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Contents

[1] Text with EEA relevance.

EN

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

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

Corrigenda

([1]) Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

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)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/625 of the European Parliament and the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ([1]), and in particular Article 126(1) thereof,

Whereas:

(1) Regulation (EU) 2017/625 lays down rules for the performance of official controls and other official activities by the competent authorities of the Member States, in particular to ensure compliance, by consignments of animals and goods from third countries or regions thereof intended for human consumption, upon entry into the Union, with Union legislation on food and feed safety.

(2) Regulation (EU) 2017/625 empowers the Commission to adopt delegated acts to supplement the conditions laid down in that Regulation for the entry into Union of food-producing animals and certain goods. Those conditions may include additional requirements, namely the possibility of allowing the entry of animals and goods only from third countries that appear on lists drawn up by the Commission for that purpose. These additional requirements include guarantees of compliance with:

— measures to monitor substances and groups of residues in animals and goods intended for human consumption, in accordance with Council Directives 96/23/EC ([2]) and 96/22/EC ([3]),

([1]) OJ L 95, 7.4.2017, p. 1.

([2]) 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 (OJ L 125, 23.5.1996, p. 10).

([3]) Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ L 125, 23.5.1996, p. 3).

— the rules for the prevention, control and eradication of transmissible spongiform encephalopathies in live animals and products of animal origin, in accordance with Regulation (EC) No 999/2001 of the European Parliament and of the Council ([4]),

— the general principles and requirements governing food in general and food safety in particular at Union and national level, in accordance with Regulation (EC) No 178/2002 of the European Parliament and of the Council ([5]),

— the general rules for food business operators on the hygiene of foodstuffs, in accordance with Regulation (EC) No 852/2004 of the European Parliament and of the Council ([6]),

— the specific rules on the hygiene of food of animal origin for food business operators, in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council ([7]),

— the specific rules on official controls performed, and for actions taken, by the competent authorities on the production of certain animals and products of animal origin intended for human consumption, in accordance with Commission Delegated Regulation (EU) 2019/624 ([8]) and Commission Implementing Regulation (EU) 2019/627 ([9]).

(3) Commission Delegated Regulation (EU) 2019/625 ([10]) lays down such additional requirements and applies since 14 December 2019. It does not cover the requirements already laid down in Directive 96/23/EC.

(4) At present, third countries from which animals and products of animal origin are authorised for the entry into the Union as regards the Union rules on public health are included and kept on lists drawn on the basis of various requirements, including the existence of a control plan for pharmacologically active substances, pesticides and contaminants setting out guarantees on the monitoring of certain groups of substances and their residues and contaminants, in accordance with the requirements of Directive 96/23/EC.

(5) Regulation (EU) 2017/625 repealed Directive 96/23/EC with effect from 14 December 2019 and provided for the transitional application, until 14 December 2022, of certain provisions of that Directive.

(6) The introduction of additional requirements to ensure compliance with the measures for monitoring substances and groups of residues in animals and goods intended for human consumption laid down in Directive 96/23/EC should be combined with the additional requirements already laid down in Delegated Regulation (EU) 2019/625.

(7) It is thus appropriate to lay down all these additional requirements in one single Delegated Regulation, thereby simplifying their interpretation and application and enhancing transparency for third countries.

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

([5]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

([6]) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

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

([8]) Commission Delegated Regulation (EU) 2019/624 of 8 February 2019 concerning specific rules for the performance of official controls on the production of meat and for production and relaying areas of live bivalve molluscs in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 131, 17.5.2019, p. 1).

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

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

(8) Regulation (EC) No 853/2004 lays down requirements for food business operators entering products of animal origin into the Union. Accordingly, the additional requirements laid down in this Regulation for official controls should be consistent with those already laid down in Regulation (EC) No 853/2004.

(9) When laying down requirements for the entry into the Union of consignments of certain animals and good intended for human consumption, reference should be made to the Combined Nomenclature codes set out in Council Regulation (EEC) No 2658/87 ([11]), to identify these goods and animals clearly.

(10) Consignments of certain animals and goods intended for human consumption should only be allowed to enter the Union, based on a risk analysis, where the third countries or regions thereof from which these animals and goods originate can ensure compliance with the requirements on the safety of those animals and goods and those third countries or regions thereof are included, in accordance with Article 127(2) of Regulation (EU) 2017/625, in the lists laid down in Commission Implementing Regulation (EU) 2021/405 ([12]).

(11) In addition to the requirements laid down in Article 127(3) of Regulation (EU) 2017/625, specific requirements should be laid down for certain animals and goods intended for human consumption, to ensure that third countries or regions thereof provide guarantees on the efficiency of official controls on food safety as regards those animals and goods. Third countries or regions thereof should only appear on the lists laid down in Implementing Regulation (EU) 2021/405, after having provided evidence and guarantees that the animals and goods originating in them comply with the Union requirements on food safety laid down in Regulations (EC) No 999/2001, (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004, (EU) 2017/625, Delegated Regulation (EU) 2019/624 and Implementing Regulation (EU) 2019/627, or with requirements recognised to be equivalent thereto.

(12) Under Article 127(3) of Regulation (EU) 2017/625, the Commission may subject the decision to include third countries in lists laid down in Implementing Regulation (EU) 2021/405 to the provision, by those third countries, of appropriate evidence and guarantees of compliance with the Union requirements on the use of pharmacologically active substances in food-producing animals and of the compliance of consignments of products of animal origin and composite products intended to enter into the Union with the maximum residue limits of pharmacologically active substances, maximum residue levels of pesticides and maximum levels of contaminants established in Union legislation. This ensures that those food-producing animals, products of animal origin and composite products offer the same level of health protection as the one provided for by Union legislation on food and food safety.

(13) To ensure that same level of health protection, evidence and guarantees should be provided by submitting a pharmacological substance, pesticide and contaminant control plan that meets certain requirements provided for in this Regulation. To ensure continuous compliance with those requirements, updated control plans should be submitted to the Commission on a yearly basis.

(14) Third countries may also be included in the list laid down in Annex -I to Implementing Regulation (EU) 2021/405 if they provide appropriate evidence and guarantees that the food-producing animals and products of animal origin, including those used in composite products entering the Union, originate in a Member State or a third country included in a list of third countries with approved control plan for pharmacologically active substances, pesticides and contaminants for those food-producing animals and products of animal origin, including those used in composite products. Information on the procedures in place to ensure the traceability of the concerned food-producing animals and products of animal origin and to guarantee the origin of those animals and products should be provided to benefit from that listing.

([11]) Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1).

([12]) 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).

(15) Union legislation lays down rules on the use of pharmacologically active substances and establishes limits for their residues in products of animal origin arising from such use. Food-producing animals and products of animal origin including those used in composite products should only enter the Union from third countries ensuring that controls on the use of pharmacologically active substances and the residues thereof in products of animal origin are at least equivalent to those of the Union control plans included in the multi-annual national control plans referred to in Commission Delegated Regulation (EU) 2022/1644 ([13]) and Commission Implementing Regulation (EU) 2022/1646 ([14]). The rules laid down in Commission Implementing Regulation (EU) 2021/808 ([15]) should apply to the official controls on those substances and residues.

(16) The use, in food-producing animals in the Union, of beta-agonists and substances that have a hormonal or thyrostatic action is prohibited under Directive 96/22/EC. Similarly, Commission Regulation (EU) No 37/2010 ([16]) lists in Table 2 of the Annex to that Regulation pharmacologically active substances that are prohibited for use in the Union. Only third countries that provide guarantees that food-producing animals and products of animal origin, including those used in composite products, comply with these provisions or with requirements recognised to be equivalent thereto should be allowed to enter the Union such animals and such products.

(17) Regulation (EC) No 396/2005 of the European Parliament and of the Council ([17]) lays down a coordinated control programme of the Union on the maximum residue levels of pesticides in or on food and feed of plant and animal origin, with a view to assessing consumer exposure and the application of legislation in the EU. This Union control programme forms an integral part of the multiannual national control programmes for pesticides residues that Member States are to establish. Food-producing animals and products of animal origin including those used in composite products should only enter the Union from third countries, which ensure that controls on pesticide residues are carried out according to the same stringent criteria as those imposed on Member States through the multiannual national control programmes for pesticide residues set out in Commission Implementing Regulation (EU) 2021/1355 ([18]). It should thus be ensured that evidence is provided through statistically representative sampling that the products intended for entry into the Union comply with Union legislation on pesticide residues.

([13]) Commission Delegated Regulation (EU) 2022/1644 of 7 July 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with specific requirements for the performance of official controls on the use of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and of prohibited or unauthorised pharmacologically active substances and residues thereof (OJ L 248, 26.9.2022, p. 3).

([14]) Commission Implementing Regulation (EU) 2022/1646 of 23 September 2022 on uniform practical arrangements for the performance of official controls on the use of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and of prohibited or unauthorised pharmacologically active substances and residues thereof, on specific content of multi-annual national control plans and specific arrangements for their preparation (OJ L 248, 26.9.2022, p. 32).

([15]) Commission Implementing Regulation (EU) 2021/808 of 22 March 2021 on the performance of analytical methods for residues of pharmacologically active substances used in food-producing animals and on the interpretation of results as well as on the methods to be used for sampling and repealing Decisions 2002/657/EC and 98/179/EC (OJ L 180, 21.5.2021, p. 84).

([16]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

([17]) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

([18]) Commission Implementing Regulation (EU) 2021/1355 of 12 August 2021 on multiannual national control programmes for pesticides residues to be established by Member States (OJ L 291, 13.8.2021, p. 120).

(18) Commission Delegated Regulation (EU) 2022/931 ([19]) and Commission Implementing Regulation (EU) 2022/932 ([20]) provide for the establishment and the content of risk-based control plans for contaminants in food. Products of animal origin and composite products should only enter the Union from third countries, which ensure that controls on contaminants are carried out to provide evidence that products of animal origin and composite products intended for the entry into the Union comply with EU legislation on contaminants.

(19) Commission Decision 2011/163/EU ([21]) sets out, in accordance with Directive 96/23/EC, a list of third countries authorised for the entry of certain animal species or products of animal origin into the Union.

(20) Following the repeal of Directive 96/23/EC, Commission Implementing Regulation (EU) 2022/2293 ([22]) replaced Decision 2011/163/EU in its entirety.

(21) Consignments of certain goods intended for human consumption should only be allowed to enter the Union where those goods are dispatched from, and obtained or prepared in, establishments which appear on the list drawn up and kept up to date in accordance with Article 127(3), point (e)(ii), of Regulation (EU) 2017/625. In addition, in order to ensure compliance with Union food hygiene rules, or with rules recognised to be at least equivalent thereto, it is appropriate to provide that, when drawing up and updating that list, the third country should provide additional guarantees to those provided for in Article 127(3), points (e)(i) and (iv), of Regulation (EU) 2017/625.

(22) The lists of establishments referred to in Article 127(3), point (e)(i), of Regulation (EU) 2017/625 should be made available to the public to ensure transparency for food business operators and consumers. To strengthen such transparency, Member States should only allow the entry of consignments of animals and goods where the official certificates required for such consignments under the relevant Union rules are issued by the competent authorities of the third country after the publication of those lists.

(23) It is not necessary to lay down such listing requirements as regards goods intended for transit, since those goods represent a low risk from a food safety perspective and are not placed on the market within the Union. Moreover, such requirements should not apply to establishments carrying out only primary production activities, transport operations, storage of products of animal origin not requiring temperature-controlled storage conditions or production of highly refined products of animal origin referred to in Section XVI of Annex III to Regulation (EC) No 853/2004.

(24) Commission Regulation (EU) No 210/2013 ([23]) requires establishments producing sprouts to be approved by the competent authorities in accordance with Article 6 of Regulation (EC) No 852/2004. In order to ensure compliance with Union food hygiene rules, or with rules recognised to be at least equivalent thereto, sprouts should only be allowed entry into the Union if they are produced in establishments, which appear on lists drawn up and updated in accordance with this Regulation.

([19]) Commission Delegated Regulation (EU) 2022/931 of 23 March 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council by laying down rules for the performance of official controls as regards contaminants in food (OJ L 162, 17.6.2022, p. 7).

([20]) Commission Implementing Regulation (EU) 2022/932 of 9 June 2022 on uniform practical arrangements for the performance of official controls as regards contaminants in food, on specific additional content of multi-annual national control plans and specific additional arrangements for their preparation (OJ L 162, 17.6.2022, p. 13).

([21]) 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).

([22]) 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 (See page 31 of this Official Journal).

([23]) Commission Regulation (EU) No 210/2013 of 11 March 2013 on the approval of establishments producing sprouts pursuant to Regulation (EC) No 852/2004 of the European Parliament and of the Council (OJ L 68, 12.3.2013, p. 24).

(25) In order to ensure compliance with Union food hygiene rules, or with rules recognised to be at least equivalent thereto, products from establishments manufacturing fresh meat, minced meat, meat preparations, meat products, mechanically separated meat and raw materials intended for the production of gelatine and collagen should only be allowed entry into the Union if those establishments appear on lists drawn up and updated in accordance with Article 127(3), point (e)(ii), of Regulation (EU) 2017/625. In addition, the raw materials these products are manufactured from should come from establishments (slaughterhouses, game-handling establishments, cutting plants and establishments handling fishery products) appearing on lists drawn up and updated in accordance with Article 127(3), point (e)(ii), of Regulation (EU) 2017/625.

(26) Consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods should only be allowed entry into the Union from production areas in third countries or regions thereof that appear on lists drawn up and updated in accordance with Article 127(3), point (e)(ii), of Regulation (EU) 2017/625 in order to ensure compliance with the applicable specific requirements for these products laid down in Regulation (EC) No 853/2004 and Implementing Regulation (EU) 2019/627, or with rules recognised to be at least equivalent thereto. The publication of those lists should ensure transparency for food business operators and consumers as regards the production areas from which live bivalve molluscs, echinoderms, tunicates and marine gastropods are allowed to enter the Union.

(27) Consignments of fishery products should only be allowed to enter the Union where those consignments are dispatched from, obtained or prepared in an on-land establishment, reefer, factory or freezer vessels flying the flag of a third country that appears on lists drawn up and updated in accordance with Article 127(3), point (e)(ii), of Regulation (EU) 2017/625 in order to ensure compliance with Union requirements, in particular with the specific requirements for fishery products laid down in Regulation (EC) No 853/2004 and Implementing Regulation (EU) 2019/627, or with rules recognised to be at least equivalent thereto. The publication of such lists should ensure transparency for food business operators and consumers as regards the vessels whose fishery products may enter the Union.

(28) The risk associated with composite products depends on the type of ingredients thereof and on the conditions of storage of those ingredients. Requirements on the consignments of composite products should therefore be laid down, to ensure that the composite products presenting a risk enter the Union from third countries authorised for entry into the Union pursuant to Implementing Regulation (EU) 2021/405. Composite products presenting a risk are those that contain processed products of animal origin, for which specific requirements are laid down in Annex III to Regulation (EC) No 853/2004, or for which a residue-monitoring plan is required.

(29) Given the number of notifications received in the Rapid Alert System for Food and Feed established by Regulation (EC) No 178/2002, the consignments of certain animals and goods intended to be placed on the market for human consumption present an enhanced risk of non-compliance with Union requirements on food safety. The consignments of such animals and goods should therefore be subject to individual certification for each consignment prior to the entry into the Union. That certification also contributes to reminding food business operators and the competent authorities of third countries or regions thereof of the relevant Union requirements. Commission Implementing Regulation (EU) 2020/2235 ([24]) lays down model animal health certificates or model official certificates or both for that purpose. Consignments for such animals and goods for which the Union is not the final destination should be accompanied by animal health certificates or official certificates with animal health attestation, whilst public health attestation for those animals and goods is not needed, since they will not be placed on the market in the Union. As regards certain composite products, which present a low risk, private attestation by the food business operator entering goods into the Union should replace the certification to ensure a proportionate, risk-based approach.

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

(30) Shelf-stable composite products representing a negligible risk, such as those where the only animal product present in the final composite product are food improvement agents, namely vitamin D3, food additives, food enzymes or food flavourings, should be exempted from controls at the borders and from private attestation requirements.

(31) The provisions of this Regulation aim to replace entirely those of Delegated Regulation (EU) 2019/625. Delegated Regulation (EU) 2019/625 should therefore be repealed.

(32) As Annexes I, II, III and IV to Directive 96/23/EC cease to apply on 14 December 2022, this Regulation should apply from 15 December 2022,

HAS ADOPTED THIS REGULATION:

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) 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) 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;

(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 ([25]);

(23) 'contaminant' means contaminant as defined in Article 1(1), second subparagraph, of Council Regulation (EEC) No 315/93 ([26]);

(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;

([25]) 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).

([26]) 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).

(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 ([27]) and included in the Union list of novel foods established by Commission Implementing Regulation (EU) 2017/2470 ([28]) ('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;

(35) 'sprouts' means sprouts as defined in Article 2, point (a), of Commission Implementing Regulation (EU) No 208/2013 ([29]);

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

(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;

([27]) 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).

([28]) 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).

([29]) 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).

(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) 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;

(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

— insects, frogs, frogs' legs, snails, reptiles and reptile meat.

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) 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.

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 ([30]) 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.

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.

([30]) 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).

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.

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.

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;

(d) production of highly refined products of animal origin referred to by HS headings 2930, 2932, 3503, 3507 or 3913 of Part Two of Annex I to Regulation (EEC) No 2658/87;

(e) production of gelatine capsules referred to by HS headings 3913, 3926 or 9602 of Part Two of Annex I to Regulation (EEC) No 2658/87.

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

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:

(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 ([31]);

(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:

(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.

([31]) 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).

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:

(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:

(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 ([32]), Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([33]), Regulation (EC) No 1334/2008 of the European Parliament and of the Council ([34]), or that only contain vitamin D3.

([32]) 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).

([33]) 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).

([34]) 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).

CHAPTER VI

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

Article 21

Official certificates

1. Each consignment of the following products shall enter the Union only where the consignment is accompanied by an official certificate except in case of consignments for which the Union is not the final destination:

(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;

(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, 0712 34, 0712 35, 0712 50, 0712 60, 0713 10, 0713 33, 0712 34, 0713 39, 0713 40, 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;

(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;

(f) composite products referred to in Article 20(2), points (a) and (b), of this Regulation, with the exclusion of shelf-stable composite products that do not contain colostrum-based products or processed meat other than gelatine, collagen or highly refined products of animal origin.

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.

3. No official certificate is necessary 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, where those capsules are not derived from ruminant bones.

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:

(a) the consignments of the composite products referred to in Article 20(2), point (b), of this Regulation, where the composite products do not contain colostrum-based products or processed meat other than gelatine, collagen or highly refined products of animal origin; and

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

2. By way of derogation from paragraph 1, 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 the placing on the market.

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.

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.

Done at Brussels, 6 September 2022.

For the Commission
The President
Ursula VON DER LEYEN

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.

(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.

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:

(a) point A.1 of Annex II to Delegated Regulation (EU) 2022/1646 for group A substances referred to in Annex I to Delegated Regulation (EU) 2022/1644

(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.

(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);

(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.

(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.

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.

(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.

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

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 (*), 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.

