease of profitability, as described in recital (257).

#### 5.5.7. Labour costs

- (253) The average labour costs of the Union producers developed as follows over the period considered:

Table 9

#### Average labour costs per employee

	2016	2017	2018	Review investigation period
Average labour costs per employee (EUR)	70 000 – 80 000	70 000 – 80 000	71 400 – 81 400	72 800 – 82 800
<i>Index</i>	100	100	102	104

Source: Questionnaire responses

- (254) The average labour costs of the Union producers increased by 4 % during the period considered, lower than the inflation in the Union during this period.

#### 5.5.8. Inventories

- (255) Stock levels of the Union producers developed over the period considered as follows:

Table 10

#### Inventories

	2016	2017	2018	Review investigation period
Closing stocks (tonnes)	20 000 – 25 000	16 200 – 21 200	24 400 – 39 400	24 000 – 28 000
<i>Index</i>	100	81	122	120
Closing stocks as a percentage of production (%)	5 – 10	3 – 8	5 – 10	5 – 11
<i>Index</i>	100	71	107	110

Source: Questionnaire responses

- (256) The closing stocks of the Union producers increased during the period considered. The level of inventories is at a stable level following the increased sales and production. The much lower level of stock was the exception for the year-end 2017. The exception is linked with the increased demand for citric acid due to the replacement of phosphates in the chemical composition of certain products, as explained in recital (220).

5.5.9. Profitability, cash flow, investments, return on investments and ability to raise capital

- (257) Profitability, cash flow, investments and return on investments of the Union producers developed over the period considered as follows:

Table 11

**Profitability, cash flow, investments and return on investments**

	2016	2017	2018	Review investigation period
Profitability of sales in the Union to unrelated customers (% of sales turnover)	15 – 20	18 – 23	14 – 19	11 – 16
<i>Index</i>	100	120	94	79
Cash flow Index	100	140	100	102
Investments (EUR)	40 000 000 – 50 000 000	35 600 000 – 45 600 000	31 200 000 – 41 200 000	39 600 000 – 49 600 000
<i>Index</i>	100	89	78	99
Return on investments (%)	30 – 40	37 – 48	27 – 38	26 – 36
<i>Index</i>	100	125	92	86

Source: Questionnaire responses

- (258) The Commission established the profitability of the Union producers by expressing the pre-tax net profit of the sales of the like product to unrelated customers in the Union as a percentage of the turnover of those sales.
- (259) The profitability during the period considered was at the highest level in 2017. The exceptional circumstances were linked to the replacement of phosphates, as described in recital (220) and higher profitability in that year should be linked with increased demand in that specific year. Overall profitability of the industry in the review investigation period was above 10 %.
- (260) The net cash flow is the ability of the Union producers to self-finance their activities. Its development remained at similar levels throughout the period considered, except in the year 2017.
- (261) The return on investments is the profit as a percentage of the net book value of investments. Its development was similar to the development of profitability, and remained at satisfactory levels throughout the period considered.
- (262) None of the Union producers reported difficulties in raising capital during the period considered.

**5.6. Conclusion on injury**

- (263) Most injury indicators such as production, sales volume, employment, capacity, productivity and cash flow developed positively. While the trend of the financial indicators such as profitability and return of investments is negative, their absolute levels are satisfactory and do not indicate a sign of material injury.
- (264) Therefore, the Commission concluded that the Union industry did not suffer material injury within the meaning of Article 3(5) of the basic Regulation during the review investigation period.

## 6. LIKELIHOOD OF RECURRENCE OF INJURY

### 6.1. General remarks

- (265) The Commission concluded in recital (262) that the Union industry did not suffer material injury during the period considered, and assessed, in accordance with Article 11(2) of the basic Regulation, whether there would be a likelihood of recurrence of injury originally caused by the dumped imports from China if the measures against Chinese imports were allowed to lapse <sup>(64)</sup>.
- (266) The above trends concerning prices and volumes of imports of the product under review from China show that while the Chinese exporters maintained a sizeable presence on the Union market, the measures in force (duty and undertakings) have led to an improvement in market conditions. The Union industry was the main beneficiary of this development, as the market presence of other third countries remained limited. This indicates that the removal of injury is mainly due to the existence of the measures in force.
- (267) As mentioned in recitals (196) to (197), exporting producers in the PRC have massive and increasing spare capacity enabling them to increase their exports very rapidly. In addition, given the more lucrative prices on the Union market compared to most third country markets, it is likely that significant quantities currently exported to these countries could also be redirected to the Union market should the anti-dumping measures be allowed to lapse.
- (268) In addition, major international markets have trade defence measures against Chinese citric acid. It will therefore be more difficult for the Chinese exporting producers to sell in those markets than into an unprotected Union market should the anti-dumping measures be allowed to lapse.
- (269) In addition, the price levels of the Chinese exporters undercut Union industry's prices significantly even with measures in place. Without duties, undercutting by exporting producers without undertakings would be in excess of 29 %. The foregoing shows the price levels at which Chinese exporting producers would likely enter the Union market in the absence of measures. Without the measures in place, the Union industry would not be able to maintain its prices, likely incurring into losses like in the original investigation.
- (270) The likelihood of low-priced Chinese exports in the absence of measures is also confirmed by the numerous anti-dumping investigations on Chinese citric acid in other countries mentioned in recital (200).
- (271) The combination of the high export capacity of Chinese producers and injurious prices would directly lead to a rapid loss of Union industry sales and/or drop in its prices, whose effect would lead to a deep financial deterioration, jeopardising the Union industry's survival – as shown by the shutdown of other Union producers, mentioned in recital (276).
- (272) Following disclosure, CCCMC and three cooperating exporting producers commented with regard to likelihood of recurrence of injury that increased imports at lower prices would not make commercial or market sense, should the measures expire. In addition, CCCMC also claimed that trade defence measures in other countries would not have significant impact on decision-making of exporting producers from China. These claims were neither substantiated nor did they demonstrate in any way that the wide array of substantive elements and reasoning mentioned above were incorrect. Moreover, the Commission observed that import prices without duties, as shown in Table 3 are already well below the Union industry's costs of production (as shown in Table 11). Consequently, even maintaining such low import prices would put pressure on the Union industry which would likely materialise in injury again. Therefore, these claims cannot be accepted.

<sup>(64)</sup> See Appellate Body Report, *United States – Anti-Dumping Measures on Oil Country Tubular Goods (OCTG) from Mexico* (WT/DS282/AB/R), paras. 108 and 122 – 123.

- (273) Therefore, it is concluded that the absence of measures would in all likelihood result in a significant increase of dumped imports from China at injurious prices and material injury would be likely to recur.

## 7. UNION INTEREST

- (274) In accordance with Article 21 of the basic Regulation, the Commission examined whether maintaining the existing anti-dumping measures would be against the interest of the Union as whole. The determination of the Union interest was based on an appreciation of all the various interests involved, including those of the Union industry, importers and users.

### 7.1. Interest of the Union industry

- (275) Both Union producers accounting together for 100 % of Union production cooperated in this investigation. As stated in recital (263), Union industry has recovered from the injury caused by past dumping and their operations are viable when not subject to unfair competition by dumped imports.
- (276) The Union industry was following the increased demand for citric acid, including investments needed to increase their production capacity and plans to expand it further.
- (277) At the same time, removal of the measures would very likely lead to increased unfair competition by dumped Chinese imports, threatening the continued operation of the remaining producers in an otherwise viable industry. It is recalled that three producers in the Union had closed down before the imposition of measures against the Chinese imports.
- (278) The Commission therefore concluded that it is in the interest of the Union industry to maintain the measures in force.

### 7.2. Interest of unrelated importers

- (279) As stated in recital (18), only one unrelated importer submitted a questionnaire reply. Therefore there was not much interest among importers in the current investigation.
- (280) Importers of citric acid are often traders of a wider range of chemical products and are thus not limited to citric acid. Furthermore, the traders import chemical products from other third countries apart from China, and also trade in products produced by the Union industry. Therefore, the potential impact of maintaining the duties on importers is expected to be very limited.

### 7.3. Interest of users

- (281) As set out in recital (23), the Commission received questionnaire replies from four users from the health, beauty and home hygiene industry. In spite of the food and beverage industry constituting the biggest user of citric acid, no user from that industry cooperated in the investigation.
- (282) For most users, citric acid accounts for a small or even negligible part of their costs structure. In some specific type of products, in particular in the area of home hygiene products such as dishwasher tablets, the content of citric acid is much higher.
- (283) In their comments, the cooperating users claimed that the Union industry is fully recovered, and indicated that it is not able to fully meet the demand in the Union. The comments also mentioned that, especially for products with exceptionally high content of citric acid, the production of these products in the Union is less competitive compared with countries where citric acid is not subject to duties. Users also pointed to the good financial situation of the Union producers.
- (284) The existing measures have not affected the availability of citric acid from non-Union sources, as the continuing sizeable presence of Chinese exports confirms. Increases in production capacity are planned in the Union, both by the Union producers and by the Chinese investment in the Union referred to in recital (199).

- (285) The profitability of cooperating users was high, and for the vast majority of users the financial impact of cost of citric acid as a raw material was negligible. For the users involved in production of the type of products containing higher content of citric acid, those products were only a part of a much wider portfolio. During the previous expiry review, when more users cooperated in the investigation, the Commission established that citric acid accounts for no more than 5 % of raw material costs of users producing chemical products. Therefore, the effect of the measures on these users was considered to be limited.
- (286) On balance, the positive effect of the measures on the Union industry by far outweighed the limited negative impact of the measures in force on the users.

#### 7.4. Other factors – security of sources of supply

- (287) Security of supply is an important element of the market of citric acid. For the majority of applications of citric acid, the price factor was negligible, whereas availability of the product under review as a raw material was crucial. In the absence of measures, the survival of the Union industry would be in jeopardy, with effects beyond industry itself, e. g., reduction in available sources of supply or reduction of competitors in the market.

#### 7.5. Conclusion on Union interest

- (288) On the basis of the above, the Commission concluded that there were no compelling reasons of Union interest against the maintenance of the existing measures on imports of citric acid originating in China.

### 8. ANTI-DUMPING MEASURES

- (289) On the basis of the conclusions reached by the Commission on recurrence of dumping, recurrence of injury and Union interest, the anti-dumping measures on citric acid from China should be maintained.
- (290) In light of the withdrawal of the United Kingdom of Great Britain and Northern Ireland ('UK') from the European Union, effective from 1 January 2021, the Commission also analysed the impact of such a withdrawal on the conclusions of this expiry review.
- (291) In this respect, the Commission noted that the share of the total imports of citric acid into the UK out of the total imports on an EU-28 basis was less than 10 % throughout the period considered (source: 14.6 Database). Neither the attractiveness of the Union market nor the price level of imports of the product concerned in the Union would be affected by the reduction of the internal market to EU-27.
- (292) Sales by the two sole Union producers to the UK were in the same order of magnitude.
- (293) For the two Chinese exporting producers where the dumping margin was calculated as explained in recital (189), removing export sales to the UK for the purposes of calculating a dumping margin would not have an impact of more than 1 percentage point. As a corollary dumping margins for non-cooperating producers would also not change.
- (294) Therefore, the Commission concluded that the results of this investigation leading to the maintenance of the anti-dumping measures would not vary, regardless of whether UK is considered for the analysis or not. No comments were made on this point by any interested party.
- (295) All interested parties were informed of the essential facts and considerations on the basis of which it was intended to recommend that the existing measures be maintained. They were also granted a period to make representations subsequent to this disclosure.
- (296) In view of Article 109 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council <sup>(65)</sup>, when an amount is to be reimbursed following a judgment of the Court of Justice of the European Union, the interest to be paid should be the rate applied by the European Central Bank to its principal refinancing operations, as published in the C series of the *Official Journal of the European Union* on the first calendar day of each month.

<sup>(65)</sup> OJ L 193, 30.7.2018, p. 1.

(297) The measures provided for in this regulation are in accordance with the opinion of the Committee established by Article 15(1) Regulation (EU) 2016/1036,

HAS ADOPTED THIS REGULATION:

#### Article 1

1. A definitive anti-dumping duty is imposed on imports of citric acid and trisodium citrate dihydrate, currently falling under CN codes 2918 14 00 and ex 2918 15 00 (TARIC code 2918 15 00 11 and 2918 15 00 19) and originating in the People's Republic of China.

