

Fylgiskjal 1.**COMMISSION IMPLEMENTING REGULATION (EU) 2022/2293****of 18 November 2022****amending Implementing Regulation (EU) 2021/405 as regards the list of third countries with an approved control plan on the use of pharmacologically active substances, the maximum residue limits of pharmacologically active substances and pesticides and the maximum levels of contaminants****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC ⁽¹⁾, and in particular Article 29(1), fourth subparagraph, and Article 29(2) thereof,

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ⁽²⁾, and in particular Article 127(2) thereof,

Whereas:

- (1) Regulation (EU) 2017/625 lays down rules for official controls and other control activities performed by the competent authorities of the Member States in order to verify compliance with Union legislation in the area of, among others, food safety at any stage of production, processing and distribution. In particular, it provides that only consignments of certain animals and goods from a third country or region thereof which appears on a list drawn up by the Commission for that purpose are to enter the Union.
- (2) Commission Delegated Regulation (EU) 2022/2292 ⁽³⁾ supplements Regulation (EU) 2017/625 as regards the conditions for the entry into 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 relevant requirements established in the rules on food safety referred to in Article 1(2)(a) of Regulation (EU) 2017/625 or with requirements recognised to be at least equivalent thereto. In particular, Delegated Regulation (EU) 2022/2292 identifies the animals and goods intended for human consumption that are subject to the requirement to come from a third country or region thereof which appears on the list referred to in Article 126(2)(a) of Regulation (EU) 2017/625.

⁽¹⁾ OJ L 125, 23.5.1996, p. 10.

⁽²⁾ OJ L 95, 7.4.2017, p. 1.

⁽³⁾ 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 (see page 1 of this Official Journal).

- (3) Commission Implementing Regulation (EU) 2021/405 ⁽⁴⁾ lays down the lists of third countries or regions thereof from which the entry into the Union of consignments of certain animals and goods intended for human consumption is permitted in accordance with Article 126(2)(a) of Regulation (EU) 2017/625.
- (4) Regulation (EU) 2017/625 repealed Directive 96/23/EC, but provides that Article 29(1) and (2) of that Directive are to continue to apply until 14 December 2022.
- (5) Commission Decision 2011/163/EU ⁽⁵⁾ lists the third countries for which control plans on the use of pharmacologically active substances, maximum residue limits of pharmacologically active substances, maximum residue levels of pesticides and maximum levels of contaminants, which are referred to in Article 29(1) of Directive 96/23/EC in conjunction with Annex I to that Directive, have been approved.
- (6) Article 7 of Delegated Regulation (EU) 2022/2292 provides that, in addition to the conditions laid down in Regulation (EU) 2017/625, consignments of food-producing animals, products of animal origin and composite products are to enter the Union only from a third country 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 for human consumption.
- (7) In the interest of ensuring transparency and consistency as well as of facilitating the entry of consignments of certain animals and goods intended for human consumption into the Union, all lists of third countries required to ensure that goods and animals exported to the Union comply with the relevant requirements referred to in Article 1(2) of Regulation (EU) 2017/625 upon entry into the Union, should be laid down in one single implementing act. Therefore, Decision 2011/163/EU should be repealed and the list set out in the Annex to that Decision should be inserted in Implementing Regulation (EU) 2021/405.
- (8) Implementing Regulation (EU) 2021/405 should therefore be amended accordingly.
- (9) As Delegated Regulation (EU) 2022/2292 applies from 15 December 2022, this Regulation should apply from that date as well.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Implementing Regulation (EU) 2021/405

Implementing Regulation (EU) 2021/405 is amended as follows:

- (1) the following Article 2a is inserted after Article 2:

'Article 2a

List of third countries with approved control plans for pharmacologically active substances, pesticides and contaminants in certain food-producing animals and products of animal origin intended for human consumption

1. The control plans for pharmacologically active substances, pesticides and contaminants, referred to in Article 6(1) of Commission Delegated Regulation (EU) 2022/2292 ⁽⁶⁾, submitted to the Commission by the third countries or regions thereof listed in the table set out in Annex -I to this Regulation, are approved for the food-producing animals and the products of animal origin intended for human consumption marked with an "X" in that table.

⁽⁴⁾ 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).

⁽⁵⁾ 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).

2. The third countries or regions thereof, which made a request to be included in the list referred to in Article 6(2) of Delegated Regulation (EU) 2022/2292 but did not submit control plans for pharmacologically active substances, pesticides and contaminants and which, according to that request, intend to use for the production of products intended for export to the Union only raw material either from Member States or from other third countries approved for imports of such raw material into the Union in accordance with paragraph 1 of this Article, are marked with a “Δ”, for the relevant species or commodity, in the table in Annex -I to this Regulation.