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(*) 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

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 (17)	Milk	Eggs	Rabbit	Wild game	Farmed game	Honey	Casings
AD	Andorra	X	X	Δ	X		P						X	
AE	United Arab Emirates						Δ P	X (2) O	O				X (3)	
AL	Albania		X				X (14) P	O	X					X
AM	Armenia						X (14) P	O	O				X	
AR	Argentina	X	X		X	X	X (14) 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 (14) P	X	X				X	
BD	Bangladesh						X P	O	O					
BF	Burkina Faso												X	
BJ	Benin												X	
BN	Brunei						X (15) P	O	O					
BR	Brazil	X			X	X	X P	O	O				X	X
BW	Botswana	X					P							
BY	Belarus				X (8)		X (14) P	X	X				X	X

Country ISO Code	Third country (1) or regions thereof	Bovine	Ovine/ caprine	Porcine	Equine	Poultry	Aquaculture (17)	Milk	Eggs	Rabbit	Wild game	Farmed game	Honey	Casings
BZ	Belize						X (15) P	O	O					
CA	Canada	X	X	X	X	X	X M	X	X	X	X	X	X	
CH	Switzerland (7)	X	X	X	X	X	X (14) M	X	X	X	X	X	X	X
CL	Chile	X	X (5)	X		X	X (14) 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 (15) 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 (5)				X (14) P	O	O					
FO	Faroes Islands						X (14) P	O	O					
GB	United Kingdom (6)	X	X	X	X	X	X (14) 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 [17]	Milk	Eggs	Rabbit	Wild game	Farmed game	Honey	Casings
GE	Georgia												X	
GG	Guernsey						O M	X	O					
GL	Greenland		X [5]				M					X		
GT	Guatemala						X [15] P	O	O				X	
HK	Hong Kong						Δ P		Δ					
HN	Honduras						X P	O	O					
ID	Indonesia						X P	O	O					
IL	Israel [4]					X	X [14] P	X	X				X	
IM	Isle of Man	X	X	X			X [14] M	X	O				X	
IN	India					O	X P	O	X				X	X
IR	Iran						X [15] X [16] P	O	O					X
JE	Jersey	X					M	X	O					
JM	Jamaica						M						X	
JP	Japan	X		X		X	X [14] M	X	X				Δ	X
KE	Kenya						X [14] P	O	O					
KR	South Korea					X	X M	O	O				Δ	
LB	Lebanon													X

Country ISO Code	Third country (1) or regions thereof	Bovine	Ovine/ caprine	Porcine	Equine	Poultry	Aquaculture (17)	Milk	Eggs	Rabbit	Wild game	Farmed game	Honey	Casings
LK	Sri Lanka						X P	O	O					
MA	Morocco					X	X (14) Δ M	O	O					X
MD	Moldova					X	X (14) P	X	X				X	
ME	Montenegro	X	X (5)	X		X	X (14) P	X	X				X	
MG	Madagascar						X P	O	O				X	
MK	North Macedonia	X	X	X		X	X (14) P	X	X		X		X	
MM	Myanmar						X P	O	O				X	
MN	Mongolia													X
MU	Mauritius						X (14) P	O	O				Δ	
MX	Mexico			Δ			X P	O	X				X	
MY	Malaysia					Δ	X P	O	O					
MZ	Mozambique						X (15) P	O	O					
NA	Namibia	X	X (5)				P				X			
NC	New Caledonia						X (15) P	O	O			X	X	
NG	Nigeria						X (15) P	O	O					
NI	Nicaragua						X (15) P	O	O				X	

Country ISO Code	Third country (1) or regions thereof	Bovine	Ovine/ caprine	Porcine	Equine	Poultry	Aquaculture (17)	Milk	Eggs	Rabbit	Wild game	Farmed game	Honey	Casings
NZ	New Zealand	X	X	O	X	O	X (14) M	X	O	O	X	X	X	X
PA	Panama						X P	O	O					
PE	Peru						X M	O	O					
PH	Philippines						X P	O	O					
PK	Pakistan													X
PM	Saint Pierre and Miquelon					X	P							
PN	Pitcairn Islands												X	
PY	Paraguay	X					P							X
RS	Serbia	X	X	X	X (8)	X	X (14) P	X	X	X	X		X	X
RU	Russia	X	X	X		X	O P	X	X			X (9)	X	X
RW	Rwanda												X	
SA	Saudi Arabia						X P	O	O					
SG	Singapore	Δ	Δ	Δ	X (10)	Δ	X (14) P	Δ	Δ		X (10)	X (10)		
SM	San Marino	X		Δ			O P	X	O				X	
SV	El Salvador												X	
SY	Syria													X
SZ	Eswatini	X					P							
TG	Togo												X	

Country ISO Code	Third country [1] or regions thereof	Bovine	Ovine/ caprine	Porcine	Equine	Poultry	Aquaculture [17]	Milk	Eggs	Rabbit	Wild game	Farmed game	Honey	Casings
TH	Thailand	O		O		X	X M	O	Δ				X	
TN	Tunisia						X [14] M	O	O					X
TR	Turkey					X	X [14] M	X	X				X	X
TW	Taiwan						X P	O	X				X	
TZ	Tanzania						X [15] P	O	O				X	
UA	Ukraine	X		X		X	X [14] M	X	X	X			X	X
UG	Uganda												X	
US	United States	X	X [11]	X		X	X M	X	X	X	X	X	X	
UY	Uruguay	X	X		X		X [14] M	X	O		X		X	X
UZ	Uzbekistan													X
VE	Venezuela						X [15] P	O	O					
VN	Vietnam						X M	O	O				X	
WF	Wallis and Futuna												X	
XK	Kosovo [12]					Δ								
ZA	South Africa						P				X	X [13]		
ZM	Zambia												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 (OJ 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) Caprine 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) Ratites 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.’

COMMISSION REGULATION (EU) 2022/2294

of 23 November 2022

implementing Regulation (EC) No 1338/2008 of the European Parliament and of the Council as regards statistics on healthcare facilities, healthcare human resources and healthcare utilisation

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work ([1]), and in particular Article 9(1) and Annex II, point (d), thereof,

Whereas:

(1) Regulation (EC) No 1338/2008 sets out the subjects covered in the healthcare domain for which data and metadata are to be provided for the production of European statistics. In particular data and metadata on healthcare facilities, healthcare human resources, healthcare utilisation, individual and collective services, and the reference periods, intervals and time limits for the data provision should be set out by implementing measures.

(2) Pursuant to Article 6(1) of Regulation (EC) No 1338/2008, in 2015 and 2018, the Commission launched pilot studies that were completed voluntarily by Member States. The Commission also discussed the needs of users of the statistics with Member States. The outcome of those pilot studies and those discussions was that Union-wide data are needed to strengthen the evidence-base on healthcare information, hence benefitting decisions on public health and social policy.

(3) In accordance with Article 6(2) of Regulation (EC) No 1338/2008, the Commission carried out a cost-benefit analysis, taking into account the benefits of the availability of variables on healthcare facilities, healthcare human resources and healthcare utilisation in relation to the cost of data collection. It follows from that analysis that those variables should be collected to ensure the comparability and availability of Union-wide data.

(4) The measures provided for in this Regulation are in accordance with the opinion of the European Statistical System Committee, established by Article 7 of Regulation (EC) No 223/2009 of the European Parliament and of the Council ([2]),

HAS ADOPTED THIS REGULATION:

Article 1

Scope

This Regulation lays down rules for the development and production of European statistics in the area of healthcare facilities, healthcare human resources and healthcare utilisation and individual and collective services, as referred to in Annex II, point (d), first, second and third indent, to Regulation (EC) No 1338/2008.

([1]) OJ L 354, 31.12.2008, p. 70.

([2]) Regulation (EC) No 223/2009 of the European Parliament and of the Council of 11 March 2009 on European statistics and repealing Regulation (EC, Euratom) No 1101/2008 of the European Parliament and of the Council on the transmission of data subject to statistical confidentiality to the Statistical Office of the European Communities, Council Regulation (EC) No 322/97 on Community Statistics, and Council Decision 89/382/EEC, Euratom establishing a Committee on the Statistical Programmes of the European Communities (OJ L 87, 31.3.2009, p. 164).

Article 2

Definitions

For the purpose of this Regulation, the definitions set out in Annex I shall apply.

Article 3

Data required

Member States shall transmit to the Commission (Eurostat) data for the list of variables, the characteristics and breakdowns as set out in Annex II.

Article 4

Metadata

Member States shall provide the Commission (Eurostat) with the necessary reference metadata and quality reports, in particular concerning:

(a) the data sources and their coverage;

(b) the compilation methods used;

(c) information on features of national healthcare facilities, healthcare human resources and healthcare utilisation specific to the Member States that deviate from the definitions set out in Annex I and the variables set out in Annex II;

(d) information on any changes to the statistical concepts mentioned in Annex I and Annex II.

Article 5

Reference period

1. The reference period shall be the calendar year.

2. The first reference year shall be 2021.

3. By derogation from paragraph 2, the first reference year for data on health employment, hospital care and surgical procedures referred to in points 1, 6 and 7 of Annex II shall be 2023.

Article 6

Provision of data and metadata to the Commission (Eurostat)

1. Member States shall provide the data and reference metadata referred to in Articles 3 and 4 respectively to the Commission (Eurostat) on an annual basis within 14 months after the end of the reference year.

2. By way of derogation from paragraph 1, Member States shall provide the data and reference metadata on hospital care and surgical procedures referred to in points 6 and 7 of Annex II within 20 months after the end of the reference year.

3. Data and reference metadata shall be transmitted to the Commission (Eurostat) using the single entry point or be made available for retrieval by the Commission (Eurostat) by electronic means.

Article 7

Data sources

1. The data shall be compiled mainly from administrative records, as referred to in Article 17a of Regulation (EC) No 223/2009 and shall cover the whole Member State.

2. Where administrative records are not available or of insufficient quality or coverage, use of other sources, methods or innovative approaches shall be accepted insofar as they enable the production of data that are comparable and compliant with the requirements laid down by this Regulation.

Article 8

Entry into force

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

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

Done at Brussels, 23 November 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Definitions referred to in Article 2

1	'Practising physicians' means medical doctors who have graduated in medicine from medical faculties or similar institutions and are licensed to practice. Practising physicians provide services for individual patients, families and communities. It also refers to interns and resident physicians who have graduated in medicine from medical faculties or similar institutions and who provide services under supervision of other medical doctors.
2	'Category of practising physicians' means the predominant (main) area of practice of doctors.
3	'General practitioners' means medical doctors who assume responsibility for the provision of continuing and comprehensive medical care to individuals, families and communities.
4	'Other generalist (non-specialist) medical practitioners' means practitioners who do not limit their practice to certain disease categories or methods of treatment. They do not work in an area of specialisation.
5	'Paediatricians' means medical doctors who deal with the development, care and diseases of children.
6	'Obstetricians' means medical doctors who specialise in pregnancy and childbirth. 'Gynaecologists' means medical doctors who specialise in the functions and diseases specific to women and girls, especially those affecting the reproductive system.
7	'Psychiatrists' means medical doctors who specialise in the prevention, diagnosis and treatment of mental illness.
8	'Group of non-surgical specialists' means medical doctors who specialise in the diagnosis and non-surgical treatment of physical disorders and diseases.
9	'Group of surgical specialists' means medical doctors who specialise in the use of surgical techniques to treat disorders and diseases.
10	'Other specialists not elsewhere classified' means physician specialists not covered by definitions 5 to 9.
11	'Medical doctors not further defined' means medical practitioners who cannot be classified in the other categories (definitions 3 to 10).
12	'Practising midwives' means persons who have a recognised qualification in midwifery, have a license to practice and provide services directly to patients. A midwife is a midwifery professional or a midwifery associate professional. Midwifery professionals provide care and advice to women during pregnancy, labour and childbirth and the post-natal period. Midwifery professionals deliver babies working independently or in collaboration with medical doctors, nurses and other healthcare workers and provide advice and assistance to parents in relation to baby care. Midwifery associate professionals deliver or assist doctors or midwifery professionals in the delivery of babies. Midwifery associate professionals provide antenatal and post-natal care and instruct parents in baby care.
13	'Practising nurses' means persons who have a recognised qualification in nursing, have a license to practice and provide services directly to patients. A nurse is a nursing professional or a nursing associate professional. Nursing professionals assume responsibility for the planning and management of the care of patients, including the supervision of other healthcare workers, working autonomously or in teams with medical doctors and others in the practical application of preventive and curative measures. Nursing associate professionals generally work under the supervision of, and in support of implementation of healthcare, treatment and referrals plans established by medical, nursing and other health professionals.

14	'Practising dentists' means persons who have a recognised qualification in dentistry, have a license to practice and provide services for patients. Dentists diagnose and treat diseases, injuries and malformations of the teeth, gums and related oral structures. They restore normal oral function using a broad range of treatments, such as surgery and other specialist techniques, and advice on oral health. It also refers to interns and resident dentists who have graduated in dentistry from the faculties of medicine and dentistry or similar institutions and who provide services under supervision of other dentists.
15	'Practising pharmacists' means persons who have a recognised qualification in pharmacy and have a license to practice. Pharmacists compound and dispense medications following prescriptions issued by physicians, dentists, or other authorized health practitioners. Pharmacists prepare, dispense or sell medicines and drugs for patients and provide advice.
16	'Medical graduates' means persons who have graduated in medicine from medical faculties or similar institutions in the reporting country, i.e., who have completed basic medical education.
17	'Dentistry graduates' means persons who have obtained a recognised qualification in dentistry in the reporting country.
18	'Pharmacy graduates' means persons who have obtained a recognised qualification in pharmacy in the reporting country.
19	'Midwifery graduates' means persons who have obtained a recognised qualification in midwifery in the reporting country.
20	'Nursing graduates' means persons who have obtained a recognised qualification in nursing in the reporting country.
21	'Hospitals' means the licensed establishments that are primarily engaged in providing medical, diagnostic and treatment services that include physician, nursing and other health services to inpatients and the specialised accommodation services required by inpatients and which may also provide day care, outpatient and home healthcare services.
22	'Hospital beds' means those beds which are regularly maintained and staffed and immediately available for the care of admitted patients. Both occupied and unoccupied beds are included in this concept. Excluded are recovery trolleys and beds for same day care (day case care and outpatient care), provisional and temporary beds. Hospital beds can be partitioned by category of care (definitions 23 and 24) and by function (definitions 25-28) of care.
23	'Somatic care' means healthcare relating to the body, as distinguished from psychiatric care.
24	'Psychiatric care' means healthcare concerning the mind, e.g. dealing with mental and behavioural disorders.
25	'Curative care' means the healthcare services during which the principal intent is to relieve symptoms or to reduce the severity of an illness or injury, or to protect against its exacerbation or complication that could threaten life or normal function.
26	'Rehabilitative care' means the services to stabilise, improve or restore impaired body functions and structures, compensate for the absence or loss of body functions and structures, improve activities and participation and prevent impairments, medical complications and risks.
27	'Long-term care (health)' means the range of medical and personal care services that are consumed with the primary goal of alleviating pain and suffering and reducing or managing the deterioration in health status in patients with a degree of long-term dependency.

28	'Hospital beds for somatic care with function not elsewhere classified' means beds in hospitals that are not classified as being for curative care, rehabilitative care or long-term care.
29	'Hospital beds for psychiatric care' means beds in hospitals accommodating patients with mental health problems. Beds for social long-term care shall be excluded.
30	'Residential long-term care facilities' means the establishments that are primarily engaged in providing residential long-term care that combines nursing, supervisory or other types of care as required by the residents, where a significant part of the production process and the care provided is a mix of health and social services with the health services being largely at the level of nursing care in combination with personal care services.
31	'Beds in residential long-term care facilities' means beds in residential long-term care facilities that are available to persons requiring long-term care.
32	'Magnetic resonance imaging (MRI) units' means machines with an imaging technique designed to visualise internal structures of the body using magnetic and electromagnetic fields which induce a resonance effect of hydrogen atoms. The electromagnetic emission created by these atoms is registered and processed by a dedicated computer to produce the images of the body structures.
33	'Computed tomography (CT) scanner', also known as Computerized axial tomography (CAT) scanner, means an x-ray machine which combines many x-ray images with the aid of a computer to generate cross-sectional views and, if needed, three-dimensional images of the internal organs and structures of the body.
34	'Ambulatory care' means the provision of healthcare services directly to outpatients who do not require inpatient services, including both care provided in offices of general medical practitioners and medical specialists and in establishments specialising in the treatment of day cases and in the delivery of home care services.
35	'Immunisation against influenza' means vaccination that protects against infection by influenza viruses.
36	'Breast cancer screening (mammography) programme' means an organised screening programme intended for the early detection of breast cancer using bilateral mammography.
37	'Cervical cancer screening programme' means an organised screening programme intended for the early detection of cervical cancer.
38	'Inpatient' means a patient who receives treatment and/or care in a healthcare facility, who is formally admitted and who requires an overnight stay. 'Inpatient care' means the care of an inpatient.
39	'Outpatient' means a patient who receives medical and ancillary services in a healthcare facility and who is not formally admitted and does not stay overnight. 'Outpatient care' means the care of an outpatient.
40	'Day case' means a patient who receives planned medical and paramedical services delivered in a healthcare facility and who is formally admitted for diagnosis, treatment or other types of healthcare and is discharged on the same day. 'Day care' is the care of a day case.
41	'Hospital inpatient discharge' means the discharge (formal release) of an inpatient from a hospital. Healthy newborns shall be excluded.
42	'Hospital inpatient bed-days' means the days that an inpatient spends in a hospital. Healthy newborns shall be excluded.

43	'Hospital day case discharge' means the discharge of a day case. It is the release of a patient who was formally admitted in a hospital for receiving planned medical and paramedical services, and who was discharged on the same day. Healthy newborns shall be excluded.
44	'Resident' means a usual resident of a geographical area, that is either (i) a person who has lived in his/her place of usual residence for a continuous period of at least 12 months before the reference date; or (ii) a person who arrived in his/her place of usual residence during the 12 months before the reference date with the intention of staying there for at least 1 year. Where the circumstances described in point (i) or (ii) cannot be established, 'usual residence' shall mean the place of legal or registered residence.
45	'Non-resident' means a person who is a not a resident of the reporting country.
46	'Surgical procedures' means medical interventions involving an incision with instruments usually performed in an operating theatre and normally involving anaesthesia and/or respiratory assistance. Surgical procedures can be performed either as inpatient cases, day cases or, in certain instances, as outpatient cases.
47	'Cataract surgery' means a surgical procedure to remove the lens of an eye and, in most cases, to replace it with an artificial lens.
48	'Tonsillectomy' means a surgical removal of the tonsils.
49	'Transluminal coronary angioplasty' means a procedure that opens blocked coronary arteries to improve blood flow to the heart muscle.
50	'Coronary artery bypass graft' means a surgical operation where atheromatous blockages in a patient's coronary arteries are bypassed with harvested venous or arterial conduits.
51	'Cholecystectomy' means a surgical procedure to remove the gallbladder.
52	'Repair of inguinal hernia' means a surgical correction of an inguinal hernia. An inguinal hernia is an opening, weakness, or bulge in the lining tissue of the abdominal wall in the groin area between the abdomen and the thigh.
53	'Caesarean section' means a surgical procedure to deliver a baby through incisions in the abdomen and uterus.
54	'Hip replacement' means a surgical procedure to remove damaged sections of a hip joint and to replace them with a prosthesis.
55	'Total knee replacement' means a surgical procedure whereby the diseased knee joint is replaced with a prosthesis.
56	'Partial excision of mammary gland' means surgical removal of some of the breast tissue due to an area of disease such as a mass/lesion, cyst, tumour, or benign or malignant neoplasm.
57	'Total mastectomy' means a surgical removal of an entire breast.

