►**B**

COMMISSION DELEGATED REGULATION (EU) 2022/2292

of 6 September 2022

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 food-producing animals and certain goods intended for human consumption

(Text with EEA relevance)

(OJ L 304, 24.11.2022, p. 1)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Delegated Regulation (EU) 2023/1149 of 5 April 2023	L 152	1	13.6.2023
►**M2**	Commission Delegated Regulation (EU) 2023/2652 of 15 September 2023	L 2652	1	28.11.2023

Corrected by:

►**C1** Corrigendum, OJ L 316, 8.12.2022, p. 100 (2022/2292)

▼B

COMMISSION DELEGATED REGULATION (EU) 2022/2292

of 6 September 2022

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 food-producing animals and certain goods intended for human consumption

(Text with EEA relevance)

CHAPTER I

SCOPE AND DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation supplements Regulation (EU) 2017/625 as regards the requirements for the entry in the Union of consignments of food-producing animals and certain goods intended for human consumption from third countries or regions thereof in order to ensure that they comply with the applicable requirements established by the rules referred to in Article 1(2), point (a), of Regulation (EU) 2017/625 or with requirements recognised to be at least equivalent thereto.

2. The requirements referred to in paragraph 1 cover:

(a) the identification of food-producing animals and certain goods intended for human consumption subject to the following requirements for entry into the Union:

(i) the requirement that those food-producing animals and certain goods intended for human consumption shall come from a third country or region thereof listed in accordance with Article 126(2), point (a), of Regulation (EU) 2017/625;

(ii) the requirement that those food-producing animals and certain goods intended for human consumption be dispatched from, and obtained or prepared in, establishments which comply with applicable requirements referred to in Article 126(1) of Regulation (EU) 2017/625, or with requirements recognised to be at least equivalent thereto, and which appear on lists drawn up and updated in accordance with Article 127(3), points (e)(ii) and (iii), of Regulation (EU) 2017/625;

(iii) the requirement that each consignment of food-producing animals and certain goods intended for human consumption be accompanied, by an official certificate, or official attestation or any other evidence of compliance with the rules referred to in Article 1(2), point (a), of Regulation (EU) 2017/625, such as a private attestation, in accordance with Article 126(2), point (c), of Regulation (EU) 2017/625;

▼B

(b) requirements for the entry into the Union of food-producing animals and certain goods intended for human consumption from a third country or region thereof, listed in accordance with Article 127(2) of Regulation (EU) 2017/625;

(c) requirements that consignments of food-producing animals and certain goods intended for human consumption from third countries be dispatched from, and obtained or prepared in, establishments which comply with the applicable requirements referred to in Article 126(1) of Regulation (EU) 2017/625, or with requirements recognised to be at least equivalent thereto, and which appear on lists drawn up and updated in accordance with Article 127(3), points (e)(ii)and (iii) of Regulation (EU) 2017/625;

(d) requirements for the entry into the Union for placing on the market of the specific following commodities in addition to the requirements laid down in accordance with Article 126 of Regulation (EU) 2017/625:

(i) fresh meat, minced meat, meat preparations, meat products, mechanically separated meat and raw materials intended for the production of gelatine and collagen;

(ii) live bivalve molluscs, echinoderms, tunicates and marine gastropods;

(iii) fishery products;

(iv) composite products;

(e) additional requirements for the official certificates, official attestations and private attestations that shall accompany food-producing animals and certain goods intended for human consumption for entry into the Union;

(f) requirements for the use of pharmacologically active substances in food-producing animals and the residues thereof and for the levels of contaminants and pesticide residues in products of animal origin and composite products, where those food-producing animals, products of animal origin and composite products enter the Union from third countries and are intended to be placed on the market of the Union, and those requirements are necessary to ensure that such food-producing animals, products of animal origin and composite products provide a level of human health protection equivalent to that provided by the relevant Union rules on food safety;

(g) the requirement that food-producing animals, products of animal origin and composite products shall only enter the Union from third countries that provide evidence and guarantees of compliance with the requirements set out in this Regulation by submitting a control plan.

3. This Regulation shall not apply to:

(a) animals and goods not intended for human consumption, however when the destination of the animals and goods has not been decided on entry into the Union and intention for human consumption cannot yet be excluded, this Regulation applies;

▼B

(b) animals and goods intended for human consumption only for transit through the Union without being placed on the market;

(c) goods intended for human consumption for the purpose of samples for product analysis and quality testing without being placed on the market.

Article 2

Definitions

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

(1) ‘entering the Union’ or ‘entry into the Union’ means entering the Union or entry into the Union as defined in Article 3, point (40), of Regulation (EU) 2017/625;

(2) ‘consignment’ means consignment as defined in Article 3, point (37), of Regulation (EU) 2017/625;

(3) ‘animals’ means animals as defined in Article 3, point (9), of Regulation (EU) 2017/625;

(4) ‘goods’ means goods as defined in Article 3, point (11), of Regulation (EU) 2017/625;

(5) ‘equivalent’ means equivalent as defined in Article 2(1), point (e), of Regulation (EC) No 852/2004;

(6) ‘establishment’ means an establishment as defined in Article 2(1), point (c), of Regulation (EC) No 852/2004;

(7) ‘official certificate’ means official certificate as defined in Article 3, point (27), of Regulation (EU) 2017/625;

(8) ‘official attestation’ means official attestation as defined in Article 3, point (28), of Regulation (EU) 2017/625;

(9) ‘private attestation’ means an attestation signed by the food business operator entering goods into the Union;

(10) ‘placing on the market’ means placing on the market as defined in Article 3, point (8), of Regulation (EC) No 178/2002;

(11) ‘fresh meat’ means fresh meat as defined in point 1.10 of Annex I to Regulation (EC) No 853/2004;

(12) ‘minced meat’ means minced meat as defined in point 1.13 of Annex I to Regulation (EC) No 853/2004;

(13) ‘meat preparations’ means meat preparations as defined in point 1.15 of Annex I to Regulation (EC) No 853/2004;

(14) ‘meat products’ means meat products as defined in point 7.1 of Annex I to Regulation (EC) No 853/2004;

(15) ‘mechanically separated meat’ means mechanically separated meat as defined in point 1.14 of Annex I to Regulation (EC) No 853/2004;

▼B

(16) ‘gelatine’ means gelatine as defined in point 7.7 of Annex I to Regulation (EC) No 853/2004;

(17) ‘collagen’ means collagen as defined in point 7.8 of Annex I to Regulation (EC) No 853/2004;

(18) ‘highly refined products of animal origin’ means highly refined products referred to in Section XVI, point 1, of Annex III to Regulation (EC) No 853/2004;

(19) ‘bivalve molluscs’ means bivalve molluscs as defined in point 2.1 of Annex I to Regulation (EC) No 853/2004;

(20) ‘fishery products’ means fishery products as defined in point 3.1 of Annex I to Regulation (EC) No 853/2004;

(21) ‘composite product’ means food containing both products of plant origin and processed products of animal origin;

(22) ‘pharmacologically active substance’ means pharmacologically active substance as defined in Article 2, point (a), of Commission Delegated Regulation (EU) 2019/2090 ([1]);

(23) ‘contaminant’ means contaminant as defined in Article 1(1), second subparagraph, of Council Regulation (EEC) No 315/93 ([2]);

(24) ‘pesticide residues’ means pesticide residues as defined in Article 3(2), point (c), of Regulation (EC) No 396/2005;

(25) ‘product of animal origin’ means product of animal origin as defined in point 8.1 of Annex I to Regulation (EC) No 853/2004;

(26) ‘control plan for pharmacologically active substances, pesticides and contaminants’ means a control plan on the use of pharmacologically active substances, the maximum residue limits of pharmacologically active substances, the maximum residue levels of pesticides and the maximum levels of contaminants in food-producing animals, products of animal origin, including those used in composite products;

([1]) Commission Delegated Regulation (EU) 2019/2090 of 19 June 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and Council regarding cases of suspected or established non-compliance with Union rules applicable to the use or residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives or with Union rules applicable to the use or residues of prohibited or unauthorised pharmacologically active substances (OJ L 317, 9.12.2019, p. 28).