2. The rates of the definitive anti-dumping duty applicable to the net, free-at-Union-frontier price, before duty, of the product described in paragraph 1 and produced by the companies listed below shall be as follows:

Company	Definitive anti-dumping duty (%)	TARIC additional code
COFCO Bio-Chemical Energy (Yushu) Co. Ltd – No 1 Dongfeng Avenue, Wukeshu Economic Development Zone, Changchun City 130401, PRC	35,7	A874
Laiwu Taihe Biochemistry Co., Ltd. – No 89, Changjiang Street, Laiwu City, Shandong Province, PRC	15,3	A880
RZBC Co., Ltd. – No 9 Xinghai West Road, Rizhao City, Shandong Province, PRC	36,8	A876
RZBC (Juxian) Co., Ltd. – No 209 Laiyang Road, Juxian Economic Development Zone, Rizhao City, Shandong Province, PRC	36,8	A877
TTCA Co., Ltd. – West, Wenhe Bridge North, Anqiu City, Shandong Province, PRC	42,7	A878
Weifang Ensign Industry Co., Ltd. – No 1567 Changsheng Street, Changle, Weifang, Shandong Province, PRC	33,8	A882
Jiangsu Guoxin Union Energy Co., Ltd. – No 1 Redian Road, Yixing Economic Development Zone, Jiangsu Province, PRC	32,6	A879
All other companies	42,7	A999

3. The definitive anti-dumping duty applicable to imports originating in the People's Republic of China, as set out in paragraph 2, is hereby extended to imports of the same citric acid and trisodium citrate dihydrate consigned from Malaysia, whether declared as originating in Malaysia or not (CN codes ex 2918 14 00 (TARIC code 2918 14 00 10) and ex 2918 15 00 (TARIC code 2918 15 00 11)).

4. The application of the individual duty rates specified for the companies mentioned in paragraph 2 shall be conditional upon presentation to the Member States' customs authorities of a valid commercial invoice, on which shall appear a declaration dated and signed by an official of the entity issuing such invoice, identified by his/her name and function, drafted as follows: 'I, the undersigned, certify that the (volume) of (product under review) sold for export to the European Union covered by this invoice was manufactured by (company name and address) (TARIC additional code) in [country concerned]. I declare that the information provided in this invoice is complete and correct.' If no such invoice is presented, the duty applicable to all other companies shall apply.

5. Unless otherwise specified, the provisions in force concerning customs duties shall apply.

*Article 2*

1. Imports declared for release into free circulation which are invoiced by companies from which undertakings are accepted by the Commission and whose names are listed in Decision 2008/899/EC, further amended by Decision 2012/501/EU and Regulation (EU) 2016/704, shall be exempt from the anti-dumping duty imposed by Article 1, on condition that:

- (a) they are manufactured, shipped and invoiced directly by the said companies to the first independent customer in the Union; and
- (b) such imports are accompanied by an undertaking invoice which is a commercial invoice containing at least the elements and the declaration stipulated in the Annex to this Regulation; and
- (c) the goods declared and presented to customs correspond precisely to the description on the undertaking invoice.

2. A customs debt shall be incurred at the time of acceptance of the declaration for release into free circulation:

- (a) whenever it is established, in respect of imports described in paragraph 1, that one or more of the conditions listed in that paragraph are not fulfilled; or
- (b) when the Commission withdraws its acceptance of the undertaking pursuant to Article 8(9) of Council Regulation (EC) No 1225/2009 <sup>(66)</sup> in a Regulation or Decision which refers to particular transactions and declares the relevant undertaking invoices as invalid.

*Article 3*

This Regulation shall enter into force on the 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, 14 April 2021.

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

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<sup>(66)</sup> OJ L 343, 22.12.2009, p. 51..

## ANNEX

The following elements shall be indicated in the commercial invoice accompanying the companies' sales to the European Union of goods, which are subject to the undertaking:

1. The heading 'COMMERCIAL INVOICE ACCOMPANYING GOODS SUBJECT TO AN UNDERTAKING'.
  2. The name of the company issuing the commercial invoice.
  3. The commercial invoice number.
  4. The date of issue of the commercial invoice.
  5. The TARIC additional code under which the goods on the invoice are to be customs-cleared at the European Union border.
  6. The exact description of the goods, including:
    - the product code number (PCN) used for the purpose of the undertaking,
    - plain language description of the goods corresponding to the PCN concerned,
    - the company product code number (CPC),
    - TARIC code,
    - quantity (to be given in tonnes).
  7. The description of the terms of the sale, including:
    - price per tonne,
    - the applicable payment terms,
    - the applicable delivery terms,
    - total discounts and rebates.
  8. Name of the company acting as an importer in the European Union to which the commercial invoice accompanying the goods subject to an undertaking is issued directly by the company.
  9. The name of the official of the company that has issued the commercial invoice and the following signed declaration:

'I, the undersigned, certify that the sale for direct export to the European Union of the goods covered by this invoice is being made within the scope and under the terms of the Undertaking offered by (COMPANY), and accepted by the European Commission through Implementing Decision (EU) 2015/87. I declare that the information provided in this invoice is complete and correct.'
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**COMMISSION IMPLEMENTING REGULATION (EU) 2021/608****of 14 April 2021****amending Implementing Regulation (EU) 2019/1793 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety <sup>(1)</sup>, and in particular Article 53(1)(b) thereof,

Having regard to 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) <sup>(2)</sup>, and in particular point (b) of the first subparagraph of Article 47(2), points (a) and (b) of the first subparagraph of Article 54(4) and points (a), (b) and (c) of the first paragraph of Article 90 thereof.

Whereas:

- (1) Commission Implementing Regulation (EU) 2019/1793 <sup>(3)</sup> lays down rules concerning the temporary increase of official controls at the entry into the Union on certain food and feed of non-animal origin from certain third countries listed in Annex I to that Implementing Regulation and special conditions governing the entry into the Union of certain food and feed from certain third countries due to the risk of contamination by mycotoxins, including aflatoxins, pesticide residues, pentachlorophenol and dioxins, and microbiological contamination, listed in Annex II to that Implementing Regulation.
- (2) Implementing Regulation (EU) 2019/1793 lays down requirements as regards the model official certificate for the entry into the Union of consignments of food and feed listed in Annex II to that Implementing Regulation and rules for the issuance of such certificate, both on paper and in electronic form. In accordance with Commission Implementing Regulation (EU) 2019/1715 <sup>(4)</sup>, TRACES is the component of the Information Management System for Official Controls (IMSOC) enabling the entire process of certificate production to be performed electronically, thus preventing possible fraudulent or deceptive practices in respect of official certificates. Therefore, Implementing Regulation (EU) 2019/1793 sets out a model official certificate that is compatible with TRACES.

<sup>(1)</sup> OJ L 31, 1.2.2002, p. 1.

<sup>(2)</sup> OJ L 95, 7.4.2017, p. 1.

<sup>(3)</sup> Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660 (OJ L 277, 29.10.2019, p. 89).

<sup>(4)</sup> Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components ('the IMSOC Regulation') (OJ L 261, 14.10.2019, p. 37).

- (3) The certification requirements of Implementing Regulation (EU) 2019/1793 are consistent with the requirements laid down in Commission Implementing Regulation (EU) 2019/628 <sup>(5)</sup> for official certificates for the entry into the Union. Commission Implementing Regulation (EU) 2020/2235 <sup>(6)</sup> repeals and replaces Implementing Regulation (EU) 2019/628 as of 21 April 2021, while amending and clarifying the requirements for model official certificates laid down in that Implementing Regulation.
- (4) In particular, Implementing Regulation (EU) 2020/2235 makes a distinction between official certificates issued on paper, electronic official certificates issued in accordance with the requirements of Article 39(1) of Implementing Regulation (EU) 2019/1715 and official certificates issued on paper and completed in, and printed from, TRACES. In addition, that Implementing Regulation lays down linguistic requirements for official certificates for the entry into the Union to facilitate official controls at the border control posts of introduction into the Union. To align the official certificates for different categories of goods and to ensure consistency with the new certification requirements in the official certificates for the entry into the Union laid down in Implementing Regulation (EU) 2020/2235, it is appropriate to amend Article 11 of Implementing Regulation (EU) 2019/1793.
- (5) Article 12 of Implementing Regulation (EU) 2019/1793 provides that the lists set out in its Annexes I and II are to be reviewed on a regular basis not exceeding a period of six months, in order to take into account new information related to risks and non-compliance with Union legislation.
- (6) The occurrence and relevance of recent food incidents notified through the Rapid Alert System for Food and Feed ('RASFF'), as established by Regulation (EC) No 178/2002, and information regarding official controls performed by Member States on food and feed of non-animal origin indicate that the lists set out in Annexes I and II to Implementing Regulation (EU) 2019/1793 should be amended.
- (7) In particular, due to the high frequency of non-compliance with the relevant requirements provided for in Union legislation with respect to contamination by *Salmonella* detected during official controls performed by Member States in accordance with Implementing Regulation (EU) 2019/1793 in 2019 and in the first semester of 2020 and due to the high number of notifications in the RASFF during that period, it is appropriate to increase, from 20 % to 50 %, the frequency of identity and physical checks to be performed on black pepper (*Piper nigrum*) from Brazil.
- (8) Due to the high frequency of non-compliance with the relevant requirements provided for in Union legislation with respect to contamination by pesticide residues detected during official controls performed by Member States in accordance with Implementing Regulation (EU) 2019/1793 in the second semester of 2019 and in the first semester of 2020, it is appropriate to increase, from 10 % to 20 %, the frequency of identity and physical checks to be performed on peppers of the *Capsicum* species (other than sweet) from Thailand.
- (9) Due to the high frequency of non-compliance with the relevant requirements provided for in Union legislation with respect to contamination by aflatoxins detected during official controls performed by Member States in accordance with Implementing Regulation (EU) 2019/1793 in the second semester of 2019 and in the first semester of 2020 and due to the high number of notifications in the RASFF in the first semester of 2020, it is appropriate to increase, from 10 % to 50 %, the frequency of identity and physical checks to be performed on groundnuts from India.

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<sup>(5)</sup> Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (OJ L 131, 17.5.2019, p. 101).

<sup>(6)</sup> Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1).

- (10) Sweet peppers (*Capsicum annuum*) from Turkey are already listed in Annex I to Implementing Regulation (EU) 2019/1793 due to the risk of contamination by pesticide residues. For consignments of peppers of the *Capsicum* species (other than sweet) from Turkey, the data resulting from notifications received through the RASFF in the first semester of 2020 indicate the emergence of new risks to human health, due to possible pesticide residues contamination, requiring an increased level of official controls. The existing entry concerning sweet peppers (*Capsicum annuum*) from Turkey should therefore be amended to cover all peppers of the *Capsicum* species.
- (11) For goji berries from China listed in Annex I to Implementing Regulation (EU) 2019/1793 due to the risk of contamination by pesticide residues, and for dried grapes from Turkey listed in that Annex due to the risk of contamination by ochratoxin A, the available information for the second semester of 2019 and the first semester of 2020 indicates an overall satisfactory degree of compliance with the relevant requirements provided for in Union legislation. As an increased level of official controls is therefore no longer justified for those commodities, the entries in Annex I to Implementing Regulation (EU) 2019/1793 concerning those commodities should be deleted.
- (12) For groundnuts from Brazil listed in Annex II to Implementing Regulation (EU) 2019/1793 due to the risk of contamination by aflatoxins, the frequency of non-compliance with the relevant requirements provided for in Union legislation detected during official controls performed by Member States has decreased in the second semester of 2019 and remained at low levels in the first semester of 2020. It is therefore appropriate to delete the entry concerning groundnuts from Brazil from Annex II to Implementing Regulation (EU) 2019/1793, include it in Annex I to that Implementing Regulation and set the frequency of identity and physical checks at 10 %.
- (13) For groundnuts from China listed in Annex II to Implementing Regulation (EU) 2019/1793 due to the risk of contamination by aflatoxins, the frequency of non-compliance with the relevant requirements provided for in Union legislation detected during official controls performed by Member States has decreased in the second semester of 2019 and in the first semester of 2020. It is therefore appropriate to delete the entry concerning groundnuts from China from Annex II to Implementing Regulation (EU) 2019/1793, include it in Annex I to that Implementing Regulation and set the frequency of identity and physical checks at 10 %. Due to the volume of trade in this commodity, that frequency is sufficient to ensure an appropriate level of monitoring.
- (14) For hazelnuts from Turkey listed in Annex II to Implementing Regulation (EU) 2019/1793 due to the risk of contamination by aflatoxins, the frequency of non-compliance with the relevant requirements provided for in Union legislation detected during official controls performed by Member States has decreased in the second semester of 2019 and in the first semester of 2020. It is therefore appropriate to delete the entry concerning hazelnuts from Turkey from Annex II to Implementing Regulation (EU) 2019/1793, include it in Annex I to that Implementing Regulation and set the frequency of identity and physical checks at 5 %. Due to the volume of trade in this commodity, that frequency is sufficient to ensure an appropriate level of monitoring.
- (15) Foodstuffs containing or consisting of betel leaves (*Piper betle*) originating in, or consigned from Bangladesh are listed in Annex IIa to Implementing Regulation (EU) 2019/1793 due to the risk of contamination by *Salmonella*. Consequently, the importation into the Union of these products has been prohibited since June 2014. Bangladesh provided written guarantees by submitting a new action plan on 27 July 2020 with measures covering all steps of the chain of production, which the Commission assessed as satisfactory. Following this assessment, it is appropriate to delete the entry concerning foodstuffs containing or consisting of betel leaves (*Piper betle*) originating in, or consigned from, Bangladesh from Annex IIa to Implementing Regulation (EU) 2019/1793, include it in Annex II to that Implementing Regulation and set the frequency of identity and physical checks at 50 %.
- (16) In order to ensure efficient protection against potential health risks arising from microbiological or chemical contamination of *Sesamum* seeds, in the columns referring to 'CN code' in the tables in Annexes I and II to Implementing Regulation (EU) 2019/1793 the CN code for roasted *Sesamum* seeds should be added in the rows referring to '*Sesamum* seeds (food)'.

