

Official Journal of the European Union

L 71



English edition

Legislation

Volume 66

9 March 2023

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⁽¹⁾ Text with EEA relevance.

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2023/511

of 24 November 2022

supplementing Regulation (EU) No 575/2013 of the European Parliament and of the Council with regard to regulatory technical standards for the calculation of risk-weighted exposure amounts of collective investment undertakings under the mandate-based approach

(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 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and amending Regulation (EU) No 648/2012 ⁽¹⁾, and in particular Article 132a(4), third subparagraph, thereof,

Whereas:

- (1) In order to avoid undue variability in capital requirements across institutions, and to make the mandate-based approach operational in situations where there is insufficient information, it is necessary to specify the method for calculating the risk-weighted exposure amount for a collective investment undertaking (CIU) under the mandate-based approach for the cases where missing inputs do not allow for the computation of the risk weighted exposure amount.
- (2) Where a CIU enters into derivative transactions and the underlyings of the derivatives or the underlying risk of the derivatives' positions are unknown, the replacement cost of the positions cannot be determined by institutions, therefore neither can their exposure value. In that case, institutions should base their calculations on the notional amount of a derivative's position, which would usually be known and would be the best indicator of the size of the position, therefore providing an approximation for the exposure value.
- (3) Where the CIU's mandate does not exclude entering into derivatives but does not include sufficient information to determine whether an underlying constitutes an on- or off-balance sheet exposure, it cannot be excluded that such an exposure is constituted. It is therefore necessary to include that exposure in the calculation of the risk-weighted exposure amounts of the CIU's exposures.
- (4) Where the mandate does not provide sufficient information about the exposure value of such position, it cannot be excluded that the exposure value is the full notional amount of the derivative position.
- (5) Where the mandate does not specify the notional amount of the derivative position, to ensure a sufficiently prudent approach, that amount should be derived from the maximum notional amount of derivatives allowed under the mandate.

⁽¹⁾ OJ L 176, 27.6.2013, p. 1.

- (6) Where the replacement costs or the potential future exposure for the purposes of calculating the exposure amount associated with counterparty credit risk are unknown, institutions should base their calculations on the sum of notional amounts of the transactions in the netting set, which would be the best available conservative estimate to allow for the use of the mandate-based approach.
- (7) There are cases in which it is not possible for institutions to ascertain the relevant netting sets for a certain type of derivative in the CIU, since there is no information available on the counterparties or on whether the transactions are subject to a legally enforceable bilateral netting arrangement referred to in Article 272, point (4), of Regulation (EU) No 575/2013. In those cases, institutions should assume that neither netting effects nor counterparty diversification exist for that type of derivative. Therefore, institutions should assume that the CIU has entered into a single derivative with the maximum notional amount allowed by the mandate for that type of derivative.
- (8) This Regulation is based on the draft regulatory technical standards submitted to the Commission by the European Banking Authority.
- (9) The European Banking Authority has conducted open public consultations on the draft regulatory technical standards on which this Regulation is based, analysed the potential related costs and benefits and requested the advice of the Banking Stakeholder Group established in accordance with Article 37 of Regulation (EU) No 1093/2010 of the European Parliament and of the Council ⁽²⁾,

HAS ADOPTED THIS REGULATION:

Article 1

Determination of the exposure value of a CIU's derivatives' positions where the underlying is unknown for the purposes of Article 132a(2) of Regulation (EU) No 575/2013

1. When applying the mandate-based approach in accordance with Article 132a(2) of Regulation (EU) No 575/2013, where the CIU's mandate does not exclude that the underlying of a CIU's derivative position constitutes an on- or off-balance sheet exposure, but the exposure value or, in the case of off-balance sheet exposures, the applicable percentage pursuant to Article 111 of Regulation (EU) No 575/2013, is unknown, institutions shall use the full notional amount of the derivative position as the exposure value for the calculation of the risk-weighted exposure amounts.
2. For the purposes of determining the exposure value as set out in paragraph 1, where the notional amount of the derivative positions is unknown, institutions shall use a conservative estimation based on the maximum notional amount of the derivatives allowed under a CIU's mandate as the exposure value.

