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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	28 March 2022
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

No. Cion doc.:	C(2022) 1804 final
Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 28.3.2022 amending Delegated Regulation (EU) 2019/625 as regards Combined Nomenclature and Harmonised System codes and import conditions of certain composite products, amending Delegated Regulation (EU) 2019/2122 as regards certain goods and pet birds exempted from official controls at border control posts and amending Delegated Regulation (EU) 2021/630 as regards requirements for composite products exempted from official controls at border control posts

Delegations will find attached document C(2022) 1804 final.

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EUROPEAN
COMMISSION

Brussels, 28.3.2022
C(2022) 1804 final

COMMISSION DELEGATED REGULATION (EU) .../...

of 28.3.2022

amending Delegated Regulation (EU) 2019/625 as regards Combined Nomenclature and Harmonised System codes and import conditions of certain composite products, amending Delegated Regulation (EU) 2019/2122 as regards certain goods and pet birds exempted from official controls at border control posts and amending Delegated Regulation (EU) 2021/630 as regards requirements for composite products exempted from official controls at border control posts

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Regulation (EU) 2017/625 of the European Parliament and of the Council lays down rules for the performance of official controls and other control activities by the competent authorities of the Member States, including for the establishment of requirements to be fulfilled for the entry into the Union of consignments of animals and goods from third countries or regions thereof and official controls performed on such consignments that are intended for human consumption in order to ensure that they comply with Union legislation in the area of food and food safety.

Commission Delegated Regulation (EU) 2019/625 supplements Regulation (EU) 2017/625 with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption.

The main purpose of the amendment to Delegated Regulation (EU) 2019/625 is the adaptation of import conditions for shelf-stable composite products containing colostrum-based products, considering the animal health risks related to colostrum-based products and the absence of effective treatments to mitigate them, by laying down that these products should originate from listed third countries authorised to export colostrum-based products and by imposing certificate requirements.

This Delegated Regulation also clarifies a number of applicable Combined Nomenclature codes or Harmonised System codes, used to identify the goods or animals to which the import requirements in Delegated Regulation (EU) 2019/625 apply and updates references to acts mentioned in that Delegated Regulation. It also amends import conditions for vitamin D3 derived from lanolin, for bee pollen flour and for shelf-stable composite products containing vitamin D3, food enzymes, food additives, flavourings and food ingredients with flavouring properties.

Moreover, Article 8(2), point (b), of Delegated Regulation (EU) 2019/625 is aligned with the amendments of Regulation (EU) 2017/625 as regards echinoderms resulting from the entry into force of Regulation (EU) 2021/1756 of the European Parliament and of the Council.

Finally, the amendments to Delegated Regulation (EU) 2019/625 clarify the certification requirements in case of entry from a third country of these animals and goods both coming from another third country, and in case of transit.

To be consistent with the amendments in Delegated Regulation (EU) 2019/625, Delegated Regulation (EU) 2021/630 needs to be amended to provide that only shelf-stable composite products not containing colostrum-based products or any processed meat other than gelatine, collagen or highly refined products may be exempted from official controls at border control posts. This Delegated Regulation also provides new legal references in Commission Delegated Regulation (EU) 2021/630 as a consequence of changes in Article 12(2) of Delegated Regulation (EU) 2019/625.

Furthermore, this Delegated Regulation amends Delegated Regulation (EU) 2019/2122 in order to better clarify which document should accompany each the different categories of animals and goods exempted from official controls at border control posts and from which third countries such samples may enter the Union. This Delegated Regulation provides for a clarification with respect to small quantities of goods which are sent to natural persons which are exempted from official controls at border control posts. The Delegated Regulation also clarifies which goods of animal origin that passengers arriving in the Union may carry in their personal luggage are exempted from official controls at border control posts. This Delegated

Regulation also, in respect of the provisions for pet birds, makes minor updates to certain references to acts mentioned in Delegated Regulation (EU) 2019/2122. In particular, it replaces the references to Commission Decision 2007/25/EC with references to Commission Delegated Regulation (EU) 2021/1933 supplementing Regulation (EU) No 576/2013 of the European Parliament and of the Council with regard to rules for non-commercial movements of pet birds into a Member State from a territory or a third country and Commission Implementing Regulation (EU) 2021/1938 establishing the model identification document for non-commercial movements of pet birds into a Member State from a territory or a third country and repealing Decision 2007/25/EC

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

This Delegated Regulation has been discussed on 7 September and 7 December 2021 at the meeting of the expert group on food hygiene and control of food of animal origin, representing competent authorities of all Member States, and is supported by these experts.