- (17) Part II of the model official certificate in Annex IV to Implementing Regulation (EU) 2019/1793 sets out the health information that the certifying officer is to provide when completing the certificate. In order to ensure legal certainty, it should be clarified that the health information for food or feed of non-animal origin can contain more than one certification, where such certification is mandatory pursuant to Article 11(1) of Implementing Regulation (EU) 2019/1793 in conjunction with Annex II to that Implementing Regulation.
- (18) Implementing Regulation (EU) 2019/1793 should therefore be amended accordingly. In order to ensure consistency and clarity, it is appropriate to replace Annexes I, II, IIa and IV to that Implementing Regulation in their entirety.
- (19) As Implementing Regulation (EU) 2020/2235 applies from 21 April 2021, Article 1(1) of this Regulation should also apply from that date.
- (20) 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*

### **Amendments to Implementing Regulation (EU) 2019/1793**

Implementing Regulation (EU) 2019/1793 is amended as follows:

- (1) Article 11 is replaced by the following:

*Article 11*

#### **Official certificate**

1. Each consignment of food and feed listed in Annex II shall be accompanied by an official certificate in accordance with the model set out in Annex IV ("official certificate").
2. The official certificate shall comply with the following requirements:
  - (a) the official certificate shall be issued by the competent authority of the third country of origin or of the third country where the consignment is consigned from if that country is different from the country of origin;
  - (b) the official certificate shall bear the identification code of the consignment to which it relates, referred to in Article 9(1);
  - (c) the official certificate shall bear the signature of the certifying officer and the official stamp;
  - (d) where the official certificate contains multiple or alternative statements, the statements which are not relevant shall be crossed out, initialled and stamped by the certifying officer, or completely removed from the certificate;
  - (e) the official certificate shall consist of one of the following:
    - (i) a single sheet of paper;
    - (ii) several sheets of paper where all sheets are indivisible and constitute an integrated whole;
    - (iii) a sequence of pages with each page numbered so as to indicate that it is a particular page in a finite sequence;
  - (f) where the official certificate consists of a sequence of pages as referred to in point (e)(iii) of this paragraph, each page shall bear the unique code referred to in Article 89(1)(a) of Regulation (EU) 2017/625, the signature of the certifying officer and the official stamp;
  - (g) the official certificate shall be presented to the competent authority of the border control post of entry into the Union where the consignment is subjected to official controls;
  - (h) the official certificate shall be issued before the consignment to which it relates leaves the control of the competent authorities in the third country issuing the certificate;

- (i) the official certificate shall be drawn up in the official language, or in one of the official languages, of the Member State of the border control post of entry into the Union;
  - (j) the official certificate shall be valid for not more than four months from the date of issue, but in any case no longer than six months from the date of the results of the laboratory analyses referred to Article 10(1).
3. By way of derogation from point (i) of paragraph 2, a Member State may consent to official certificates being drawn up in another official language of the Union and accompanied, if necessary, by an authenticated translation.
  4. The colour of the signature and of the stamp other than an embossed or watermarked stamp, which are referred to in point (c) of paragraph 2, shall be different to the colour of the printing.
  5. Points (c) to (g) of paragraph 2 and paragraph 4 shall not apply to electronic official certificates issued in accordance with the requirements of Article 39(1) of Commission Implementing Regulation (EU) 2019/1715 (\*).
  6. Points (d), (e) and (f) of paragraph 2 shall not apply to official certificates issued in paper and completed in, and printed from, TRACES.
  7. Competent authorities may issue a replacement official certificate only in accordance with the rules laid down in Article 6 of Commission Implementing Regulation (EU) 2020/2235 (\*\*).
  8. The official certificate shall be completed on the basis of the notes set out in Annex IV.

(\*) Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components (“the IMSOC Regulation”) (OJ L 261, 14.10.2019, p. 37).

(\*\*) Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1).;

(2) Annexes I, II, IIa and IV are replaced by the text set out in the Annex to this Regulation.

#### Article 2

#### Entry into force and application

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

Article 1(1) shall apply from 21 April 2021.

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

Done at Brussels, 14 April 2021.

For the Commission  
The President  
Ursula VON DER LEYEN

## ANNEX I

**Food and feed of non-animal origin from certain third countries subject to a temporary increase of official controls at border control posts and control points**

Row	Food and feed (intended use)	CN code (*)	TARIC sub-division	Country of origin	Hazard	Frequency of identity and physical checks (%)
1	<ul style="list-style-type: none"> <li>— Groundnuts (peanuts), in shell</li> <li>— Groundnuts (peanuts), shelled</li> <li>— Peanut butter</li> <li>— Groundnuts (peanuts), otherwise prepared or preserved</li> <li>— Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil</li> <li>— Groundnut flours and meals <b>(Food and feed)</b></li> </ul>	<ul style="list-style-type: none"> <li>— 1202 41 00</li> <li>— 1202 42 00</li> <li>— 2008 11 10</li> <li>— 2008 11 91; 2008 11 96; 2008 11 98</li> <li>— 2305 00 00</li> <li>— ex 1208 90 00</li> </ul>	<b>20</b>	<b>Bolivia (BO)</b>	Aflatoxins	50
2	<ul style="list-style-type: none"> <li>— Black pepper (<i>Piper nigrum</i>) <b>(Food – neither crushed nor ground)</b></li> </ul>	ex 0904 11 00	<b>10</b>	<b>Brazil (BR)</b>	<i>Salmonella</i> ( <sup>2</sup> )	50
3	<ul style="list-style-type: none"> <li>— Groundnuts (peanuts), in shell</li> <li>— Groundnuts (peanuts), shelled</li> <li>— Peanut butter</li> <li>— Groundnuts (peanuts), otherwise prepared or preserved</li> <li>— Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil</li> <li>— Groundnut flours and meals <b>(Food and feed)</b></li> </ul>	<ul style="list-style-type: none"> <li>— 1202 41 00</li> <li>— 1202 42 00</li> <li>— 2008 11 10</li> <li>— 2008 11 91; 2008 11 96; 2008 11 98</li> <li>— 2305 00 00</li> <li>— ex 1208 90 00</li> </ul>	<b>20</b>	<b>Brazil (BR)</b>	Aflatoxins	10

4	— Groundnuts (peanuts), in shell	— 1202 41 00		<b>China (CN)</b>	Aflatoxins	10
	— Groundnuts (peanuts), shelled	— 1202 42 00				
	— Peanut butter	— 2008 11 10				
	— Groundnuts (peanuts), otherwise prepared or preserved	— 2008 11 91; 2008 11 96; 2008 11 98				
	— Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	— 2305 00 00				
— Groundnut flours and meals <b>(Food and feed)</b>	— ex 1208 90 00	<b>20</b>				
5	Sweet peppers ( <i>Capsicum annuum</i> ) <b>(Food – crushed or ground)</b>	ex 0904 22 00	<b>11</b>	<b>China (CN)</b>	<i>Salmonella</i> <sup>(6)</sup>	20
6	Tea, whether or not flavoured <b>(Food)</b>	0902		<b>China (CN)</b>	Pesticide residues <sup>(3)(7)</sup>	20
7	Aubergines ( <i>Solanum melongena</i> ) <b>(Food – fresh or chilled)</b>	0709 30 00		<b>Dominican Republic (DO)</b>	Pesticide residues <sup>(3)</sup>	20
8	— Sweet peppers ( <i>Capsicum annuum</i> )	— 0709 60 10; 0710 80 51		<b>Dominican Republic (DO)</b>	Pesticide residues <sup>(3)(8)</sup>	50
	— Peppers of the <i>Capsicum</i> species (other than sweet)	— ex 0709 60 99; ex 0710 80 59	<b>20</b> <b>20</b>			
	— Yardlong beans ( <i>Vigna unguiculata</i> ssp. <i>sesquipedalis</i> , <i>Vigna unguiculata</i> ssp. <i>unguiculata</i> )	— ex 0708 20 00; ex 0710 22 00	<b>10</b> <b>10</b>			
	<b>(Food – fresh, chilled or frozen)</b>					
9	— Sweet peppers ( <i>Capsicum annuum</i> )	— 0709 60 10; 0710 80 51		<b>Egypt (EG)</b>	Pesticide residues <sup>(3)(9)</sup>	20
	— Peppers of the <i>Capsicum</i> species (other than sweet)	— ex 0709 60 99; ex 0710 80 59	<b>20</b> <b>20</b>			
	<b>(Food – fresh, chilled or frozen)</b>					
10	<i>Sesamum</i> seeds <b>(Food)</b>	— 1207 40 90 — ex 2008 19 19 — ex 2008 19 99	<b>40</b> <b>40</b>	<b>Ethiopia (ET)</b>	<i>Salmonella</i> <sup>(2)</sup>	50

11	— Hazelnuts, in shell — Hazelnuts, shelled — Flour, meal and powder of hazelnuts — Hazelnuts, otherwise prepared or preserved <b>(Food)</b>	— 0802 21 00 — 0802 22 00 — ex 1106 30 90 — ex 2008 19 19; ex 2008 19 95; ex 2008 19 99	<b>40</b> <b>30</b> <b>20</b> <b>30</b>	<b>Georgia (GE)</b>	Aflatoxins	50
12	Palm oil <b>(Food)</b>	1511 10 90; 1511 90 11; ex 1511 90 19; 1511 90 99	<b>90</b>	<b>Ghana (GH)</b>	Sudan dyes <sup>(10)</sup>	50
13	Curry leaves ( <i>Bergera/Murraya koenigii</i> ) <b>(Food – fresh, chilled, frozen or dried)</b>	ex 1211 90 86	<b>10</b>	<b>India (IN)</b>	Pesticide residues <sup>(3)</sup> <sup>(11)</sup>	50
14	Okra <b>(Food – fresh, chilled or frozen)</b>	ex 0709 99 90; ex 0710 80 95	<b>20</b> <b>30</b>	<b>India (IN)</b>	Pesticide residues <sup>(3)</sup> <sup>(12)</sup>	10
15	Beans ( <i>Vigna</i> spp., <i>Phaseolus</i> spp.) <b>(Food – fresh or chilled)</b>	0708 20		<b>Kenya (KE)</b>	Pesticide residues <sup>(3)</sup>	10
16	Chinese celery ( <i>Apium graveolens</i> ) <b>(Food – fresh or chilled herb)</b>	ex 0709 40 00	<b>20</b>	<b>Cambodia (KH)</b>	Pesticide residues <sup>(3)</sup> <sup>(13)</sup>	50
17	Yardlong beans ( <i>Vigna unguiculata</i> ssp. <i>sesquipedalis</i> , <i>Vigna unguiculata</i> ssp. <i>unguiculata</i> ) <b>(Food – fresh, chilled or frozen vegetables)</b>	ex 0708 20 00; ex 0710 22 00	<b>10</b> <b>10</b>	<b>Cambodia (KH)</b>	Pesticide residues <sup>(3)</sup> <sup>(14)</sup>	50
18	Turnips ( <i>Brassica rapa</i> ssp. <i>rapa</i> ) <b>(Food – prepared or preserved by vinegar or acetic acid)</b>	ex 2001 90 97	<b>11; 19</b>	<b>Lebanon (LB)</b>	Rhodamine B	50
19	Turnips ( <i>Brassica rapa</i> ssp. <i>rapa</i> ) <b>(Food – prepared or preserved by brine or citric acid, not frozen)</b>	ex 2005 99 80	<b>93</b>	<b>Lebanon (LB)</b>	Rhodamine B	50
20	Peppers of the <i>Capsicum</i> species (sweet or other than sweet) <b>(Food – dried, roasted, crushed or ground)</b>	0904 21 10; ex 0904 21 90; ex 0904 22 00; ex 2005 99 10; ex 2005 99 80	<b>20</b> <b>11; 19</b> <b>10; 90</b> <b>94</b>	<b>Sri Lanka (LK)</b>	Aflatoxins	50