([2]) Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food (OJ L 37, 13.2.1993, p. 1).

▼B

(27) ‘insects’ means food consisting of, isolated from or produced from insects or their parts including any life stadia of insects intended for human consumption which are, when applicable, authorised in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council ([3]) and included in the Union list of novel foods established by Commission Implementing Regulation (EU) 2017/2470 ([4]) (‘the Union list of novel foods’);

(28) ‘transit’ means transit as defined in Article 3, point (44), of Regulation (EU) 2017/625;

(29) ‘reptile meat’ means the edible parts, either unprocessed or processed, derived from farmed reptiles, belonging to the species *Alligator mississippiensis*, *Crocodylus johnstoni*, *Crocodylus niloticus*, *Crocodylus porosus*, *Timon lepidus*, *Python reticulatus*, *Python molurus bivittatus* or *Pelodiscus sinensis*, which are, when applicable, authorised in accordance with Regulation (EU) 2015/2283 and included in the Union list of novel foods;

(30) ‘snails’ means snails as defined in point 6.2 of Annex I to Regulation (EC) No 853/2004 and any other species of snails of the family of *Helicidae*, *Hygromiidae* or *Sphincterochilidae*, intended for human consumption;

(31) ‘food’ means food as defined in Article 2 of Regulation (EC) No 178/2002;

(32) ‘feed’ or ‘feedingstuff’ means feed or feedingstuff as defined in Article 3, point (4), of Regulation (EC) No 178/2002;

(33) ‘audit’ means audit as defined in Article 3, point (30), of Regulation (EU) 2017/625;

(34) ‘competent authorities’ means competent authorities as defined in Article 3, point (3), of Regulation (EU) 2017/625;

▼M2

(34a) ‘honey’ shall be understood as honey within the meaning of Council Directive 2001/110/EC ([5]) including as regards the main types of honey;

(34b) ‘apiculture products’ means honey, beeswax, royal jelly, propolis or pollen, intended for human consumption;

▼B

(35) ‘sprouts’ means sprouts as defined in Article 2, point (a), of Commission Implementing Regulation (EU) No 208/2013 ([6]);

(36) ‘primary production’ means primary production as defined in Article 3, point (17), of Regulation (EC) No 178/2002;

([3]) Regulation (EU) 2015/2283 of the European Parliament of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

([4]) Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel food (OJ L 351, 30.12.2017, p. 72).

([5]) Council Directive 2001/110/EC of 20 December 2001 relating to honey (OJ L 10, 12.1.2002, p. 47).

([6]) Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts (OJ L 68, 12.3.2013, p. 16).

▼B

(37) ‘slaughterhouse’ means slaughterhouse as defined in point 1.16 of Annex I to Regulation (EC) No 853/2004;

(38) ‘game-handling establishment’ means game-handling establishment as defined in point 1.18 of Annex I to Regulation (EC) No 853/2004;

(39) ‘cutting plant’ means cutting plant as defined in point 1.17 of Annex I to Regulation (EC) No 853/2004;

(40) ‘production area’ means production area as defined in point 2.5 of Annex I to Regulation (EC) No 853/2004;

(41) ‘factory vessel’ means factory vessel as defined in point 3.2 of Annex I to Regulation (EC) No 853/2004;

(42) ‘freezer vessel’ means freezer vessel as defined in point 3.3 of Annex I to Regulation (EC) No 853/2004;

(43) ‘reefer vessel’ means a vessel equipped to store and transport palletised or loose cargo (bulk) goods in temperature-controlled holds or chambers;

(44) ‘dairy products’ means dairy products as defined in point 7.2 of Annex I to Regulation (EC) No 853/2004;

(45) ‘egg products’ means egg products as defined in point 7.3 of Annex I to Regulation (EC) No 853/2004;

(46) ‘food business operator’ means a food business operator as defined in Article 3, point (3), of Regulation (EC) No 178/2002.

(47) ‘operator’ means operator as defined in Article 3, point (29), of Regulation (EU) 2017/625;

(48) ‘border control post’ means border control post as defined in Article 3, point (38), of Regulation (EU) 2017/625.

CHAPTER II

CONDITIONS FOR THE ENTRY INTO THE UNION AS REGARDS THIRD COUNTRIES OF ORIGIN OR REGIONS THEREOF

Article 3

Food-producing animals and goods which are required to come from third countries or regions thereof that are included in the list referred to in Article 126(2), point (a), of Regulation (EU) 2017/625

Consignments of the following food-producing 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 Implementing Regulation (EU) 2021/405:

(a) live animals for which Combined Nomenclature codes (‘CN codes’) have been laid down in Part Two, Chapter 1, of Annex I to Regulation (EEC) No 2658/87, where those live animals are food-producing animals;

▼B

(b) 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 Regulation (EEC) No 2658/87:

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

(ii) Harmonised System headings ('HS headings') 0901, 1702, 2105, 2106, 2301, 3001, 3002, 3302, 3501, 3502, 3503, 3504, 3507, 3913, 3926, 4101, 4102, 4103 or 9602;

(c) live snails, other than sea snails, referred to by the CN code 0307 60 00 of Part Two of Annex I to Regulation (EEC) No 2658/87;

(d) pollen flour falling under the CN code ex 1212 99 95 of Part Two of Annex I to Regulation (EEC) No 2658/87.

Article 4

Additional requirements for the entry into the Union of food-producing animals and goods from a third country or region thereof

In addition to the requirements laid down in Article 127(3) of Regulation (EU) 2017/625, the Commission shall only decide on the inclusion of third countries or regions thereof in the list referred to in Article 126(2), point (a), of that Regulation if the following requirements are recognised by the Commission as being at least equivalent to the relevant requirements in the Union for the food-producing animals and goods referred to in Article 3 of this Regulation:

(a) the legislation of the third country on:

(i) the production of products of animal origin;

(ii) the use of veterinary medicinal products, including rules on their prohibition or authorisation, their distribution, their placing on the market and the rules covering administration and inspection;

(iii) the preparation and use of feed, including the procedures for using additives and the preparation and use of medicated feedingstuffs, as well as the hygiene quality of the raw materials used for preparing feedingstuffs and of the final product;

(b) the hygiene conditions of production, manufacture, handling, storage and dispatch currently applied to products of animal origin destined for the Union;

(c) any experience of marketing of the products of animal origin from the third country and the results of any official controls on entry in the Union;

(d) when available, the results of audits carried out by the Commission in the third country related to other food-producing animals and goods for which the third country is already listed in accordance with Article 127(2) of Regulation (EU) 2017/625, in particular the results of the assessment of the competent authorities in the third country audited, and the action that the competent authorities have taken in the light of any recommendations addressed to them following such audits by the Commission;

▼B

(e) the existence, implementation and communication of a zoonoses control programme approved by the Commission when applicable;

(f) the third country's requirements as regards pharmacologically active substances, pesticides and contaminants, in accordance with Article 6.