Before adopting this Delegated Regulation, the Commission conducted public consultations in an open and transparent way in accordance with the procedures laid down in the Interinstitutional Agreement on Better Law-Making.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Commission Delegated Regulation (EU) 2019/625 and its amendments are adopted pursuant to Article 48, points (b), (d), (e), (f) and (h), and Article 126(1) of Regulation (EU) 2017/625, which became applicable with effect from 14 December 2019.

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amending Delegated Regulation (EU) 2019/625 as regards Combined Nomenclature and Harmonised System codes and import conditions of certain composite products, amending Delegated Regulation (EU) 2019/2122 as regards certain goods and pet birds exempted from official controls at border control posts and amending Delegated Regulation (EU) 2021/630 as regards requirements for composite products exempted from official controls at border control posts

(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)¹, and in particular Article 48, points (b), (d), (e), (f) and (h), and Article 126(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) 2019/625² supplements Regulation (EU) 2017/625 as regards the requirements for entry in 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 or with requirements recognised to be at least equivalent thereto.
- (2) Apart from requiring that products of animal origin intended for human consumption enter the Union from a third country or region thereof included in the relevant lists, Article 3, point (a), of Delegated Regulation (EU) 2019/625 refers to specific Combined Nomenclature codes ('CN codes') and Harmonised System codes ('HS codes') that must have been laid down for the products concerned.
- (3) Until 31 December 2020, the importation of vitamin D3 derived from lanolin of sheep wool referred to by the HS codes under heading 2936 in Part Two of Annex I to

¹ OJ L 95, 7.4.2017, p. 1.

² 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).

Council Regulation (EEC) No 2658/87³ was allowed based on transitional measures laid down in Commission Regulation (EU) 2017/185⁴. The Union is highly dependent on the importation of this product. Due to the robust process by which vitamin D3 is obtained from lanolin, there is no public health concern related to the importation of such product. Importation of vitamin D3 derived from lanolin should therefore be authorised again and the appropriate heading introduced in Article 3, point (a), of Delegated Regulation (EU) 2019/625.

- (4) Hardened gelatine or unhardened gelatine capsules are produced from gelatine by enhanced heating. Such gelatine should therefore comply with the import conditions for gelatine, such as the requirement that these products originate from third countries or regions thereof authorised to export these products to the Union and the guarantees to be provided on the manufacturing of raw materials in accordance with Article 7 of Delegated Regulation (EU) 2019/625. However, as the public health risk from establishments manufacturing such gelatine is negligible, gelatine capsules should be exempted from the requirements for entry into the Union in relation to establishments and certification, except, as regards certification, when derived from ruminant bones in accordance with Regulation (EC) No 999/2001 of the European Parliament and of the Council⁵.
- (5) Articles 3, 5, 12 and 13 of Delegated Regulation (EU) 2019/625 provide for import requirements for consignments of goods referred to by certain CN codes or HS codes in Part Two of Annex I to Regulation (EEC) No 2658/87. It is appropriate to clarify the applicable codes in order to avoid any ambiguity as regards which codes apply to those goods. Missing codes should be added and codes which are not relevant or redundant should be removed.
- (6) Bee pollen flour, referred to by CN code ex1212 99 95, may represent a public health risk related to the presence of residues of environmental contaminants similar to other apiculture products. Similar requirements for entry into the Union should apply to bee pollen flour as to other apiculture products.
- (7) Regulation (EU) 2021/1756 of the European Parliament and of the Council⁶ amends Article 18 of Regulation (EU) 2017/625, extending to all echinoderms which are not filter feeders, and not only to Holothuroidea, the possibility laid down in Article 18(7), point (g), of Regulation (EU) 2017/625 of derogating from the requirement to classify the production and relaying areas. Consequently, Article 8(2), point (b), of Delegated Regulation (EU) 2019/625, which details the conditions of this derogation, should be amended accordingly.
- (8) In accordance with Article 12(2), point (c), of Delegated Regulation (EU) 2019/625, composite products referred to in Article 12(1) of that Regulation that do not need to

³ 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).