21	— Groundnuts (peanuts), in shell	— 1202 41 00		<b>Madagascar (MG)</b>	Aflatoxins	50
	— Groundnuts (peanuts), shelled	— 1202 42 00				
	— Peanut butter	— 2008 11 10				
	— Groundnuts (peanuts), otherwise prepared or preserved	— 2008 11 91; 2008 11 96; 2008 11 98				
	— Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	— 2305 00 00				
	— Groundnut flours and meals ( <b>Food and feed</b> )	— ex 1208 90 00	<b>20</b>			
22	Jackfruit ( <i>Artocarpus heterophyllus</i> ) ( <b>Food – fresh</b> )	ex 0810 90 20	<b>20</b>	<b>Malaysia (MY)</b>	Pesticide residues <sup>(1)</sup>	20
23	Sesamum seeds ( <b>Food</b> )	— 1207 40 90		<b>Nigeria (NG)</b>	Salmonella <sup>(2)</sup>	50
		— ex 2008 19 19	<b>40</b>			
		— ex 2008 19 99	<b>40</b>			
24	Spice mixes ( <b>Food</b> )	0910 91 10; 0910 91 90		<b>Pakistan (PK)</b>	Aflatoxins	50
25	Watermelon ( <i>Egusi, Citrullus</i> spp.) seeds and derived products ( <b>Food</b> )	ex 1207 70 00;	<b>10</b>	<b>Sierra Leone (SL)</b>	Aflatoxins	50
		ex 1208 90 00;	<b>10</b>			
		ex 2008 99 99	<b>50</b>			
26	— Groundnuts (peanuts), in shell	— 1202 41 00		<b>Senegal (SN)</b>	Aflatoxins	50
	— Groundnuts (peanuts), shelled	— 1202 42 00				
	— Peanut butter	— 2008 11 10				
	— Groundnuts (peanuts), otherwise prepared or preserved	— 2008 11 91; 2008 11 96; 2008 11 98				
	— Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	— 2305 00 00				
	— Groundnut flours and meals ( <b>Food and feed</b> )	— ex 1208 90 00	<b>20</b>			
27	Turnips ( <i>Brassica rapa</i> ssp. <i>rapa</i> ) ( <b>Food – prepared or preserved by vinegar or acetic acid</b> )	ex 2001 90 97	<b>11; 19</b>	<b>Syria (SY)</b>	Rhodamine B	50

28	Turnips ( <i>Brassica rapa</i> ssp. <i>rapa</i> ) (Food – prepared or preserved by brine or citric acid, not frozen)	ex 2005 99 80	<b>93</b>	<b>Syria (SY)</b>	Rhodamine B	50
29	Peppers of the <i>Capsicum</i> species (other than sweet) (Food – fresh, chilled or frozen)	ex 0709 60 99; ex 0710 80 59	<b>20</b> <b>20</b>	<b>Thailand (TH)</b>	Pesticide residues <sup>(3)</sup> <sup>(15)</sup>	20
30	— Hazelnuts ( <i>Corylus</i> sp.), in shell	— 0802 21 00		<b>Turkey (TR)</b>	Aflatoxins	5
	— Hazelnuts ( <i>Corylus</i> sp.), shelled	— 0802 22 00				
	— Mixtures of nuts or dried fruits containing hazelnuts	— ex 0813 50 39;	<b>70</b>			
		ex 0813 50 91;	<b>70</b>			
		ex 0813 50 99	<b>70</b>			
	— Hazelnut paste	— ex 2007 10 10;	<b>70</b>			
		ex 2007 10 99;	<b>40</b>			
		ex 2007 99 39;	<b>05; 06</b>			
		ex 2007 99 50;	<b>33</b>			
		ex 2007 99 97	<b>23</b>			
	— Hazelnuts, otherwise prepared or preserved, including mixtures	— ex 2008 19 12;	<b>30</b>			
		ex 2008 19 19;	<b>30</b>			
		ex 2008 19 92;	<b>30</b>			
		ex 2008 19 95;	<b>20</b>			
		ex 2008 19 99;	<b>30</b>			
		ex 2008 97 12;	<b>15</b>			
		ex 2008 97 14;	<b>15</b>			
		ex 2008 97 16;	<b>15</b>			
		ex 2008 97 18;	<b>15</b>			
		ex 2008 97 32;	<b>15</b>			
		ex 2008 97 34;	<b>15</b>			
		ex 2008 97 36;	<b>15</b>			
		ex 2008 97 38;	<b>15</b>			
		ex 2008 97 51;	<b>15</b>			
		ex 2008 97 59;	<b>15</b>			
		ex 2008 97 72;	<b>15</b>			
		ex 2008 97 74;	<b>15</b>			
		ex 2008 97 76;	<b>15</b>			
		ex 2008 97 78;	<b>15</b>			

		ex 2008 97 92;	<b>15</b>			
		ex 2008 97 93;	<b>15</b>			
		ex 2008 97 94;	<b>15</b>			
		ex 2008 97 96;	<b>15</b>			
		ex 2008 97 97;	<b>15</b>			
		ex 2008 97 98	<b>15</b>			
	— Flour, meal and powder of hazelnuts	— ex 1106 30 90	<b>40</b>			
	— Hazelnut oil <b>(Food)</b>	— ex 1515 90 99	<b>20</b>			
31	Mandarins (including tangerines and satsumas); clementines, wilkings and similar citrus hybrids <b>(Food – fresh or dried)</b>	0805 21; 0805 22; 0805 29		<b>Turkey (TR)</b>	Pesticide residues <sup>(3)</sup>	5
32	Oranges <b>(Food – fresh or dried)</b>	0805 10		<b>Turkey (TR)</b>	Pesticide residues <sup>(3)</sup>	10
33	Pomegranates <b>(Food – fresh or chilled)</b>	ex 0810 90 75	<b>30</b>	<b>Turkey (TR)</b>	Pesticide residues <sup>(3)</sup> <sup>(16)</sup>	20
34	— Sweet peppers ( <i>Capsicum annuum</i> ) — Peppers of the <i>Capsicum</i> species (other than sweet) <b>(Food – fresh, chilled or frozen)</b>	— 0709 60 10; 0710 80 51; — ex 0709 60 99; ex 0710 80 59	<b>20</b> <b>20</b>	<b>Turkey (TR)</b>	Pesticide residues <sup>(3)</sup> <sup>(17)</sup>	10
35	Unprocessed whole, ground, milled, cracked, chopped apricot kernels intended to be placed on the market for the final consumer <sup>(18)</sup> <sup>(19)</sup> <b>(Food)</b>	ex 1212 99 95	<b>20</b>	<b>Turkey (TR)</b>	Cyanide	50
36	Peppers of the <i>Capsicum</i> species (other than sweet) <b>(Food – fresh, chilled or frozen)</b>	ex 0709 60 99; ex 0710 80 59	<b>20</b> <b>20</b>	<b>Uganda (UG)</b>	Pesticide residues <sup>(3)</sup>	20
37	— Groundnuts (peanuts), in shell — Groundnuts (peanuts), shelled — Peanut butter — Groundnuts (peanuts), otherwise prepared or preserved	— 1202 41 00 — 1202 42 00 — 2008 11 10 — 2008 11 91; 2008 11 96; 2008 11 98		<b>United States (US)</b>	Aflatoxins	10

	— Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil — Groundnut flours and meals <b>(Food and feed)</b>	— 2305 00 00 — ex 1208 90 00	<b>20</b>			
38	— Pistachios, in shell — Pistachios, shelled — Pistachios, roasted	— 0802 51 00 — 0802 52 00 — ex 2008 19 13; ex 2008 19 93	<b>20</b> <b>20</b>	<b>United States (US)</b>	Aflatoxins	10
39	— Dried apricots — Apricots, otherwise prepared or preserved <b>(Food)</b>	— 0813 10 00 — 2008 50		<b>Uzbekistan (UZ)</b>	Sulphites <sup>(20)</sup>	50
40	— Coriander leaves — Basil (holy, sweet) — Mint — Parsley <b>(Food – fresh or chilled herbs)</b>	— ex 0709 99 90 — ex 1211 90 86 — ex 1211 90 86 — ex 0709 99 90	<b>72</b> <b>20</b> <b>30</b> <b>40</b>	<b>Vietnam (VN)</b>	Pesticide residues <sup>(3)</sup> <sup>(21)</sup>	50
41	Okra <b>(Food – fresh, chilled or frozen)</b>	ex 0709 99 90; ex 0710 80 95	<b>20</b> <b>30</b>	<b>Vietnam (VN)</b>	Pesticide residues <sup>(3)</sup> <sup>(21)</sup>	50
42	Peppers of the <i>Capsicum</i> species (other than sweet) <b>(Food – fresh, chilled or frozen)</b>	ex 0709 60 99; ex 0710 80 59	<b>20</b> <b>20</b>	<b>Vietnam (VN)</b>	Pesticide residues <sup>(3)</sup> <sup>(21)</sup>	50

<sup>(1)</sup> Where only certain products under any CN code are required to be examined, the CN code is marked 'ex'.

<sup>(2)</sup> The sampling and the analyses shall be performed in accordance with the sampling procedures and the analytical reference methods set out in point 1(a) of Annex III.

<sup>(3)</sup> Residues of at least those pesticides listed in the control programme adopted in accordance with Article 29(2) of Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1) that can be analysed with multi-residue methods based on GC-MS and LC-MS (pesticides to be monitored in/on products of plant origin only).

<sup>(4)</sup> Residues of Amitraz.

<sup>(5)</sup> Residues of Nicotine.

<sup>(6)</sup> The sampling and the analyses shall be performed in accordance with the sampling procedures and the analytical reference methods set out in point 1(b) of Annex III.

<sup>(7)</sup> Residues of Tolfenpyrad.

<sup>(8)</sup> Residues of Amitraz (amitraz including the metabolites containing the 2,4 -dimethylaniline moiety expressed as amitraz), Diafenthiuron, Dicofol (sum of p, p' and o,p' isomers) and Dithiocarbamates (dithiocarbamates expressed as CS<sub>2</sub>, including maneb, mancozeb, metiram, propineb, thiram and ziram).

<sup>(9)</sup> Residues of Dicofol (sum of p, p' and o,p' isomers), Dinotefuran, Folpet, Prochloraz (sum of prochloraz and its metabolites containing the 2,4,6-Trichlorophenol moiety expressed as prochloraz), Thiophanate-methyl and Triforine.

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- (<sup>10</sup>) For the purposes of this Annex, 'Sudan dyes' refers to the following chemical substances: (i) Sudan I (CAS Number 842-07-9); (ii) Sudan II (CAS Number 3118-97-6); (iii) Sudan III (CAS Number 85-86-9); (iv) Scarlet Red; or Sudan IV (CAS Number 85-83-6).
- (<sup>11</sup>) Residues of Acephate.
- (<sup>12</sup>) Residues of Diafenthuron.
- (<sup>13</sup>) Residues of Phenthoate.
- (<sup>14</sup>) Residues of Chlorbufam.
- (<sup>15</sup>) Residues of Formetanate (sum of formetanate and its salts expressed as formetanate (hydrochloride)), Prothiofos and Triforine.
- (<sup>16</sup>) Residues of Prochloraz.
- (<sup>17</sup>) Residues of Diafenthuron, Formetanate (sum of formetanate and its salts expressed as formetanate (hydrochloride)) and Thiophanate-methyl.
- (<sup>18</sup>) 'Unprocessed products' as defined in Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).
- (<sup>19</sup>) 'Placing on the market' and 'final consumer' as defined in Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).
- (<sup>20</sup>) Reference methods: EN 1988-1:1998, EN 1988-2:1998 or ISO 5522:1981.
- (<sup>21</sup>) Residues of Dithiocarbamates (dithiocarbamates expressed as CS<sub>2</sub>, including maneb, mancozeb, metiram, propineb, thiram and ziram), Phenthoate and Quinalphos.
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## ANNEX II

**Food and feed from certain third countries subject to special conditions for the entry into the Union  
due to contamination risk by mycotoxins, including aflatoxins, pesticide residues,  
pentachlorophenol and dioxins, and to microbiological contamination**

**1. Food and feed of non-animal origin referred to in Article 1(1)(b)(i)**

Row	Food and feed (intended use)	CN code (1)	TARIC sub-division	Country of origin	Hazard	Frequency of identity and physical checks (%)
1	— Groundnuts (peanuts), in shell	— 1202 41 00		<b>Argentina (AR)</b>	Aflatoxins	5
	— Groundnuts (peanuts), shelled	— 1202 42 00				
	— Peanut butter	— 2008 11 10				
	— Groundnuts (peanuts), otherwise prepared or preserved	— 2008 11 91; 2008 11 96; 2008 11 98				
	— Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil	— 2305 00 00				
	— Groundnut flours and meals ( <b>Food and feed</b> )	— ex 1208 90 00	<b>20</b>			
2	— Hazelnuts (Corylus sp.), in shell	— 0802 21 00		<b>Azerbaijan (AZ)</b>	Aflatoxins	20
	— Hazelnuts (Corylus sp.), shelled	— 0802 22 00				
	— Mixtures of nuts or dried fruits containing hazelnuts	— ex 0813 50 39;	<b>70</b>			
		ex 0813 50 91;	<b>70</b>			
		ex 0813 50 99	<b>70</b>			
	— Hazelnut paste	— ex 2007 10 10;	<b>70</b>			
		ex 2007 10 99;	<b>40</b>			
		ex 2007 99 39;	<b>05; 06</b>			
		ex 2007 99 50;	<b>33</b>			
	— Hazelnuts, otherwise prepared or preserved, including mixtures	ex 2007 99 97	<b>23</b>			
— ex 2008 19 12;		<b>30</b>				
ex 2008 19 19;		<b>30</b>				
	ex 2008 19 92;	<b>30</b>				

		ex 2008 19 95;	<b>20</b>			
		ex 2008 19 99;	<b>30</b>			
		ex 2008 97 12;	<b>15</b>			
		ex 2008 97 14;	<b>15</b>			
		ex 2008 97 16;	<b>15</b>			
		ex 2008 97 18;	<b>15</b>			
		ex 2008 97 32;	<b>15</b>			
		ex 2008 97 34;	<b>15</b>			
		ex 2008 97 36;	<b>15</b>			
		ex 2008 97 38;	<b>15</b>			
		ex 2008 97 51;	<b>15</b>			
		ex 2008 97 59;	<b>15</b>			
		ex 2008 97 72;	<b>15</b>			
		ex 2008 97 74;	<b>15</b>			
		ex 2008 97 76;	<b>15</b>			
		ex 2008 97 78;	<b>15</b>			
		ex 2008 97 92;	<b>15</b>			
		ex 2008 97 93;	<b>15</b>			
		ex 2008 97 94;	<b>15</b>			
		ex 2008 97 96;	<b>15</b>			
		ex 2008 97 97;	<b>15</b>			
		ex 2008 97 98	<b>15</b>			
	— Flour, meal and powder of hazelnuts	— ex 1106 30 90	<b>40</b>			
	— Hazelnut oil <b>(Food)</b>	— ex 1515 90 99	<b>20</b>			
3	— Foodstuffs containing or consisting of betel leaves ( <i>Piper betle</i> ) <b>(Food)</b>	ex 1404 90 00 <sup>(10)</sup>	<b>10</b>	<b>Bangladesh (BD)</b>	<i>Salmonella</i> <sup>(6)</sup>	50
4	— Brazil nuts in shell — Mixtures of nuts or dried fruits containing Brazil nuts in shell <b>(Food)</b>	— 0801 21 00 — ex 0813 50 31; ex 0813 50 39; ex 0813 50 91; ex 0813 50 99	<b>20</b> <b>20</b> <b>20</b> <b>20</b>	<b>Brazil (BR)</b>	Aflatoxins	50
5	— Groundnuts (peanuts), in shell — Groundnuts (peanuts), shelled	— 1202 41 00 — 1202 42 00		<b>Egypt (EG)</b>	Aflatoxins	20