ANNEX II

List of variables, their characteristics and breakdowns, referred to in Article 3

Variables	Characteristics and breakdowns
1. **Data on Health Employment**	
1.1. Number of practising physicians by age and sex	Headcount at the end of the reference period. Breakdown by age and by sex. Age: less than 35, 35-44, 45-54, 55-64, 65-74, 75 and older.
1.2. Number of practising physicians by category	Headcount at the end of the reference period. Breakdown by category. Categories: general practitioners, other generalist (non-specialist) medical practitioners, paediatricians, obstetricians and gynaecologists, psychiatrists, group of non-surgical specialists, group of surgical specialists, other specialists not elsewhere classified, medical doctors not further defined.
1.3. Number of practising midwives	Headcount at the end of the reference period. Total number.
1.4. Number of practising nurses	Headcount at the end of the reference period. Total number.
1.5. Number of practising dentists	Headcount at the end of the reference period. Total number.
1.6. Number of practising pharmacists	Headcount at the end of the reference period. Total number.
2. **Data on Health Graduates**	
2.1. Number of medical graduates	Total number during the reference period.
2.2. Number of dentistry graduates	Total number during the reference period.
2.3. Number of pharmacy graduates	Total number during the reference period.
2.4. Number of midwifery graduates	Total number during the reference period.
2.5. Number of nursing graduates	Total number during the reference period.
3. **Data on Hospital Beds and Beds in Residential Long-Term Care Facilities**	
3.1. Number of hospital beds for somatic care	Average number during the reference period or total number at the end of the reference period. Breakdown by function. Functions: curative care, rehabilitative care, long-term care, function not elsewhere classified.
3.2. Number of hospital beds for psychiatric care	Average number during the reference period or total number at the end of the reference period.
3.3. Number of beds in residential long-term care facilities	Average number during the reference period or total number at the end of the reference period.

4. **Data on Devices for Medical Imaging**	
4.1. Number of MRI units	Total number at the end of the reference period.
4.2. Number of CT scanners	Total number at the end of the reference period.
5. **Data on Ambulatory Care**	
5.1. Immunisation rate of people aged 65 and older against influenza	Number of people aged 65 and over who have been immunised against influenza during the reference period divided by the average annual population aged 65 and over. or Number people aged 65 and over who have been immunised against influenza for the influenza season, defined as July 1 to June 30, which ended in the reference period divided by the population aged 65 and over in the beginning of the reference period.
5.2. Rate of women aged between 50 and 69 screened against breast cancer within a national breast cancer screening (mammography) programme	Rate: number of women aged 50-69 who have been screened against breast cancer within a national breast cancer screening (mammography) programme within 24 months before the end of the reference period (or according to the specific screening frequency recommended in each country) divided by the number of women aged 50-69 eligible for an organised screening programme. If a country does not have such a programme, it will deliver no value with an appropriate flag instead.
5.3. Rate of women aged between 20 and 69 screened against cervical cancer within a national cervical cancer screening programme	Rate: number of women aged 20-69 who have been screened for cervical cancer within a national cervical cancer screening programme within 36 months before the end of the reference period (or according to the specific screening frequency recommended in each country) divided by the number of women aged 20-69 eligible for an organised screening programme. If a country does not have such a programme, it will deliver no value with an appropriate flag instead.
6. **Data on Hospital Care**	
6.1. Number of hospital inpatient discharges	Total number during the reference period. Breakdown by diagnosis, sex, age group and geographical dimension. Mental and behavioural disorders do not need to be broken down by diagnosis and can be delivered as a group. Age groups: less than 1, 1-4, 5-9, 10-14, 15-19, 20-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-74, 75-79, 80-84, 85-89, 90-94, 95 and older Geographical dimension: NUTS2 region of the residence of the discharged patient (for non-residents: country of residence).

6.2. Number of hospital inpatient bed-days	Total number during the reference period. Breakdown by diagnosis, sex, age group and geographical dimension. Mental and behavioural disorders do not need to be broken down by diagnosis and can be delivered as a group. Age groups: less than 1, 1-4, 5-9, 10-14, 15-19, 20-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-74, 75-79, 80-84, 85-89, 90-94, 95 and older. Geographical dimension: NUTS2 region of the residence of the discharged patient (for non-residents: country of residence).
6.3. Number of hospital day case discharges	Total number during the reference period. Breakdown by diagnosis, sex, age group and geographical dimension. Mental and behavioural disorders do not need to be broken down by diagnosis and can be delivered as a group. Age groups: less than 1, 1-4, 5-9, 10-14, 15-19, 20-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-74, 75-79, 80-84, 85-89, 90-94, 95 and older. Geographical dimension: NUTS2 region of the residence of the discharged patient (for non-residents: country of residence).
6.4. Number of hospital inpatient discharges for patients who have received somatic curative care	Total number during the reference period.
6.5. Number of hospital inpatient bed-days for patients who have received somatic curative care	Total number during the reference period.
7. **Data on Surgical Procedures**	
7.1. Cataract surgery	Total number during the reference period. Breakdown of procedures by inpatient cases, day cases and outpatient cases.
7.2. Tonsillectomy	Total number during the reference period. Breakdown of procedures by inpatient cases, day cases and outpatient cases.
7.3. Transluminal coronary angioplasty	Total number during the reference period. Breakdown of procedures by inpatient cases and day cases.
7.4. Coronary artery bypass graft	Total number during the reference period. Breakdown of procedures by inpatient cases and day cases.
7.5. Cholecystectomy	Total number during the reference period. Breakdown of procedures by inpatient cases and day cases.
7.6. Repair of inguinal hernia	Total number during the reference period. Breakdown of procedures by inpatient cases and day cases.

7.7. Caesarean section	Total number during the reference period. Breakdown of procedures by inpatient cases and day cases.
7.8. Hip replacement	Total number during the reference period. Breakdown of procedures by inpatient cases and day cases.
7.9. Total knee replacement	Total number during the reference period. Breakdown of procedures by inpatient cases and day cases.
7.10. Partial excision of mammary gland	Total number during the reference period. Breakdown of procedures by inpatient cases and day cases.
7.11. Total mastectomy	Total number during the reference period. Breakdown of procedures by inpatient cases and day cases.

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2295

of 23 November 2022

amending Regulation (EC) No 474/2006 as regards the list of air carriers banned from operating or subject to operational restrictions within the Union

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 2111/2005 of the European Parliament and of the Council of 14 December 2005 on the establishment of a Community list of air carriers subject to an operating ban within the Community and on informing air transport passengers of the identity of the operating carrier, and repealing Article 9 of Directive 2004/36/CE ([1]), and in particular Article 4(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 474/2006 ([2]) establishes the list of air carriers, which are subject to an operating ban within the Union.

(2) Certain Member States and the European Union Aviation Safety Agency ('the Agency') communicated to the Commission, pursuant to Article 4(3) of Regulation (EC) No 2111/2005, information that is relevant for updating that list. Third countries and international organisations also provided relevant information. On the basis of the information provided, the list should be updated.

(3) The Commission informed all air carriers concerned, either directly or through the authorities responsible for their regulatory oversight, about the essential facts and considerations, which would form the basis of a decision to impose an operating ban on them within the Union or to modify the conditions of an operating ban imposed on an air carrier, which is included in the list set out in Annex A or B to Regulation (EC) No 474/2006.

(4) The Commission gave the air carriers concerned the opportunity to consult all relevant documentation, to submit written comments and to make an oral presentation to the Commission and to the Committee established by Article 15 of Regulation (EC) No 2111/2005 (the 'EU Air Safety Committee').

(5) The Commission has informed the EU Air Safety Committee about the ongoing joint consultations, within the framework of Regulation (EC) No 2111/2005 and Commission Regulation (EC) No 473/2006 ([3]), with the competent authorities and air carriers of Armenia, Kazakhstan, Nepal, Nigeria and Pakistan. The Commission also informed the EU Air Safety Committee about the aviation safety situation in Argentina, Congo Brazzaville, Equatorial Guinea, Iraq, Madagascar, Russia and South Sudan.

(6) The Agency informed the Commission and the EU Air Safety Committee about the technical assessments conducted for the initial evaluation and the continuous monitoring of third country operator ('TCO') authorisations, issued pursuant to Commission Regulation (EU) No 452/2014 ([4]).

([1]) OJ L 344, 27.12.2005, p. 15.

([2]) Commission Regulation (EC) No 474/2006 of 22 March 2006 establishing the Community list of air carriers which are subject to an operating ban within the Community referred to in Chapter II of Regulation (EC) No 2111/2005 of the European Parliament and of the Council (OJ L 84, 23.3.2006, p. 14).

([3]) Commission Regulation (EC) No 473/2006 of 22 March 2006 laying down implementing rules for the Community list of air carriers, which are subject to an operating ban within the Community referred to in Chapter II of Regulation (EC) No 2111/2005 of the European Parliament and of the Council (OJ L 84, 23.3.2006, p. 8).

([4]) Commission Regulation (EU) No 452/2014 of 29 April 2014 laying down technical requirements and administrative procedures related to air operations of third country operators pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 133, 6.5.2014, p. 12).

(7) The Agency also informed the Commission and the EU Air Safety Committee about the results of the analysis of ramp inspections carried out under the Safety Assessment of Foreign Aircraft programme ('SAFA'), in accordance with Commission Regulation (EU) No 965/2012 ([5]).

(8) In addition, the Agency informed the Commission and the EU Air Safety Committee about the technical assistance projects carried out in third countries affected by an operating ban under Regulation (EC) No 474/2006. Furthermore, the Agency provided information on the plans and requests for further technical assistance and cooperation to improve the administrative and technical capability of civil aviation authorities in third countries with a view to helping them resolve non-compliance with applicable international civil aviation safety standards. Member States were invited to respond to such requests on a bilateral basis in coordination with the Commission and the Agency. In that regard, the Commission reiterated the usefulness of providing information to the international aviation community, particularly through the International Civil Aviation Organisation's ('ICAO') Aviation Safety Implementation Assistance Partnership tool, on technical assistance to third countries provided by the Union and Member States to improve aviation safety around the world.

(9) Eurocontrol provided the Commission and the EU Air Safety Committee with an update on the status of the SAFA and TCO alarming functions, including statistics about alert messages for banned air carriers.

Union air carriers

(10) Following the Agency's analysis of information resulting from ramp inspections carried out on the aircraft of Union air carriers, as well as standardisation inspections carried out by the Agency, and complemented with information stemming from specific inspections and audits carried out by national aviation authorities, Member States and the Agency, acting as competent authorities, have taken certain corrective and enforcement measures, and informed the Commission and the EU Air Safety Committee about those measures.

(11) Member States and the Agency, acting as competent authorities, reiterated their readiness to act, as necessary, in the event that pertinent safety information indicates imminent safety risks resulting from non-compliance by Union air carriers with relevant safety standards.

Air carriers from Armenia

(12) In June 2020, air carriers certified in Armenia were included in Annex A to Regulation (EC) No 474/2006, by Commission Implementing Regulation (EU) 2020/736 ([6]).

(13) The Commission and the Agency visited the Civil Aviation Committee of Armenia ('CAC') from 27 to 30 September 2022. On that occasion, the Commission reviewed the progress made by the CAC in dealing with the identified safety deficiencies that led to the imposition of the aforementioned ban on the Armenian air carriers. Part of the review carried out during the visit focused on the actions already taken and those planned to address the root causes of the identified safety concerns, notably in terms of the CAC's capacity to conduct effective oversight of air carriers certified in Armenia.

(14) In this respect, the Commission reviewed the actions already taken by the CAC to fulfil its responsibilities for the implementation of the State Safety Program, the Occurrence Reporting System, the Quality Management System and the Air Operators Certification ('AOC') process. The visit also reviewed not only the CAC's ability to comply with relevant safety regulations and standards, but also its ability to detect any significant safety risk within a certified air carrier and act in an effective manner to contain such risk.

([5]) Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1).

([6]) Commission Implementing Regulation (EU) 2020/736 of 2 June 2020 amending Regulation (EC) No 474/2006 as regards the list of air carriers banned from operating or subject to operational restrictions within the Union (OJ L 172, 3.6.2020, p. 7).

(15) The visit confirmed that the CAC made limited progress in addressing the identified safety deficiencies and observations raised during the 2020 Union on-site assessment visit. While a Corrective Action Plan ('CAP') has been defined and enacted, it should however be reopened, reviewed and additional actions should be included in order to make the CAP fit-for-purpose. This will be a key activity under a technical assistance project, which the Agency is providing.

(16) At this occasion, the CAC also informed the Commission that a new air carrier *Fly Arna* (AM AOC No. 075) has been certified. Since the CAC has not demonstrated a sufficient ability to implement and enforce the relevant safety standards, the issuance of an AOC to this new air carrier does not guarantee sufficient compliance with the relevant international safety standards.

(17) The visit also provided an opportunity to reiterate to the Armenian competent authorities and government representatives, that a proper and effective safety oversight can only be guaranteed if the CAC is supported by the appropriate resources and expertise, notably in terms of adequate number of qualified staff, as well as by ensuring the stability of senior management.

(18) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that with respect to air carriers from Armenia, the list of air carriers, which are subject to an operating ban within the Union should be amended to include *Fly Arna* in Annex A to Regulation (EC) No 474/2006.

(19) Member States should continue verifying the effective compliance of air carriers certified in Armenia with the relevant international safety standards through prioritisation of ramp inspections of those air carriers, pursuant to Regulation (EU) No 965/2012.

Air carriers from Kazakhstan

(20) In December 2016, air carriers certified in Kazakhstan were removed from Annex A to Regulation (EC) No 474/2006, by Commission Implementing Regulation (EU) 2016/2214 ([7]), with the exception of *Air Astana*, which had been removed from Annex B to Regulation (EC) No 474/2006 already in 2015 by Commission Implementing Regulation (EU) 2015/2322 ([8]).

(21) On 20 October 2022, the Commission, the Agency, Member States and representatives of the Civil Aviation Committee of Kazakhstan ('CAC KZ') and the Aviation Administration of Kazakhstan Joint Stock Company ('AAK') held a technical meeting.

(22) During that meeting, the CAC KZ and the AAK presented the progress made with respect to the implementation and further development of their CAP, and provided the Commission with evidence of the actions taken to address and/or close a number of the observations and recommendations raised during the 2021 Union on-site assessment visit. The meeting was also an opportunity for the CAC KZ and the AAK to provide an update on the ongoing developments in the Kazakh aviation legislative framework, notably in terms of amendments to the Kazakh Primary Aviation Law, which are expected to be adopted in December 2022. The AAK also informed about the actions taken to develop secondary aviation legislation, which can only be adopted after the Primary Aviation Law has been adopted.

(23) Based on a review of the CAP submitted prior to the meeting, as well as the discussions and evidence provided during the meeting, note was taken of the progress made in addressing the observations and recommendations stemming from the 2021 Union on-site assessment visit. All of the observations and recommendations have been addressed and a number of them have been closed. However, further action needs to be taken to close all the remaining observations in a satisfactory manner and necessary resources should be provided to ensure an adequate

([7]) Commission Implementing Regulation (EU) 2016/2214 of 8 December 2016 amending Regulation (EC) No 474/2006 as regards the list of air carriers which are subject to an operating ban within the Union (OJ L 334, 9.12.2016, p. 6).

([8]) Commission Implementing Regulation (EU) 2015/2322 of 10 December 2015 amending Regulation (EC) No 474/2006 establishing the Community list of air carriers which are subject to an operating ban within the Community (OJ L 328, 12.12.2015, p. 67).

safety oversight. A number of additional specific issues were identified, requiring further attention, including the development and implementation of a procedure to carry out unannounced inspections, notably for AOC holders and Approved Maintenance Organizations, and the recruitment of a qualified expert to ensure the supervision of designated flight examiners.

(24) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that at this time there are no grounds for amending the list of air carriers, which are subject to an operating ban within the Union with respect to air carriers from Kazakhstan.

(25) Member States should continue verifying the effective compliance of air carriers certified in Kazakhstan with the relevant international safety standards through prioritisation of ramp inspections of all those carriers, pursuant to Regulation (EU) No 965/2012.

(26) Where any relevant safety information reveals imminent safety risks resulting from non-compliance with the relevant international safety standards, further action by the Commission may become necessary, in accordance with Regulation (EC) No 2111/2005.

Air carriers from Nepal

(27) In December 2013, air carriers certified in Nepal were included in Annex A to Regulation (EC) No 474/2006, by Commission Implementing Regulation (EU) 1264/2013 ([9]).

(28) As part of its continuous monitoring activities, on 14 September 2022, the Commission met with the representatives of the Civil Aviation Authority of Nepal ('CAAN'). At that occasion, the CAAN provided the Commission with information regarding the safety oversight in Nepal and notably their revised considerations about the functional separation of the regulatory and service provider roles of CAAN, which is a longstanding issue identified during the Commission consultations with Nepal, as well as by the ICAO Universal Safety Oversight Audit Programme ('USOAP').

(29) As a follow up to that meeting, on 10 November 2022, the CAAN submitted to the Commission the information and documentary evidence about the adoption of a new CAAN Regulation, which in CAAN's view ensures the functional separation of CAAN's regulatory and service provider roles, namely by preventing the transfer of staff between regulatory and service provider sections of the CAAN. The implementation of this new regulation and progress in aligning the CAAN's safety oversight with the relevant international safety standards would allow the Commission to consider whether a Union on-site assessment visit to Nepal should be organised in 2023. On the basis of evidence gathered during such a visit the Commission could assess if a removal of air carriers certified in Nepal from the Annex A to Regulation (EC) No 474/2006 would be justified.

(30) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that at this time there are no grounds for amending the list of air carriers, which are subject to an operating ban within the Union with respect to air carriers from Nepal.

(31) Member States should continue verifying the effective compliance of air carriers certified in Nepal with the relevant international safety standards through prioritisation of ramp inspections of those air carriers, pursuant to Regulation (EU) No 965/2012.

Air carriers from Nigeria

(32) In May 2017, the air carrier *Med-View Airline* was included in Annex A to Regulation (EC) No 474/2006, by Commission Implementing Regulation (EU) 2017/830 ([10]).

([9]) Commission Implementing Regulation (EU) No 1264/2013 of 3 December 2013 amending Regulation (EC) No 474/2006 establishing the Community list of air carriers which are subject to an operating ban within the Community (OJ L 326, 6.12.2013, p. 7).

([10]) Commission Implementing Regulation (EU) 2017/830 of 15 May 2017 amending Regulation (EC) No 474/2006 as regards the list of air carriers which are banned from operating or are subject to operational restrictions within the Union (OJ L 124, 17.5.2017, p. 3).

(33) By letter of 25 May 2022, the Nigerian Civil Aviation Authority ('NCAA') confirmed in writing the cessation of activities by the air carrier *Med-View Airline*.