⁴ Commission Regulation (EU) 2017/185 of 2 February 2017 laying down transitional measures for the application of certain provisions of Regulations (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and of the Council (OJ L 29, 3.2.2017, p. 21).

⁵ Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (OJ L 147, 31.5.2001, p. 1).

⁶ Regulation (EU) 2021/1756 of the European Parliament and of the Council of 6 October 2021 amending Regulation (EU) 2017/625 as regards official controls on animals and products of animal origin exported from third countries to the Union in order to ensure compliance with the prohibition of certain uses of antimicrobials and Regulation (EC) No 853/2004 as regards the direct supply of meat from poultry and lagomorphs (OJ L 357, 8.10.2021, p. 27).

be transported or stored under controlled temperatures and which contain processed products of animal origin other than processed meat, for which requirements are laid down in Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council⁷, are to originate from third countries or regions thereof authorised to export meat products, dairy products, colostrum-based products, fishery products or egg products to the Union on the basis of the Union animal and public health requirements and which are listed at least for one of these products of animal origin pursuant to Article 3 of Delegated Regulation (EU) 2019/625.

- (9) Considering the animal health risks related to colostrum-based products and the absence of effective treatments to mitigate them, shelf-stable composite products containing colostrum-based products should originate from countries authorised to export colostrum-based products to the Union. Shelf-stable composite products containing colostrum-based products should also no longer benefit from the possibility of being accompanied by a private attestation instead of an official certificate.
- (10) Gelatine, collagen and certain highly refined products can be imported without submitting a residue monitoring plan and, consequently, it should not be necessary that countries are listed in the Annex to Commission Decision 2011/163/EU⁸ to be allowed to export these products to the Union or to use these products as ingredients in composite products for export to the Union, although listing in accordance with Articles 18, 19 or 22 of Commission Implementing Regulation (EU) 2021/405⁹ remains mandatory. In addition, certain third countries should be able export to the Union shelf-stable composite products not containing colostrum-based products or processed meat using processed products of animal origin that have been sourced either from a Member State or from a third country listed, for the relevant species/commodity from which those processed products are derived, in the Annex to Decision 2011/163/EU.
- (11) Shelf-stable composite products where the only animal products present in the final composite product are vitamin D3, food additives, food enzymes or food flavourings, represent a negligible risk due to their manufacturing process. These products should therefore be exempted from the listing of countries and from the private attestation requirements.
- (12) Article 13 of Delegated Regulation (EU) 2019/625 lays down requirements as regards the certification for entry into the Union of certain animals and goods intended for human consumption. Certification requirements in case of entry from a third country of these animals and goods, both coming from another third country, and in case of transit, should be clarified.
- (13) Article 14(1) of Delegated Regulation (EU) 2019/625 lays down that a private attestation is to accompany consignments of certain composite products. The current wording should be clarified as regards the composite products to which this provision applies.

⁷ 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).

⁸ 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).

⁹ 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).

- (14) Regulation (EU) 2016/429 of the European Parliament and of the Council¹⁰ applies from 21 April 2021, resulting in the repeal of several acts referred to in Delegated Regulation (EU) 2019/625. For reasons of clarity and consistency, it is appropriate to update these references.
- (15) Commission Delegated Regulation (EU) 2019/2122¹¹ establishes certain categories of animals and goods exempted from official controls at border control posts.
- (16) Article 4 of Delegated Regulation (EU) 2019/2122 provides for different documents that need to accompany certain samples exempted from official controls at border control posts. It should be clarified which documents are to accompany samples of animal origin, in accordance with the rules applicable to their entry into the Union. In particular, it should be clarified that certificates accompanying samples are to contain at least the relevant animal health attestation. Furthermore, it should be clarified from which third countries such samples may enter the Union.
- (17) Article 10 of Delegated Regulation (EU) 2019/2122 provides that small consignments of certain goods sent to natural persons which are not intended to be placed on the market are exempted from official controls at border control posts. In the interest of legal certainty, the categories of exempted goods should be clarified. In addition, the terminology used to refer to some of those goods in Annexes I and III to Delegated Regulation (EU) 2019/2122 should be aligned with the terminology in Regulation (EU) 609/2013 of the European Parliament and of the Council¹².
- (18) Article 11 of Delegated Regulation (EU) 2019/2122 provides that pet birds entering the Union during a non-commercial movement in accordance with Commission Decision 2007/25/EC¹³ are exempted from official controls at border control posts. Decision 2007/25/EC was, however, replaced by Commission Delegated Regulation (EU) 2021/1933¹⁴ and Commission Implementing Regulation (EU) 2021/1938¹⁵ and repealed by the latter. References to that Decision in Delegated Regulation (EU) 2019/2122 should therefore be updated.