Article 2

Calculation of the exposure values for the counterparty credit risk of a netting set of a CIU's derivatives' positions

1. When calculating the exposure value of a netting set for counterparty credit risk in accordance with the approaches set out in Part 3, Title II, Chapter 6, Sections 3, 4 or 5, where relevant, of Regulation (EU) No 575/2013, institutions shall apply the following:
 - (a) where the institution is not able to calculate the replacement cost of the netting set according to the relevant approach, due to missing inputs, that institution shall use the sum of notional amounts of all the derivatives in the netting set as the replacement cost;

⁽²⁾ Regulation (EU) No 1093/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Banking Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/78/EC (OJ L 331, 15.12.2010, p. 12).

- (b) where the institution is not able to calculate the potential future exposure of the netting set according to the relevant approach, due to missing inputs, that institution shall replace it by 0,15 times the sum of notional amounts of all the derivatives in the netting set.
2. When calculating the exposure value for counterparty credit risk in accordance with paragraph 1, where the notional amount of the derivatives in the netting set is unknown, institutions shall use a conservative estimation based on the maximum notional amount of the derivatives allowed under a CIU's mandate to determine the exposure value of that netting set.
3. For the purposes of paragraphs 1 and 2, where it is not possible for institutions to ascertain the relevant netting sets for a certain type of derivative in the CIU, they shall assume that the CIU has entered into a single derivative with the maximum notional amount permitted by the mandate for that type of derivative.

Article 3

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, 24 November 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2023/512**of 2 March 2023****approving a non-minor amendment to the product specification for a name entered in the register of protected designations of origin and protected geographical indications ('Aceto Balsamico di Modena' (PGI))**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 52(3)(b) thereof,

Whereas:

- (1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, the application from Italy for approval of a non-minor amendment to the product specification of the Protected Geographical Indication 'Aceto Balsamico di Modena' was published in the *Official Journal of the European Union* ⁽²⁾.
- (2) On 31 August 2021 the Commission received from Germany three notices of opposition and one reasoned statement. Two other reasoned statements of opposition from Germany were submitted on 11 October 2021. On 16 September 2021 the Commission received the fourth notice of opposition from an opponent based in Türkiye. The related reasoned statement of opposition was submitted on 16 November 2021.
- (3) After examining the reasoned statements of opposition and founding them admissible, in accordance with Article 51(3) of Regulation (EU) No 1151/2012, the Commission, by letter of 10 December 2021, invited both Italy and Germany and Italy and the opponent from Türkiye to engage in appropriate consultations in view of reaching an agreement.
- (4) On 4 March 2021 Germany informed the Commission that one of the oppositions was withdrawn, but maintained by two other opponents from Germany.
- (5) The consultations between Italy and Germany on one side and Italy and the opponent from Türkiye on the other ended without an agreement being reached. The Commission should therefore take a decision on the amendments in accordance with the procedure provided for in Article 52(3)(b) of Regulation (EU) No 1151/2012 taking into account the results of these consultations.
- (6) The opponents considered that the amendments to the product specification would result in non-compliance with the conditions laid down in Article 5(2) of Regulation (EU) No 1151/2012, notably for breaking the link between the product and the geographical area. To that end, alleged changes to the organoleptic characteristics of 'Aceto Balsamico di Modena', the change of the minimum total acidity for the aged product and a correction procedure for possible deviations from the parameters were questioned. These amendments were also contested as lowering the quality of 'Aceto Balsamico di Modena' and resulting in non-compliance with the requirements laid down for wine vinegars under point 17 of Part II of Annex VII to Regulation (EU) No 1308/2013 of the European Parliament and of the Council ⁽³⁾ establishing a common organisation of the markets in agricultural products (acidity of at least 60 grams per litre = at least 6 %).

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.⁽²⁾ OJ C 231, 16.6.2021, p. 11.⁽³⁾ Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