(34) On 7 November 2022, the Commission, with the participation of the Agency, organised a meeting with the NCAA, at its request, for the purpose of being updated on key safety oversight developments that have taken place in Nigeria between 2019 and 2022, notably in light of the safety oversight support provided by the Agency to the NCAA in 2019.

(35) During that meeting, the NCAA provided a comprehensive presentation of the safety oversight improvements made, notably in the areas of primary aviation legislation, qualification of technical staff, and surveillance obligations.

(36) Of particular note are the legislative changes to the Nigerian Civil Aviation Act, the re-organisation of the regional offices, the efforts to obtain an ISO 9001 certification for the NCAA, the development of plans for the digitalisation and automation of NCAA processes, the improvements to staff training, and the establishment of an occurrence reporting system.

(37) The NCAA emphasized its commitment to continuous improvement, including in safety oversight and in regularly informing the Commission and the Agency. The Commission noted this positive development, and stressed that the NCAA should be given all necessary support and resources to fulfil its safety oversight obligations.

(38) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that the list of air carriers, which are subject to an operating ban within the Union, should be amended to remove the air carrier *Med-View Airline* from Annex A to Regulation (EC) No 474/2006.

(39) Member States should continue verifying the effective compliance of air carriers certified in Nigeria with the relevant international safety standards through prioritisation of ramp inspections of those air carriers, pursuant to Regulation (EU) No 965/2012.

(40) Where any relevant safety information reveals imminent safety risks resulting from non-compliance with the relevant international safety standards, further action by the Commission may become necessary, in accordance with Regulation (EC) No 2111/2005.

Air carriers from Pakistan

(41) In March 2007, *Pakistan International Airlines* was included in Annex B to Regulation (EC) No 474/2006 by Commission Regulation (EC) No 235/2007 ([11]) and subsequently removed from that Annex in November 2007 by Commission Regulation (EC) No 1400/2007 ([12]).

(42) On 1 July 2020, the Commission opened consultations with the Pakistan Civil Aviation Authority ('PCAA') pursuant to Article 3(2) of Regulation (EC) No 473/2006, on the basis of the TCO authorisation suspensions of *Pakistan International Airlines* and *Vision Air,* and a statement made by the Pakistan Transport Minister about fraudulently obtained pilot licenses in Pakistan.

(43) In that context, the Commission, in cooperation with the Agency and Member States, has organised a number of technical and information meetings with the PCAA on 9 July and 25 September 2020, 15 and 16 March 2021, 15 October 2021 and 16 March 2022. Those discussions focused on efforts made by the PCAA in dealing with the safety oversight concerns previously identified by the Commission and the Agency experts, as well as those identified by ICAO during its USOAP visit that took place between 29 November and 10 December 2021.

([11]) Commission Regulation (EC) No 235/2007 of 5 March 2007 amending Regulation (EC) No 474/2006 establishing the Community list of air carriers which are subject to an operating ban within the Community (OJ L 66, 6.3.2007, p. 3).

([12]) Commission Regulation (EC) No 1400/2007 of 28 November 2007 amending Regulation (EC) No 474/2006 establishing the Community list of air carriers which are subject to an operating ban within the Community (OJ L 311, 29.11.2007, p. 12).

(44) As part of its continuous monitoring activities, on 25 October 2022, the Commission, the Agency, Member States and representatives of the PCAA held a technical meeting. During that meeting, the PCAA informed the participants about the actions and measures already implemented, as well as about those planned, to address the identified safety oversight concerns.

(45) The information and data presented during the meeting indicate the commitment and efforts of the PCAA to resolve the safety oversight situation in Pakistan, notably through the adoption of an amended Civil Aviation Authority Ordinance by the end of 2022, as well as the associated secondary legislation planned for the first quarter of 2023. Overall, the proposed plans, as presented during the meeting, appear to be fit-for-purpose to comply with and effectively implement the relevant safety standards. However, this can be assessed only after the relevant regulations are adopted.

(46) On this basis, whilst acknowledging the actions taken to date, the Commission will continue its monitoring of Pakistan's safety oversight system in order to determine whether further action is required pursuant to Regulation (EC) No 2111/2005. In this context, the Commission intends to carry out, with the Agency and Member States, a Union on-site assessment visit to Pakistan in 2023.

(47) In accordance with the common criteria set out in the Annex to Regulation (EC) No 2111/2005, the Commission considers that at this time there are no grounds for amending the list of air carriers, which are subject to an operating ban within the Union with respect to air carriers certified in Pakistan.

(48) Member States should continue verifying the effective compliance of air carriers certified in Pakistan with the relevant international safety standards through prioritisation of ramp inspections of those air carriers, pursuant to Regulation (EU) No 965/2012.

(49) Where any relevant safety information reveals imminent safety risks resulting from non-compliance with the relevant international safety standards, further action by the Commission can become necessary, in accordance with Regulation (EC) No 2111/2005.

(50) Regulation (EC) No 474/2006 should therefore be amended accordingly.

(51) Articles 5 and 6 of Regulation (EC) No 2111/2005 recognise the need for decisions to be taken swiftly and, where appropriate, urgently, given the safety implications. It is therefore essential, for the protection of sensitive information and the traveling public, that any decisions in the context of updating the list of air carriers, which are subject to an operating ban or restriction within the Union, are published and enter into force immediately after their adoption.

(52) The measures provided for in this Regulation are in accordance with the opinion of the EU Air Safety Committee established pursuant to Article 15 of Regulation (EC) No 2111/2005,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 474/2006 is amended as follows:

(1) Annex A is replaced by the text in Annex I to this Regulation;

(2) Annex B is replaced by the text in Annex II to this Regulation.

Article 2

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

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

Done at Brussels, 23 November 2022.

For the Commission,
On behalf of the President,
Adina VĂLEAN
Member of the Commission

ANNEX I

'ANNEX A

LIST OF AIR CARRIERS WHICH ARE BANNED FROM OPERATING WITHIN THE UNION, WITH EXCEPTIONS [1]

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number or Operating Licence Number	ICAO three letter designator	State of the Operator
AVIOR AIRLINES	ROI-RNR-011	ROI	Venezuela
BLUE WING AIRLINES	SRBWA-01/2002	BWI	Suriname
IRAN ASEMAN AIRLINES	FS-102	IRC	Iran
IRAQI AIRWAYS	001	IAW	Iraq
AIR ZIMBABWE (PVT)	177/04	AZW	Zimbabwe
All air carriers certified by the authorities with responsibility for regulatory oversight of Afghanistan, including			**Afghanistan**
ARIANA AFGHAN AIRLINES	AOC 009	AFG	Afghanistan
KAM AIR	AOC 001	KMF	Afghanistan
All air carriers certified by the authorities with responsibility for regulatory oversight of Angola, with the exception of *TAAG Angola Airlines* and *Heli Malongo*, including			**Angola**
AEROJET	AO-008/11-07/17 TEJ	TEJ	Angola
GUICANGO	AO-009/11-06/17 YYY	Unknown	Angola
AIR JET	AO-006/11-08/18 MBC	MBC	Angola
BESTFLYA AIRCRAFT MANAGEMENT	AO-015/15-06/17YYY	Unknown	Angola
HELIANG	AO 007/11-08/18 YYY	Unknown	Angola
SJL	AO-014/13-08/18YYY	Unknown	Angola
SONAIR	AO-002/11-08/17 SOR	SOR	Angola
All air carriers certified by the authorities with responsibility for regulatory oversight of Armenia, including			**Armenia**
AIRCOMPANY ARMENIA	AM AOC 065	NGT	Armenia
ARMENIA AIRWAYS	AM AOC 063	AMW	Armenia

[1] Air carriers listed in Annex A could be permitted to exercise traffic rights by using wet-leased aircraft of an air carrier which is not subject to an operating ban, provided that the relevant safety standards are complied with.

ARMENIAN HELICOPTERS	AM AOC 067	KAV	Armenia
FLY ARNA	AM AOC 075	ACY	Armenia
FLYONE ARMENIA	AM AOC 074	FIE	Armenia
NOVAIR	AM AOC 071	NAI	Armenia
SHIRAK AVIA	AM AOC 072	SHS	Armenia
SKYBALL	AM AOC 073	N/A	Armenia
All air carriers certified by the authorities with responsibility for regulatory oversight of Congo (Brazzaville), including			**Congo (Brazzaville)**
CANADIAN AIRWAYS CONGO	CG-CTA 006	TWC	Congo (Brazzaville)
EQUAFLIGHT SERVICES	CG-CTA 002	EKA	Congo (Brazzaville)
EQUAJET	RAC06-007	EKJ	Congo (Brazzaville)
TRANS AIR CONGO	CG-CTA 001	TSG	Congo (Brazzaville)
SOCIETE NOUVELLE AIR CONGO	CG-CTA 004	Unknown	Congo (Brazzaville)
All air carriers certified by the authorities with responsibility for regulatory oversight of Democratic Republic of Congo (DRC), including			**Democratic Republic of Congo (DRC)**
AIR FAST CONGO	AAC/DG/OPS-09/03	Unknown	Democratic Republic of Congo (DRC)
AIR KATANGA	AAC/DG/OPS-09/08	Unknown	Democratic Republic of Congo (DRC)
BUSY BEE CONGO	AAC/DG/OPS-09/04	Unknown	Democratic Republic of Congo (DRC)
COMPAGNIE AFRICAINE D'AVIATION (CAA)	AAC/DG/OPS-09/02	Unknown	Democratic Republic of Congo (DRC)
CONGO AIRWAYS	AAC/DG/OPS-09/01	Unknown	Democratic Republic of Congo (DRC)
KIN AVIA	AAC/DG/OPS-09/10	Unknown	Democratic Republic of Congo (DRC)
MALU AVIATION	AAC/DG/OPS-09/05	Unknown	Democratic Republic of Congo (DRC)
SERVE AIR CARGO	AAC/DG/OPS-09/07	Unknown	Democratic Republic of Congo (DRC)

SWALA AVIATION	AAC/DG/OPS-09/06	Unknown	Democratic Republic of Congo (DRC)
MWANT JET	AAC/DG/OPS-09/09	Unknown	Democratic Republic of Congo (RDC)
All air carriers certified by the authorities with responsibility for regulatory oversight of Djibouti, including			**Djibouti**
DAALLO AIRLINES	Unknown	DAO	Djibouti
All air carriers certified by the authorities with responsibility for regulatory oversight of Equatorial Guinea, including			**Equatorial Guinea**
CEIBA INTERCONTINENTAL	2011/0001/MTTCT/ DGAC/SOPS	CEL	Equatorial Guinea
CRONOS AIRLINES	2011/0004/MTTCT/ DGAC/SOPS	Unknown	Equatorial Guinea
All air carriers certified by the authorities with responsibility for regulatory oversight of Eritrea, including			**Eritrea**
ERITREAN AIRLINES	AOC No 004	ERT	Eritrea
NASAIR ERITREA	AOC No 005	NAS	Eritrea
All air carriers certified by the authorities with responsibility for regulatory oversight of Kyrgyzstan, including			**Kyrgyzstan**
AEROSTAN	*08*	*BSC*	Kyrgyzstan
AIR COMPANY AIR KG	50	KGC	Kyrgyzstan
AIR MANAS	17	MBB	Kyrgyzstan
AVIA TRAFFIC COMPANY	23	AVJ	Kyrgyzstan
FLYSKY AIRLINES	53	FSQ	Kyrgyzstan
HELI SKY	47	HAC	Kyrgyzstan
KAP.KG AIRCOMPANY	52	KGS	Kyrgyzstan
SKY KG AIRLINES	41	KGK	Kyrgyzstan
TEZ JET	46	TEZ	Kyrgyzstan
VALOR AIR	07	VAC	Kyrgyzstan
All air carriers certified by the authorities with responsibility for regulatory oversight of Liberia.			**Liberia**
All air carriers certified by the authorities with responsibility for regulatory oversight of Libya, including			**Libya**

AFRIQIYAH AIRWAYS	007/01	AAW	Libya
AIR LIBYA	004/01	TLR	Libya
AL MAHA AVIATION	030/18	Unknown	Libya
BERNIQ AIRWAYS	032/21	BNL	Libya
BURAQ AIR	002/01	BRQ	Libya
GLOBAL AIR TRANSPORT	008/05	GAK	Libya
HALA AIRLINES	033/21	HTP	Libya
LIBYAN AIRLINES	001/01	LAA	Libya
LIBYAN WINGS AIRLINES	029/15	LWA	Libya
PETRO AIR	025/08	PEO	Libya
All air carriers certified by the authorities with responsibility for regulatory oversight of Nepal, including			**Nepal**
AIR DYNASTY HELI. S.	035/2001	Unknown	Nepal
ALTITUDE AIR	085/2016	Unknown	Nepal
BUDDHA AIR	014/1996	BHA	Nepal
FISHTAIL AIR	017/2001	Unknown	Nepal
SUMMIT AIR	064/2010	Unknown	Nepal
HELI EVEREST	086/2016	Unknown	Nepal
HIMALAYA AIRLINES	084/2015	HIM	Nepal
KAILASH HELICOPTER SERVICES	087/2018	Unknown	Nepal
MAKALU AIR	057A/2009	Unknown	Nepal
MANANG AIR PVT	082/2014	Unknown	Nepal
MOUNTAIN HELICOPTERS	055/2009	Unknown	Nepal
PRABHU HELICOPTERS	081/2013	Unknown	Nepal
NEPAL AIRLINES CORPORATION	003/2000	RNA	Nepal
SAURYA AIRLINES	083/2014	Unknown	Nepal
SHREE AIRLINES	030/2002	SHA	Nepal
SIMRIK AIR	034/2000	Unknown	Nepal
SIMRIK AIRLINES	052/2009	RMK	Nepal
SITA AIR	033/2000	Unknown	Nepal
TARA AIR	053/2009	Unknown	Nepal
YETI AIRLINES	037/2004	NYT	Nepal
The following air carriers certified by the authorities with responsibility for regulatory oversight of Russia			**Russia**

AURORA AIRLINES	486	SHU	Russia
AVIACOMPANY 'AVIASTAR-TU' CO. LTD	458	TUP	Russia
IZHAVIA	479	IZA	Russia
JOINT STOCK COMPANY 'AIR COMPANY "YAKUTIA"'	464	SYL	Russia
JOINT STOCK COMPANY 'RUSJET'	498	RSJ	Russia
JOINT STOCK COMPANY 'UVT AERO'	567	UVT	Russia
JOINT STOCK COMPANY SIBERIA AIRLINES	31	SBI	Russia
JOINT STOCK COMPANY SMARTAVIA AIRLINES	466	AUL	Russia
JOINT-STOCK COMPANY 'IRAERO' AIRLINES	480	IAE	Russia
JOINT-STOCK COMPANY 'URAL AIRLINES'	18	SVR	Russia
JOINT–STOCK COMPANY ALROSA AIR COMPANY	230	DRU	Russia
JOINT-STOCK COMPANY NORDSTAR AIRLINES	452	TYA	Russia
JS AVIATION COMPANY 'RUSLINE'	225	RLU	Russia
JSC YAMAL AIRLINES	142	LLM	Russia
LLC 'NORD WIND'	516	NWS	Russia
LLC 'AIRCOMPANY IKAR'	36	KAR	Russia
LTD. I FLY	533	RSY	Russia
POBEDA AIRLINES LIMITED LIABILITY COMPANY	562	PBD	Russia
PUBLIC JOINT STOCK COMPANY 'AEROFLOT - RUSSIAN AIRLINES'	1	AFL	Russia
ROSSIYA AIRLINES, JOINT STOCK COMPANY	2	SDM	Russia
SKOL AIRLINE LLC	228	CDV	Russia
UTAIR AVIATION, JOINT-STOCK COMPANY	6	UTA	Russia
All air carriers certified by the authorities with responsibility for regulatory oversight of Sao Tome and Principe, including			**Sao Tome and Principe**
AFRICA'S CONNECTION	10/AOC/2008	ACH	Sao Tome and Principe

STP AIRWAYS	03/AOC/2006	STP	Sao Tome and Principe
All air carriers certified by the authorities with responsibility for regulatory oversight of Sierra Leone			**Sierra Leone**
All air carriers certified by the authorities with responsibility for regulatory oversight of Sudan, including			**Sudan**
ALFA AIRLINES SD	54	AAJ	Sudan
BADR AIRLINES	35	BDR	Sudan
BLUE BIRD AVIATION	11	BLB	Sudan
ELDINDER AVIATION	8	DND	Sudan
GREEN FLAG AVIATION	17	GNF	Sudan
HELEJETIC AIR	57	HJT	Sudan
KATA AIR TRANSPORT	9	KTV	Sudan
KUSH AVIATION CO.	60	KUH	Sudan
NOVA AIRWAYS	46	NOV	Sudan
SUDAN AIRWAYS CO.	1	SUD	Sudan
SUN AIR	51	SNR	Sudan
TARCO AIR	56	TRQ	Sudan’

ANNEX II

'ANNEX B

LIST OF AIR CARRIERS WHICH ARE SUBJECT TO OPERATIONAL RESTRICTIONS WITHIN THE UNION [1]

Name of the legal entity of the air carrier as indicated on its AOC (and its trading name, if different)	Air Operator Certificate ('AOC') Number	ICAO three letter designator	State of the Operator	Aircraft type restricted	Registration mark(s) and, when available, construction serial number(s) of restricted aircraft	State of registry
IRAN AIR	FS100	IRA	Iran	All aircraft of type Fokker F100 and of type Boeing B747	Aircraft of type Fokker F100 as mentioned on the AOC; aircraft of type Boeing B747 as mentioned on the AOC	Iran
AIR KORYO	GAC-AOC/ KOR-01	KOR	North Korea	All fleet with the exception of: 2 aircraft of type TU-204.	All fleet with the exception of: P-632, P-633.	North Korea

[1] Air carriers listed in Annex B could be permitted to exercise traffic rights by using wet-leased aircraft of an air carrier which is not subject to an operating ban, provided that the relevant safety standards are complied with.'

DECISIONS

COUNCIL DECISION (EU) 2022/2296

of 21 November 2022

on guidelines for the employment policies of the Member States

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 148(2) thereof,

Having regard to the proposal from the European Commission,

Having regard to the opinion of the European Parliament ([1]),

Having regard to the opinion of the European Economic and Social Committee ([2]),

After consulting the Committee of the Regions,

Having regard to the opinion of the Employment Committee ([3])

Whereas:

(1) Member States and the Union are to work towards developing a coordinated strategy for employment and particularly for promoting a skilled, trained and adaptable workforce, as well as labour markets that are future-oriented and responsive to economic change, with a view to achieving the objectives of full employment and social progress, balanced growth, a high level of protection and improvement of the quality of the environment laid down in Article 3 of the Treaty on European Union (TEU). Member States are to regard promoting employment as a matter of common concern and are to coordinate their action in that respect within the Council, taking into account national practices related to the responsibilities of management and labour.

(2) The Union is to combat social exclusion and discrimination, and promote social justice and protection, equality between women and men, solidarity between generations and the protection of the rights of the child as laid down in Article 3 TEU. In defining and implementing its policies and activities, the Union is to take into account requirements linked to the promotion of a high level of employment, the guarantee of adequate social protection, the fight against poverty and social exclusion, a high level of education and training and protection of human health as laid down in Article 9 of the Treaty on the Functioning of the European Union (TFEU).