Article 5

Animals and products to which Articles 6 to 12 apply

1. The requirements laid down in Articles 6 to 12 shall apply to the following animals and products:

(a) live animals for which CN codes have been laid down in Part Two, Section 1, Chapter 1, of Annex I to Regulation (EEC) No 2658/87, where those animals are food-producing animals;

(b) products of animal origin, for which CN codes have been laid down in Part Two, Chapters 2 to 5, 15 and 16 of Annex I to Regulation (EEC) No 2658/87, and for which Harmonised System subheadings ('HS subheadings') have been laid down under HS headings 0901, 2105, 3501, 3502 and 3504;

(c) composite products for which CN codes have been laid down in Part Two, Section III, Chapter 15, and Section IV, Chapters 16 to 22, of Annex I to Regulation (EEC) No 2658/87.

2. The requirements laid down in Articles 6 to 12 shall not apply to

— gelatine and to raw materials for the production of gelatine, referred to in Section XIV, Chapter I, point 1, of Annex III to Regulation (EC) No 853/2004, and

— collagen and to raw materials for the production of collagen, referred to in Section XV, Chapter I, point 1, of Annex III to that Regulation, and

— highly refined products of animal origin, and

▼M2

— fishery products from wild catch, insects, frogs, frogs' legs, snails, reptiles and reptile meat.

▼B

Article 6

Additional requirements for the entry into the Union of food-producing animals, products of animal origin and composite products, as regards pharmacologically active substances and residues thereof, contaminants and pesticide residues

1. In addition to the requirements laid down in Regulation (EU) 2017/625, consignments of food-producing animals, products of animal origin and composite products shall enter the Union only from a third country that has in place a control plan for pharmacologically active substances, pesticides and contaminants setting out guarantees as regards compliance with:

(a) the Union requirements on the use of pharmacologically active substances, the maximum residue limits of pharmacologically active substances, maximum residue levels of pesticides and maximum levels of contaminants; and

▼B

(b) the additional requirements specified in Articles 9 to 12 of this Regulation.

2. In addition to the requirements laid down in Article 127(3) of Regulation (EU) 2017/625, the Commission shall decide on the inclusion of a third country in the list referred to in Article 126(2), point (a), of that Regulation only if that third country provides evidence and guarantees of compliance with the requirements laid down in paragraph 1 of this Article, together with the information listed in Part II of Annex I to this Regulation, in the request for inclusion in the list of third countries which that third country is to submit under Article 127(2) of Regulation (EU) 2017/625.

3. After having approved the inclusion of the third country in the list of authorised third countries, the Commission shall ensure, in accordance with Article 127(3) of Regulation (EU) 2017/625, that the third country continues to comply with the requirements laid down in paragraph 1 of this Article.

4. For the purposes of paragraph 3, the Commission shall take into account the updated evidence and guarantees of compliance with the requirements laid down in paragraph 1, including the required information on the third country's control plan for pharmacologically active substances, pesticides and contaminants in accordance with Part II of Annex I, to be submitted by that third country by 31 March of each year.

Article 7

Inclusion of a third country in a list of third countries that comply with Union requirements on pharmacologically active substances and residues thereof, contaminants and pesticide residues

In addition to the conditions laid down in Regulation (EU) 2017/625, consignments of food-producing animals, products of animal origin and composite products, shall enter the Union only from a third country that complies with the requirements provided for in Article 6(1) and is included in the list of third countries approved for the entry into the Union of the concerned food-producing animals or products of animal origin, set out in Annex -I to Implementing Regulation (EU) 2021/405.

Article 8

Derogation from the requirements for the entry into the Union of food-producing animals, products of animal origin and composite products

1. By way of derogation from Article 7, consignments of food-producing animals, products of animal origin and composite products may enter the Union from third countries that do not have an approved control plan for pharmacologically active substances, pesticides and contaminants but ensure that the food-producing animals and products of animal origin, including those used in composite products, originate in a Member State or a third country included in the list set out in Annex -I to Implementing Regulation (EU) 2021/405 as regards those food-producing animals or products of animal origin.

▼B

2. In addition to the requirements laid down in Article 127(3) of Regulation (EU) 2017/625, the Commission shall decide on the inclusion of a third country in the list referred to in Article 126(2), point (a), of that Regulation only if the competent authority of that third country provides the Commission with evidence and guarantees of compliance with the requirements laid down in paragraph 1 of this Article. Such evidence and guarantees shall consist of information on the procedures in place in that third country to guarantee the traceability and origin of those food-producing animals and those products of animal origin.

3. Where a third country is included, in accordance with paragraphs (1) and (2), in the list of authorised third countries for specific food-producing animals or products of animal origin, the entry for that third country shall be accompanied by the following note:

‘Third country, only entering the Union specific food-producing animals or products of animal origin – as such or as ingredients of composite products –, which originate (a) from other third countries authorised for the entry into the Union of such food-producing animals or products of animal origin; or (b) from Member States, in accordance with Article 8 of Commission Delegated Regulation (EU) 2022/2292.’.

For third countries that, because of animal health requirements, may not enter the Union specific food-producing animals or products of animal origin as such, the entry for that third country shall be accompanied by the following note:

‘Third country, only entering the Union composite products containing processed products of animal origin, which originate (a) from other third countries authorised for the entry into the Union of such products of animal origin; or (b) from Member States, in accordance with Article 8 of Commission Delegated Regulation (EU) 2022/2292.’.

4. For the production of casings intended for entry into the Union, third countries may use raw materials of animal origin sourced from Member States or from other third countries or regions thereof which are authorised for the entry into the Union of fresh meat, or of certain meat products and treated stomachs, bladders and intestines, and which are listed in the relevant lists of such fresh meat and meat products of Commission Implementing Regulation (EU) 2021/404 ([7]) or Implementing Regulation (EU) 2021/405. Third countries entering the Union casings shall be listed in Annex -I to Implementing Regulation (EU) 2021/405 for casings. In addition, the establishments from which the casings are to be entered the Union shall be listed in accordance with Article 13(1) of this Regulation.

5. After having approved the inclusion of the third country in the lists of authorised third countries referred to in this Article, the Commission shall ensure, in accordance with Article 127(4) of Regulation (EU) 2017/625, that the third country continues to comply with the requirements laid down in paragraph 1 of this Article.

([7]) 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).