¹⁰ 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') (OJ L 84, 31.3.2016, p. 1).

¹¹ Commission Delegated Regulation (EU) 2019/2122 of 10 October 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards certain categories of animals and goods exempted from official controls at border control posts, specific controls on passengers' personal luggage and on small consignments of goods sent to natural persons which are not intended to be placed on the market and amending Commission Regulation (EU) No 142/2011 (OJ L 321, 12.12.2019, p. 45).

¹² Regulation (EU) 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

¹³ Commission Decision 2007/25/EC of 22 December 2006 as regards certain protection measures in relation to highly pathogenic avian influenza and movements of pet birds accompanying their owners into the Community (OJ L 8, 13.1.2007, p. 29).

¹⁴ Commission Delegated Regulation (EU) 2021/1933 of 14 July 2021 supplementing Regulation (EU) No 576/2013 of the European Parliament and of the Council with regard to rules for non-commercial movements of pet birds into a Member State from a territory or a third country (OJ L 396, 10.11.2021, p. 4).

¹⁵ Commission Implementing Regulation (EU) 2021/1938 of 9 November 2021 establishing the model identification document for non-commercial movements of pet birds into a Member State from a territory or a third country and repealing Decision 2007/25/EC (OJ L 396, 10.11.2021, p. 47).

- (19) Commission Delegated Regulation (EU) 2021/630¹⁶ exempts certain categories of food from official controls at border control posts. In order to ensure legal certainty, it is necessary to exclude shelf-stable composite products containing colostrum-based products or processed meat other than gelatine, collagen or highly refined products referred to in Section XVI of Annex III to Regulation (EC) No 853/2004 from the products to be exempted from official controls at border control post in accordance with Delegated Regulation (EU) 2021/630.
- (20) Shelf-stable composite products where all the animal products present in the final composite product fall within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council¹⁷, Regulation (EC) No 1333/2008 of the European Parliament and of the Council¹⁸ or Regulation (EC) No 1334/2008 of the European Parliament and of the Council¹⁹, or that animal part is vitamin D3 only, represent a negligible risk. They should therefore be exempted from official controls at border control posts.
- (21) Animal health requirements for dairy and egg products contained in composite products laid down in Article 163, point (a), of Commission Delegated Regulation (EU) 2020/692²⁰, were amended by Commission Delegated Regulation (EU) 2021/1703²¹. In order to ensure legal certainty, it is necessary to refer in Delegated Regulation (EU) 2021/630 to the new legal requirements for dairy and egg products contained in composite products.
- (22) Since the amendments to Delegated Regulations (EU) 2019/625, (EU) 2019/2122 and (EU) 2021/630 are linked to each other insofar as they concern the adaptation of import conditions for shelf-stable composite products containing colostrum-based products, and since the other amendments to Delegated Regulation (EU) 2019/2122 merely concern minor updates of references, it is appropriate to make those amendments in one single act.
- (23) Delegated Regulations (EU) 2019/625, (EU) 2019/2122 and (EU) 2021/630 should therefore be amended accordingly,

¹⁶ Commission Delegated Regulation (EU) 2021/630 of 16 February 2021 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards certain categories of goods exempted from official controls at border control posts and amending Commission Decision 2007/275/EC (OJ L 132, 19.4.2021, p. 17).

¹⁷ Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p. 7).

¹⁸ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

¹⁹ Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).

²⁰ 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).

²¹ Commission Delegated Regulation (EU) 2021/1703 of 13 July 2021 amending Delegated Regulation (EU) 2020/692 as regards the animal health requirements for the entry into the Union of products of animal origin contained in composite products (OJ L 339, 24.9.2021, p. 29).