(3) In accordance with the TFEU, the Union has developed and implemented policy coordination instruments for economic and employment policies. As part of those instruments, the guidelines for the employment policies of the Member States (the 'Guidelines') set out in the Annex to this Decision, together with the broad guidelines for the economic policies of the Member States and of the Union set out in Council Recommendation (EU) 2015/1184 ([4]), form the Integrated Guidelines. They are to guide policy implementation in the Member States and in the Union, reflecting the interdependence between the Member States. The resulting set of coordinated European and national policies and reforms are to constitute an appropriate overall sustainable economic, employment and social policy mix, which should achieve positive spill over effects for labour markets and society at large, and effectively respond to the impact of the COVID-19 pandemic, Russia's war of aggression against Ukraine and the rising cost of living.

([1]) Opinion of 18 October 2022 (not yet published in the Official Journal).
([2]) Opinion of 21 September 2022 (not yet published in the Official Journal).
([3]) Opinion of 21 October 2022 (not yet published in the Official Journal).
([4]) Council Recommendation (EU) 2015/1184 of 14 July 2015 on broad guidelines for the economic policies of the Member States and of the European Union (OJ L 192, 18.7.2015, p. 27).

(4) In order to enhance economic and social progress, to facilitate the green and digital transitions and to achieve inclusive, competitive and resilient labour markets in the Union, Member States should promote quality education, training, upskilling and reskilling, as well as lifelong learning, future-oriented vocational education and training and improved career opportunities by strengthening the links between the education system and the labour market and recognising skills, knowledge and competences acquired through non-formal and informal learning.

(5) The Guidelines are consistent with the Stability and Growth Pact, existing Union legislation and various Union initiatives, including Council Directive 2001/55/EC ([5]), Council Recommendations of 10 March 2014 ([6]), 15 February 2016 ([7]), 19 December 2016 ([8]), 15 March 2018 ([9]), 22 May 2018 ([10]), 22 May 2019 ([11]), 8 November 2019 ([12]), 30 October 2020 ([13]),24 November 2020 ([14]), 29 November 2021 ([15]) and 16 June 2022 ([16]), Commission Recommendation (EU) 2021/402 ([17]), Council Recommendation (EU) 2021/1004 ([18]), Council Resolution of 26 February 2021 ([19]), Commission Communication of 9 December 2021 on building an economy that works for people: an action plan for the social economy, Decision (EU) 2021/2316 of the European Parliament and of the Council ([20]), Directive of the European Parliament and of the Council 2022/2041 of 19 October 2022 on adequate minimum wages in the European Union ([21]) and Directive of the European Parliament and of the Council on improving the gender balance among directors of listed companies and related measures.

(6) The European Semester combines the different instruments in an overarching framework for integrated multilateral coordination and surveillance of economic and employment policies within the Union. While pursuing environmental sustainability, productivity, fairness and macroeconomic stability, the European Semester integrates the principles of the European Pillar of Social Rights and of its monitoring tool, the Social Scoreboard, and provides for strong engagement with social partners, civil society and other stakeholders. It supports the delivery of the

([5]) Council Directive 2001/55/EC of 20 July 2001 on minimum standards for giving temporary protection in the event of a mass influx of displaced persons and on measures promoting a balance of efforts between Member States in receiving such persons and bearing the consequences thereof (OJ L 212, 7.8.2001, p. 12).
([6]) Council Recommendation of 10 March 2014 on a Quality Framework for Traineeships (OJ C 88, 27.3.2014, p. 1).
([7]) Council Recommendation of 15 February 2016 on the integration of the long-term unemployed into the labour market (OJ C 67, 20.2.2016, p. 1).
([8]) Council Recommendation of 19 December 2016 on Upskilling Pathways: New Opportunities for Adults (OJ C 484, 24.12.2016, p. 1).
([9]) Council Recommendation of 15 March 2018 on a European Framework for Quality and Effective Apprenticeships (OJ C 153, 2.5.2018, p. 1).
([10]) Council Recommendation of 22 May 2018 on key competences for lifelong learning (OJ C 189, 4.6.2018, p. 1).
([11]) Council Recommendation of 22 May 2019 on High-Quality Early Childhood Education and Care Systems (OJ C 189, 5.6.2019, p. 4).
([12]) Council Recommendation of 8 November 2019 on access to social protection for workers and the self-employed (OJ C 387, 15.11.2019, p. 1).
([13]) Council Recommendation of 30 October 2020 on A Bridge to Jobs – Reinforcing the Youth Guarantee and replacing the Council Recommendation of 22 April 2013 on establishing a Youth Guarantee (OJ C 372, 4.11.2020, p. 1).
([14]) Council Recommendation of 24 November 2020 on vocational education and training (VET) for sustainable competitiveness, social fairness and resilience (OJ C 417, 2.12.2020, p. 1).
([15]) Council Recommendation of 29 November 2021 on blended learning approaches for high-quality and inclusive primary and secondary education (OJ C 504, 14.12.2021, p. 21).
([16]) Council Recommendation of 16 June 2022 on a European approach to micro-credentials for lifelong learning and employability (OJ C 243, 27.6.2022, p. 10), Council Recommendation of 16 June 2022 on individual learning accounts (OJ C 243, 27.6.2022, p. 26) and Council Recommendation of 16 June 2022 on ensuring a fair transition towards climate neutrality (OJ C 243, 27.6.2022, p. 35).
([17]) Commission Recommendation (EU) 2021/402 of 4 March 2021 on an effective active support to employment following the COVID-19 crisis (EASE) (OJ L 80, 8.3.2021, p. 1).
([18]) Council Recommendation (EU) 2021/1004 of 14 June 2021 establishing a European Child Guarantee (OJ L 223, 22.6.2021, p. 14).
([19]) Council Resolution on a strategic framework for European cooperation in education and training towards the European Education Area and beyond (2021-2030) (OJ C 66, 26.2.2021, p. 1).
([20]) Decision (EU) 2021/2316 of the European Parliament and of the Council of 22 December 2021 on a European Year of Youth (2022) (OJ L 462, 28.12.2021, p. 1).
([21]) (OJ L 275, 25.10.2022).

Sustainable Development Goals. The Union's and Member States' economic and employment policies should go hand in hand with Europe's fair transition to a climate neutral, environmentally sustainable and digital economy, improve competitiveness, ensure adequate working conditions, foster innovation, promote social justice and equal opportunities and upward socioeconomic convergence, as well as tackle inequalities and regional disparities.

(7) Climate change and other environment-related challenges, the need to accelerate energy independence, a socially fair and just green transition, ensuring Europe's open strategic autonomy, globalisation, digitalisation, artificial intelligence, an increase in teleworking, the platform economy and demographic change are deeply transforming European economies and societies. The Union and its Member States are to work together to effectively and proactively address those structural developments and adapt existing systems as needed, recognising the close interdependence of the Member States' economies and labour markets, and related policies. This requires coordinated, ambitious and effective policy action at both Union and national levels while recognising the role of social partners, in accordance with the TFEU and the Union's provisions on economic governance, taking into account the European Pillar of Social Rights.Such policy action should encompass a boost in sustainable investment, a renewed commitment to appropriately sequenced reforms that enhance sustainable and inclusive economic growth, the creation of quality jobs, productivity, adequate working conditions, social and territorial cohesion, upward socioeconomic convergence, resilience and the exercise of fiscal responsibility, with support from existing Union funding programmes, and in particular the Recovery and Resilience Facility established by Regulation (EU) 2021/241 of the European Parliament and of the Council ([22]) and the cohesion policy funds, including the European Social Fund Plus established by Regulation (EU) 2021/1057 of the European Parliament and of the Council ([23]) and the European Regional Development Fund governed by Regulation (EU) 2021/1058 of the European Parliament and of the Council ([24]), as well as the Just Transition Fund established by Regulation (EU) 2021/1056 of the European Parliament and of the Council ([25]). Policy action should combine supply- and demand-side measures, while taking into account their economic, environmental, employment and social impacts.

(8) The European Parliament, the Council and the Commission proclaimed the European Pillar of Social Rights ([26]). It sets out twenty principles and rights to support well-functioning and fair labour markets and welfare systems, structured around three categories: equal opportunities and access to the labour market, fair working conditions, and social protection and inclusion. The principles and rights give strategic direction to the Union, making sure that the transitions to climate-neutrality and environmental sustainability, digitalisation and demographic change are socially fair and just and preserve territorial cohesion. The European Pillar of Social Rights, with its accompanying Social Scoreboard, constitutes a reference framework to monitor the employment and social performance of Member States, to drive reforms at national, regional and local level and to reconcile the 'social' and the 'market' in today's modern economy, including by promoting the social economy. On 4 March 2021, the Commission put forward an Action Plan for the implementation of the European Pillar of Social Rights (the 'Action Plan'), including ambitious yet realistic headline targets and complementary sub-targets for 2030, in the areas of employment, skills, education and poverty reduction, as well as the revised Social Scoreboard.

(9) On 8 May 2021, at the Porto Social Summit, Heads of State or Government recognised the European Pillar of Social Rights as a fundamental element of the recovery, noting that its implementation will strengthen the Union's drive towards a digital, green and fair transition and contribute to achieving upward social and economic convergence and addressing demographic challenges. They stressed that the social dimension, social dialogue and the active involvement of social partners are at the core of a highly competitive social market economy. They found that the Action Plan provides useful guidance for the implementation of the European Pillar of Social Rights, including in the areas of employment, skills, health and social protection. They welcomed the new Union headline targets for 2030 on employment (at least 78 % of the population aged 20-64 should be in employment), skills (at least 60 % of

([22]) Regulation (EU) 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Facility (OJ L 57, 18.2.2021, p. 17).

([23]) Regulation (EU) 2021/1057 of the European Parliament and of the Council of 24 June 2021 establishing the European Social Fund Plus (ESF+) and repealing Regulation (EU) No 1296/2013 (OJ L 231, 30.6.2021, p. 21).

([24]) Regulation (EU) 2021/1058 of the European Parliament and of the Council of 24 June 2021 on the European Regional Development Fund and on the Cohesion Fund (OJ L 231 30.6.2021, p. 60).

([25]) Regulation (EU) 2021/1056 of the European Parliament and of the Council of 24 June 2021 establishing the Just Transition Fund (OJ L 231, 30.6.2021, p. 1).

([26]) Interinstitutional Proclamation on the European Pillar of Social Rights (OJ C 428, 13.12.2017, p. 10).

all adults should participate in training every year) and poverty reduction (by at least 15 million people, including five million children), as well as the revised Social Scoreboard with a view to monitoring progress towards the implementation of the principles of the European Pillar of Social Rights as part of the policy coordination framework in the context of the European Semester. In addition, the Porto Social Commitment called on Member States to set ambitious national targets which, taking due account of the starting position of each country, should constitute an adequate contribution to the achievement of the Union headline targets for 2030. In Porto, Heads of State or Government noted that, as Europe gradually recovers from the COVID-19 pandemic, the priority will be to move from protecting to creating jobs and improving job quality, and stressed that implementation of the principles of the European Pillar of Social Rights will be essential to ensure the creation of more and better jobs for all within the framework of an inclusive recovery.

They emphasised their commitment to unity and solidarity, which also means ensuring equal opportunities for all and that no one is left behind. They affirmed their determination, as established by the European Council's Strategic Agenda 2019-2024, to continue deepening the implementation of the European Pillar of Social Rights at Union and national levels, with due regard for respective competences and the principles of subsidiarity and proportionality. Lastly, they stressed the importance of closely following, including at the highest level, the progress achieved towards the implementation of the European Pillar of Social Rights and the Union headline targets for 2030.

(10) Following the Russian invasion of Ukraine, the European Council, in its conclusions of 24 February 2022, condemned Russia's actions, which seek to undermine European and global security and stability, and expressed solidarity with the Ukrainian people, underlining the violation of international law and the principles of the United Nations Charter. In the current context, temporary protection, as granted by Council Implementing Decision (EU) 2022/382 ([27]) activating Directive 2001/55/EC, is necessary in light of the scale of the influx of refugees and displaced persons. This allows persons displaced from Ukraine to enjoy harmonised rights across the Union that offer an adequate level of protection. By participating in Europe's labour markets, persons displaced from Ukraine can contribute to strengthening the Union's economy and help support their country and people at home. In the future, the acquired experience and skills can contribute to rebuilding Ukraine. For unaccompanied children and teenagers, temporary protection confers the right to legal guardianship and access to childhood education and care. Member States should involve social partners in the design, implementation and evaluation of policy measures aimed at addressing the employment and skills challenges, including the recognition of qualifications, stemming from the Russia's war of aggression against Ukraine. Social partners play a key role in mitigating the impact of the war in terms of preserving employment and production.

(11) Reforms to the labour market, including national wage-setting mechanisms, should respect national practices of social dialogue and the autonomy of the social partners, with a view to providing fair wages that enable a decent standard of living and sustainable growth and upward socioeconomic convergence. They should allow for the necessary opportunity for a broad consideration of socioeconomic factors, including improvements in sustainability, competitiveness, innovation, the creation of quality jobs, working conditions, in-work poverty, education, training and skills, public health and social inclusion, as well as real incomes. In that regard, the Recovery and Resilience Facility and other Union funds are supporting Member States in implementing reforms and investments that are in line with the Union's priorities, making European economies and societies more sustainable, resilient and better prepared for the green and digital transitions in the post-COVID-19 pandemic context. Russia's war of aggression against Ukraine has further aggravated pre-existing socioeconomic challenges from the COVID-19 pandemic. Member States and the Union should continue to ensure that the social, employment and economic impacts are mitigated and that transitions are socially fair and just, also in light of the fact that increased open strategic autonomy and an accelerated green transition will help reduce the dependence on imports of energy and other strategic products and technologies, in particular from Russia. Strengthening resilience and pursuing an inclusive and resilient society in which people are protected and empowered to anticipate and manage change, and in which they can actively participate in society and the economy, are essential.

([27]) Council Implementing Decision (EU) 2022/382 of 4 March 2022 establishing the existence of a mass influx of displaced persons from Ukraine within the meaning of Article 5 of Directive 2001/55/EC, and having the effect of introducing temporary protection (OJ L 71, 4.3.2022, p. 1).

A coherent set of active labour market policies, consisting of temporary hiring and transition incentives, skills policies and improved employment services, is needed to support labour market transitions, also in light of the green and digital transformations, as highlighted in Commission Recommendation (EU) 2021/402 and in Council Recommendation of 16 June 2022 on ensuring a fair transition towards climate neutrality. Decent working conditions, including occupational health and safety, and both the physical and mental health of workers should be promoted.

(12) Discrimination in all its forms should be tackled, gender equality ensured and employment of young people supported. Equal access and opportunities for all should be ensured and poverty and social exclusion, in particular that of children, persons with disabilities and the Roma people, should be reduced, in particular by ensuring an effective functioning of labour markets and adequate and inclusive social protection systems, as set out in Council Recommendation of 8 November 2019, and by removing barriers to inclusive and future-oriented education, training, lifelong learning and labour-market participation, including through investments in early childhood education and care, in line with the European Child Guarantee, and in digital and green skills. Timely and equal access to affordable long-term care and healthcare services, including prevention and healthcare promotion, are particularly relevant, also in light of the COVID-19 pandemic that started in 2020 and in a context of ageing societies. The potential of persons with disabilities to contribute to economic growth and social development should be further realised. As new economic and business models take hold in workplaces throughout the Union, employment relationships are also changing. Member States should ensure that employment relationships stemming from new forms of work maintain and strengthen Europe's social model.

(13) The Integrated Guidelines should serve as a basis for country-specific recommendations that the Council may address to Member States. Member States are to make full use of their REACT-EU resources established by Regulation (EU) 2020/2221 of the European Parliament and of the Council ([28]), which reinforces the 2014-2020 cohesion policy funds and the Fund for European Aid to the Most Deprived (FEAD) until 2023. Due to the current Ukrainian crisis, Regulation (EU) 2020/2221 has been further complemented by Regulation (EU) 2022/562 of the European Parliament and of the Council ([29]), as well as by a further amendment to Regulation (EU) 2021/1060 of the European Parliament and of the Council ([30]) concerning increased pre-financing for REACT-EU, and by a new unit cost in order to help accelerate the integration of people leaving Ukraine and entering the Union as provided for in Regulation (EU) 2022/613 of the European Parliament and of the Council ([31]).

In addition, for the 2021-2027 programming period, Member States should make full use of the European Social Fund Plus, the European Regional Development Fund, the Recovery and Resilience Facility and other Union funds, including the Just Transition Fund as well as the InvestEU established by Regulation (EU) 2021/523 of the European Parliament and of the Council ([32]), to foster quality employment and social investments, to fight poverty and social exclusion, to combat discrimination, to ensure accessibility, and to promote upskilling and reskilling opportunities of the workforce, lifelong learning and high-quality education and training for all, including digital literacy and skills in order to empower them with the knowledge and qualifications required for a digital and green economy. Member

([28]) Regulation (EU) 2020/2221 of the European Parliament and of the Council of 23 December 2020 amending Regulation (EU) No 1303/2013 as regards additional resources and implementing arrangements to provide assistance for fostering crisis repair in the context of the COVID-19 pandemic and its social consequences and for preparing a green, digital and resilient recovery of the economy (REACT-EU) (OJ L 437, 28.12.2020, p. 30).

([29]) Regulation (EU) 2022/562 of the European Parliament and of the Council of 6 April 2022 amending Regulations (EU) No 1303/2013 and (EU) No 223/2014 as regards Cohesion's Action for Refugees in Europe (CARE) (OJ L 109, 8.4.2022, p. 1).

([30]) Regulation (EU) 2021/1060 of the European Parliament and of the Council of 24 June 2021 laying down common provisions on the European Regional Development Fund, the European Social Fund Plus, the Cohesion Fund, the Just Transition Fund and the European Maritime, Fisheries and Aquaculture Fund and financial rules for those and for the Asylum, Migration and Integration Fund, the Internal Security Fund and the Instrument for Financial Support for Border Management and Visa Policy (OJ L 231, 30.6.2021, p. 159).

([31]) Regulation (EU) 2022/613 of the European Parliament and of the Council of 12 April 2022 amending Regulations (EU) No 1303/2013 and (EU) No 223/2014 as regards increased pre-financing from REACT-EU resources and the establishment of a unit cost (OJ L 115, 13.4.2022, p. 38).

([32]) Regulation (EU) 2021/523 of the European Parliament and of the Council of 24 March 2021 establishing the InvestEU Programme and amending Regulation (EU) 2015/1017 (OJ L 107, 26.3.2021, p. 30).

States are also to make full use of the European Globalisation Adjustment Fund for Displaced Workers established by Regulation (EU) 2021/691 of the European Parliament and of the Council ([33]) to support workers made redundant as a result of major restructuring events, such as the COVID-19 pandemic, socioeconomic transformations that are the result of more global trends, and technological and environmental changes. While the Integrated Guidelines are addressed to Member States and the Union, they should be implemented in partnership with all national, regional and local authorities, closely involving parliaments, as well as the social partners and representatives of civil society.

(14) The Employment Committee and the Social Protection Committee are to monitor how the relevant policies are implemented in light of the guidelines for employment policies, in line with their respective Treaty-based mandates. Those committees and other Council preparatory bodies involved in the coordination of economic and social policies are to work closely together. Policy dialogue between the European Parliament, the Council and the Commission should be maintained, in particular as regards the guidelines for the employment policies of the Member States.