- (7) Moreover, the opponents alleged non-compliance with the minimum requirements for the content of the product specification, with regard to Article (7)(1)(g) of Regulation (EU) No 1151/2012, concerning the removal of indication of the control body for 'Aceto Balsamico di Modena'.
- (8) Furthermore, the opponents alleged that the existing scope of protection has been unduly extended and, thus, the registration of the amendments would jeopardise the existence of names, trade marks or products, including balsamic vinegars of other origins. This claim would, in particular, concern the alleged inclusion of the obligation of bottling in the demarcated area, an additional rule on shape of containers, as well as the introduction of isotopic ratio parameters. As a result, the opponents claim that the planned amendments allegedly prejudice the interests of the bottlers of 'Aceto Balsamico di Modena' and German producers of other vinegars.
- (9) Finally, the opponents claimed that newly introduced reduction of minimum acidity could lead to confusion between 'Aceto Balsamico di Modena' PGI and 'Aceto Balsamico Tradizionale di Modena' PDO.
- (10) The Commission has assessed the arguments exposed in the reasoned statements of opposition from Germany and Türkiye in the light of the provisions of Regulation (EU) No 1151/2012, taking into account the results of the appropriate consultations carried out between the applicant and the opponents and it has concluded that the amendment to the product specification for the protected geographical indication 'Aceto Balsamico di Modena' should be approved.
- (11) Italy claimed that the opponents had not demonstrated their legitimate interest in lodging the oppositions, as required by Article 51(1) of Regulation (EU) No 1151/2012, since the opponents contested amendments that were either not applied for or that did not result in trade and/or market barriers.

In the context of the procedure applicable to applications for amendments to the specification that are not minor, any natural or legal person having a legitimate interest may lodge an opposition to the application for amendment submitted. In the present case, the risk of harm to the interests of the opponents was not considered as purely improbable, nor hypothetical and, therefore, it was concluded that the opponents demonstrated legitimate interest in lodging the oppositions.

- (12) The analysis of the reservations submitted by the opponents revealed that indeed some of the claims were made with regard to the elements in the product specification that in fact have not changed as a result of the present amendments, but that consisted of mere editorial changes. These editorial changes aimed at bringing the single document in line with Article 8(1)(c) of Regulation (EU) No 1151/2012 and better reflecting the conditions established in the product specification of 'Aceto Balsamico di Modena' PGI. This concerns, in particular, the alleged changes to the organoleptic characteristics, the alleged changes concerning the use of additives and the use of plastic containers, as well as alleged obligation of bottling in the demarcated area. These rules have not changed, while the rewording that appeared in the single document and might have been perceived as amendments to the product specification, in fact resulted from the rectification of discrepancies between the product specification and the summary of the product specification that was published the *Official Journal of the European Union* ⁽⁴⁾. The Commission's assessment of the application for amendment of 'Aceto Balsamico di Modena' PGI has focussed on the substantial amendments applied for.
- (13) The changes concerning a minimum percentage of acidity for the 'invecchiato' (aged) type from 6 % to 5,5 % or allowed correction procedure for possible deviations cannot be considered as negatively impacting the link between the product and its geographical origin. The reasons behind these amendments have been explained and duly justified in the publication of the application, while it is evident that the nature and scale of these amendments do not alter the essential characteristics of 'Aceto Balsamico di Modena' PGI and consequently cannot make the link disappear.

⁽⁴⁾ OJ C 152, 6.7.2007, p. 18 and Commission Regulation (EC) No 583/2009 of 3 July 2009 entering a name in the register of protected designations of origin and protected geographical indications [Aceto Balsamico di Modena (PGI)] (OJ L 175, 4.7.2009, p. 7).