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Delegated Regulation (EU) 2019/625

Delegated Regulation (EU) 2019/625 is amended as follows:

- (1) Article 3 is replaced by the following:

‘Article 3

Animals and goods which are required to come from third countries or regions thereof included in the list referred to in Article 126(2)(a) of Regulation (EU) 2017/625

Consignments of the following animals and goods intended for human consumption shall enter the Union only from a third country or region thereof included in the list for those animals and goods laid down in Commission Implementing Regulation (EU) 2021/405*:

- (a) products of animal origin, including reptile meat and dead whole insects, parts of insects or processed insects, intended for human consumption, for which the following codes have been laid down in Part Two of Annex I to Council Regulation (EEC) No 2658/87**:
 - (i) Combined Nomenclature codes (“CN codes”) in Chapters 2 to 5, 15, 16 or 29; or
 - (ii) Harmonised System codes (“HS codes”) under headings 0901, 1702, 2101, 2105, 2106, 2301, 3001, 3002, 3302, 3501, 3502, 3503, 3504, 3507, 3913, 3926, 4101, 4102, 4103 or 9602;
- (b) live insects referred to by the CN code 0106 49 00 of Part Two of Annex I to Regulation (EEC) No 2658/87;
- (c) live snails referred to by the CN code 0307 60 00 of Part Two of Annex I to Regulation (EEC) No 2658/87;
- (d) bee pollen flour referred to by the CN code ex1212 99 95 of Part Two of Annex I to Regulation (EEC) No 2658/87.

* 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).

** 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).’;

- (2) in Article 5(1), point (a) is replaced by the following:

- ‘(a) products of animal origin for which requirements are laid down in Annex III to Regulation (EC) No 853/2004 and for which the following codes have been laid down in Part Two of Annex I to Regulation (EEC) No 2658/87:
 - (i) CN codes in Chapters 2 to 5, 15 or 16; or

- (ii) HS codes under headings 1702, 2101, 2105, 2106, 2301, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 4101, 4102, or 4103;';
- (3) in Article 8(2), point (b) is replaced by the following:
 '(b) marine gastropods that are not filter feeders and echinoderms that are not filter feeders.';
- (4) in Article 11, paragraph 3 is replaced by the following:
 '3. When consignments of fishery products enter the Union directly from a reefer, factory or a freezer vessel flying the flag of a third country, the official certificate referred to in Article 14(3) of Commission Implementing Regulation (EU) 2020/2235* may be signed by the captain.

* 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).';

- (5) Article 12 is replaced by the following:

Article 12

Requirements for composite products

1. Consignments of composite products referred to by the CN codes under headings 0901, 1517, 1518, 1601 00, 1602, 1603 00, 1604, 1605, 1702, 1704, 1806, 1901, 1902, 1904, 1905, 2001, 2004, 2005, 2008, 2101, 2103, 2104, 2105 00, 2106, 2202 or 2208 of Annex I to Regulation (EEC) No 2658/87 shall enter the Union for placing on the market only if each processed product of animal origin contained in the composite products was either produced in establishments that are located in third countries or regions thereof and authorised to export those processed products of animal origin to the Union in accordance with Article 5 or in establishments located in Member States.
2. Pending the establishment by the Commission of a specific list of third countries or regions thereof authorised to export composite products to the Union, consignments of composite products from third countries or regions thereof may enter the Union, subject to compliance with the following rules:
 - (a) composite products referred to in paragraph 1 that need to be transported or stored under controlled temperatures shall originate from third countries or regions thereof authorised to export to the Union each processed product of animal origin contained in the composite products pursuant to Article 3;
 - (b) composite products referred to in paragraph 1 that do not need to be transported or stored under controlled temperatures and which contain any quantity of colostrum-based products or processed meat, shall originate from third countries or regions thereof authorised to export to the Union the

colostrum-based products or processed meat contained in the composite products pursuant to Article 3;

- (c) composite products referred to in paragraph 1 that do not need to be transported or stored under controlled temperatures and which contain processed products of animal origin for which requirements are laid down in Annex III to Regulation (EC) No 853/2004 and other than colostrum-based products or processed meat, shall originate from third countries or regions thereof that are authorised to export meat products, dairy products, fishery products or egg products to the Union on the basis of Union animal and public health requirements and are listed at least for one of these products of animal origin pursuant to Article 3.