(15) The Social Protection Committee was consulted,

HAS ADOPTED THIS DECISION:

Article 1

The guidelines for the employment policies of the Member States (the 'Guidelines'), as set out in the Annex, are hereby adopted. The Guidelines shall form part of the Integrated Guidelines.

Article 2

The Member States shall take the Guidelines into account in their employment policies and reform programmes, which shall be reported in accordance with Article 148(3) TFEU.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 21 November 2022.

For the Council
The President
Z. NEKULA

([33]) Regulation (EU) 2021/691 of the European Parliament and of the Council of 28 April 2021 on the European Globalisation Adjustment Fund for Displaced Workers (EGF) and repealing Regulation (EU) No 1309/2013 (OJ L 153, 3.5.2021, p. 48).

ANNEX

Guideline 5: Boosting the demand for labour

Member States should actively promote a sustainable social market economy and facilitate and support investment in the creation of quality jobs, also taking advantage of the potential linked to the digital and green transitions, in light of the Union headline target for 2030 on employment. To that end, they should reduce the barriers that businesses face in hiring people, foster responsible entrepreneurship and genuine self-employment and, in particular, support the creation and growth of micro, small and medium-sized enterprises, including through access to finance. Member States should actively promote the development and tap into the full potential of the social economy, foster social innovation and social enterprises, and encourage those business models creating quality job opportunities and generating social benefits, notably at local level, in particular in the circular economy and in territories most affected by the transition to a green economy due to their sectoral specialisation.

Following the COVID-19 pandemic, well-designed short-time work schemes and similar arrangements should also facilitate and support restructuring processes, on top of preserving employment, when appropriate, helping to modernise the economy, including via associated skills development. Well-designed hiring and transition incentives and upskilling and reskilling measures should be considered in order to support job creation and transitions throughout the working life, and to address labour and skill shortages, also in light of the digital and green transformations, demographic change, as well as of the impact of Russia's war of aggression against Ukraine.

Taxation should be shifted away from labour to other sources more supportive of employment and inclusive growth and in line with climate and environmental objectives, taking account of the redistributive effect of the tax system, as well as its effects on women's participation in the labour market, while protecting revenue for adequate social protection and growth-enhancing expenditure.

Member States, including those with statutory minimum wages, should promote collective bargaining with a view to wage setting and ensure an effective involvement of social partners in a transparent and predictable manner, allowing for an adequate responsiveness of wages to productivity developments and fostering fair wages that enable a decent standard of living, paying particular attention to lower and middle income groups with a view to strengthening upward socioeconomic convergence. Wage-setting mechanisms should take into account socioeconomic conditions, including employment growth, competitiveness and regional and sectoral developments. Respecting national practices and the autonomy of the social partners, Member States and social partners should ensure that all workers have adequate wages by benefitting, directly or indirectly, from collective agreements or adequate statutory minimum wages, taking into account their impact on competitiveness, job creation and in-work poverty.

Guideline 6: Enhancing labour supply and improving access to employment, lifelong acquisition of skills and competences

In the context of the digital and green transitions, demographic change and Russia's war of aggression against Ukraine, Member States should promote sustainability, productivity, employability and human capital, fostering acquisition of skills and competences throughout people's lives and responding to current and future labour market needs, in light of the Union headline target for 2030 on skills. Member States should also modernise and invest in their education and training systems to provide high quality and inclusive education, including vocational education and training, access to digital learning, language training (e.g. in the case of refugees including from Ukraine) and acquisition of entrepreneurial skills. Member States should work together with the social partners, education and training providers, enterprises and other stakeholders to address structural weaknesses in education and training systems and improve their quality and labour-market relevance, also with a view to enabling the green and digital transitions, addressing existing skills mismatches and preventing the emergence of new shortages, in particular for activities related to REPowerEU, such as renewable energy deployment or buildings' renovation.

Particular attention should be paid to challenges faced by the teaching profession, including by investing in teachers' and trainers' digital competences. Education and training systems should equip all learners with key competences, including basic and digital skills as well as transversal competences, to lay the foundations for adaptability and resilience throughout life, while ensuring that teachers are prepared to foster those competencies in learners. Member States should support working age adults in accessing training and increase individuals' incentives and motivation to seek training including, where appropriate, through individual training entitlements, such as individual learning accounts, and ensuring their

transferability during professional transitions, as well as through a reliable system of training quality assessment. Member States should explore the use of micro-credentials to support lifelong learning and employability. They should enable everyone to anticipate and better adapt to labour-market needs, in particular through continuous upskilling and reskilling and the provision of integrated guidance and counselling, with a view to supporting fair and just transitions for all, strengthening social outcomes, addressing labour-market shortages and skills mismatches, improving the overall resilience of the economy to shocks and making potential adjustments easier.

Member States should foster equal opportunities for all by addressing inequalities in education and training systems. In particular, children should be provided access to affordable and good quality early childhood education and care, in line with the European Child Guarantee. Member States should raise overall qualification levels, reduce the number of early leavers from education and training, support access to education of children from disadvantaged groups and remote areas, increase the attractiveness of vocational education and training (VET), support access to and completion of tertiary education, facilitate the transition from education to employment for young people through quality traineeships and apprenticeships, as well as increase adult participation in continuing learning, particularly among learners from disadvantaged backgrounds and the least qualified. Taking into account the new requirements of digital, green and ageing societies, Member States should strengthen work-based learning in their VET systems, including through quality and effective apprenticeships, and increase the number of science, technology, engineering and mathematics (STEM) graduates both in VET and in tertiary education, especially women. Furthermore, Member States should enhance the labour-market relevance of tertiary education and, where appropriate, research; improve skills monitoring and forecasting; make skills more visible and qualifications comparable, including those acquired abroad; and increase opportunities for recognising and validating skills and competences acquired outside formal education and training, including for refugees and persons under a temporary protection status. They should upgrade and increase the supply and uptake of flexible continuous VET. Member States should also support low-skilled adults to maintain or develop their long-term employability by boosting access to and uptake of quality learning opportunities, through the implementation of Council Recommendation of 19 December 2016 on Upskilling Pathways, including a skills assessment, an offer of education and training matching labour-market opportunities, and the validation and recognition of the skills acquired.

Member States should provide unemployed and inactive people with effective, timely, coordinated and tailor-made assistance based on support for job searches, training, requalification and access to other enabling services, paying particular attention to vulnerable groups and people particularly affected by the green and digital transitions or labour market shocks. Comprehensive strategies that include in-depth individual assessments of unemployed people should be pursued as soon as possible, at the latest after 18 months of unemployment, with a view to significantly reducing and preventing long-term and structural unemployment. Youth unemployment and the issue of young people not in employment, education or training (NEETs) should continue to be addressed through prevention of early leaving from education and training and structural improvement of the school-to-work transition, including through the full implementation of the reinforced Youth Guarantee, which should also support quality youth employment opportunities in the post-pandemic recovery. In addition, Member States should boost efforts notably at highlighting how the green and digital transitions offer a renewed perspective for the future and opportunities to counter the negative impact of the pandemic on young people.

Member States should aim to remove barriers and disincentives to, and provide incentives for, participation in the labour market, in particular for low-income earners, second earners (often women) and those furthest from the labour market, including people with a migrant background and marginalised Roma people. In view of high labour shortages in certain occupations and sectors, Member States should contribute to fostering labour supply, notably through promoting adequate wages and decent working conditions, as well as effective active labour market policies, respecting the role of social partners. Member States should also support a work environment adapted for persons with disabilities, including through targeted financial support and services that enable them to participate in the labour market and in society.

The gender employment and pay gaps as well as gender stereotypes should be tackled. Member States should ensure gender equality and increased labour market participation of women, including through ensuring equal opportunities and career progression and eliminating barriers to access to leadership at all levels of decision making, as well as by tackling violence and harassment at work which is a problem that mainly affects women. Equal pay for equal work, or work of equal value,

and pay transparency should be ensured. The reconciliation of work, family and private life for both women and men should be promoted, in particular through access to affordable, quality long-term care and early childhood education and care services. Member States should ensure that parents and other people with caring responsibilities have access to suitable family-related leave and flexible working arrangements in order to balance work, family and private life, and promote a balanced use of those entitlements between parents.

Guideline 7: Enhancing the functioning of labour markets and the effectiveness of social dialogue

In order to benefit from a dynamic and productive workforce and new work patterns and business models, Member States should work together with the social partners on fair, transparent and predictable working conditions, balancing rights and obligations. They should reduce and prevent segmentation within labour markets, fight undeclared work and bogus self-employment, and foster the transition towards open-ended forms of employment. Employment protection rules, labour law and institutions should all provide both a suitable environment for recruitment and the necessary flexibility for employers to adapt swiftly to changes in the economic context, while protecting labour rights and ensuring social protection, an appropriate level of security, and healthy, safe and well-adapted working environments for all workers. Promoting the use of flexible working arrangements such as teleworking can contribute to higher employment levels and more inclusive labour markets in the context of the post-pandemic environment. At the same time, it is important to ensure that the workers' rights in terms of working time, working conditions, mental health at work and work-life balance are respected. Employment relationships that lead to precarious working conditions should be prevented, including in the case of platform workers, especially if low-skilled, and by fighting abuse of atypical contracts. Access to effective, impartial dispute resolution and a right to redress, including adequate compensation, where applicable, should be ensured in cases of unfair dismissal.

Policies should aim to improve and support labour-market participation, matching and transitions, including in disadvantaged regions. Member States should effectively activate and enable those who can participate in the labour market, especially vulnerable groups such as lower-skilled people, persons with disabilities, people with a migrant background, including persons under a temporary protection status, and marginalised Roma people. Member States should strengthen the scope and effectiveness of active labour-market policies by increasing their targeting, outreach and coverage and by better linking them with social services, training and income support for the unemployed, whilst they are seeking work and based on their rights and responsibilities. Member States should enhance the capacity of public employment services to provide timely and tailor-made assistance to jobseekers, respond to current and future labour-market needs, and implement performance-based management, supported also via digitalisation.

Member States should provide the unemployed with adequate unemployment benefits of reasonable duration, in line with their contributions and national eligibility rules. Unemployment benefits should not disincentivise a prompt return to employment and should be accompanied by active labour market policies.

The mobility of learners and workers should be adequately supported with the aim of enhancing their skills and employability and exploiting the full potential of the European labour market, while also ensuring fair conditions for all those pursuing a cross-border activity and stepping up administrative cooperation between national administrations with regard to mobile workers, benefitting from the assistance of the European Labour Authority. The mobility of workers in critical occupations and of cross-border, seasonal and posted workers should be supported in the case of temporary border closures triggered by public health considerations.

Member States should also strive to create the appropriate conditions for new forms of work, delivering on their job-creation potential while ensuring they are compliant with existing social rights. Member States should thus provide advice and guidance on the rights and obligations which apply in the context of atypical contracts and new forms of work, such as work through digital platforms. In this regard, social partners can play an instrumental role and Member States should support them in reaching out and representing people in atypical and platform work. Member States should also consider providing support for enforcement – such as guidelines or dedicated trainings for labour inspectorates – concerning the challenges stemming from new forms of organising work, such as algorithmic management, data surveillance and permanent or semi-permanent telework.

Building on existing national practices, and in order to achieve more effective social dialogue and better socioeconomic outcomes, including in times of crisis, as in the case of Russia's war of aggression against Ukraine and the rising cost of living, Member States should ensure the timely and meaningful involvement of the social partners in the design and implementation of employment, social and, where relevant, economic reforms and policies, including by supporting increased capacity of the social partners. Member States should foster social dialogue and collective bargaining. The social partners should be encouraged to negotiate and conclude collective agreements in matters relevant to them, fully respecting their autonomy and the right to collective action.

Where relevant, and building on existing national practices, Member States should take into account the relevant experience of civil society organisations' in employment and social issues.

Guideline 8: Promoting equal opportunities for all, fostering social inclusion and fighting poverty

Member States should promote inclusive labour markets, open to all, by putting in place effective measures to fight all forms of discrimination and promote equal opportunities for all, and in particular for groups that are under-represented in the labour market, with due attention to the regional and territorial dimension. They should ensure equal treatment with regard to employment, social protection, healthcare, childcare, long-term care, education and access to goods and services, including housing, regardless of gender, racial or ethnic origin, religion or belief, disability, age or sexual orientation.

Member States should modernise social protection systems to provide adequate, effective, efficient and sustainable social protection for all, throughout all stages of life, fostering social inclusion and upward social mobility, incentivising labour market participation, supporting social investment, fighting poverty and social exclusion and addressing inequalities, including through the design of their tax and benefit systems and by assessing the distributional impact of policies. Complementing universal approaches with targeted ones will improve the effectiveness of social protection systems. The modernisation of social protection systems should also aim to improve their resilience to multi-faceted challenges. Particular attention should be paid to the most vulnerable households affected by the green and digital transitions and by rising energy costs.

Member States should develop and integrate the three strands of active inclusion: adequate income support, inclusive labour markets and access to quality enabling services, to meet individual needs. Social protection systems should ensure adequate minimum income benefits for everyone lacking sufficient resources and promote social inclusion by supporting and encouraging people to actively participate in the labour market and society, including through targeted provision of social services.

The availability of affordable, accessible and quality services such as early childhood education and care, out-of-school care, education, training, housing, and health and long-term care is a necessary condition for ensuring equal opportunities. Particular attention should be given to fighting poverty and social exclusion, including in-work poverty, in line with the Union headline target for 2030 on poverty reduction. Child poverty and social exclusion should be especially addressed by comprehensive and integrated measures, including through the full implementation of the European Child Guarantee.

Member States should ensure that everyone, including children, has access to essential services of good quality. For those in need or in a vulnerable situation, Member States should ensure access to adequate social housing or housing assistance. They should ensure a clean and fair energy transition and address energy poverty as an increasingly important form of poverty due to rising energy prices, partly linked to Russia's war of aggression against Ukraine, including, where appropriate, via targeted temporary income support measures or by adapting existing support measures. Inclusive housing renovation policies should also be implemented. The specific needs of persons with disabilities, including accessibility, should be taken into account in relation to those services. Homelessness should be tackled specifically. Member States should ensure timely access to affordable preventive and curative health care and long-term care of good quality, while safeguarding sustainability in the long term.

In line with the activation of Council Directive 2001/55/EC [1], Member States should offer an adequate level of protection to displaced persons from Ukraine. For unaccompanied minors, Member States should implement the necessary measures. Children should be ensured access to childhood education and care and essential services in line with the European Child Guarantee.

In a context of increasing longevity and demographic change, Member States should secure the adequacy and sustainability of pension systems for workers and the self-employed, providing equal opportunities for women and men to acquire and accrue pension rights, including through supplementary schemes to ensure an adequate income in old age. Pension reforms should be supported by policies that aim to reduce the gender pension gap and measures that extend working lives, such as by raising the effective retirement age, notably by facilitating labour market participation of older persons, and should be framed within active ageing strategies. Member States should establish a constructive dialogue with social partners and other relevant stakeholders, and allow for an appropriate phasing in of the reforms.

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[1] Council Directive 2001/55/EC of 20 July 2001 on minimum standards for giving temporary protection in the event of a mass influx of displaced persons and on measures promoting a balance of efforts between Member States in receiving such persons and bearing the consequences thereof (OJ L 212, 7.8.2001, p. 12).

COMMISSION IMPLEMENTING DECISION (EU) 2022/2297

of 19 October 2022

setting up the European Solar Research Infrastructure for Concentrated Solar Power (EU-SOLARIS ERIC)

(notified under document C(2022) 7351)

(Only the French, German, Greek, Portuguese and Spanish texts are authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 723/2009 of 25 June 2009 on the Community legal framework for a European Research Infrastructure Consortium (ERIC) ([1]), and in particular Article 6(1), point (a) thereof,

Whereas:

(1) Germany, Spain, France, Cyprus and Portugal, submitted to the Commission an application to set up the European Solar Research Infrastructure for Concentrated Solar Power (EU-SOLARIS ERIC) ('the application'). Portugal has made known its decision to participate in EU-SOLARIS ERIC initially as an observer.

(2) The applicants have agreed that Spain would be the host Member State of EU-SOLARIS ERIC.

(3) Regulation (EC) No 723/2009 has been incorporated in the Agreement on the European Economic Area (EEA) by Decision of the EEA Joint Committee No 72/2015 ([2]).

(4) The Commission has, pursuant to Article 5(2) of Regulation (EC) No 723/2009, assessed the application and concluded that it meets the requirements set out in that Regulation. In the course of the assessment, the Commission obtained the views of independent experts in the field of Solar Research Infrastructure for Concentrated Solar Power.

(5) The measures set out in this Decision are in accordance with the opinion of the Committee established under Article 20 of Regulation (EC) No 723/2009,

HAS ADOPTED THIS DECISION:

Article 1

1. The European Solar Research Infrastructure for Concentrated Solar Power (EU-SOLARIS ERIC) is hereby set up.

2. The essential elements of the Statutes of EU-SOLARIS ERIC are set out in the Annex.

Article 2

This Decision is addressed to the Federal Republic of Germany, the Kingdom of Spain, the French Republic, the Republic of Cyprus and the Portuguese Republic.

([1]) OJ L 206, 8.8.2009, p. 1.

([2]) Decision of the EEA Joint Committee No 72/2015 of 20 March 2015 amending Protocol 31 to the EEA Agreement, on cooperation in specific fields outside the four freedoms [2016/755] (OJ L 129, 19.5.2016, p. 85).

Done at Brussels, 19 October 2022.

For the Commission
Mariya GABRIEL
Member of the Commission

ANNEX

ESSENTIAL ELEMENTS OF THE STATUTES OF EU-SOLARIS ERIC

The following Articles and paragraphs of the Articles of the Statutes of EU-SOLARIS ERIC provide for the essential elements in accordance with Article 6(3) of Council Regulation (EC) No 723/2009.

1. **Name and seat (Article 1 of the Statutes of EU-SOLARIS ERIC)**

1. A European Research Infrastructure Consortium (ERIC) is created, under the name of 'European Solar Research Infrastructure for Concentrated Solar Power' (hereinafter, 'EU-SOLARIS ERIC'), pursuant to the provisions of Council Regulation (EC) No 723/2009, of 25 June 2009, on the Community legal framework for a European Research Infrastructure (hereinafter 'the ERIC Regulation').

2. The statutory seat of EU-SOLARIS ERIC is established in Almería, Spain.

2. **Vision, mission and strategic objectives (Article 2 of the Statutes of EU-SOLARIS ERIC)**

1. EU-SOLARIS ERIC shall establish and operate a world-class distributed research infrastructure on Concentrated Solar Power/Solar Thermal Energy (CSP/STE) to be set up as a central hub responsible for the coordinated operation of national research centres in CSP/STE technologies, which shall dedicate part of their research and development capacities to EU-SOLARIS ERIC, sharing contents, tools and know-how related to CSP/STE technologies.

2. All research facilities that are part of the ERIC will remain property of their institutions as well as the rights to handle the access to them and the conditions under which it is granted.

3. The relationship between EU-SOLARIS ERIC and the national research centres shall be regulated through signature of specific Service-Level Agreements.