▼B

CHAPTER III

CONDITIONS FOR THE ENTRY INTO THE UNION AS REGARDS THE USE OF PHARMACOLOGICALLY ACTIVE SUBSTANCES AND RESIDUES THEREOF, CONTAMINANTS AND PESTICIDE RESIDUES

Article 9

Requirements as regards the use of pharmacologically active substances in food-producing animals and residues thereof in products of animal origin and composite products

1. Food-producing animals, products of animal origin and composite products shall only enter the Union from third countries which provide guarantees that the controls on the use of pharmacologically active substances referred to in Annex I to Delegated Regulation (EU) 2022/1644 and on the residues thereof are at least equivalent to those required for the multiannual national control plans of Member States referred to in Article 4 of Implementing Regulation (EU) 2022/1646.

2. Where a third country authorises the use in food-producing animals of pharmacologically active substances which are not authorised for such animals in the Union, food-producing animals, products of animal origin and composite products shall only enter the Union insofar as that third country provides guarantees that No residues thereof are present in those animals and products. The methods of analysis used to demonstrate the absence of such residues shall comply with the requirements laid down in Annex I to Implementing Regulation (EU) 2021/808 or with requirements equivalent thereto.

Article 10

Requirements as regards the prohibition of certain substances

1. Food-producing animals, products of animal origin and composite products shall only enter the Union from third countries which provide guarantees of compliance with the prohibition of the use of beta-agonists and any stilbene, thyrostatic, oestrogenic, androgenic and gestagenic substances in farm animals laid down in Directive 96/22/EC, and with the prohibition of the use of the substances listed in Table 2 of the Annex to Regulation (EU) No 37/2010.

2. Food-producing animals, products of animal origin and composite products from third countries that authorise the use of the substances referred to in paragraph 1 in food-producing animals or do not have rules on the use of those substances shall only enter the Union insofar as those third countries provide guarantees that:

(a) they have set up a segregated production system to ensure that food-producing animals, products of animal origin and composite products intended for entry into the Union are not treated with the substances referred to in paragraph 1; and

(b) they have set up an appropriate animal identification and traceability system, as well as a system for the control of the distribution of the substances referred to in paragraph 1 and for the record keeping of the administration of veterinary medicinal products.

▼B

Article 11

Requirements as regards residues of pesticides in products of animal origin and composite products

Products of animal origin and composite products shall only enter the Union from third countries which provide guarantees that representative controls on pesticide residues are performed in order to demonstrate that those products comply with the maximum residue levels laid down in Regulation (EC) No 396/2005. Those guarantees shall be at least equivalent to those provided for by the multiannual national control programmes for pesticide residues referred to in Implementing Regulation (EU) 2021/1355.

Article 12

Requirements as regards contaminants in products of animal origin and composite products

Products of animal origin and composite products shall only enter the Union from third countries which provide guarantees that those products comply with the maximum tolerances for contaminants established on the basis of Regulation (EEC) No 315/93. Those guarantees shall be at least equivalent to those provided for by the multiannual national control plans established in accordance with Delegated Regulation (EU) 2022/931 and Implementing Regulation (EU) 2022/932.

CHAPTER IV

CONDITIONS FOR THE ENTRY INTO THE UNION AS REGARDS ESTABLISHMENTS

Article 13

Requirements for establishments

1. Consignments of the following goods shall only enter the Union where those consignments are dispatched from, and obtained or prepared in, establishments that appear on lists drawn up and kept up-to-date in accordance with Article 127(3), points (e)(ii) and (iii), of Regulation (EU) 2017/625:

(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 subheadings under headings 1702, 2105, 2106, 2301, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 4101, 4102 or 4103;

(b) sprouts falling under the following HS subheadings: 0704 90, 0706 90, 0708 10, 0708 20, 0708 90 or 1214 90 of Part Two of Annex I to Regulation (EEC) No 2658/87;

▼M2

(c) honey and other apiculture products for which the following HS headings have been laid down in Part Two of Annex I to Regulation (EEC) No 2658/87: 0409, 0410, 1212, 1521 or 1702.

▼B

2. Establishments referred to in paragraph 1 of this Article may be placed on the lists referred to in Article 127(3), point (e), of Regulation (EU) 2017/625 only if, in addition to the guarantees laid down in Article 127(3), points (e)(ii) and (iv), of Regulation (EU) 2017/625, the third country where the establishments are located provides the following guarantees:

(a) such establishments, together with any establishments handling raw materials of animal origin used in the manufacture of the products of animal origin referred to in paragraph 1(a), comply with applicable requirements referred to in Article 126(1) of Regulation (EU) 2017/625, in particular those of Regulation (EC) No 853/2004, or with requirements recognised to be at least equivalent thereto;

(b) such establishments, where appropriate, only handle raw materials of animal origin that come from third countries with an approved residue monitoring plan for that product category in accordance with Delegated Regulation (EU) 2022/1644 and Implementing Regulation (EU) 2022/1646, or from Member States;

(c) it has real powers to stop such establishments from entering the Union, products of animal origin in the event that the establishments fail to meet the relevant Union requirements or requirements recognised to be at least equivalent thereto.

3. The Commission shall provide the Member States with any new and updated lists that it receives from the competent authorities of the third country in accordance with Article 127(3), point (e)(iii), of Regulation (EU) 2017/625 and shall publish such lists on its website.

4. Member States shall only allow the entry into the Union of the consignments referred to in paragraph 1 provided that the official certificates which are required to accompany such consignments pursuant to applicable Union rules are issued by the competent authorities of the third country starting with the date of publication, by the Commission, of the lists of establishments referred to in paragraph 1.

Article 14

Establishments not subject to the requirements of Article 13(1)

The requirements laid down in Article 13(1) shall not apply to establishments that only carry out the following activities:

(a) primary production;

(b) transport operations;

(c) storage of products of animal origin not requiring temperature-controlled storage conditions;

▼M2

(d) production of highly refined products of animal origin referred to by HS headings 2932 or 3503 of Part Two of Annex I to Regulation (EEC) No 2658/87.

———————

▼B

CHAPTER V

ADDITIONAL REQUIREMENTS FOR THE ENTRY INTO THE UNION OF CERTAIN GOODS INTENDED FOR HUMAN CONSUMPTION

Article 15

Requirements for consignments of fresh meat, minced meat, meat preparations, mechanically separated meat and meat products, and raw materials intended for the production of gelatine and collagen

▼M2

Consignments of the following products of animal origin shall only enter the Union if they have been manufactured from raw materials obtained in slaughterhouses, game-handling establishments, cutting plants and establishments handling fishery products, appearing on lists of establishments drawn up and kept up to date in accordance with Article 127(3), point (e), of Regulation (EU) 2017/625 or obtained in Member States:

▼B

(a) fresh meat;

(b) minced meat;

(c) meat preparations;

(d) mechanically separated meat and meat products, excluding casings as defined in Article 2, point (45), of Commission Delegated Regulation (EU) 2020/692 ([8]);

(e) raw materials intended for the production of gelatine and collagen referred to, respectively, in Section XIV, Chapter I, point 4(a), and in Section XV, Chapter I, point 4(a), of Annex III to Regulation (EC) No 853/2004.

Article 16

Requirements for consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods

1. Notwithstanding Article 14 of this Regulation, consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods for which CN codes have been laid down under heading 0307 of Part Two of Annex I to Regulation (EEC) No 2658/87 shall enter the Union only from production areas in third countries that appear on lists drawn up by the competent authorities of the third country in accordance with Article 127(3), point (e), of Regulation (EU) 2017/625 and published by the Commission.