	<ul style="list-style-type: none"> <li>— Peanut butter</li> <li>— Groundnuts (peanuts), otherwise prepared or preserved</li> <li>— Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil</li> <li>— Groundnut flours and meals <i>(Food and feed)</i></li> </ul>	<ul style="list-style-type: none"> <li>— 2008 11 10</li> <li>— 2008 11 91; 2008 11 96; 2008 11 98</li> <li>— 2305 00 00</li> <li>— ex 1208 90 00</li> </ul>	<b>20</b>			
6	<ul style="list-style-type: none"> <li>— Pepper of the genus Piper; dried or crushed or ground fruit of the genus Capsicum or of the genus Pimenta</li> <li>— Ginger, saffron, turmeric (curcuma), thyme, bay leaves, curry and other spices <i>(Food – dried spices)</i></li> </ul>	<ul style="list-style-type: none"> <li>— 0904</li> <li>— 0910</li> </ul>		<b>Ethiopia (ET)</b>	Aflatoxins	50
7	<ul style="list-style-type: none"> <li>— Groundnuts (peanuts), in shell</li> <li>— Groundnuts (peanuts), shelled</li> <li>— Peanut butter</li> <li>— Groundnuts (peanuts), otherwise prepared or preserved</li> <li>— Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil</li> <li>— Groundnut flours and meals <i>(Food and feed)</i></li> </ul>	<ul style="list-style-type: none"> <li>— 1202 41 00</li> <li>— 1202 42 00</li> <li>— 2008 11 10</li> <li>— 2008 11 91; 2008 11 96; 2008 11 98</li> <li>— 2305 00 00</li> <li>— ex 1208 90 00</li> </ul>	<b>20</b>	<b>Ghana (GH)</b>	Aflatoxins	50
8	<ul style="list-style-type: none"> <li>— Groundnuts (peanuts), in shell</li> <li>— Groundnuts (peanuts), shelled</li> <li>— Peanut butter</li> <li>— Groundnuts (peanuts), otherwise prepared or preserved</li> </ul>	<ul style="list-style-type: none"> <li>— 1202 41 00</li> <li>— 1202 42 00</li> <li>— 2008 11 10</li> <li>— 2008 11 91; 2008 11 96; 2008 11 98</li> </ul>		<b>Gambia (GM)</b>	Aflatoxins	50



	— Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil — Groundnut flours and meals <b>(Food and feed)</b>	— 2305 00 00 — ex 1208 90 00	<b>20</b>			
9	Nutmeg ( <i>Myristica fragrans</i> ) <b>(Food – dried spices)</b>	0908 11 00; 0908 12 00		<b>Indonesia (ID)</b>	Aflatoxins	20
10	Betel leaves ( <i>Piper betle</i> L.) <b>(Food)</b>	ex 1404 90 00	<b>10</b>	<b>India (IN)</b>	<i>Salmonella</i> ( <sup>2</sup> )	10
11	Peppers of the <i>Capsicum</i> species (sweet or other than sweet) <b>(Food – dried, roasted, crushed or ground)</b>	0904 21 10; ex 0904 22 00; ex 0904 21 90; ex 2005 99 10; ex 2005 99 80	<b>11; 19</b> <b>20</b> <b>10; 90</b> <b>94</b>	<b>India (IN)</b>	Aflatoxins	20
12	Nutmeg ( <i>Myristica fragrans</i> ) <b>(Food – dried spices)</b>	0908 11 00; 0908 12 00		<b>India (IN)</b>	Aflatoxins	20
13	— Groundnuts (peanuts), in shell — Groundnuts (peanuts), shelled — Peanut butter — Groundnuts (peanuts), otherwise prepared or preserved — Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil — Groundnut flours and meals <b>(Food and feed)</b>	— 1202 41 00 — 1202 42 00 — 2008 11 10 — 2008 11 91; 2008 11 96; 2008 11 98 — 2305 00 00 — ex 1208 90 00	<b>20</b>	<b>India (IN)</b>	Aflatoxins	50
14	Guar gum <b>(Food and feed)</b>	ex 1302 32 90	<b>10</b>	<b>India (IN)</b>	Pentachlorophenol and dioxins ( <sup>3</sup> )	5
15	Peppers of the <i>Capsicum</i> species (other than sweet) <b>(Food – fresh, chilled or frozen)</b>	ex 0709 60 99; ex 0710 80 59	<b>20</b> <b>20</b>	<b>India (IN)</b>	Pesticide residues( <sup>4</sup> )( <sup>5</sup> )	10

16	<i>Sesamum</i> seeds (Food)	— 1207 40 90		<b>India (IN)</b>	<i>Salmonella</i> <sup>(6)</sup> Pesticide resi- dues <sup>(4)</sup> <sup>(11)</sup>	20
		— ex 2008 19 19	<b>40</b>			
		— ex 2008 19 99	<b>40</b>			50
17	— Pistachios, in shell	— 0802 51 00		<b>Iran (IR)</b>	Aflatoxins	50
	— Pistachios, shelled	— 0802 52 00				
	— Mixtures of nuts or dried fruits containing pistachios	— ex 0813 50 39;	<b>60</b>			
		ex 0813 50 91;	<b>60</b>			
		ex 0813 50 99	<b>60</b>			
		— Pistachio paste	— ex 2007 10 10;			
	— Pistachios, prepared or pre- served, including mixtures	ex 2007 10 99;	<b>30</b>			
		ex 2007 99 39;	<b>03; 04</b>			
		ex 2007 99 50;	<b>32</b>			
		ex 2007 99 97	<b>22</b>			
		— ex 2008 19 13;	<b>20</b>			
		ex 2008 19 93;	<b>20</b>			
		ex 2008 97 12;	<b>19</b>			
		ex 2008 97 14;	<b>19</b>			
		ex 2008 97 16;	<b>19</b>			
		ex 2008 97 18;	<b>19</b>			
		ex 2008 97 32;	<b>19</b>			
		ex 2008 97 34;	<b>19</b>			
		ex 2008 97 36;	<b>19</b>			
		ex 2008 97 38;	<b>19</b>			
		ex 2008 97 51;	<b>19</b>			
		ex 2008 97 59;	<b>19</b>			
		ex 2008 97 72;	<b>19</b>			
		ex 2008 97 74;	<b>19</b>			
		ex 2008 97 76;	<b>19</b>			
		ex 2008 97 78;	<b>19</b>			
	ex 2008 97 92;	<b>19</b>				
	ex 2008 97 93;	<b>19</b>				
ex 2008 97 94;	<b>19</b>					
ex 2008 97 96;	<b>19</b>					
ex 2008 97 97;	<b>19</b>					
ex 2008 97 98	<b>19</b>					
— Flour, meal and powder of pistachios (Food)	— ex 1106 30 90	<b>50</b>				

18	Watermelon (Egusi, <i>Citrullus</i> spp.) seeds and derived products <b>(Food)</b>	ex 1207 70 00; ex 1208 90 00; ex 2008 99 99	<b>10</b> <b>10</b> <b>50</b>	<b>Nigeria (NG)</b>	Aflatoxins	50
19	Peppers of the <i>Capsicum</i> species (other than sweet) <b>(Food – fresh, chilled or frozen)</b>	ex 0709 60 99; ex 0710 80 59	<b>20</b> <b>20</b>	<b>Pakistan (PK)</b>	Pesticide residues <sup>(4)</sup>	20
20	— Groundnuts (peanuts), in shell — Groundnuts (peanuts), shelled — Peanut butter — Groundnuts (peanuts), otherwise prepared or preserved — Oilcake and other solid residues, whether or not ground or in the form of pellets, resulting from the extraction of groundnut oil — Groundnut flours and meals <b>(Food and feed)</b>	— 1202 41 00 — 1202 42 00 — 2008 11 10 — 2008 11 91; 2008 11 96; 2008 11 98 — 2305 00 00 — ex 1208 90 00	<b>20</b>	<b>Sudan (SD)</b>	Aflatoxins	50
21	Sesamum seeds <b>(Food)</b>	— 1207 40 90 — ex 2008 19 19 — ex 2008 19 99	<b>40</b> <b>40</b>	<b>Sudan (SD)</b>	Salmonella <sup>(6)</sup>	20
22	— Dried figs — Mixtures of nuts or dried fruits containing figs — Dried fig paste  — Dried figs, prepared or preserved, including mixtures	— 0804 20 90 — ex 0813 50 99 — ex 2007 10 10; ex 2007 10 99; ex 2007 99 39; ex 2007 99 50; ex 2007 99 97 — ex 2008 97 12; ex 2008 97 14; ex 2008 97 16; ex 2008 97 18; ex 2008 97 32; ex 2008 97 34; ex 2008 97 36;	<b>50</b> <b>50</b> <b>20</b> <b>01; 02</b> <b>31</b> <b>21</b> <b>11</b> <b>11</b> <b>11</b> <b>11</b> <b>11</b> <b>11</b>	<b>Turkey (TR)</b>	Aflatoxins	20

		ex 2008 97 38;	<b>11</b>			
		ex 2008 97 51;	<b>11</b>			
		ex 2008 97 59;	<b>11</b>			
		ex 2008 97 72;	<b>11</b>			
		ex 2008 97 74;	<b>11</b>			
		ex 2008 97 76;	<b>11</b>			
		ex 2008 97 78;	<b>11</b>			
		ex 2008 97 92;	<b>11</b>			
		ex 2008 97 93;	<b>11</b>			
		ex 2008 97 94;	<b>11</b>			
		ex 2008 97 96;	<b>11</b>			
		ex 2008 97 97;	<b>11</b>			
		ex 2008 97 98;	<b>11</b>			
		ex 2008 99 28;	<b>10</b>			
		ex 2008 99 34;	<b>10</b>			
		ex 2008 99 37;	<b>10</b>			
		ex 2008 99 40;	<b>10</b>			
		ex 2008 99 49;	<b>60</b>			
		ex 2008 99 67;	<b>95</b>			
		ex 2008 99 99	<b>60</b>			
	— Flour, meal or powder of dried figs <b>(Food)</b>	— ex 1106 30 90	<b>60</b>			
23	— Pistachios, in shell	— 0802 51 00		<b>Turkey (TR)</b>	Aflatoxins	50
	— Pistachios, shelled	— 0802 52 00				
	— Mixtures of nuts or dried fruits containing pistachios	— ex 0813 50 39;	<b>60</b>			
		ex 0813 50 91;	<b>60</b>			
		ex 0813 50 99	<b>60</b>			
	— Pistachio paste	— ex 2007 10 10;	<b>60</b>			
		ex 2007 10 99;	<b>30</b>			
	— Pistachios, prepared or preserved, including mixtures	— ex 2007 99 39;	<b>03; 04</b>			
		ex 2007 99 50;	<b>32</b>			
		ex 2007 99 97;	<b>22</b>			
		ex 2008 19 13;	<b>20</b>			
		ex 2008 19 93;	<b>20</b>			
		ex 2008 97 12;	<b>19</b>			
		ex 2008 97 14;	<b>19</b>			
		ex 2008 97 16;	<b>19</b>			

		ex 2008 97 18;	<b>19</b>			
		ex 2008 97 32;	<b>19</b>			
		ex 2008 97 34;	<b>19</b>			
		ex 2008 97 36;	<b>19</b>			
		ex 2008 97 38;	<b>19</b>			
		ex 2008 97 51;	<b>19</b>			
		ex 2008 97 59;	<b>19</b>			
		ex 2008 97 72;	<b>19</b>			
		ex 2008 97 74;	<b>19</b>			
		ex 2008 97 76;	<b>19</b>			
		ex 2008 97 78;	<b>19</b>			
		ex 2008 97 92;	<b>19</b>			
		ex 2008 97 93;	<b>19</b>			
		ex 2008 97 94;	<b>19</b>			
		ex 2008 97 96;	<b>19</b>			
		ex 2008 97 97;	<b>19</b>			
		ex 2008 97 98	<b>19</b>			
	— Flour, meal and powder of pistachios <b>(Food)</b>	— ex 1106 30 90	<b>50</b>			
24	Vine leaves <b>(Food)</b>	ex 2008 99 99	<b>11; 19</b>	<b>Turkey (TR)</b>	Pesticide residues <sup>(4)(7)</sup>	20
25	Sesamum seeds <b>(Food)</b>	— 1207 40 90 — ex 2008 19 19 — ex 2008 19 99	<b>40</b> <b>40</b>	<b>Uganda (UG)</b>	Salmonella <sup>(6)</sup>	20
26	Pitahaya (dragon fruit) <b>(Food – fresh or chilled)</b>	ex 0810 90 20	<b>10</b>	<b>Vietnam (VN)</b>	Pesticide residues <sup>(4)(8)</sup>	10

(1) Where only certain products under any CN code are required to be examined, the CN code is marked 'ex'.