4. To that end, the following constitute the purposes and objectives of EU-SOLARIS ERIC.

5. Vision: To become the European reference research infrastructure in the technological development of CSP/STE and related applications

6. Mission: To offer the best conditions for the development of CSP/STE research activities for the scientific and industrial communities

7. Strategic objectives:

a) To coordinate, as a unique infrastructure of distributed character, main existing R & D installations in Europe, providing the most complete and high quality scientific infrastructure portfolio at international level to the CSP/STE sector.

b) To establish a single entry point where highly specialised facilities, resources and research services are effectively and optimally offered to users demanding CSP/STE related services.

c) To reinforce the collaboration between the scientific institutions, academia and industry, also fostering collaborative research among main European research centres of the sector.

d) To identify new requirements for the improvement of the research facilities, and for the construction of new ones (when needed), also optimizing and promoting the specialization of existing ones avoiding unnecessary technological duplication and repetition.

e) To identify and establish the best research and experimental practices, leading and coordinating the open dissemination of results and experimental data whenever possible, thus contributing to the reinforcement of the European leadership position at an international level.

f) To maintain Europe at the forefront and leadership of CSP/STE technologies development.

3. **Tasks and activities (Article 3 of the Statutes of EU-SOLARIS ERIC)**

1. In order to fulfil its purposes and objectives, EU-SOLARIS ERIC shall, directly or via third parties, engage in the following activities:

a) grant effective access to resources and services made available by the National Nodes, in accordance with the rules established in these Statutes, for the European research and industrial community;

b) improve the interoperability between the Research Centres specialised in the field of CSP/STE technologies of the Members and Observers;

c) establish and apply technological advances related to resources and services associated to CSP/STE;

d) enter into collaboration agreements with third parties;

e) provide training and facilitate the mobility of researchers in order to reinforce and structure the European Research Area;

f) establish international relations with other organizations and authorities, public or private, European and non-European, interested in its activities and in related fields;

g) coordinate activities with other European R & D actors in the field of CSP/STE;

h) any other activities required to fulfil EU-SOLARIS ERIC's purposes and objectives.

2. EU-SOLARIS ERIC shall offer access to a portfolio of research facilities and joint research and development activities through a coordinated, long-term development program among National Nodes for non-economic purposes. Nevertheless, EU-SOLARIS ERIC may engage in limited profit-making activities, provided that:

a) they are closely linked to its main activities, set out in these Statutes; and

b) they do not jeopardize achieving EU-SOLARIS ERIC's purposes or objectives.

3. EU-SOLARIS ERIC shall record the costs and revenues of these economic activities separately and shall charge market prices for them. Any income generated by these economic activities shall be used to further its purposes.

4. **Duration and commencement of operations (Article 4 of the Statutes of EU-SOLARIS ERIC)**

Without prejudice to the provisions of these Statutes on the winding-up and liquidation of EU-SOLARIS ERIC, it shall exist for an indefinite period of time.

5. **Liability and insurance (Article 5 of the Statutes of EU-SOLARIS ERIC)**

1. EU-SOLARIS ERIC shall be responsible for its debts generated as a result of its activity.

2. The financial liability of the members for the debts of the ERIC shall be limited to their respective contributions provided to the ERIC.

3. EU-SOLARIS ERIC shall take out and maintain appropriate insurance to cover any risk relating to the operation of the ERIC.

6. **Procedure for winding-up and liquidation of EU-SOLARIS ERIC (Article 6 of the Statutes of EU-SOLARIS ERIC)**

1. EU-SOLARIS ERIC shall inform the European Commission, via the Managing Director, of any facts which might seriously undermine the purpose of EU-SOLARIS ERIC or obstruct its capacity to fulfil the conditions established in the ERIC Regulation.

2. In particular, EU-SOLARIS ERIC shall be wound up and liquidated in any of the following events:

   a) as a result of a resolution adopted by the General Assembly, by the majority established in these Statutes; or

   b) as a result of a decision given by the European Commission, in the terms provided for in the ERIC Regulation.

3. The procedure will be as follows:

   a) EU-SOLARIS ERIC's Managing Director shall inform the European Commission of the General Assembly's decision to wind-up and liquidate EU-SOLARIS ERIC, within ten (10) days subsequent to the date on which the resolution is adopted.

   b) Without prejudice to Article 5 of the Statutes, any assets and liabilities remaining after payment of the EU-SOLARIS ERIC's debts shall be apportioned among the Members in proportion to their accumulated contribution to EU-SOLARIS ERIC at the time of dissolution.

   c) EU-SOLARIS ERIC's Managing Director shall inform the European Commission of the completion of the process to wind-up and liquidate EU-SOLARIS ERIC, within ten (10) days as of the completion of such process.

   d) EU-SOLARIS ERIC shall cease to exist on the day on which the European Commission publishes the appropriate notice in the *Official Journal of the European Union*

   e) If at any time during its existence, EU-SOLARIS ERIC is unable to pay its debts, it shall immediately notify the European Commission in accordance with Article 16(4) of Regulation (EC) No 723/2009.

7. **User access policy (Article 7 of the Statutes of EU-SOLARIS ERIC)**

1. EU-SOLARIS ERIC shall promote scientific merit-based access to the services and infrastructures that support and encourage excellence in research in the field of activity of EU-SOLARIS ERIC, as well as a culture of practical improvements through training activities.

2. Access to EU-SOLARIS-ERIC shall be open to all types of users, including from all European and non-European countries, not necessarily for free. Requests will undergo a streamlined process involving eligibility and feasibility checks according to the procedures and evaluation criteria.

3. The procedures and evaluation criteria that grant or limit access to the data and tools of EU-SOLARIS ERIC's infrastructure, and the cost of such access, shall be defined in the access rules or in the internal regulations which shall be drawn up by the Managing Director and approved by the General Assembly, having consulted the Scientific & Technical Committee (STC) and the Board of National Nodes (BNN).

4. Procedures and evaluation criteria shall be made publicly available on the website of EU-SOLARIS ERIC.

5. EU-SOLARIS ERIC shall provide the users of the infrastructure of EU-SOLARIS ERIC with access rules and guidelines to guarantee that the research undertaken using EU-SOLARIS ERIC's infrastructure resources belonging to Research Centres of Member countries (as stated in Article 2 of the Statutes), recognizes and honours the property rights, privacy, ethics and protection of the owner's research infrastructure and data, as well as the obligations on secrecy and confidentiality, and that users comply with the conditions for access, the security measures and the management of the information of the research institutions that participate in EU-SOLARIS ERIC infrastructure.

8. **Scientific evaluation policy (Article 8 of the Statutes of EU-SOLARIS ERIC)**

The procedure for the scientific assessment of the projects that seek access to the infrastructure of EU-SOLARIS ERIC shall take into account the scientific merit, the unmet needs of the sector and the potential use and impact in the sector, and shall be based on the principles of transparency, equity and impartiality. Such procedure shall be defined in internal regulations, which shall be drawn up by the Managing Director and approved by the General Assembly, having consulted the STC and the BNN.

9. **Dissemination policy (Article 9 of the Statutes of EU-SOLARIS ERIC)**

1. EU-SOLARIS ERIC shall take appropriate measures to promote its infrastructure and its use in research and in any service related to EU-SOLARIS ERIC's objectives.

2. EU-SOLARIS ERIC shall promote the dissemination and exchange of the results obtained through use of its research infrastructure.

3. Without prejudice to potential Intellectual Property Rights, EU-SOLARIS ERIC shall ensure that its users make available to the public the results of the research carried out at the ERIC infrastructures and that they do so via EU-SOLARIS ERIC, in accordance with European and national grant terms and conditions. This will not apply to R & D activities carried out by the Research Centres when using their own infrastructures out of the scope of the ERIC.

4. The dissemination policy shall define the different groups of targets and EU-SOLARIS ERIC shall use all of the channels within its scope to ensure maximum dissemination amongst them.

10. **Intellectual Property Rights policy (Article 10 of the Statutes of EU-SOLARIS ERIC)**

1. Any and all Intellectual Property Rights (hereinafter 'IPR'), which are created, obtained or developed by EU-SOLARIS ERIC shall vest in and be owned absolutely by EU-SOLARIS ERIC. Nevertheless, limited Data Proprietary periods can be awarded to users.

2. Without prejudice to the conditions established in the contracts entered into between EU-SOLARIS ERIC and Members or Observers, all of the IPR created, arising, obtained or developed by the staff of a Member or Observer shall belong to that Member or Observer.

3. With respect to questions of IPR, the relations between the Members and Observers of EU-SOLARIS ERIC shall be governed by the respective national legislation of Members and Observers and by international agreements to which the Members and Observers are parties.

4. The provisions of these Statutes and the internal regulations shall be without prejudice to the background IPR owned by Members and Observers.

5. The Members of EU-SOLARIS ERIC shall agree and approve, through the General Assembly, the EU-SOLARIS' IPR policy and regulations, under proposal of the Managing Director and having consulted the STC and the BNN. The IPR regulation shall determine the rules of EU-SOLARIS ERIC relating to the identification, protection, management and maintenance of IPR of EU-SOLARIS ERIC, including access to those rights.

6. The BNN may recommend to the Managing Director agreements with the national infrastructure centres and consortiums with regard to the research infrastructure of EU-SOLARIS ERIC, in order to guarantee that such entities, and third parties, have access to the scientific knowledge of EU-SOLARIS ERIC research infrastructure.

11. **Employment policy (Article 11 of the Statutes of EU-SOLARIS ERIC)**

1. EU-SOLARIS ERIC shall comply with the principle of equality and non-discrimination.

2. Consequently, in its policy to recruit personnel, EU-SOLARIS ERIC shall offer equal opportunities and shall refrain from discriminating against persons based on gender, race, beliefs, ideology, disability, sexual orientation or for any other criterion which is deemed to be discriminatory in accordance with Community Law.

3. The Managing Director may propose modifications of internal employment regulations, always under the approval of the General Assembly.

12. **Procurement policy (Article 12 of the Statutes of EU-SOLARIS ERIC)**

1. EU-SOLARIS ERIC shall apply in its procurement fair and non-discriminatory treatment for all the bidders, persons offering goods and persons rendering services. The EU-SOLARIS ERIC procurement policy shall comply with the principles of transparency, non-discrimination and competition.

2. The Managing Director shall establish detailed internal regulations and criteria to ensure transparency, equality and non-discrimination when awarding contracts. Such rules must be approved by the General Assembly.

3. The Managing Director shall be responsible for all of EU-SOLARIS ERIC procurement. To this end, the Managing Director shall comply with the national and European procurement regulations applicable at the time. All of the bids should be published on the website of EU-SOLARIS ERIC. The decision to award a contract should be published and should include full justification.

COMMISSION IMPLEMENTING DECISION (EU) 2022/2298

of 23 November 2022

postponing the expiry date of the approval of propiconazole for use in biocidal products of product-type 8 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 14(5) thereof,

After consulting the Standing Committee on Biocidal Products,

Whereas:

(1) Propiconazole was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council ([2]) as an active substance for use in biocidal products of product-type 8. Pursuant to Article 86 of Regulation (EU) No 528/2012, it was therefore considered approved until 31 March 2020 under that Regulation subject to the requirements set out in Annex I to Directive 98/8/EC.

(2) On 1 October 2018, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of propiconazole for use in biocidal products of product-type 8 ('the application').

(3) On 8 February 2019, the evaluating competent authority of Finland informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of that Regulation, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.

(4) Commission Implementing Decision (EU) 2020/27 ([3]) postponed the expiry date of the approval of propiconazole for use in biocidal products of product-type 8 to 31 March 2021 in order to allow sufficient time for the examination of the application.

(5) Commission Implementing Decision (EU) 2021/354 ([4]) postponed again the expiry date of the approval of propiconazole for use in biocidal products of product-type 8 to 31 December 2022.

(6) On 2 June 2021, the evaluating competent authority submitted the assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency'). Within 270 days of receipt of a recommendation from the evaluating competent authority, the Agency is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.

(7) On 9 March 2022, the Agency adopted its opinion ([5]) on renewal of the approval of propiconazole in accordance with Article 14(3) of Regulation (EU) No 528/2012.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

([3]) Commission Implementing Decision (EU) 2020/27 of 13 January 2020 postponing the expiry date of approval of propiconazole for use in biocidal products of product-type 8 (OJ L 8, 14.1.2020, p. 39).

([4]) Commission Implementing Decision (EU) 2021/354 of 25 February 2021 postponing the expiry date of approval of propiconazole for use in biocidal products of product-type 8 (OJ L 68, 26.2.2021, p. 219).

([5]) Biocidal Products Committee (BPC) opinion on the application for approval of the active substance: propiconazole, Product type: 8, ECHA/BPC/324/2022, adopted on 9 March 2022.

(8) Propiconazole is classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([6]), and therefore meets the exclusion criterion set out in point (c) of Article 5(1) of Regulation (EU) No 528/2012. Furthermore, propiconazole is considered as having endocrine disrupting properties that may cause adverse effects in humans, and therefore meets the exclusion criterion set out in point (d) of Article 5(1) of Regulation (EU) No 528/2012. While the examination to decide whether at least one of the conditions of the first subparagraph of Article 5(2) of that Regulation is fulfilled, and whether the approval of propiconazole may therefore be renewed, is ongoing, it will not be possible to complete this examination before the current expiry of approval.

(9) Consequently, for reasons beyond the control of the applicant, the approval of propiconazole for use in biocidal products of product-type 8 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of the approval for a period of time sufficient to complete the full procedure of the examination of the application. Taking into account the time needed to assess if at least one of the conditions of the first subparagraph of Article 5(2) of Regulation (EU) No 528/2012 is fulfilled, and the time to decide whether to renew the approval of propiconazole for use in biocidal products of product-type 8, the expiry date should be postponed to 31 December 2023.

(10) After the postponement of the expiry date of the approval, propiconazole remains approved for use in biocidal products of product-type 8 subject to the requirements set out in Annex I to Directive 98/8/EC,

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of the approval of propiconazole for use in biocidal products of product-type 8 set out in Implementing Decision (EU) 2021/354 is postponed to 31 December 2023.

Article 2

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

Done at Brussels, 23 November 2022.

For the Commission
The President
Ursula VON DER LEYEN

([6]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

CORRIGENDA

Corrigendum to Council Decision (EU) 2022/1994 of 17 October 2022 on the position to be taken on behalf of the European Union within the Sub-Committee on Geographical Indications established by the Comprehensive and Enhanced Partnership Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Armenia, of the other part, as regards the adoption of its rules of procedure

(Official Journal of the European Union L 273 of 21 October 2022)

On page 20, Council Decision (EU) 2022/1994 should read:

'COUNCIL DECISION (EU) 2022/1994

of 17 October 2022

on the position to be taken on behalf of the European Union within the Sub-Committee on Geographical Indications established by the Comprehensive and Enhanced Partnership Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Armenia, of the other part, as regards the adoption of its rules of procedure

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207(4), first subparagraph, in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The Comprehensive and Enhanced Partnership Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Armenia, of the other part [1] (the "Agreement") was concluded by the Union by means of Council Decision (EU) 2018/104 [2], applied provisionally from 1 June 2018 and entered into force on 1 March 2021.

(2) Pursuant to Article 240(2) of the Agreement, the Sub-Committee on Geographical Indications (the "Sub-Committee") is to determine its own rules of procedure.

(3) It is appropriate to establish the position to be taken on the Union's behalf within the Sub-Committee, as regards its rules of procedure, as those rules will be binding on the Union.

(4) In order to ensure the effective implementation of the Agreement, the rules of procedure of the Sub-Committee should be adopted.

(5) The position of the Union within the Sub-Committee should therefore be based on the draft Decision of that Sub-Committee attached to this Decision,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf within the Sub-Committee on Geographical Indications as regards the adoption of its rules of procedure shall be based on the draft Decision of that Sub-Committee attached to this Decision.

Article 2

This Decision shall enter into force on the date of its adoption.

[1] OJ L 23, 26.1.2018, p. 4.

[2] Council Decision (EU) 2018/104 of 20 November 2017 on the signing, on behalf of the Union, and provisional application of the Comprehensive and Enhanced Partnership Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Armenia, of the other part (OJ L 23, 26.1.2018, p. 1).

Done at Luxembourg, 17 October 2022.

For the Council
The President
J. BORRELL FONTELLES

DRAFT

DECISION No … OF THE EU-ARMENIA SUB-COMMITTEE ON GEOGRAPHICAL INDICATIONS

of …

adopting its rules of procedure

THE EU-ARMENIA SUB-COMMITTEE ON GEOGRAPHICAL INDICATIONS,

Having regard to the Comprehensive and Enhanced Partnership Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Armenia, of the other part [1] (the 'Agreement'), and in particular Article 240 thereof,

Whereas:

(1) Pursuant to Article 240 of the Agreement, the Sub-Committee on Geographical Indications is to monitor the implementation of the Agreement in the field of geographical indications and is to serve as a means to intensify the cooperation and dialogue on geographical indications.

(2) Pursuant to Article 240(2) of the Agreement, the Sub-Committee on Geographical Indications may adopt decisions.

(3) Pursuant to Article 240(2) of the Agreement, the Sub-Committee on Geographical Indications is to determine its own rules of procedure,

HAS ADOPTED THIS DECISION:

Article 1

The rules of procedure of the Sub-Committee on Geographical Indications, as set out in the Annex, are hereby adopted.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels,

For the Sub-Committee on Geographical Indications
The Chair

[1] OJ L 23, 26.1.2018, p. 4.

ANNEX

Rules of procedure of the EU-Armenia Sub-Committee on Geographical Indications

Article 1

General provisions

1. The Sub-Committee on Geographical Indications (the "Sub-Committee"), established in accordance with Article 240 of the Comprehensive and Enhanced Partnership Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Armenia, of the other part (the "Agreement") shall assist the Partnership Committee in trade configuration, established by Article 363(7) of the Agreement, in the performance of its functions.

2. The Sub-Committee shall perform its functions as set out in Article 240 of the Agreement.

3. The Sub-Committee shall be composed of representatives of the European Commission and of the Republic of Armenia, responsible for matters relating to geographical indications.

4. For the purpose of these rules of procedure the "Parties" shall be defined as provided for in Article 382 of the Agreement.

5. The Parties shall each appoint a Head of Delegation who shall be the contact person for all matters relating to the Sub-Committee.

6. The Heads of Delegation shall act as Chair of the Sub-Committee in accordance with Article 2.

7. Each Head of Delegation may delegate all or any of the functions of Head of Delegation to a nominated deputy, in which case all references hereafter to the Head of Delegation apply equally to the nominated deputy. The Head of Delegation shall notify the Secretariat of the Sub-Committee regarding such a nomination.

Article 2

Chairmanship

The Parties shall hold the chairmanship of the Sub-Committee, alternately, for a period of 12 months. The first period shall begin on the date of the first Partnership Council meeting and end on 31 December of the same year.

Article 3

Meetings

1. The Sub-Committee shall meet once a year, unless the Chair decide otherwise, or at the request of either Party, alternately in the Union and in the Republic of Armenia, at a time and a place and in a manner, which may include by videoconference, agreed by the Parties, but no later than 90 days after the request.

2. Each meeting of the Sub-Committee shall be convened by its Chair. The notice of convening the meeting shall be issued by the Secretariat of the Sub-Committee no later than 28 calendar days prior to the start of the meeting, unless the Parties agree otherwise.