- (14) Moreover, the similarity in the level of acidity does not have a capacity to create confusion between 'Aceto Balsamico di Modena' PGI and 'Aceto Balsamico Tradizionale di Modena' PDO or lead to the evocation of the latter. Even if products under both designations share certain characteristics, like the level of acidity, they are made of different raw materials and follow different production method and thus remain distinct.
- (15) Finally, 'Aceto Balsamico di Modena' PGI is not defined as a wine vinegar and thus not subject to the rules applicable to wine vinegars, in particular with regard to the minimum acidity.
- (16) With respect to the oppositions concerning the extension of the size range of the bottles, the amendment cannot be considered as imposing any limitations on the operators involved in packaging of 'Aceto Balsamico di Modena'. On the contrary, allowing additional capacities of containers such as 0,100 l, 0,150 l, 0,200 l or 1,5 l can be considered as liberalising the conditions for bottling. A possible effect of an increased competition that might result from the marketing of 'Aceto Balsamico di Modena' in a wider range of bottle sizes would be in line with the founding principles of the EU competition policy and should not be considered as detrimental to the reputation of the 'Aceto Balsamico di Modena' PGI.
- (17) The aim of the characteristics of the containers with a capacity of less than 0,250 litres included in section 3.5 of the single document is to ensure a minimum standard of uniformity among the bottles, in which the product will be sold. This packaging rule is not included in the description of the product, nor is elaborated with regard to the product specificity under the section of the single document devoted to the link and thus it cannot be considered as an essential feature of the presentation of the product. As these requirements are set only for new containers with a capacity of less than 0,250 litres, which were not allowed before the present amendment, the contested change will not negatively impact investments in containers already made by the bottlers of 'Aceto Balsamico di Modena' and consequently, it will not result in their economic loss.
- (18) Information regarding the control body has not been provided directly in the single document, as it is not required there in line with Annex I to Commission Implementing Regulation (EU) No 668/2014 ⁽⁵⁾. However, this information has been included in the product specification, as stipulated in Article 7(1)(g) of Regulation (EU) No 1151/2012.
- (19) With reference to the opponents' objections to the required compliance with the isotopic ratio parameters, such parameters have been introduced to better detect possible adulteration of the wine vinegar and improve the control system for 'Aceto Balsamico di Modena'. The verification of the isotopic ratio is in any event carried out at the production stage and thus affecting only producers of 'Aceto Balsamico di Modena'.
- (20) Accordingly, the amendments to the product specification published in the *Official Journal of the European Union* regarding the name 'Aceto Balsamico di Modena' (PGI) should be approved.
- (21) The measures provided for in this Regulation are in accordance with the opinion of the Agricultural Product Quality Policy Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The amendments to the product specification published in the *Official Journal of the European Union* regarding the name 'Aceto Balsamico di Modena' (PGI) are hereby approved.

⁽⁵⁾ Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

Article 2

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, 2 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2023/513**of 8 March 2023****amending Annexes XV and XIX to Implementing Regulation (EU) 2021/404 as regards the list of third countries, territories or zones thereof authorised for the entry into the Union of meat products from ungulates, poultry and game birds and of eggs and egg products****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ⁽¹⁾, and in particular Article 230(1) thereof,

Whereas:

- (1) Regulation (EU) 2016/429 lays down, inter alia, the animal health requirements for the entry into the Union of consignments of animals, germinal products and products of animal origin, and it applies from 21 April 2021. One of those animal health requirements is that those consignments must come from a third country or territory, or zone or compartment thereof listed in accordance with Article 230(1) of that Regulation.
- (2) Commission Delegated Regulation (EU) 2020/692 ⁽²⁾ supplements Regulation (EU) 2016/429 as regards the animal health requirements for the entry into the Union of consignments of certain species and categories of animals, germinal products and products of animal origin from third countries or territories, or zones or compartments thereof. Delegated Regulation (EU) 2020/692 provides that consignments of animals, germinal products and products of animal origin falling within its scope may only be permitted to enter into the Union if they come from a third country or territory, or zone or compartment thereof, listed for the particular species and categories of animals, germinal products and products of animal origin, in accordance with the animal health requirements laid down in that Delegated Regulation.
- (3) Commission Implementing Regulation (EU) 2021/404 ⁽³⁾ lays down the lists of third countries or territories, or zones or compartments thereof, from which the entry into the Union of those species and categories of animals, germinal products and products of animal origin, that fall within the scope of Delegated Regulation (EU) 2020/692, is permitted. The lists and certain general rules concerning the lists are set out in Annexes I to XXII to that Implementing Regulation.
- (4) Annex XV, Part 1 to Implementing Regulation (EU) 2021/404 sets out the list of third countries or territories, or zones thereof, authorised for entry into the Union of meat products from ungulates, poultry and game birds. Annex XIX, Part 1 to Implementing Regulation (EU) 2021/404 sets out the list of third countries or territories, or zones thereof, authorised for entry into the Union of consignments of eggs and egg products.
- (5) Moldova has submitted an application to the Commission to be authorised for the entry into the Union of consignments of meat products of poultry other than ratites, and eggs, and provided guarantees regarding compliance, by that third country, with the requirements on the notification and reporting of the listed diseases referred to in Annex I to Delegated Regulation (EU) 2020/692 relevant for poultry, and guarantees regarding

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ 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).

⁽³⁾ 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).

compliance by that third country with the relevant Union animal health requirements or with equivalent requirements. Therefore, and taking into account the poultry health situation in Moldova, it is appropriate to include that third country in the lists set out in Annex XV, Part 1 and in Annex XIX, Part 1 to Implementing Regulation (EU) 2021/404 as regards meat products of poultry other than ratites and eggs.