(2) The sampling and the analyses shall be performed in accordance with the sampling procedures and the analytical reference methods set out in point 1(b) of Annex III.

(3) The analytical report referred to in Article 10(3) shall be issued by a laboratory accredited in accordance with EN ISO/IEC 17025 for the analysis of pentachlorophenol (PCP) in food and feed.

The analytical report shall indicate:

(a) the results of sampling and analysis for the presence of PCP, performed by the competent authorities of the country of origin or of the country where the consignment is consigned from if that country is different from the country of origin;

(b) the measurement uncertainty of the analytical result;

(c) the limit of detection (LOD) of the analytical method; and

(d) the limit of quantification (LOQ) of the analytical method. The extraction before analysis shall be performed with an acidified solvent. The analysis shall be carried out according to the modified version of the QuEChERS method as set out on the websites of the European Union Reference Laboratories for Residues of Pesticides or according to an equally reliable method.

(4) Residues of at least those pesticides listed in the control programme adopted in accordance with Article 29(2) of Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1) that can be analysed with multi-residue methods based on GC-MS and LC-MS (pesticides to be monitored in/on products of plant origin only).

- (<sup>5</sup>) Residues of Carbofuran.
- (<sup>6</sup>) The sampling and the analyses shall be performed in accordance with the sampling procedures and the analytical reference methods set out in point 1(a) of Annex III.
- (<sup>7</sup>) Residues of Dithiocarbamates (dithiocarbamates expressed as CS<sub>2</sub>, including maneb, mancozeb, metiram, propineb, thiram and ziram) and Metrafenone.
- (<sup>8</sup>) Residues of Dithiocarbamates (dithiocarbamates expressed as CS<sub>2</sub>, including maneb, mancozeb, metiram, propineb, thiram and ziram), Phenthoate and Quinalphos.
- (<sup>9</sup>) The description of the goods is as laid down in the description column of the CN in Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256 7.9.1987, p. 1).
- (<sup>10</sup>) Foodstuffs containing or consisting of betel leaves (*Piper betle*) including, but not limited to, those declared under CN code 1404 90 00.
- (<sup>11</sup>) Residues of Ethylene Oxide (sum of ethylene oxide and 2-chloro-ethanol, expressed as ethylene oxide).

## 2. Compound food referred to in Article 1(1)(b)(ii)

Row	Compound food containing any of the individual products listed in the table in point 1 of this Annex due to risk of contamination by aflatoxins in a quantity above 20 % of either a single product or as the sum of products listed	
	CN code ( <sup>1</sup> )	Description ( <sup>2</sup> )
1	ex 1704 90	Sugar confectionery (including white chocolate), not containing cocoa, other than chewing gum, whether or not sugar-coated
2	ex 1806	Chocolate and other food preparations containing cocoa
3	ex 1905	Bread, pastry, cakes, biscuits and other bakers' wares, whether or not containing cocoa, communion wafers, empty cachets of a kind suitable for pharmaceutical use, sealing wafers, rice paper and similar products

(<sup>1</sup>) Where only certain products under any CN code are required to be examined, the CN code is marked 'ex'.

(<sup>2</sup>) The description of the goods is as laid down in the description column of the CN in Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256 7.9.1987, p. 1).

## ANNEX IIa

**Food and feed from certain third countries subject to suspension of entry into the Union referred to in Article 11a**

Row	Food and feed (intended use)	CN code <sup>(1)</sup>	TARIC sub-division	Country of origin	Hazard
1	— Foodstuffs consisting of dried beans <b>(Food)</b>	— 0713 35 00 — 0713 39 00 — 0713 90 00		<b>Nigeria (NG)</b>	Pesticide residues

<sup>(1)</sup> Where only certain products under any CN code are required to be examined, the CN code is marked 'ex'.

## ANNEX IV

**MODEL OFFICIAL CERTIFICATE REFERRED TO IN ARTICLE 11 OF COMMISSION IMPLEMENTING  
REGULATION (EU) 2019/1793 FOR THE ENTRY INTO THE UNION OF CERTAIN FOOD OR FEED**

COUNTRY		Official certificate to the EU							
Part 1: Details of dispatched consignment	I.1. Consignor/Exporter Name Address Tel. No		I.2. Certificate reference No		I.2.a IMSOC reference No				
			I.3. Central Competent Authority						
			I.4. Local Competent Authority						
			I.6. Operator responsible for the consignment Name Address Postal code						
	I.5. Consignee/Importer Name Address Postal code Tel. No								
	I.7. Country of origin	ISO	I.8. Region of origin		I.9. Country of destination	ISO	I.10.		
	I.11 Place of dispatch Name Address		I.12. Place of destination Name Address						
	I.13. Place of loading		I.14. Date and time of departure						
	I.15. Means of transport Aeroplane <input type="checkbox"/> Road vehicle <input type="checkbox"/> Identification: I.18. Transport conditions Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>		Vessel <input type="checkbox"/> Railway <input type="checkbox"/>	Other <input type="checkbox"/>		I.16. Entry BCP		I.17. Accompanying documents <input type="checkbox"/> Laboratory report No. Date of issuance: <input type="checkbox"/> Other Type No	
	I.19. Container No/Seal No								
I.20. Goods certified as Human consumption <input type="checkbox"/> Feedingstuff <input type="checkbox"/>									
I.21.		I.22. For internal market: <input type="checkbox"/>							
I.23 Total number of packages		I.24. Quantity Total number		Total net weight (Kg)		Total gross weight (Kg)			
I.25. Description of goods No Code and CN title									
Species (Scientific name)				Net weight		Batch No		Type of packaging	
Final consumer <input type="checkbox"/>	Number of packages								



	COUNTRY		Certificate for the entry into the Union of food or feed	
Part II: Certification	II. Health information		II.a Certificate reference No	II.b IMSOC reference No
	<p>II.1. I, the undersigned, declare that I am aware of the relevant provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1), Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1), Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1) and 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), and I certify that:</p> <p>(<sup>1</sup>) Either</p> <p>[II.1.1. <input type="checkbox"/> the food of the consignment described above with the identification code ... (indicate the identification code for the consignment referred to in Article 9(1) of Commission Implementing Regulation (EU) 2019/1793) was produced in accordance with the requirements of Regulations (EC) No 178/2002 and (EC) No 852/2004 and in particular:</p> <ul style="list-style-type: none"> <li>— primary production of such food and associated operations listed in Annex I to Regulation (EC) No 852/2004 comply with the general hygiene provisions laid down in part A of Annex I to Regulation (EC) No 852/2004;</li> <li>— (<sup>1</sup>) (<sup>2</sup>) and, in the case of any stage of production, processing and distribution after primary production and related operations:</li> <li>— it has been handled and, where appropriate, prepared, packaged and stored in a hygienic manner in accordance with the requirements of Annex II to Regulation (EC) No 852/2004 and,</li> <li>— it comes from (an) establishment(s) implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Regulation (EC) No 852/2004;]</li> </ul>			

	COUNTRY	Certificate for the entry into the Union of food or feed	
Part II: Certification	II. Health information	II.a Certificate reference No	II.b IMSOC reference No
	<p>(<sup>1</sup>) Or</p> <p>[II.1.2. <input type="checkbox"/> the feed of the consignment described above with the identification code ... (indicate the identification code for the consignment referred to in Article 9(1) of Implementing Regulation (EU) 2019/1793) was produced in accordance with the requirements of Regulation (EC) No 178/2002 and (EC) No 183/2005 and in particular:</p> <ul style="list-style-type: none"> <li>— primary production of such feed and associated operations listed in Article 5(1) of Regulation (EC) No 183/2005 comply with the provisions of Annex I to Regulation (EC) No 183/2005;</li> <li>— (<sup>1</sup>) (<sup>2</sup>) and, in the case of any stage of production, processing and distribution after primary production and related operations:</li> <li>— it has been handled and, where appropriate, prepared, packaged and stored in a hygienic manner in accordance with the requirements of Annex II to Regulation (EC) No 183/2005 and,</li> <li>— it comes from (an) establishment(s) implementing a programme based on the hazard analysis and critical control points (HACCP) principles in accordance with Regulation (EC) No 183/2005.]</li> </ul> <p><b>II.2</b> I, the undersigned, according to the provisions of Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660 (OJ L 277, 29.10.2019, p. 89), certify that:</p> <p>[II.2.1. <input type="checkbox"/> <b>Certification for food and feed of non-animal origin listed in Annex II to Implementing Regulation (EU) 2019/1793, as well as for compound food listed in that Annex, due to contamination risk by mycotoxins</b></p> <ul style="list-style-type: none"> <li>— from the consignment described above, samples were taken in accordance with: <ul style="list-style-type: none"> <li><input type="checkbox"/> Commission Regulation (EC) No 401/2006 to determine the level of aflatoxin B1 and level of total aflatoxin contamination for food</li> <li><input type="checkbox"/> Commission Regulation (EC) No 152/2009 to determine the level of aflatoxin B1 for feed</li> </ul> on ..... date), subject to laboratory analyses on ..... (date) in the ..... (name of the laboratory) with methods covering at least the hazards identified in Annex II to Implementing Regulation (EU) 2019/1793.</li> <li>— The details of the methods of laboratory analyses and all results are attached and show compliance with Union legislation on maximum levels of aflatoxins.]</li> </ul>		

	COUNTRY	Certificate for the entry into the Union of food or feed	
Part II: Certification	II. Health information	II.a Certificate reference No	II.b IMSOC reference No
	<p><sup>(3)</sup> And/Or [II.2.2. <input type="checkbox"/> <b>Certification for food and feed of non-animal origin listed in Annex II to Implementing Regulation (EU) 2019/1793, as well as for compound food listed in that Annex, due to contamination risk by pesticide residues</b></p> <ul style="list-style-type: none"> <li>— from the consignment described above, samples were taken in accordance with Commission Directive 2002/63/EC on ..... (date), subject to laboratory analyses on ..... (date) in the ..... (name of the laboratory) with methods covering at least the hazards identified in Annex II to Implementing Regulation (EU) 2019/1793.</li> <li>— The details of the methods of laboratory analyses and all results are attached and show compliance with Union legislation on maximum residue levels of pesticides.]</li> </ul> <p><sup>(3)</sup> And/Or [II.2.3. <input type="checkbox"/> <b>Certification for guar gum listed in Annex II to Implementing Regulation (EU) 2019/1793, including for compound food listed in that Annex, due to contamination risk by pentachlorophenol and dioxins</b></p> <ul style="list-style-type: none"> <li>— from the consignment described above, samples were taken in accordance with Commission Directive 2002/63/EC on ..... (date), subject to laboratory analyses on ..... (date) in the ..... (name of the laboratory) with methods covering at least the hazards identified in Annex II to Implementing Regulation (EU) 2019/1793.</li> <li>— The details of the methods of laboratory analyses and all results are attached and show that the goods do not contain more than 0.01 mg/kg pentachlorophenol.]</li> </ul> <p><sup>(3)</sup> And/Or [II.2.4. <input type="checkbox"/> <b>Certification for food of non-animal origin listed in Annex II to Implementing Regulation (EU) 2019/1793, as well as for compound food listed in that Annex due to risk of microbiological contamination</b></p> <ul style="list-style-type: none"> <li>— from the consignment described above, samples were taken in accordance with Annex III to Implementing Regulation (EU) 2019/1793 on ..... (date), subject to laboratory analyses on ..... (date) in the ..... (name of the laboratory) with methods covering at least the hazards identified in Annex II to Implementing Regulation (EU) 2019/1793.</li> <li>— The details of the methods of laboratory analyses and all results are attached and show the absence of Salmonella in 25 g.]</li> </ul> <p><b>II.3</b> This certificate has been issued before the consignment to which it relates has left the control of the competent authority issuing it.</p> <p><b>II.4</b> This certificate is valid during four months from the date of issue, but in any case no longer than six months from the date of the results of the last laboratory analyses.</p>		

	COUNTRY	Certificate for the entry into the Union of food or feed	
Part II: Certification	II. <b>Health information</b>	II.a Certificate reference No	II.b IMSOC reference No
		<b>Notes</b> <b>See notes for completion in this Annex.</b> Part II: (1) Delete or cross out as appropriate (e.g. if food or feed) (2) It applies only in the case of any stage of production, processing and distribution after primary production and related operations. (3) Delete or cross out as appropriate in the case where you do not select this point for providing the certification. (4) The colour of the signature shall be different to that of the printing. The same rule applies to stamps other than those that are embossed or are a watermark.	
	Certifying officer:  <div style="display: flex; justify-content: space-between;"> <div style="width: 45%;">             Name (in capital letters):               Date:               Stamp           </div> <div style="width: 45%;">             Qualification and title:               Signature:           </div> </div>		

**NOTES ON THE COMPLETION OF THE MODEL OFFICIAL CERTIFICATE REFERRED TO IN ARTICLE 11 OF COMMISSION IMPLEMENTING REGULATION (EU) 2019/1793 FOR THE ENTRY INTO THE UNION OF CERTAIN FOOD OR FEED**

### General

To positively select any option, please tick or mark the relevant box with a cross (X).