2. The following products may enter the Union, even if harvested in areas which have not been classified by the competent authorities in the third country of production in accordance with Article 18(6) of Regulation (EU) 2017/625:

([8]) 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).

▼B

(a) *pectinidae*, except where data from monitoring programmes established under Article 57 of Implementing Regulation (EU) 2019/627 enable the competent authorities to classify fishing grounds as provided for in Section VII, Chapter IX, point 2, of Annex III to Regulation (EC) No 853/2004;

(b) marine gastropods that are not filter feeders and echinoderms that are not filter feeders.

Article 17

Listing of production areas

1. Before the lists referred to in Article 16(1) of this Regulation are drawn up by the competent authorities of the third country, particular account shall be taken of the guarantees that the competent authorities of the third country can give concerning compliance with the requirements of Article 52 of Implementing Regulation (EU) 2019/627 on the classification and control of production areas.

2. The Commission shall carry out an on-the-spot control visit before the lists referred to in Article 16(1) are drawn up.

3. Once the lists referred to in Article 16(1) are drawn up, and where the competent authorities of the third country offer sufficient guarantees on the classification and control of production areas under their responsibility, the on-the-spot Commission control visit does not need to be carried out prior to the addition of a new production area to an existing list established in accordance with Article 13.

Article 18

Special requirements for fishery products

Consignments of fishery products for which CN codes have been laid down under headings 0301, 0302, 0303, 0304, 0305, 0306, 0307, 0308, 0309, 1504, 1516, 1517, 1603, 1604, 1605 or 2106 of Part Two of Annex I to Regulation (EEC) No 2658/87, shall enter the Union for placing on the market only if they have been obtained or prepared, at any stage of their production, in an on-land establishment, a factory or freezer vessel or stored in a cold-store or a reefer vessel that appears on a list drawn up and updated in accordance with Article 127(3), point (e), of Regulation (EU) 2017/625 and published by the Commission.

Article 19

Special requirements for listing vessels

1. A vessel may be included in the lists of establishments referred to in Article 127(3), point (e)(ii), of Regulation (EU) 2017/625 provided that the competent authorities of the third country whose flag the vessel is flying, and the competent authorities of another third country to which the competent authorities of the third country whose flag the vessel is flying have delegated responsibility for the inspection of the vessel concerned, provide the Commission with a joint communication stating that all of the following requirements are met:

▼B

(a) both third countries appear on the list of third countries or regions thereof, drawn up in accordance with Article 127(3) of Regulation (EU) 2017/625, from which entry into the Union of fishery products is permitted;

(b) all fishery products from the vessel concerned that are destined for placing on the market in the Union are landed directly in the third country to which the third country whose flag the vessel is flying has delegated responsibility for the inspection of the vessel concerned;

(c) the delegated competent authorities have inspected the vessel and have declared that it complies with the applicable Union requirements;

(d) the delegated competent authorities have declared that they will regularly inspect the vessel to ensure that it continues to comply with the applicable Union requirements.

2. A vessel may be included in the lists of establishments referred to in Article 127(3), point (e)(ii), of Regulation (EU) 2017/625 on the basis of a joint communication from the competent authorities of the third country whose flag the vessel is flying and from the competent authorities of a Member State to which the competent authorities of the third country whose flag the vessel is flying have delegated responsibility for the inspection of the vessel concerned, if all of the following requirements are met:

(a) all fishery products from the vessel concerned that are destined for placing on the market in the Union are landed directly in the Member State to which the third country whose flag the vessel is flying has delegated responsibility for the inspection of the vessel concerned;

(b) the delegated competent authorities have inspected the vessel and have declared that it complies with the applicable Union requirements;

(c) the delegated competent authorities have declared that they will regularly inspect the vessel to ensure that it continues to comply with the applicable Union requirements.

Article 20

Requirements for consignments of composite products

1. Consignments of composite products referred to by the CN codes under headings 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 Part Two 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 enter the Union those processed products of animal origin in accordance with Article 13 of this Regulation 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 enter the Union composite products, consignments of composite products from third countries or regions thereof may enter the Union, subject to compliance with the following rules:

▼B

(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, under Article 3, to enter the Union each processed product of animal origin contained in the composite products;

(b) composite products referred to in paragraph 1 that do not need to be transported or stored under controlled temperatures and that contain any quantity of colostrum-based products or meat products, shall originate from third countries or regions thereof authorised, under Article 3, to enter the Union the colostrum-based products or meat products contained in the composite products;

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

3. The third countries or regions thereof entering the Union composite products shall be listed in Annex -I to Implementing Regulation (EU) 2021/405 as having an approved control plan, in accordance with Article 6 of this Regulation, for the species or commodities from which the processed products of animal origin contained in the composite products, with the exception of collagen, gelatine and highly refined products of animal origin, are derived.

4. Paragraphs 2 and 3 shall not apply to shelf-stable composite products that only contain processed products of animal origin or composite products that fall under the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council ([9]), Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([10]), Regulation (EC) No 1334/2008 of the European Parliament and of the Council ([11]), or that only contain vitamin D3.

([9]) 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).

([10]) 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).

([11]) 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).

▼B

CHAPTER VI

CONDITIONS FOR THE ENTRY INTO THE UNION AS REGARDS CERTIFICATION AND ATTESTATION

Article 21

Official certificates

1. ►M2 Each consignment of the following animals and goods shall enter the Union for placing on the market only where the consignment is accompanied by an official certificate: ◄

(a) live animals for which CN codes have been laid down in Part Two, Section I, Chapter 1, of Annex I to Regulation (EEC) No 2658/87, where those live animals are food-producing animals;

(b) 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; or

(ii) HS headings 0901, 1702, 2105, 2106, 2301, 3001, 3002, 3501, 3502, 3503, 3504, 3507, 3913, 3926, 4101, 4102, 4103 or 9602;

▼M2

(c) sprouts and seeds intended for the production of sprouts and referred to by the following HS subheadings: 0704 90, 0706 90, 0708 10, 0708 20, 0708 90, 0713 10, 0713 33, 0713 34, 0713 35, 0713 39, 0713 40, 0713 50, 0713 60, 0713 90, 0910 99, 1201 10, 1201 90, 1207 50, 1207 99, 1209 10, 1209 21, 1209 91 or 1214 90 of Part Two of Annex I to Regulation (EEC) No 2658/87;

▼B

(d) pollen flour referred to by the CN code 1212 99 95 of Part Two of Annex I to Regulation (EEC) No 2658/87;

(e) live snails, other than sea snails, referred to by the CN code 0307 60 00 of Part Two of Annex I to Regulation (EEC) No 2658/87;

▼M2

(f) composite products referred to in Article 20(2), points (a) and (b) with the exclusion of shelf-stable composite products that do not contain meat products other than

(i) gelatine or collagen not derived from ruminant bones

(ii) highly refined products as described in Annex III, Section XVI of Regulation (EC) No 853/2004, intended for human consumption.

▼B

2. 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 Implementing Regulation (EU) 2020/2235 may be signed by the captain.