3. Composite products shall enter the Union only from a third country or region thereof included in the list laid down in the Annex to Decision 2011/163/EU as having an approved residues monitoring plan in accordance with Directive 96/23/EC for the species/commodity from which the processed products of animal origin contained in the composite products, with the exception of collagen, gelatine and the highly refined products listed in Section XVI, point 1, of Annex III to Regulation (EC) No 853/2004, are derived.

4. Paragraphs 2 and 3 of this Article shall not apply to shelf-stable composite products where all the animal products present in the final composite product fall within the scope of and are used in the shelf -stable composite product in accordance with Regulation (EC) No 1332/2008 of the European Parliament and of the Council*, Regulation (EC) No 1333/2008 of the European Parliament and of the Council** or, Regulation (EC) No 1334/2008 of the European Parliament and of the Council***, or that animal part is vitamin D3 only.

* Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p. 7).

** Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

*** Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).’;

(6) Article 13 is amended as follows:

(a) paragraph 1 is amended as follows:

(i) point (a) is replaced by the following:

‘(a) products of animal origin intended for human consumption, for which the following codes have been laid down in Part Two of Annex I to Regulation (EEC) No 2658/87:

(i) CN codes in Chapters 2 to 5, 15, 16 or 29;

(ii) HS codes under headings 1702, 2101, 2105, 2106, 2301, 3001, 3002, 3501, 3502, 3503, 3504, 3507, 3913, 3926, 4101, 4102, 4103 or 9602;’;

(ii) the following point (da) is inserted after point (d):

‘(da) bee pollen flour referred to by the CN code ex1212 99 95 of Part Two of Annex I to Regulation (EEC) No 2658/87;’;

(iii) point (e) is replaced by the following:

‘(e) composite products referred to in Article 12(2)(a) and (b) with the exclusion of shelf-stable composite products that do not contain colostrum-based products or processed meat other than gelatine, collagen or highly refined products referred to in Section XVI of Annex III to Regulation (EC) No 853/2004.’;

(b) the following paragraphs are added:

‘5. The competent authorities of a third country of dispatch may certify a consignment of animals or goods referred to in paragraph 1 requiring public health attestation and coming from another third country, if that competent authority can ensure compliance of the consignment with the requirements for entry into the Union laid down in this Regulation.

The first subparagraph shall not apply in case of transit of a consignment through the Union without placing on the market.

6. By way of derogation from point (a)(ii) of paragraph 1, no official certificate is needed in case of entry into the Union of gelatine capsules using HS codes under headings 3913, 3926 or 9602, when not derived from ruminant bones.’;

(7) Article 14 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. A private attestation confirming that the consignments comply with the applicable requirements referred to in Article 126(2) of Regulation (EU) 2017/625, prepared and signed by the importing food business operator, shall accompany:

(a) the consignments of the composite products to which Article 12(2)(b) applies, where the composite products do not contain colostrum-based products or processed meat other than gelatine, collagen or highly refined products referred to in Section XVI of Annex III to Regulation (EC) No 853/2004; and

(b) the consignments of the composite products to which Article 12(2)(c) applies.’;

(b) in paragraph 4, point (e) is replaced by the following:

‘(e) the processed products of animal origin used in the composite product have undergone at least the treatments referred to in Article 163 of Commission Delegated Regulation (EU) 2020/692* with a brief description of any processes undergone and temperatures applied to the composite product.

*

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).’.