Whenever mentioned, 'ISO' means the international standard two-letter code for a country, in accordance with the international standard ISO 3166 alpha-2 <sup>(1)</sup>.

Only one of the options may be selected in boxes I.15, I.18, I.20.

Unless otherwise indicated, the boxes are compulsory.

If the consignee, the entry border control post (BCP) or the transport details (that is to say, the means and date) change after the certificate has been issued, the operator responsible for the consignment must advise the competent authority of the Member State of entry. Such a change shall not result in a request for a replacement certificate.

In case the certificate is submitted in the information management system for official controls (IMSOC), the following applies:

- the entries or boxes specified in Part I constitute the data dictionaries for the electronic version of the official certificate;
- the sequences of boxes in Part I of the model official certificate and the size and shape of those boxes are indicative;
- where a stamp is required, its electronic equivalent is an electronic seal. Such seal shall comply with the rules for the issuance of electronic certificates referred to in Article 90(f) of Regulation (EU) 2017/625.

<sup>(1)</sup> List of country names and code elements under: [http://www.iso.org/iso/country\\_codes/iso-3166-1\\_decoding\\_table.htm](http://www.iso.org/iso/country_codes/iso-3166-1_decoding_table.htm).

**Part I: Details of the dispatched consignment**

Country:	The name of the third country issuing the certificate.
Box I.1.	Consignor/Exporter: the name and address (street, city and region, province or state, as appropriate) of the natural or legal person dispatching the consignment that must be located in the third country.
Box I.2.	Certificate reference No: the unique mandatory code assigned by the competent authority of the third country in accordance with its own classification. This box is compulsory for all certificates not submitted in the IMSOC.
Box I.2.a	IMSOC reference No: the unique reference code automatically assigned by the IMSOC, if the certificate is registered in the IMSOC. This box must not be completed if the certificate is not submitted in the IMSOC.
Box I.3.	Central competent authority: name of the central authority in the third country issuing the certificate.
Box I.4.	Local competent authority: if applicable, the name of the local authority in the third country issuing the certificate.
Box I.5.	Consignee/Importer: name and address of the natural or legal person for whom the consignment is intended in the Member State.
Box I.6.	Operator responsible for the consignment: the name and address of the person in the European Union in charge of the consignment when presented to the BCP and who makes the necessary declarations to the competent authorities either as the importer or on behalf of the importer. This box is optional.
Box I.7.	Country of origin: the name and ISO code of the country where the goods are originating from, grown, harvested or produced.
Box I.8.	Not applicable.
Box I.9.	Country of destination: the name and ISO code of the European Union Member State of destination of the products.
Box I.10.	Not applicable.
Box I.11.	Place of dispatch: the name and address of the holdings or establishments from which the products come from.  Any unit of a company in the food or feed sector. Only the establishment shipping the products is to be named. In the case of trade involving more than one third country (triangular movement), the place of dispatch is the last third-country establishment of the export chain from which the final consignment is transported to the European Union.
Box I.12.	Place of destination: this information is optional.  For the placing on the market: the place where the products are sent for final unloading. Give the name, address and approval number of the holdings or establishments of the place of destination, if applicable.
Box I.13.	Place of loading: not applicable.
Box I.14.	Date and time of departure: the date when the means of transport departs (aeroplane, vessel, railway or road vehicle).
Box I.15.	Means of transport: means of transport leaving the country of dispatch.  Mode of transport: aeroplane, vessel, railway, road vehicle or other. 'Other' means modes of transport not covered by Council Regulation (EC) No 1/2005 (!).  Identification of the means of transport: for aeroplanes the flight number, for vessels the ship name(s), for railways the train identity and wagon number, for road transports the registration number plate with trailer number plate if applicable.  In the case of a ferry, state the identification of the road vehicle, the registration number plate with trailer number plate if applicable, and the name of the scheduled ferry.

Box I.16	Entry BCP: state the name of the BCP and its identification code assigned by the IMSOC.
Box I.17.	Accompanying documents: Laboratory report: indicate the reference number and the date of issuance of the report/results of laboratory analyses referred to in Article 10(1) of Implementing Regulation (EU) 2019/1793. Other: the type and reference number of document must be stated when a consignment is accompanied by other documents such as commercial documents (for example, the airway bill number, the bill of lading number or the commercial number of the train or road vehicle).
Box I.18.	Transport conditions: category of required temperature during the transport of products (ambient, chilled, frozen). Only one category may be selected.
Box I.19.	Container No/Seal No: if applicable, the corresponding numbers. The container number must be provided if the goods are transported in closed containers. Only the official seal number must be stated. An official seal applies if a seal is affixed to the container, truck or rail wagon under the supervision of the competent authority issuing the certificate.
Box I.20.	Goods certified as: state the intended use for products as specified in the relevant European Union official certificate. Human consumption: concerns only products intended for human consumption. Feedingstuff: concerns only products intended for animal feed.
Box I.21.	Not applicable.
Box I.22.	For internal market: for all consignments destined to be placed on the market in the European Union.
Box I.23.	Total number of packages: the number of packages. In the case of bulk consignments, this box is optional.
Box I.24.	Quantity: Total net weight: this is defined as the mass of the goods themselves without immediate containers or any packaging. Total gross weight: overall weight in kilograms. This is defined as the aggregate mass of the products and of the immediate containers and all their packaging, but excluding transport containers and other transport equipment.
Box I.25.	Description of goods: State the relevant Harmonised System code and the title defined by the World Customs Organisation as referred to in Council Regulation (EEC) No 2658/87 <sup>(1)</sup> . This customs description shall be supplemented, if necessary, by additional information required to classify the products. Indicate the species, types of products, the number of packages, type of packaging, batch number, net weight, and indicate 'final consumer' where products are packed for a final consumer. Species: the scientific name or as defined in accordance with European Union legislation. Type of packaging: identify the type of packaging according to the definition given in Annexes V and VI to Recommendation No 21 of UN/CEFACT (United Nations Centre for Trade Facilitation and Electronic Business).
<p><sup>(1)</sup> Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97 (OJ L 3, 5.1.2005, p. 1).</p> <p><sup>(2)</sup> Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).'</p>	

### Part II: Certification

This part must be completed by a certifying officer authorised by the competent authority of the third country to sign the official certificate, as provided for in Article 88(2) of Regulation (EU) 2017/625.

Box II.	<p>Health information: please complete this part in accordance with the specific European Union health requirements relating to the nature of the products and as defined in the equivalence agreements with certain third countries or in other European Union legislation, such as that for certification.</p> <p>Select among points II.2.1, II.2.2, II.2.3 and II.2.4, the point corresponding to the category of product and the hazard(s) for which the certification is given.</p> <p>In case the official certificate is not submitted in the IMSOC, the statements which are not relevant must be crossed out, initialled and stamped by the certifying officer, or completely removed from the certificate.</p> <p>In case the certificate is submitted in the IMSOC, the statements which are not relevant must be crossed out or completely removed from the certificate.</p>
Box II.a	Certificate reference No: same reference code as in box I.2.
Box II.b	IMSOC reference No: same reference code as in box I.2.a, mandatory only for official certificates issued in the IMSOC.
Certifying officer:	Official of the competent authority of the third country authorised to sign official certificates by the competent authority: indicate the name in capital letters, qualification and title, where applicable, identification number and original stamp of the competent authority and date of signature.

# DECISIONS

## COMMISSION IMPLEMENTING DECISION (EU) 2021/609

of 14 April 2021

### amending Implementing Decision (EU) 2020/439 as regards harmonised standards on packaging for terminally sterilised medical devices and sterilisation of health care products

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) In accordance with Article 5(1) of Directive 98/79/EC of the European Parliament and of the Council <sup>(2)</sup>, Member States are to presume compliance with the essential requirements referred to in Article 3 of that Directive in respect of *in vitro* diagnostic medical devices which are in conformity with the relevant national standards adopted pursuant to the harmonised standards the references of which have been published in the *Official Journal of the European Union*.
- (2) By letters M/023 – BC/CEN/03/023/93-08 of 5 August 1993 and M/252 of 12 September 1997, the Commission made requests to the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) for the drafting of new harmonised standards and the revision of existing harmonised standards in support of Directive 98/79/EC.
- (3) On the basis of request M/252, CEN revised the harmonised standard EN ISO 11737-2:2009, the reference of which has been published by Commission Implementing Decision (EU) 2020/439 <sup>(3)</sup>. That revision resulted in the adoption of the harmonised standard EN ISO 11737-2:2020 on sterilisation of health care products.
- (4) On the basis of request M/023 – BC/CEN/03/023/93-08, CEN drafted the harmonised standards EN ISO 11607-1:2020 and EN ISO 11607-2:2020 on packaging for terminally sterilised medical devices.
- (5) The Commission together with CEN has assessed whether the harmonised standards drafted and revised by CEN comply with the relevant requests.
- (6) The harmonised standards EN ISO 11607-1:2020, EN ISO 11607-2:2020 and EN ISO 11737-2:2020 satisfy the requirements which they aim to cover and which are set out in Directive 98/79/EC. It is therefore appropriate to publish the references of those standards in the *Official Journal of the European Union*.
- (7) It is necessary to replace the reference of harmonised standard EN ISO 11737-2:2009, published by Implementing Decision (EU) 2020/439, as that standard has been revised.

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

<sup>(2)</sup> Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

<sup>(3)</sup> Commission Implementing Decision (EU) 2020/439 of 24 March 2020 on the harmonised standards for *in vitro* diagnostic medical devices drafted in support of Directive 98/79/EC of the European Parliament and of the Council (OJ L 90 I, 25.3.2020, p. 33).



- (8) Annex I to Implementing Decision (EU) 2020/439 lists the references of harmonised standards drafted in support of Directive 98/79/EC. In order to ensure that the references of harmonised standards drafted in support of Directive 98/79/EC are listed in one act, the references of standards EN ISO 11607-1:2020 and EN ISO 11607-2:2020 should be included in that Implementing Decision.
- (9) Implementing Decision (EU) 2020/439 should therefore be amended accordingly.
- (10) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the date of its publication,

HAS ADOPTED THIS DECISION:

*Article 1*

Annex I to Implementing Decision (EU) 2020/439 is amended in accordance with the Annex to this Decision.

*Article 2*

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

Done at Brussels, 14 April 2021.

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

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## ANNEX

Annex I is amended as follows:

(1) entry 5 is replaced by the following:

No	Reference of the standard
'5.	EN ISO 11737-2:2020 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)';

(2) the following entries 42 and 43 are added:

No	Reference of the standard
'42.	EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
43.	EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)'.