▼M2

3. No official certificate shall be required for the entry into the Union of gelatine capsules covered by HS headings 3913, 3926 or 9602 of Part Two of Annex I to Regulation (EEC) No 2658/87, nor for gelatine capsules as part of the products of animal origin referred to in point 1(b) of this Article or as part of the composite products referred to in Article 20(1) of this Regulation, where those capsules are not derived from ruminant bones.

▼B

4. The official certificates referred to in paragraph 1 shall certify that the products comply with:

(a) the requirements laid down in Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 or provisions recognised to be equivalent to those requirements;

(b) any specific requirements for entry into the Union set out in this Regulation.

5. The official certificates referred to in paragraph 1 may include details required in accordance with other Union legislation on public and animal health matters.

6. The official certificate for sprouts and seeds intended for the production of sprouts referred to in paragraph 1(c) shall accompany the consignment until it reaches its destination as indicated in the official certificate. In the case of splitting of the consignment, a copy of the official certificate shall accompany each part of the consignment.

7. The competent authorities of the third country of dispatch may certify consignments of products of animal origin that only require public health attestation, or consignments of sprouts, coming from another third country, if the competent authorities of the third country of dispatch can ensure compliance of the consignments with the requirements for entry into the Union laid down in this Regulation.

Article 22

Private attestation

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 food business operator entering goods into the Union, shall accompany:

▼M2

(a) the consignments of the composite products referred to in Article 20(2), point (b), where the composite products do not contain colostrum-based products or meat products other than:

(i) gelatine or collagen not derived from ruminant bones;

(ii) highly refined products as described in Annex III, Section XVI of Regulation (EC) No 853/2004, intended for human consumption;

▼B

(b) the consignments of the composite products referred to in Article 20(2), point (c), of this Regulation.

▼M2

2. By way of derogation from paragraph 1 of this Article, for the composite products exempted from official controls at border control posts in accordance with Article 48, point (h), of Regulation (EU) 2017/625, the private attestation shall accompany the composite products at the time of their placing on the market, except for the products referred to in Article 20(4) of this Regulation, for which a private attestation is not required.

▼B

3. The private attestation referred to in paragraph 1 shall ensure the traceability of the consignments and shall include:

(a) information regarding the consignor and consignee of the goods entered into the Union;

(b) the list of products of plant origin and processed products of animal origin contained in the composite products, indicated in descending order of weight, as recorded at the time of their use in the manufacture of the composite products;

(c) the approval number the establishment(s) manufacturing the processed products of animal origin contained in the composite products was assigned upon being granted approval under Article 4(3) of Regulation (EC) No 853/2004, indicated by the food business operator entering goods in the Union.

4. The private attestation referred to in paragraph 1 shall attest that:

(a) the third country or region thereof producing the composite products is listed at least for one of the following categories of products of animal origin:

(i) meat products;

(ii) dairy products or colostrum-based products;

(iii) fishery products;

(iv) egg products;

(b) the establishment producing the composite products fulfils hygiene standards recognised to be equivalent to those required by Regulation (EC) No 852/2004;

(c) the composite products do not need to be stored or transported under controlled temperature;

(d) the processed products of animal origin contained in the composite products originate from third countries or regions thereof authorised to enter the Union each processed product of animal origin, or from the Member States, and are sourced from listed establishments;

(e) the processed products of animal origin used in the composite products have undergone at least one of the treatments referred to in Article 163(1) of Delegated Regulation (EU) 2020/692, with a brief description of any processes undergone and temperatures applied to the composite products.

▼B

CHAPTER VII

FINAL PROVISIONS

Article 23

References

References to Article 29 of Directive 96/23/EC shall be construed as references to this Regulation.

Article 24

Repeal

Delegated Regulation (EU) 2019/625 is repealed.

References to the repealed Delegated Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex II.

Article 25

Entry into force and application

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

It shall apply from 15 December 2022.

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

▼B

ANNEX I

This Annex sets out the information on the control plan for pharmacologically active substances, pesticides and contaminants and updated control plan for pharmacologically active substances, pesticides and contaminants which a third country is to submit for the purpose of its inclusion and maintenance in the list referred to in Article 7.

PART I

General requirements as regards the submission of the control plan for pharmacologically active substances, pesticides and contaminants and the updated control plan for pharmacologically active substances, pesticides and contaminants

1. The control plan for pharmacologically active substances, pesticides and contaminants which a third country is to submit, together with the request for its inclusion in the list referred to in Article 7 for specific food-producing animals or products of animal origin, shall include the information specified in Part II of this Annex.

2. After a third country is included in the list referred to in point 1, it shall submit, for the purposes of being maintained on that list, an annually updated control plan for pharmacologically active substances, pesticides and contaminants, with the information specified in Part III.

3. Additional information to complement the control plan for pharmacologically active substances, pesticides and contaminants and updated control plan for pharmacologically active substances, pesticides and contaminants referred to in points 1 and 2 may be provided anytime.

4. The relevant guidance documents as regards prohibited substances, residues of veterinary medicinal products, pesticide residues and contaminants, made publicly available by the Commission shall be taken into account for the submission of the control plan for pharmacologically active substances, pesticides and contaminants and updated control plan for pharmacologically active substances, pesticides and contaminants.

5. The control plan for pharmacologically active substances, pesticides and contaminants shall be sent to the Commission electronically, in the format described in the guidance documents referred to in point 4 or in another format, provided that it includes all of the information listed in Parts II and III, where applicable.

PART II

Third country control plan for pharmacologically active substances, pesticides and contaminants – required information

A. **Scope of the control plan for pharmacologically active substances, pesticides and contaminants**

(1) List of categories of food-producing animals, products of animal origin, including those used as ingredients in composite products, covered by the control plan for pharmacologically active substances, pesticides and contaminants, including details on the species and sub-species of animals.

▼B

(2) Information on the origin of the food-producing animals and products of animal origin covered by the control plan for pharmacologically active substances, pesticides and contaminants, in particular whether they are produced, within the third country, entirely from animals or products of animal origin that originate from that country or whether they include animals or products of animal origin that originate from other third countries or Member States. If the food-producing animals and products of animal origin are not produced in the third country submitting the control plan for pharmacologically active substances, pesticides and contaminants, information shall be provided on the countries of origin and the intended purpose of those animals and products of animal origin, in particular by explaining if the products of animal origin are intended for entry into the Union as such or as ingredients of composite products.

(3) National production data from the previous year for the animal species and products of animal origin covered by the control plan for pharmacologically active substances, pesticides and contaminants.

(4) An explanation of whether, for the animals and products of animal origin concerned, the control plan for pharmacologically active substances, pesticides and contaminants covers the total national production or a proportion of the national production (for example, the production of certain farms/producers and the throughput of certain establishments, intended for entry into the Union). If only part of the national production is covered, a description of the system in place to ensure that only those animals and products of animal origin from that segregated population covered by the control plan for pharmacologically active substances, pesticides and contaminants are eligible for entry into the Union.

B. **Competent authorities responsible and their legal powers**

(1) Contact details of the competent authorities: name and address of the central competent authority or authorities and contact point details for correspondence on the control plan for pharmacologically active substances, pesticides and contaminants (e.g., email addresses, telephone numbers).

(2) A description of the structure of the competent authorities, including, where relevant, the various levels of organisation (e.g. central, regional, local), the departments involved and organisational charts.