Article 2
Amendments to Delegated Regulation (EU) 2019/2122

Delegated Regulation (EU) 2019/2122 is amended as follows:

(1) Article 4 is amended as follows:

- (a) in paragraph 3, first subparagraph, point (b) is replaced by the following:
 - ‘(b) the samples are accompanied by the official document referred to in point (a) or by a copy thereof, and, where requested by the competent authority, by the certificate or declaration referred to in paragraph 4, point (b) or, where applicable, by any document required under national rules referred to in paragraph 4, point (c)(ii), until the samples reach the operator responsible for the product analysis and quality testing, including organoleptic analysis.’;
- (b) in paragraph 4, points (a) and (b) are replaced by the following:
 - ‘(a) the samples originate from third countries or regions of third countries listed:
 - (i) in Commission Implementing Regulation (EU) 2021/404^{*}, in case of samples from products of animal origin falling within the scope of Commission Delegated Regulation (EU) 2020/692^{**}; or
 - (ii) in Commission Implementing Regulation (EU) 2021/405^{***}, in case of samples from products of animal origin not falling within the scope of Delegated Regulation (EU) 2020/692;
 - (b) the official veterinarian has completed and signed at least the relevant animal health attestation for the samples in the relevant certificate or declaration drawn up in accordance with the models established in Commission Implementing Regulation (EU) 2020/2235^{****};

^{*} Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 1).

^{**} 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).

^{***} 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).

^{****} 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) in Article 10, paragraph 1 is replaced by the following:

‘1. Small consignments of products of animal origin, composite products, products derived from animal by-products, plants, plant products and other objects sent to natural persons, which are not intended to be placed on the market, are exempted from official controls at border control posts provided that they belong to at least one of the categories listed in Article 7, points (b) to (g).’;

(3) in Article 11, points (b) and (c) are replaced by the following:

‘(b) birds listed in Part B of Annex I to Regulation (EU) No 576/2013 which meet the conditions laid down in:

(i) Commission Delegated Regulation (EU) 2021/1933* and Commission Implementing Regulation (EU) 2021/1938**, provided that they undergo documentary and identity checks in accordance with Article 34 of Regulation (EU) No 576/2013; or

(ii) Article 32 of Regulation (EU) No 576/2013, provided that they undergo checks in accordance with the permit referred to in Article 32(1), point (a), of that Regulation;

(c) birds listed in Part B of Annex I to Regulation (EU) No 576/2013 which are being moved from a territory or a third country referred to in Article 1(2), point (b), of Delegated Regulation (EU) 2021/1933;

* Commission Delegated Regulation (EU) 2021/1933 of 14 July 2021 supplementing Regulation (EU) No 576/2013 of the European Parliament and of the Council with regard to rules for non-commercial movements of pet birds into a Member State from a territory or a third country (OJ L 396, 10.11.2021, p. 4).

** Commission Implementing Regulation (EU) 2021/1938 of 9 November 2021 establishing the model identification document for non-commercial movements of pet birds into a Member State from a territory or a third country and repealing Decision 2007/25/EC (OJ L 396, 10.11.2021, p. 47).’;

(4) Annexes I and III are amended in accordance with the Annex to this Regulation.

Article 3

Amendments to Delegated Regulation (EU) 2021/630

Delegated Regulation (EU) 2021/630 is amended as follows:

(1) in Article 3 paragraph 1 is replaced by the following:

‘1. The following shelf-stable composite products shall be exempted from official controls at border control posts:

- (a) shelf-stable composite products that do not contain colostrum-based products or processed meat other than gelatine, collagen or highly refined products referred to in Section XVI of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council*, provided they meet the following requirements:
 - (i) they comply with the requirements for entry into the Union laid down in Article 12(2) of Delegated Regulation (EU) 2019/625;
 - (ii) any dairy and egg products contained in the shelf-stable composite products comply with Article 163(1) of Delegated Regulation (EU) 2020/692;
 - (iii) they are identified as intended for human consumption;
 - (iv) they are securely packaged or sealed; and
 - (v) they are listed in the Annex to this Regulation;
- (b) shelf-stable composite products where all the animal products present in the final composite product fall within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council**, Regulation (EC) No 1333/2008 of the European Parliament and of the Council*** or Regulation (EC) No 1334/2008 of the European Parliament and of the Council****, or that animal part is vitamin D3 only.

* 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).

** Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p. 7).

*** Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16).

**** Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34).’;

(2) in Article 4, paragraph 1 is replaced by the following:

‘1. The competent authorities shall perform official controls on shelf-stable composite products referred to in Article 3 regularly, on a risk basis and with appropriate frequency, taking into account the criteria referred to in Article 44(2) of Regulation (EU) 2017/625.’.

Article 4

Entry into force

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

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

Done at Brussels, 28.3.2022

For the Commission
The President
Ursula VON DER LEYEN