3. Whenever possible, the regular meeting of the Sub-Committee shall be convened in advance of the regular meeting of the Partnership Committee in trade configuration.

Article 4

Delegations

Before each meeting, the Parties shall be informed by the Secretariat of the Sub-Committee of the intended composition of the delegation of each Party attending the meeting.

Article 5

Secretariat

1. An official of the European Commission and an official of the Republic of Armenia shall act jointly as Secretaries of the Sub-Committee, as appointed by the Heads of Delegations, and shall execute secretarial tasks in a joint manner, in a spirit of mutual trust and cooperation.

2. The Secretariat of the Partnership Committee in trade configuration shall be informed of any decisions, reports and other agreed actions of the Sub-Committee.

Article 6

Correspondence

1. Correspondence addressed to the Sub-Committee shall be directed to the Secretary of either Party, who in turn shall inform the other Secretary.

2. The Secretariat of the Sub-Committee shall ensure that correspondence addressed to the Sub-Committee is forwarded to the Chair of the Sub-Committee and circulated, where appropriate, as documents referred to in Article 7.

3. Correspondence from the Chair shall be sent to the Parties by the Secretariat on behalf of the Chair. Such correspondence shall be circulated, where appropriate, as provided for in Article 7.

Article 7

Documents

1. Documents shall be circulated by the Secretaries of the Sub-Committee.

2. A Party shall transmit its documents to its Secretary. The Secretary shall transmit those documents to the Secretary of the other Party.

3. The Secretary appointed by the Union shall circulate the documents to the relevant representatives of the Union and shall systematically copy the Secretary appointed by the Republic of Armenia and the Secretaries of the Partnership Committee in trade configuration in such correspondence.

4. The Secretary appointed by the Republic of Armenia shall circulate the documents to the relevant representatives of the Republic of Armenia and shall systematically copy the Secretary appointed by the Union and the Secretaries of the Partnership Committee in trade configuration in such correspondence.

Article 8

Confidentiality

Unless otherwise decided by the Parties, the meetings of the Sub-Committee shall not be public. Where a Party submits information designated as confidential to the Sub-Committee, the other Party shall treat that information as such.

Article 9

Agenda

1. A provisional agenda for each meeting, as well as draft operational conclusions as provided for in Article 10, shall be drawn up by the Secretariat of the Sub-Committee on the basis of proposals made by the Parties. The provisional agenda shall include items in respect of which the Secretariat has received a request for inclusion in the agenda by a Party, supported by relevant documents, no later than 21 calendar days before the date of the meeting.

2. The provisional agenda, together with the relevant documents, shall be circulated as provided for in Article 7 no later than 15 calendar days before the beginning of the meeting.

3. Subject to Article 8, provisional agenda of the meeting shall be made public, if possible 10 calendar days before the meeting takes place.

4. The agenda shall be adopted by the Chair of the Sub-Committee and the other Head of Delegation at the beginning of each meeting. Items other than those appearing on the provisional agenda may be placed on the agenda if the Parties so agree.

5. The Chair of the Sub-Committee may invite representatives of other bodies of the Parties or, upon agreement of the other Party, independent experts in a subject area to attend its meetings on an ad-hoc basis in order to provide information on specific subjects. The Parties shall ensure that such observers or experts respect any confidentiality requirements.

6. The Chair of the Sub-Committee may reduce the time-limits specified in paragraphs 1 and 2, in consultation with the Parties, in order to take account of special circumstances.

Article 10

Minutes and operational conclusions

1. Draft minutes of each meeting shall be drawn up jointly by the Secretaries of the Sub-Committee.

2. The minutes shall, as a general rule, include in respect of each item on the agenda:

(a) a list of the participants in the meeting, a list of officials accompanying them and a list of any observers or experts who attended the meeting;

(b) documentation submitted to the Sub-Committee;

(c) statements which the Sub-Committee has asked to be entered in the minutes; and

(d) operational conclusions of the meeting, if necessary, as provided for in paragraph 4.

3. The draft minutes shall be submitted to the Sub-Committee for approval. They shall be approved within 28 calendar days after each Sub-Committee meeting. A copy shall be sent to each of the addressees referred to in Article 7. Without prejudice to Article 8, the Parties shall publish the approved minutes as soon as possible upon approval. The minutes shall include, as a general rule, the final agenda and a summary of the discussion under each agenda point.

4. Draft operational conclusions of each meeting shall be drawn up by the Secretary of the Sub-Committee of the Party holding the chair of the Sub-Committee, and circulated to the Parties together with the provisional agenda, no later than 15 calendar days before the beginning of the meeting. That draft shall be updated as the meeting proceeds so that at the end of the meeting, unless agreed otherwise by the Parties, the Sub-Committee adopts the operational conclusions, reflecting the follow-up actions agreed by the Parties. Once agreed, the operational conclusions shall be attached to the minutes and their implementation shall be reviewed during any subsequent meeting of the Sub-Committee. To that end the Sub-Committee shall adopt a template, allowing for each action to be tracked against a specific deadline.

Article 11

Decisions

1. The Sub-Committee shall have the power to adopt decisions in the cases provided for in Article 240(3) of the Agreement. The Sub-Committee shall adopt decisions by consensus, as provided for in Article 240(2) of the Agreement. They shall be binding upon the Parties, which shall take appropriate measures to implement them.

2. Each decision shall be authenticated by the Chair of the Sub-Committee.

3. The Sub-Committee may take decisions or adopt reports by written procedure, after completion of the respective internal procedures, if the Parties so agree. The written procedure shall consist of an exchange of notes between the Secretaries, acting in agreement with the Parties. For that purpose, the text of the proposal shall be circulated pursuant to Article 7, with a time-limit of no less than 21 calendar days within which any reservations or amendments shall be made known. The Chair of the Sub-Committee may reduce that time-limit, in consultation with the Parties, in order to take account of special circumstances. The draft decisions shall be deemed adopted once the other Party expresses its agreement and shall be recorded in the minutes of the meeting of the Sub-Committee.

4. The acts of the Sub-Committee shall be entitled "Decision" or "Report" respectively. Each decision shall enter into force on the date of its adoption unless the decision provides otherwise.

5. The decisions shall be circulated to the Parties.

6. Each Party may decide on the publication of the decisions of the Sub-Committee in its respective official publication.

Article 12

Reports

The Sub-Committee shall report to the Partnership Committee in trade configuration on its activities at each regular meeting of the latter.

Article 13

Languages

1. The working languages of the Sub-Committee shall be English and Armenian. Parties may decide however to hold meetings only in English.

2. Unless otherwise decided, the Sub-Committee shall base its deliberations on documentation prepared in those languages.

3. The Sub-Committee shall adopt decisions concerning the amendment or interpretation of the Agreement in the languages of the authentic text of the Agreement. All other decisions of the Sub-Committee shall be adopted in the working languages referred to in paragraph 1.

Article 14

Expenses

1. Each Party shall meet any expenses it incurs as a result of participating in the meetings of the Sub-Committee, both with regard to staff, travel and subsistence expenditure and with regards to postal and telecommunications expenditure.

2. Expenditure in connection with the organisation of meetings and reproduction of documents shall be borne by the Party hosting the meeting.

3. Expenditure in connection with interpreting at meetings and translation of documents into or from English and Armenian as referred to in Article 13(1) shall be borne by the Party hosting the meeting.

Article 15

Amendment of rules of procedure

These rules of procedure may be amended by a decision of the Sub-Committee in accordance with Article 240(2) of the Agreement.'

Corrigendum to Commission Regulation (EU) 2022/1439 of 31 August 2022 amending Regulation (EU) No 283/2013 as regards the information to be submitted for active substances and the specific data requirements for micro-organisms

(Official Journal of the European Union L 227 of 1 September 2022)

On page 17, Annex II, the following Table of contents shall be inserted after the title 'PART B – **ACTIVE SUBSTANCES THAT ARE MICRO-ORGANISMS**':

'Table of contents

2.8. Information on metabolites of concern

2.9. Presence of transferable antimicrobial resistance genes

3. Further information

3.1. Function and target organism

3.2. Field of use envisaged

3.3. Crops or products protected or treated

3.4. Information on possible development of resistance in the target organism(s)

3.5. Literature data

4. Analytical methods

4.1. Methods for the analysis of the MPCA as manufactured

4.2. Methods to determine the density of the micro-organism and quantify residues

5. Effects on human health

5.1. Medical data

5.1.1. Therapeutic and first aid measures

5.1.2. Medical surveillance

5.1.3. Information on sensitisation and allergenicity

5.1.4. Direct observation

5.2. Assessment on potential infectivity and pathogenicity of the micro-organism to humans

5.3. Infectivity and pathogenicity studies on the micro-organism

5.3.1. Infectivity and pathogenicity

5.3.1.1. Oral infectivity and pathogenicity

5.3.1.2. Intratracheal/ intranasal infectivity and pathogenicity

5.3.1.3. Intravenous, intraperitoneal or subcutaneous single exposure

5.3.2. Cell culture study

5.4. Specific infectivity and pathogenicity studies on the micro-organism

5.5. Information and toxicity studies on metabolites

5.5.1. Information on metabolites

5.5.2. Additional toxicity studies on metabolites of concern

6. Residues in or on treated products, food and feed

6.1. Estimation of consumer exposure to residues

6.2. Data generation on residues

7. Environmental occurrence of the micro-organism, including fate and behaviour of metabolites of concern

7.1. Environmental occurrence of the micro-organism

7.1.1. Predicted environmental density of the micro-organism

7.1.1.1. Soil

7.1.1.2. Water

7.1.2. Exposure to micro-organisms known to be pathogenic either for plants or for other organisms

7.1.3. Qualitative exposure assessment of the micro-organism

7.1.4. Experimental exposure data of the micro-organism

7.2. Fate and behaviour of metabolite(s) of concern

7.2.1. Predicted environmental concentration

7.2.2. Qualitative exposure assessment

7.2.3. Experimental exposure data

8. Ecotoxicological studies

8.1. Effects on terrestrial vertebrates

8.2. Effects on aquatic organisms

8.2.1. Effects on fish

8.2.2. Effects on aquatic invertebrates

8.2.3. Effects on algae

8.2.4. Effects on aquatic macrophytes

8.3. Effects on bees

8.4. Effects on non-target arthropods other than bees

8.5. Effects on non-target meso- and macro-organisms in soil

8.6. Effects on non-target terrestrial plants

8.7. Additional studies on the micro-organism

8.8. Information and toxicity studies on metabolites

8.8.1. Information on metabolites

8.8.2. Additional toxicity studies on metabolites of concern'

Corrigendum to Commission Regulation (EU) 2022/1440 of 31 August 2022 amending Regulation (EU) No 284/2013 as regards the information to be submitted for plant protection products and the specific data requirements for plant protection products containing micro-organisms

(Official Journal of the European Union L 227 of 1 September 2022)

On page 46, Annex II, the following Table of contents shall be inserted after the title 'PART B – **PLANT PROTECTION PRODUCTS CONTAINING AN ACTIVE SUBSTANCE THAT IS A MICRO-ORGANISM**':

'Table of contents

2.8. Physical and chemical compatibility with other plant protection products including plant protection products with which its use is to be authorised

2.8.1. Physical compatibility

2.8.2. Chemical compatibility

2.9. Adherence and distribution to seeds

3. Data on application

3.1. Field of use envisaged

3.2. Mode of action on the target organism

3.3. Function, target organisms and plants or plants products to be protected and possible risk mitigation measures

3.4. Application rate

3.5. Content of micro-organism in material used (e.g. in the diluted spray, baits or treated seed)

3.6. Method of application

3.7. Number and timing of applications on the same crop, duration of protection and waiting period(s)

3.8. Proposed instructions for use

3.9. Safety intervals and other precautions to protect human health, animal health and the environment

4. Further information on the plant protection product

4.1. Procedures for cleaning and decontaminating of application equipment

4.2. Recommended methods and precautions concerning: handling, storage, transport, fire or use

4.3. Measures in case of accident

4.4. Procedures for destruction or decontamination of the plant protection product and its packaging

4.4.1. Controlled incineration

4.4.2. Others

5. Analytical methods

5.1. Methods for the analysis of the preparation

5.2. Methods to determine and quantify residues

6. Efficacy data

6.1. Preliminary tests

6.2. Minimum effective dose

6.3. Testing effectiveness

6.4. Information on possible development of resistance in target organisms

6.5. Adverse effects on treated crops

6.5.1. Phytotoxicity to target plants (including different cultivars), or to target plant products

6.5.2. Effects on the yield of treated plants or plant products

6.5.3. Effects on the quality of plants or plant products

6.5.4. Effects on transformation processes

6.5.5. Impact on treated plants or plant propagating material

6.6. Observations on undesirable or unintended side-effects on succeeding crops and other plants

6.6.1. Impact on succeeding crops

6.6.2. Impact on other plants, including adjacent crops

6.7. Compatibility in plant protection programmes

7. Effect on human health

7.1. Medical data

7.2. Assessment of potential toxicity of the plant protection product

7.3. Acute toxicity

7.3.1. Acute oral toxicity

7.3.2. Acute dermal toxicity

7.3.3. Acute inhalation toxicity

7.3.4. Skin irritation

7.3.5. Eye irritation

7.3.6. Skin sensitisation

7.4. Additional toxicity information

7.5. Data on exposure

7.6. Available toxicological data relating to non-active substances

7.7. Supplementary studies for combinations of plant protection products

8. Residues in or on treated products, food and feed

9. Fate and behaviour in the environment

10. Effects on non-target organisms

10.1. Effects on terrestrial vertebrates

10.2. Effects on aquatic organisms

10.2.1. Effects on fish

10.2.2. Effects on aquatic invertebrates

10.2.3. Effects on algae

10.2.4. Effects on aquatic macrophytes

10.3. Effects on bees

10.4. Effects on non-target arthropods other than bees

10.5. Effects on non-target meso- and macroorganisms in soil

10.6. Effects on non-target terrestrial plants

10.7. Additional toxicity studies'.

Corrigendum to Commission Regulation (EU) 2022/1441 of 31 August 2022 amending Regulation (EU) No 546/2011 as regards specific uniform principles for evaluation and authorisation of plant protection products containing micro-organisms

(Official Journal of the European Union L 227 of 1 September 2022)

On page 77, Annex, the following table of contents shall be inserted after the title 'PART A – **Uniform principles for evaluation and authorisation of chemical plant protection products**':

'*Table of contents*

On page 95, Annex, the following table of contents shall be inserted after the title 'PART B – **Uniform principles for evaluation and authorisation of plant protection products containing an active substance that is a micro-organism**':

'*Table of contents*

1.1.1. Identity of the micro-organism contained in the plant protection product

1.1.2. Quality control of the production of the micro-organism contained in the plant protection product

1.1.3. Identity of the plant protection product

1.1.4. Quality control of the plant protection product

1.2. Biological, physical, chemical and technical properties

1.2.1. Biological properties of the micro-organism in the plant protection product

1.2.2. Physical, chemical and technical properties of the plant protection product

1.3. Efficacy

1.4. Identification/detection and quantification methods

1.4.1. Analytical methods for the plant protection product

1.4.1.1. Analytical methods for micro-organisms

1.4.1.2. Analytical methods for metabolites of concern, relevant impurities, additives, co-formulants, safeners and synergist

1.4.2. Analytical methods for the determination of residues and density of the micro-organism

1.4.2.1. Density of the micro-organism

1.4.2.2. Residues of metabolites of concern

1.5. Impact on human and animal health

1.5.1. Effects on human or animal health arising from the plant protection product

1.5.2. Effects on human or animal health arising from residues of metabolites of concern

1.6. Environmental occurrence of the micro-organism, including fate and behaviour of metabolites of concern

1.6.1. Environmental occurrence of the micro-organism

1.6.2. Environmental fate and behaviour of the metabolites of concern

1.7. Effects on non-target organisms

1.8. Conclusions and proposals

2. Decision-making

2.1. Identity

2.2. Biological and technical properties

2.3. Efficacy and absence of unacceptable effects on plants and plant products

2.3.1. Efficacy

2.3.2. Absence of unacceptable effects on plants and plant products

2.4. Identification/detection and quantification methods

2.5. Impact on human and animal health

2.5.1. Effects on human and animal health arising from the plant protection product

2.5.2. Effects on human and animal health arising from residues

2.6. Fate and behaviour in the environment

2.7. Effects on non-target organisms'.

Corrigendum to Commission Implementing Regulation (EU) 2022/1860 of 10 June 2022 laying down implementing technical standards for the application of Regulation (EU) No 648/2012 of the European Parliament and of the Council with regard to the standards, formats, frequency and methods and arrangements for reporting

(Official Journal of the European Union L 262 of 7 October 2022)

On page 71, in Article 4(1):

for: 'in accordance with paragraphs 2 to 14',

read: 'in accordance with paragraphs 2 to 13'

Corrigendum to Commission Delegated Regulation (EU) 2022/2236 of 20 June 2022 amending Annexes I, II, IV and V to Regulation (EU) 2018/858 of the European Parliament and of the Council as regards the technical requirements for vehicles produced in unlimited series, vehicles produced in small series, fully automated vehicles produced in small series and special purpose vehicles, and as regards software update

(Official Journal of the European Union L 296 of 16 November 2022)

In Table 2 in Annex II, column 7, row item A6 (on page 43):

for: '… Implementing Regulation (EU) 2022/1362',

read: '… Commission Implementing Regulation (EU) 2022/1426 ([1])

([1]) Commission Implementing Regulation (EU) 2022/1426 of 5 August 2022 laying down rules for the application of Regulation (EU) 2019/2144 of the European Parliament and of the Council as regards uniform procedures and technical specifications for the type-approval of the automated driving system (ADS) of fully automated vehicles (OJ L 221, 26.8.2022, p. 1).';

in Table 2 in Annex II, column 7, row items E5, E6, E7 and E9 (on page 57):

for: '… Implementing Regulation (EU) 2022/1362',

read: '… Implementing Regulation (EU) 2022/1426'.

Corrigendum to the corrigendum to Council Regulation (EU) 2022/109 of 27 January 2022 fixing for 2022 the fishing opportunities for certain fish stocks and groups of fish stocks applicable in Union waters and for Union fishing vessels in certain non-Union waters

(Official Journal of the European Union L 34 of 16 February 2022)

On page 57, the following part should be corrected:

for:

'Species:	Plaice *Pleuronectes platessa*		Zone:	Kattegat (PLE/03AS.)
Denmark		493	Analytical TAC Article 8(2) of this Regulation applies'	
Germany		6		
Sweden		56		
Union		55		
TAC		1 038		

read:

'Species:	Plaice *Pleuronectes platessa*		Zone:	Kattegat (PLE/03AS.)
Denmark		493	Analytical TAC Article 8(2) of this Regulation applies'	
Germany		6		
Sweden		56		
Union		555		
TAC		1 038		

Corrigendum to Commission Regulation (EU) No 20/2010 of 12 January 2010 entering a name in the register of protected designations of origin and protected geographical indications [Arzùa-Ulloa (PDO)]

(Official Journal of the European Union L 8 of 13 January 2010)

On page 1, in the title of the Regulation, in recital (1) and on page 2 in the Annex to the Regulation:

for: 'Arzùa-Ulloa',

read: 'Arzúa-Ulloa'.

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