(3) A description of the role of the competent authorities involved in the implementation of the control plan for pharmacologically active substances, pesticides and contaminants, including on aspects related to the drawing up of the control plan for pharmacologically active substances, pesticides and contaminants, the coordination and supervision of the implementation of the control plan for pharmacologically active substances, pesticides and contaminants, the collection of samples, the collation and evaluation of results, the application of corrective measures, if required, that are effective, proportionate and dissuasive to stop re-occurrence of non-compliance, and the submission of an updated control plan for pharmacologically active substances, pesticides and contaminants to the Commission.

(4) The legal basis of the control plan for pharmacologically active substances, pesticides and contaminants, including references to the specific provisions giving the competent authorities the right to enter the relevant premises, to collect samples, to carry out follow-up investigations where non-compliant results are detected and to impose corrective actions in such cases, for example, restrictions on the movement of animals, the destruction of animals or the imposition of fines.

▼B

C. **Pharmacologically active substances**

(1) The requirements met by the control plan for pharmacologically active substances, pesticides and contaminants, in particular whether such requirements are those referred to in Article 4 of Implementing Regulation (EU) 2022/1646, or equivalent requirements. In the latter case, further details shall be provided on how these requirements address all of the points listed under Part II, points C to K, of this Annex.

(2) The list of groups of substances covered by the control plan for pharmacologically active substances, pesticides and contaminants for each animal species and product as specified in:

▼M2

(a) point A.1 of Annex II to Delegated Regulation (EU) 2022/1644 for group A substances referred to in Annex I to Delegated Regulation (EU) 2022/1644;

▼B

(b) point B.1 of Annex II to Delegated Regulation (EU) 2022/1644 for group B substances referred to in Annex I to Delegated Regulation (EU) 2022/1644. For group B substances, the selection of groups covered by the control plan shall take into account the authorisation and use of such substances and the risks of residues in animals and products of animal origin intended for entry into the Union.

(3) Within the groups of substances covered by the control plan, the list of substances and their marker residues to be analysed for the specific animal species and products in the specific matrices, including a justification for their selection based on the risk criteria set in Annex II to Delegated Regulation (EU) 2022/1644.

(4) The number of samples per animal species and products for each of the groups of substances covered by the control plan based on the control frequencies laid down in Annex I to Implementing Regulation (EU) 2022/1646, or equivalent guarantees. A description of the criteria for selection of sampling points and animals or products of animal origin to be sampled based on the criteria laid down in Annex II to Delegated Regulation (EU) 2022/1644

(5) A description of the sampling strategy, explaining how it addresses the provisions of Annex III to Delegated Regulation (EU) 2022/1644.

D. **Pesticides**

(1) The list of substances tested for in the control plan for pharmacologically active substances, pesticides and contaminants and the corresponding number of samples per category of food-producing animals and products of animal origin covered by the control plan for pharmacologically active substances, pesticides and contaminants in accordance with the requirements laid down in Implementing Regulation (EU) 2021/1355.

(2) A justification for the selection of substances covered by the control plan for pharmacologically active substances, pesticides and contaminants, in particular that the range of substances tested for is representative of the pesticides used.

(3) The controls shall provide guarantees on the compliance of food of animal origin intended for entry into the Union with the maximum residue levels referred to in Regulation (EC) No 396/2005. These guarantees shall be provided for all pesticides authorised in the third country, in particular for those pesticides, which are authorised in the third country, but not authorised in the Union.

▼B

(4) A justification for the selection of pesticides covered by the plan, taking into account the risks from animal feed and the environment and the pesticides for which maximum residue levels are established in the Union, as well as a justification for the number of samples planned, based on the level of confidence achieved in identifying a certain percentage of exceedance of the maximum residue levels set out in Union legislation for the animals and products of animal origin intended for entry into the Union.

E. **Contaminants**

(1) The list of contaminants tested for in the control plan for pharmacologically active substances, pesticides and contaminants and the corresponding number of samples per category of food-producing animals and products of animal origin covered by the control plan for pharmacologically active substances, pesticides and contaminants, in accordance with the requirements laid down in Delegated Regulation (EU) 2022/931 and Implementing Regulation (EU) 2022/932.

(2) A justification for the selection of contaminants covered by the control plan for pharmacologically active substances, pesticides and contaminants taking into account the risks from animal feed and the environment, as well the contaminants for which maximum limits have been set in the Union in products of animal origin covered by the control plan for pharmacologically active substances, pesticides and contaminants.

F. **Analytical methods and laboratories**

(1) The list of official laboratories or contracted laboratories, or both, involved in carrying out analyses for the control plan for pharmacologically active substances, pesticides and contaminants.

(2) The accreditation status, including the scope of accreditation, of each of the official laboratories carrying out analyses for the control plan for pharmacologically active substances, pesticides and contaminants.

(3) For each of the laboratories, a list of all the methods used in the control plan for pharmacologically active substances, pesticides and contaminants, with an indication on whether they are included or not in the scope of accreditation for the specific matrices covered by the control plan for pharmacologically active substances, pesticides and contaminants.

(4) For each of the laboratories, a list of the methods used in the control plan for pharmacologically active substances, pesticides and contaminants, with an indication of whether they are validated in accordance with the relevant Union rules, or equivalent rules, or not validated, for the specific matrices covered by the control plan for pharmacologically active substances, pesticides and contaminants, specifying the standard used for validation.

(5) For each of the substances tested for in the control plan for pharmacologically active substances, pesticides and contaminants, a list of the analytical methods and regulatory standards used for interpreting analytical results and the performance requirements of the analytical methods, including information on:

(a) the analysed substance and marker residues;

(b) the analysed matrices;

(c) the analytical method identification (e.g. ELISA, LC-MS/MS, AAS);

▼B

(d) the analytical method type (screening or confirmatory);

(e) the screening and confirmatory methods used, the limits of detection and limits of quantification or, if relevant, the decision limit for confirmation (CCα) and detection capability for screening (CCß) as defined in Article 2, second paragraph, points (14) and (15), of Implementing Regulation (EU) 2021/808;

(f) the concentration above which a result is considered non-compliant for the purpose of the control plan for pharmacologically active substances, pesticides and contaminants. In particular, differences with the limits set out in the Union legislation shall be indicated.

G. **Pharmacologically active substances authorised in veterinary medicinal products or as feed additives for use in food-producing animals and prohibitions on use in such animals**

(1) The national legislation governing the placing on the market and conditions for use of veterinary medicinal products in relation to food-producing animal species covered by the control plan for pharmacologically active substances, pesticides and contaminants, including references to the relevant provisions.

(2) The list of authorised veterinary medicinal products for the food-producing animal species covered by the control plan for pharmacologically active substances, pesticides and contaminants indicating for each product, the product name, the pharmacologically active substance(s) contained therein and target species. Those substances which are authorised in the third country but which are not authorised for such use in the Union shall be highlighted in the list. The list shall also include feed additives that are pharmacologically active, such as antibiotics, coccidiostats and histomonostats.

(3) A description of the system in place to ensure that, for each of the substances which are authorised in the third country for use in the animal species covered by the control plan for pharmacologically active substances, pesticides and contaminants, but not authorised for such use in the Union, there are no residues present at concentrations which can be reliably quantified in such animals or products of animal origin intended for entry into the Union. Evidence shall be provided that such substances are tested for in the appropriate matrices in the control plan for pharmacologically active substances, pesticides and contaminants for the relevant animals and products of animal origin.