- (6) Annexes XV and XIX to Implementing Regulation (EU) 2021/404 should therefore be amended accordingly.
- (7) 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

Annexes XV and XIX to Implementing Regulation (EU) 2021/404 are amended in accordance with the Annex to this Regulation.

Article 2

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, 8 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes XV and XIX to Implementing Regulation (EU) 2021/404 are amended as follows:

(1) In Annex XV, in Part 1, the following entry for Moldova is inserted between the entry for Morocco and the entry for Montenegro:

MD Moldova	MD-0	Not authorised	Not authorised	Not authorised	Not authorised	Not authorised	Not authorised	Not authorised	D	Not authorised	Not authorised	MPST	
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(2) In Annex XIX, in Part 1, the entry for Moldova is replaced by the following:

MD Moldova	MD-0	Eggs	E				
		Egg products	EP'				

COMMISSION IMPLEMENTING REGULATION (EU) 2023/514**of 8 March 2023****amending Implementing Regulation (EU) 2021/405 as regards highly refined products, the list of third countries with an approved control plan and the inclusion of Moldova in the list of third countries authorised for the entry into the Union of consignments of eggs intended for placing on the market as Class A eggs****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Commission Delegated Regulation (EU) 2022/2292 ⁽²⁾ supplements Regulation (EU) 2017/625 and aims to ensure that consignments of food-producing animals and certain goods intended for human consumption from third countries or regions thereof comply with certain Union food safety requirements or those recognised to be at least equivalent thereto. In particular, that Regulation 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.
- (2) Article 7 of Delegated Regulation (EU) 2022/2292 provides that certain 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 such consignments for human consumption.
- (3) Commission Implementing Regulation (EU) 2021/405 ⁽³⁾ lays down a list of third countries or regions thereof authorised for the entry into the Union of consignments of certain highly refined products, intended for human consumption.

⁽¹⁾ OJ L 95, 7.4.2017, p. 1.

⁽²⁾ 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 (OJ L 304, 24.11.2022, p. 1).

⁽³⁾ 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).

- (4) Since a recent amendment ⁽⁴⁾ of Regulation (EC) No 853/2004 of the European Parliament and of the Council ⁽⁵⁾, highly refined products also cover fat derivatives and food flavourings that are authorized in accordance with Regulation (EC) No 1334/2008 of the European Parliament and of the Council ⁽⁶⁾, subject to treatments excluding any public or animal health risk. Implementing Regulation (EU) 2021/405 should be amended to be consistent with this change.
- (5) Azerbaijan has submitted a control plan, which covers roes and caviar. The plan provides sufficient guarantees and should therefore be approved.
- (6) Lebanon has submitted a control plan, which covers honey. The plan provides sufficient guarantees and should therefore be approved.
- (7) Isle of Man is listed in the table of Annex -I to Implementing Regulation (EU) 2021/405 for its export to the Union of ovine and caprine meat. However, Isle of Man has informed the Commission that it is no longer interested in exporting caprine meat to the Union. The entry for Isle of Man for ovine and caprine meat in that table of Annex -I to Implementing Regulation (EU) 2021/405 should therefore only cover ovine meat.
- (8) Japan is listed in the table of Annex -I to Implementing Regulation (EU) 2021/405 for their export to the Union of pork meat. However, Japan has informed the Commission that it is no longer interested in submitting a control plan for pork meat but intends to use only pork meat originating either from Member States or third countries from which such products are authorised for entry into the Union. Consequently, the entry for Japan for pork meat should be adapted accordingly in Annex -I to Implementing Regulation (EU) 2021/405.
- (9) The United Kingdom is listed in the table of Annex -I to Implementing Regulation (EU) 2021/405 for their export to the Union of rabbit meat. However, the United Kingdom has informed the Commission that it is no longer interested to submit a control plan for rabbit meat but intends to use only rabbit meat originating either from Member States or third countries from which such products are authorised for entry into the Union. Consequently, the entry for United Kingdom for rabbit meat should be adapted accordingly in Annex -I to Implementing Regulation (EU) 2021/405.
- (10) Thailand has not submitted to the Commission a control plan for milk. However, Thailand has provided guarantees to use only milk originating either from Member States or third countries from which milk is authorised for entry into the Union. It has also informed the Commission that such milk to be exported to the Union will not be limited to composite products containing processed milk products. Consequently, the entry for Thailand for milk should be adapted accordingly in Annex -I to Implementing Regulation (EU) 2021/405.
- (11) The United States of America has submitted a control plan, which covers casings. The plan provides sufficient guarantees and should therefore be approved.
- (12) Rwanda is currently listed in the table of Annex -I to Implementing Regulation (EU) 2021/405 for honey and Colombia and Syria are listed for casings. As those third countries have not submitted to the Commission plans for the respective products, those entries should be deleted from the table in that Annex.
- (13) Moldova submitted a *Salmonella* control programme in flocks of laying hens in order to be authorised for the entry into the Union of class A eggs in accordance with Article 7 of Implementing Regulation (EU) 2021/405. That control programme was assessed with satisfaction by the Commission. The compliance related to the requirements on *Salmonella* control in accordance with Article 10(6) of Regulation (EC) No 2160/2003 of the European Parliament and of the Council ⁽⁷⁾ was double checked during the audit carried out by the Commission in April 2022 ⁽⁸⁾. Moldova should therefore be authorised for the entry into the Union of class A eggs.