3. The third countries or regions thereof, which made a request to be included in the list referred to in Article 6(2) of Delegated Regulation (EU) 2022/2292 but did not submit control plans for pharmacologically active substances, pesticides and contaminants for bovine, ovine/caprine, porcine, equine animals, rabbit or poultry and which, according to that request, intend to export composite products to the Union by using processed animal products from those species obtained from a Member State or from a third country or region thereof that has in place control plans for pharmacologically active substances, pesticides and contaminants, are marked with an “O”, for the species covered by the request, in the table in Annex -I to this Regulation.

4. The third countries or regions thereof, which made a request to be included in the list referred to in Article 6(2) of Delegated Regulation (EU) 2022/2292, which are marked with an “X” in the table in Annex -I to this Regulation for the categories “aquaculture”, “milk” or “eggs” and which, according to that request, intend to produce composite products, are additionally marked with an “O”, for the remaining of these categories not marked with an “X”, in the table in Annex -I to this Regulation.

5. The third countries or regions thereof, which made a request to be included in the list referred to in Article 6(2) of Delegated Regulation (EU) 2022/2292, which are marked with an “X” in the table in Annex -I to this Regulation for the categories “bovine”, “ovine/caprine”, “porcine”, “equine”, “poultry”, “aquaculture”, “milk”, “eggs”, “rabbit”, “wild game” or “farmed game” and which produce composite products with processed products derived from bivalve molluscs originating either in Member States or in third countries or regions thereof listed in Annex VIII to this Regulation, are additionally marked with a “P” in the table in Annex -I to this Regulation.

(*) 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 (OL L 304, 24.11.2022, p. 1).;

- (2) in Article 3, the words ‘and listed in Decision 2011/163/EU’ are replaced by the words ‘and listed in Annex -I to this Regulation’;
- (3) in Article 6, first paragraph, the words ‘and listed in Decision 2011/163/EU’ are replaced by the words ‘and listed in Annex -I to this Regulation’;
- (4) in Article 7, first paragraph, the words ‘and listed in Decision 2011/163/EU for “eggs” ’ are replaced by the words ‘and listed in Annex -I to this Regulation for “eggs” ’;
- (5) in Article 10, second paragraph, the words ‘and listed in Decision 2011/163/EU’ are replaced by the words ‘and listed in Annex -I to this Regulation’;
- (6) in Article 11, the words ‘and listed in Decision 2011/163/EU for “casings” ’ are replaced by the words ‘and listed in Annex -I to this Regulation for “casings” ’;
- (7) in Article 15, the words ‘and listed in Decision 2011/163/EU for “milk” ’ are replaced by the words ‘and listed in Annex -I to this Regulation for “milk” ’;
- (8) in Article 16, the words ‘and listed in Decision 2011/163/EU for “milk” ’ are replaced by the words ‘and listed in Annex -I to this Regulation for “milk” ’;
- (9) in Article 21, the words ‘listed in Decision 2011/163/EU for “honey” ’ are replaced by the words ‘listed in Annex -I for “honey” ’;
- (10) in Article 25, point (a), the words ‘and listed in Decision 2011/163/EU when applicable’ are replaced by the words ‘and listed in Annex -I to this Regulation, where applicable’;

- (11) in Article 25, point (c), the words 'and listed in Decision 2011/163/EU when applicable' are replaced by the words 'and listed in Annex -I to this Regulation, where applicable';
- (12) the text set out in the Annex to this Regulation is inserted as Annex -I before Annex I.

Article 2

Repeal

Decision 2011/163/EU is repealed.

Article 3

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.

Done at Brussels, 18 November 2022.

For the Commission
The President
Ursula VON DER LEYEN

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ANNEX

ANNEX -I

List of third countries or regions thereof with approved control plans for certain food-producing animals and products of animal origin intended for human consumption, as referred to in Article 2a, Article 3, Article 6, first paragraph, Article 7, first paragraph, Article 10, second paragraph, Articles 11, 15, 16, 21 and Article 25, points (a) and (c)

Country ISO Code	Third country (1) or regions thereof	Bovine	Ovine/caprine	Porcine	Equine	Poultry	Aquaculture (2)	Milk	Eggs	Rabbit	Wild game	Farmed game	Honey	Casings
AD	Andorra	X	X	Δ	X		P						X	
AE	United Arab Emirates						Δ P	X (3) O	O				X (3)	
AL	Albania		X				X (4) P	O	X					X
AM	Armenia						X (4) P	O	O				X	
AR	Argentina	X	X		X	X	X (4) P	X	X	X	X	X	X	X
AU	Australia	X	X		X		X M	X	X		X	X	X	X
BA	Bosnia and Herzegovina	X	X	X		X	X (4) P	X	X				X	
BD	Bangladesh						X P	O	O					
BF	Burkina Faso												X	
BJ	Benin												X	
BN	Brunei						X (5) P	O	O					
BR	Brazil	X			X	X	X P	O	O				X	X
BW	Botswana	X					P							
BY	Belarus				X (6)		X (4) P	X	X				X	X