(4) A statement on whether any of the substances included in Table 2 of the Annex to Regulation (EU) No 37/2010 are authorised for use in the food-producing animal species covered by the control plan for pharmacologically active substances, pesticides and contaminants. If such substances are authorised, a description of the system ensuring that animals treated with such substances and products derived therefrom are not eligible for entry into the Union shall be provided. If use of such substances in food-producing animals is prohibited in the third country, a reference to the national legal basis for that prohibition shall be provided.

(5) A confirmation that stilbene substances (i.e. stilbenes, stilbene derivatives, their salts and esters) or thyrostatic substances are not authorised for use in food-producing animal species covered by the control plan for pharmacologically active substances, pesticides and contaminants, regardless of their eligibility for entry into the Union, and a reference to the national legal basis for that prohibition.

▼B

(6) A statement on whether substances having an oestrogenic, androgenic or gestagenic action and beta-agonists are authorised for growth promotion purposes in the food-producing animal species covered by the control plan for pharmacologically active substances, pesticides and contaminants. If such substances are authorised, a detailed description of the system in place to ensure that treated animals are not eligible for entry into the Union shall be provided. If such substances are either not authorised or are expressly prohibited, a reference to the national legal basis for the prohibition shall be provided.

H. **Specific information for bovine, caprine and ovine animals and products of animal origin derived therefrom, including milk**

(1) A statement on whether 17-beta oestradiol and its ester-like derivatives are authorised and used in veterinary medicinal products for any purpose in the species in question, including zootechnical or therapeutic treatments. If such substances are authorised, a description of the system ensuring that animals treated with such substances and the products derived therefrom are not eligible for entry into the Union shall be provided. If such substances are prohibited, a reference to the national legal basis for the prohibition shall be provided.

(2) Bovine, caprine and ovine animals and products of animal origin derived therefrom, including milk eligible for entry into the Union from a third country included in the list of third countries with an approved control plan for pharmacologically active substances, pesticides and contaminants, referred to in Annex -I to Implementing Regulation (EU) 2021/405, shall originate in that third country, or in Member States, or in other third countries implementing a control plan for pharmacologically active substances, pesticides and contaminants approved by the Commission.

I. **Specific information for honey**

(1) If antimicrobial substances are authorised for the treatment or prevention of diseases in honeybees, a description of the system in place to provide guarantees that no residues are present, at concentrations which can be quantified, in honey intended for entry into the Union.

(2) Honey intended for entry into the Union from a third country included in a list of third countries with approved control plan for pharmacologically active substances, pesticides and contaminants as referred to in Annex -I to Implementing Regulation (EU) 2021/405 shall originate in that third country, or in Member States, or in other third countries implementing a control plan for pharmacologically active substances, pesticides and contaminants approved by the Commission.

J. **Specific information for aquaculture**

(1) If dyes are authorised for the treatment and prevention of disease at any stage of production, a description of the dyes used and the fishery products (including crustaceans) for which the treatment is authorised and of the system in place to provide guarantees that no residues are present at concentrations which can be quantified in aquaculture products intended for entry into the Union.

(2) Aquaculture products intended for entry into the Union from a third country included in a list of third countries with approved control plan for pharmacologically active substances, pesticides and contaminants as referred to in Annex -I to Implementing Regulation (EU) 2021/405 shall originate in that third country, or in Member States, or in other third countries implementing a control plan for pharmacologically active substances, pesticides and contaminants approved by the Commission.

▼B

K. **Specific information for equine animals**

(1) A description of the system in place to ensure that equine animals treated with substances prohibited or not authorised in the Union for use in food-producing animals and products for human consumption derived from such animals are not eligible for entry into the Union. The following elements of such a system shall be described:

(a) identification and traceability of equine animals;

(b) record keeping of administration of veterinary medicinal products;

(c) records indicating all treatments with pharmacologically active substances.

(2) Where equine animals are treated with substances considered essential under Union rules, a description of the system in place to ensure that food derived from such animals is not eligible for entry into the Union until six months have elapsed since the last treatment.

(3) Food-producing equine animals eligible for entry into the Union shall originate from the third country which intends to enter into the Union equine animals, or in other third countries implementing a control plan for pharmacologically active substances, pesticides and contaminants approved by the Commission.

L. **Specific information to be provided by the third countries referred to in Article 8(1) and (2)**

(1) A statement by the competent authority of the third country confirming that products of animal origin intended for entry into the Union as such, or as ingredients of composite products, only originate in third countries included in the list of third countries with an approved control plan for pharmacologically active substances, pesticides and contaminants for those food-producing animals or products of animal origin, and that the procedures it has in place for this purpose are sufficient to guarantee the traceability and origin of those products of animal origin.

(2) A comprehensive description, by the competent authority of the third country, of the procedures in place in the third country, to substantiate the statement referred to in point 1.

M. **Specific information for casings**

A description of the system in place to ensure that no antimicrobial substances, the use of which in food-producing animals is prohibited in the Union in accordance with Table 2 of the Annex to Regulation (EU) No 37/2010, are used in the treatment of casings.

PART III

Updated control plan for pharmacologically active substances, pesticides and contaminants – required information

A. **Changes introduced in the updated control plan for pharmacologically active substances, pesticides and contaminants**

(1) Updated production data of the animals and products of animal origin covered by the control plan for pharmacologically active substances, pesticides and contaminants and the impact on the number of planned samples.

(2) Details on any changes that have occurred since the previous annual submission of the control plan for pharmacologically active substances, pesticides and contaminants and that alter the information previously provided under Part II, points A to M.

▼B

(3) In the absence of changes, a statement that no changes have occurred shall be included under Part II, points A to M, where relevant.

B. **Results of the implementation of the previous year's control plan for pharmacologically active substances, pesticides and contaminants**

(1) The results of the implementation of the previous year's control plan for pharmacologically active substances, pesticides and contaminants, together with the updated control plan for pharmacologically active substances, pesticides and contaminants.

(2) A justification for any discrepancies between the number of samples, or the substances planned to be analysed, and the number of samples and/or the substances actually analysed.

(3) Details on results non-compliant with Union maximum residue limits of pharmacologically active substances, maximum residue levels of pesticides or maximum levels of contaminants, including, for each of these non-compliant results, the dates of sampling, dates of availability of the analytical results, marker residues identified, concentrations measured, analytical methods used and the laboratories involved.

(4) For each of the non-compliant results, a description of the outcome of the follow-up investigations undertaken by the competent authorities, what the reason for the non-compliance was and any measures taken to prevent recurrence.

▼B

ANNEX II

Correlation table referred to in Article 24, second paragraph

Delegated Regulation (EU) 2019/625	This Regulation
Article 1	Article 1
Article 2	Article 2
Article 3	Article 3
Article 4	Article 4
Article 5	Article 13
Article 6	Article 14
Article 7	Article 15
Article 8	Article 16
Article 9	Article 17
Article 10	Article 18
Article 11	Article 19
Article 12	Article 20
Article 13	Article 21
Article 14	Article 22