**COMMISSION IMPLEMENTING DECISION (EU) 2021/610****of 14 April 2021****amending Implementing Decision (EU) 2020/437 as regards harmonised standards on medical vehicles and their equipment, anaesthetic and respiratory equipment, biological evaluation of medical devices, packaging for terminally sterilised medical devices, sterilisation of health care products, clinical investigation of medical devices for human subjects, non-active surgical implants, medical devices utilising animal tissues and their derivatives, electroacoustics and medical electrical equipment**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) In accordance with Article 5(1) of Council Directive 93/42/EEC <sup>(2)</sup>, Member States are to presume compliance with the essential requirements referred to in Article 3 of that Directive in respect of medical devices which are in conformity with the relevant national standards adopted pursuant to the harmonised standards the references of which have been published in the *Official Journal of the European Union*.
- (2) By letters BC/CEN/CENELEC/09/89 of 19 December 1991, M/023 - BC/CEN/03/023/93-08 of 5 August 1993, M/295 of 9 September 1999, M/320 of 13 June 2002 and M/432 of 24 November 2008, the Commission made requests to the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) for the drafting of new harmonised standards and the revision of existing harmonised standards in support of Directive 93/42/EEC.
- (3) On the basis of request M/023 - BC/CEN/03/023/93-08, CEN revised the harmonised standards EN 1789:2007 +A1:2010, EN ISO 10993-16:2010, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11737-2:2009, EN 13718-1:2008, EN 13718-2:2015, EN ISO 22442-1:2007 and EN ISO 22442-2:2007, the references of which have been published by Commission Implementing Decision (EU) 2020/437 <sup>(3)</sup>. That revision resulted in the adoption of the harmonised standards EN 1789:2020 on medical vehicles and their equipment, EN ISO 10993-16:2017 on biological evaluation of medical devices, EN ISO 11607-1:2020 and EN ISO 11607-2:2020 on packaging for terminally sterilised medical devices, EN ISO 11737-2:2020 on sterilisation of health care products, EN 13718-1:2014+A1:2020 and EN 13718-2:2015+A1:2020 on medical vehicles and their equipment and finally EN ISO 22442-1:2020 and EN ISO 22442-2:2020 on medical devices utilising animal tissues and their derivatives.
- (4) On the basis of request BC/CEN/CENELEC/09/89, CEN revised the harmonised standard EN ISO 10993-18:2009, the reference of which has been published by Implementing Decision (EU) 2020/437. That revision resulted in the adoption of the harmonised standard EN ISO 10993-18:2020 on biological evaluation of medical devices.
- (5) On the basis of request M/295, CEN and Cenelec revised the harmonised standards EN ISO 14155:2011 as corrected by EN ISO 14155:2011/AC:2011, and EN 60601-2-4:2003, the references of which have been published by Implementing Decision (EU) 2020/437. That revision resulted in the adoption of the harmonised standards EN ISO 14155:2020 on clinical investigation of medical devices for human subjects and EN 60601-2-4:2011 on medical electrical equipment.

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

<sup>(2)</sup> Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

<sup>(3)</sup> Commission Implementing Decision (EU) 2020/437 of 24 March 2020 on the harmonised standards for medical devices drafted in support of Council Directive 93/42/EEC (OJ L 90 I, 25.3.2020, p. 1).

- (6) On the basis of requests M/320 and M/023 - BC/CEN/03/023/93-08, CEN revised the harmonised standard EN ISO 14607:2009, the reference of which has been published by Implementing Decision (EU) 2020/437. That revision resulted in the adoption of the harmonised standard EN ISO 14607:2018 on non-active surgical implants.
- (7) On the basis of requests M/432 and M/023 - BC/CEN/03/023/93-08, Cenelec revised the harmonised standard EN 60118-13:2005, the reference of which has been published by Implementing Decision (EU) 2020/437. That revision resulted in the adoption of the harmonised standard EN IEC 60118-13:2020 on electroacoustics.
- (8) On the basis of request M/023 - BC/CEN/03/023/93-08, CEN and Cenelec drafted the harmonised standard EN ISO 5361:2016 on anaesthetic and respiratory equipment and the harmonised standards EN IEC 60601-2-83:2020 and EN ISO 80601-2-55:2018 on medical electrical equipment.
- (9) On the basis of requests M/432 and M/023 - BC/CEN/03/023/93-08, Cenelec drafted the harmonised standard EN IEC 60601-2-66:2020 on medical electrical equipment.
- (10) The Commission together with CEN and Cenelec has assessed whether the harmonised standards drafted and revised by CEN and Cenelec comply with the relevant requests.
- (11) The harmonised standards EN 1789:2020, EN ISO 5361:2016, EN ISO 10993-16:2017, EN ISO 10993-18:2020, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-2:2020, EN 13718-1:2014+A1:2020, EN 13718-2:2015+A1:2020, EN ISO 14155:2020, EN ISO 14607:2018, EN ISO 22442-1:2020, EN ISO 22442-2:2020, EN IEC 60118-13:2020, EN 60601-2-4:2011, EN IEC 60601-2-66:2020, EN IEC 60601-2-83:2020 and EN ISO 80601-2-55:2018 satisfy the requirements which they aim to cover and which are set out in Directive 93/42/EEC. It is therefore appropriate to publish the references of those standards in the *Official Journal of the European Union*.
- (12) It is necessary to replace the references of harmonised standards EN 1789:2007+A1:2010, EN ISO 10993-16:2010, EN ISO 10993-18:2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11737-2:2009, EN 13718-1:2008, EN 13718-2:2015, EN ISO 14155:2011 as corrected by EN ISO 14155:2011/AC:2011, EN ISO 14607:2009, EN ISO 22442-1:2007, EN ISO 22442-2:2007, EN 60118-13:2005 and EN 60601-2-4:2003, published by Implementing Decision (EU) 2020/437, as those standards have been revised.
- (13) Annex I to Implementing Decision (EU) 2020/437 lists the references of harmonised standards drafted in support of Directive 93/42/EEC. In order to ensure that the references of harmonised standards drafted in support of Directive 93/42/EEC are listed in one act, the references of standards EN ISO 5361:2016, EN IEC 60601-2-66:2020, EN IEC 60601-2-83:2020 and EN ISO 80601-2-55:2018 should be included in that Implementing Decision.
- (14) Implementing Decision (EU) 2020/437 should therefore be amended accordingly.
- (15) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the date of its publication,

HAS ADOPTED THIS DECISION:

#### Article 1

Annex I to Implementing Decision (EU) 2020/437 is amended in accordance with the Annex to this Decision.

*Article 2*

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

Done at Brussels, 14 April 2021.

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

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## ANNEX

Annex I is amended as follows:

(1) entry 22 is replaced by the following:

No	Reference of the standard
'22.	EN 1789:2020 Medical vehicles and their equipment - Road ambulances'

(2) entry 81 is replaced by the following:

No	Reference of the standard
'81.	EN ISO 10993-16:2017 Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2017)'

(3) entry 83 is replaced by the following:

No	Reference of the standard
'83.	EN ISO 10993-18:2020 Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)'

(4) entries 92 and 93 are replaced by the following:

No	Reference of the standard
'92.	EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
93.	EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)'

(5) entry 96 is replaced by the following:

No	Reference of the standard
'96.	EN ISO 11737-2:2020 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)'

(6) entries 125 and 126 are replaced by the following:

No	Reference of the standard
'125.	EN 13718-1:2014+A1:2020 Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances
126.	EN 13718-2:2015+A1:2020 Medical vehicles and their equipment - Air ambulances - Part 2: Operational and technical requirements for air ambulances'

(7) entry 137 is replaced by the following:

No	Reference of the standard
'137.	EN ISO 14155:2020 Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)'

(8) entry 145 is replaced by the following:

No	Reference of the standard
'145.	EN ISO 14607:2018 Non-active surgical implants - Mammary implants - Particular requirements (ISO 14607:2018, Corrected version 2018-08)'

(9) entries 180 and 181 are replaced by the following:

No	Reference of the standard
'180.	EN ISO 22442-1:2020 Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management (ISO 22442-1:2020)
181.	EN ISO 22442-2:2020 Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling (ISO 22442-2:2020)'

(10) entry 193 is replaced by the following:

No	Reference of the standard
'193.	EN IEC 60118-13:2020 Electroacoustics - Hearing aids - Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices'

(11) entry 208 is replaced by the following:

No	Reference of the standard
'208.	EN 60601-2-4:2011 Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators'

(12) the following entries 265 to 268 are added:

No	Reference of the standard
'265.	EN ISO 5361:2016 Anaesthetic and respiratory equipment - Tracheal tubes and connectors (ISO 5361:2016)
266.	EN IEC 60601-2-66:2020 Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems (IEC 60601-2-66:2019)
267.	EN IEC 60601-2-83:2020 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
268.	EN ISO 80601-2-55:2018 Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2018)'

**COMMISSION IMPLEMENTING DECISION (EU) 2021/611****of 14 April 2021****amending Implementing Decision (EU) 2020/438 as regards harmonised standards on biological evaluation of medical devices, packaging for terminally sterilised medical devices, sterilisation of health care products and clinical investigation of medical devices for human subjects**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) In accordance with Article 5(1) of Council Directive 90/385/EEC <sup>(2)</sup>, Member States are to presume compliance with the essential requirements referred to in Article 3 of that Directive in respect of active implantable medical devices which are in conformity with the relevant national standards adopted pursuant to the harmonised standards the references of which have been published in the *Official Journal of the European Union*.
- (2) By letters BC/CEN/CENELEC/09/89 of 19 December 1991, M/023 - BC/CEN/03/023/93-08 of 5 August 1993 and M/295 of 9 September 1999, the Commission made requests to the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) for the drafting of new harmonised standards and the revision of existing harmonised standards in support of Directive 90/385/EEC.
- (3) On the basis of request M/023 - BC/CEN/03/023/93-08, CEN revised the harmonised standards EN ISO 10993-16:2010, EN ISO 11607-1:2009 and EN ISO 11737-2:2009, the references of which have been published by Commission Implementing Decision (EU) 2020/438 <sup>(3)</sup>. That revision resulted in the adoption of the harmonised standards EN ISO 10993-16:2017 on biological evaluation of medical devices, EN ISO 11607-1:2020 on packaging for terminally sterilised medical devices and EN ISO 11737-2:2020 on sterilisation of health care products.
- (4) On the basis of request BC/CEN/CENELEC/09/89, CEN revised the harmonised standard EN ISO 10993-18:2009, the reference of which has been published by Implementing Decision (EU) 2020/438. That revision resulted in the adoption of the harmonised standard EN ISO 10993-18:2020 on biological evaluation of medical devices.
- (5) On the basis of request M/295, CEN revised the harmonised standard EN ISO 14155:2011, as corrected by EN ISO 14155:2011/AC:2011, the references of which have been published by Implementing Decision (EU) 2020/438. That revision resulted in the adoption of the harmonised standard EN ISO 14155:2020 on clinical investigation of medical devices for human subjects.
- (6) On the basis of request M/023 - BC/CEN/03/023/93-08, CEN drafted the harmonised standard EN ISO 11607-2:2020 on packaging for terminally sterilised medical devices.
- (7) The Commission together with CEN has assessed whether the harmonised standards drafted and revised by CEN comply with the relevant requests.

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

<sup>(2)</sup> Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

<sup>(3)</sup> Commission Implementing Decision (EU) 2020/438 of 24 March 2020 on the harmonised standards for active implantable medical devices drafted in support of Council Directive 90/385/EEC (OJ L 90 I, 25.3.2020, p. 25).



- (8) The harmonised standards EN ISO 10993-16:2017, EN ISO 10993-18:2020, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN ISO 11737-2:2020 and EN ISO 14155:2020 satisfy the requirements which they aim to cover and which are set out in Directive 90/385/EEC. It is therefore appropriate to publish the references of those standards in the *Official Journal of the European Union*.
- (9) It is necessary to replace the references of harmonised standards EN ISO 10993-16:2010, EN ISO 10993-18:2009, EN ISO 11607-1:2009, EN ISO 11737-2:2009 and EN ISO 14155:2011 as corrected by EN ISO 14155:2011/AC:2011, published by Implementing Decision (EU) 2020/438, as those standards have been revised.
- (10) Annex I to Implementing Decision (EU) 2020/438 lists the references of harmonised standards drafted in support of Directive 90/385/EEC. In order to ensure that the references of harmonised standards drafted in support of Directive 90/385/EEC are listed in one act, the reference of standard EN ISO 11607-2:2020 should be included in that Implementing Decision.
- (11) Implementing Decision (EU) 2020/438 should therefore be amended accordingly.
- (12) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the date of its publication,

HAS ADOPTED THIS DECISION:

*Article 1*

Annex I to Implementing Decision (EU) 2020/438 is amended in accordance with the Annex to this Decision.

*Article 2*

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

Done at Brussels, 14 April 2021.

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

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## ANNEX

Annex I is amended as follows:

(1) entry 14 is replaced by the following:

No	Reference of the standard
'14.	EN ISO 10993-16:2017 Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2017)

(2) entry 16 is replaced by the following:

No	Reference of the standard
'16.	EN ISO 10993-18:2020 Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020)

(3) entry 23 is replaced by the following:

No	Reference of the standard
'23.	EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)

(4) entry 25 is replaced by the following:

No	Reference of the standard
'25.	EN ISO 11737-2:2020 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)

(5) entry 34 is replaced by the following:

No	Reference of the standard
'34.	EN ISO 14155:2020 Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)

(6) the following entry 47 is added:

No	Reference of the standard
'47.	EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)

**CORRIGENDA****Corrigendum to Council Regulation (EU) No 509/2012 of 15 June 2012 amending Regulation (EU) No 36/2012 concerning restrictive measures in view of the situation in Syria**

*(Official Journal of the European Union L 156 of 16 June 2012)*

On page 31, in Table IX.A1. Materials, chemicals, 'micro-organisms' and 'toxins', No IX.A1.003:

*for:* 'Dichloromethane, (CAS 75-09-3)',

*read:* 'Dichloromethane, (CAS 75-09-2)'.

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