Country ISO Code	Third country ⁽¹⁾ or regions thereof	Bovine	Ovine/caprine	Porcine	Equine	Poultry	Aquaculture ⁽¹⁾	Milk	Eggs	Rabbit	Wild game	Farmed game	Honey	Casings
BZ	Belize						X ⁽¹⁾ P	O	O					
CA	Canada	X	X	X	X	X	X M	X	X	X	X	X	X	
CH	Switzerland ⁽²⁾	X	X	X	X	X	X ⁽¹⁾ M	X	X	X	X	X	X	X
CL	Chile	X	X ⁽³⁾	X		X	X ⁽¹⁾ M	X	O		X		X	X
CM	Cameroon												X	
CN	China					X	X P	O	X	X			X	X
CO	Colombia						X P	X	Δ					X
CR	Costa Rica						X P	O	O					
CU	Cuba						X ⁽¹⁾ P	O	O				X	
DO	Dominican Republic												X	
EC	Ecuador						X P	O	O					
EG	Egypt													X
ET	Ethiopia												X	
FK	Falkland Islands	X	X ⁽³⁾				X ⁽¹⁾ P	O	O					
FO	Faroese Islands						X ⁽¹⁾ P	O	O					
GB	United Kingdom ⁽⁴⁾	X	X	X	X	X	X ⁽¹⁾ Δ M	X	X	X	X	X	X	X

Country ISO Code	Third country ⁽¹⁾ or regions thereof	Bovine	Ovine/caprine	Porcine	Equine	Poultry	Aquaculture ⁽⁷⁾	Milk	Eggs	Rabbit	Wild game	Farmed game	Honey	Casings
LK	Sri Lanka						X P	O	O					
MA	Morocco					X	X ⁽⁴⁾ Δ M	O	O					X
MD	Moldova					X	X ⁽⁴⁾ P	X	X				X	
ME	Montenegro	X	X ⁽²⁾	X		X	X ⁽⁴⁾ P	X	X				X	
MG	Madagascar						X P	O	O				X	
MK	North Macedonia	X	X	X		X	X ⁽⁴⁾ P	X	X		X		X	
MM	Myanmar						X P	O	O				X	
MN	Mongolia													X
MU	Mauritius						X ⁽⁴⁾ P	O	O				Δ	
MX	Mexico			Δ			X P	O	X				X	
MY	Malaysia					Δ	X P	O	O					
MZ	Mozambique						X ⁽⁵⁾ P	O	O					
NA	Namibia	X	X ⁽²⁾				P				X			
NC	New Caledonia						X ⁽⁵⁾ P	O	O			X	X	
NG	Nigeria						X ⁽⁵⁾ P	O	O					
NI	Nicaragua						X ⁽⁵⁾ P	O	O				X	

(¹) List of third countries and territories (not limited to third countries recognised by the Union).

(²) Camel milk only.

(³) Only the region of Ras al Khaimah.

(⁴) Hereinafter understood as the State of Israel, excluding the territories under the administration of the State of Israel after 5 June 1967, namely the Golan Heights, the Gaza Strip, East Jerusalem and the rest of the West Bank.

(⁵) Ovine species only.

(⁶) In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, for the purposes of this Annex, references to the United Kingdom do not include Northern Ireland.

(⁷) In accordance with the Agreement of 21 June 1999 between the European Community and the Swiss Confederation on trade in agricultural products (O) L 114, 30.4.2002, p. 132).

(⁸) Export to the Union of live equidae intended for slaughter (food-producing animals only).

(⁹) Reindeer only.

(¹⁰) Only for consignments of fresh meat originating from New Zealand, destined to the Union and being unloaded, with or without storage, in Singapore and being reloaded in an approved establishment during transit through Singapore.

(¹¹) Captive species only.

(¹²) This designation is without prejudice to positions on status and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

(¹³) Ratices only.

(¹⁴) Finfish only.

(¹⁵) Crustaceans only.

(¹⁶) Roes and caviar only.

(¹⁷) Aquaculture covers finfish, including eels, and products of finfish (such as roes and caviar), and crustaceans. The third countries or regions thereof listed for live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods in Annex VIII are marked with an "M" in this column.