⁽⁴⁾ Commission Delegated Regulation (EU) 2022/2258 of 9 September 2022 amending and correcting Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council on specific hygiene requirements for food of animal origin as regards fishery products, eggs and certain highly refined products, and amending Commission Delegated Regulation (EU) 2019/624 as regards certain bivalve molluscs (OJ L 299, 18.11.2022, p. 5).

⁽⁵⁾ 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).

⁽⁶⁾ 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).

⁽⁷⁾ Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents (OJ L 325, 12.12.2003, p. 1).

⁽⁸⁾ DG(SANTE)2021-7268 – final report available on <https://ec.europa.eu/food/audits-analysis/audit-report/details/4533>

- (14) Implementing Regulation (EU) 2021/405 should therefore be amended accordingly.
- (15) 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) in Article 22, the introductory phrase is replaced by the following:
‘Consignments of highly refined products as described in Section XVI of Annex III to Regulation (EC) No 853/2004, intended for human consumption, shall only be authorised for the entry into the Union if they come from the following third countries or regions thereof:’;
- (2) Annex -I is replaced by text set out in Annex I to this Regulation;
- (3) Annex IV is replaced by the text set out in Annex II to this Regulation.

Article 2

Entry into force and application

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

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

Done at Brussels, 8 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

Annex -I to Implementing Regulation (EU) 2021/405 is replaced by the following:

‘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
AZE	Azerbaijan						X ⁽¹⁶⁾ P							
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

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
BW	Botswana	X					P							
BY	Belarus				X ⁽⁸⁾		X ⁽¹⁴⁾ P	X	X				X	X
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					
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	The Faroe Islands						X ⁽¹⁴⁾ P	O	O					

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
GB	United Kingdom ⁽⁶⁾	X	X	X	X	X	X ⁽¹⁴⁾ Δ M	X	X	Δ	X	X	X	X
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 ⁽⁵⁾	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		Δ		X	X ⁽¹⁴⁾ M	X	X				Δ	X
KE	Kenya						X ⁽¹⁴⁾ P	O	O					

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
KR	South Korea					X	X M	O	O				Δ	
LB	Lebanon												X	X
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	

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
NG	Nigeria						X ⁽¹⁵⁾ P	O	O					
NI	Nicaragua						X ⁽¹⁵⁾ P	O	O				X	
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													
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	

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
SY	Syria													
SZ	Eswatini	X					P							
TG	Togo												X	
TH	Thailand	O		O		X	X M	Δ	Δ				X	
TN	Tunisia						X ⁽¹⁴⁾ M	O	O					X
TR	Türkiye					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	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	

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- ⁽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.
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ANNEX II

Annex IV to Implementing Regulation (EU) 2021/405 is replaced by the following:

‘ANNEX IV

List of third countries authorized for the entry into the Union of consignments of eggs intended for placing on the market as Class A eggs as referred to in the second paragraph of Article 7

COUNTRY ISO CODE	THIRD COUNTRY	REMARKS
CH	Switzerland ⁽¹⁾	
GB	United Kingdom ⁽²⁾	
JP	Japan	
MD	Moldova	
MK	North Macedonia	
UA	Ukraine	

(¹) 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).

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

COMMISSION IMPLEMENTING REGULATION (EU) 2023/515**of 8 March 2023****renewing the approval of the active substance abamectin in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011****(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2008/107/EC ⁽²⁾ included abamectin as an active substance in Annex I to Council Directive 91/414/EEC ⁽³⁾.
- (2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁴⁾.
- (3) The approval of the active substance abamectin, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 April 2023.
- (4) An application for the renewal of the approval of the active substance abamectin was submitted to Austria, the rapporteur Member State, and Malta, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ⁽⁵⁾ within the time period provided for in that Article.
- (5) The applicant submitted the supplementary dossiers to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority') in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.
- (6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the Authority and the Commission on 17 April 2019. In its draft renewal assessment report, the rapporteur Member State proposed to renew the approval of abamectin.
- (7) The Authority communicated the draft renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2008/107/EC of 25 November 2008 amending Council Directive 91/414/EEC to include abamectin, epoxiconazole, fenpropimorph, fenpyroximate and tralkoxydim as active substances (OJ L 316, 26.11.2008, p. 4).

⁽³⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

⁽⁵⁾ Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

- (8) On 15 July 2020, the Authority communicated to the Commission its conclusion ⁽⁶⁾ on whether abamectin can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority identified a number of issues that could not be finalised. In particular it identified risks as regards birds and mammals, aquatic organisms and soil macroorganisms.
- (9) On 1 February 2022, the Commission sent a mandate to the Authority with a request to review the exposure and risk assessments as regards birds and mammals, aquatic organisms and soil macroorganisms. The Authority sent to the Commission an updated conclusion on 27 July 2022 ⁽⁷⁾. In its updated Conclusion, the Authority confirmed the risks identified in the previous assessment.
- (10) The Commission presented a renewal report and the draft Regulation for abamectin to the Standing Committee on Plants, Animals, Food and Feed, on 25 March 2021 and revised versions of the two documents on 8 December 2022 to take into account the outcomes in the updated Conclusion of the Authority.
- (11) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 14(1), third subparagraph, of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments on both versions of the renewal report, which have been carefully examined.
- (12) It has been established with respect to one or more representative uses of at least one plant protection product containing abamectin that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (13) The risk assessment for the renewal of the approval of the active substance abamectin is based on representative uses as insecticide and acaricide in protected crops. While it is not necessary, in the light of this risk assessment, to maintain the restriction to use only as insecticide and acaricide, it is necessary to provide, in accordance with Article 14(1) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, for certain conditions and restrictions. It is, in particular, appropriate to restrict the use of plant protection products containing abamectin to uses which allow controlled exchange of material and energy with the surroundings, so as to prevent the release of plant protection products into the environment and mitigate the high risk identified to aquatic organisms and wild terrestrial non-target organisms. Accordingly, uses in permanent greenhouses may be authorised.
- (14) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (15) Commission Implementing Regulation (EU) 2022/378 ⁽⁸⁾ extended the approval period of abamectin to 30 April 2023 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. Given that a decision on renewal has been taken ahead of that extended expiry date, and taking into account that the current approval of abamectin expires on 30 April 2023, this Regulation should enter into force as soon as possible and apply earlier than that date.
- (16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽⁶⁾ EFSA Journal 2020;18(8):6227. Available online: www.efsa.europa.eu.

⁽⁷⁾ EFSA Journal 2022;20(8):7544. Available online: www.efsa.europa.eu.

⁽⁸⁾ Commission Implementing Regulation (EU) 2022/378 of 4 March 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances abamectin, *Bacillus subtilis* (Cohn 1872) strain QST 713, *Bacillus thuringiensis* subsp. Aizawai strains ABTS-1857 and GC-91, *Bacillus thuringiensis* subsp. Israeliensis (serotype H-14) strain AM65-52, *Bacillus thuringiensis* subsp. Kurstaki strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, *Beauveria bassiana* strains ATCC 74040 and GHA, clodinafop, *Cydia pomonella* Granulovirus (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, metconazole, metrafenone, pirimicarb, *Pseudomonas chlororaphis* strain MA342, pyrimethanil, *Pythium oligandrum* M1, rimsulfuron, spinosad, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly *T. harzianum*) strain T11, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, *Trichoderma harzianum* strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram (OJ L 72, 7.3.2022, p. 2).

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substance abamectin, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of application

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

It shall apply from 1 April 2023.

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

Done at Brussels, 8 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Abamectin CAS No 71751-41-2	Avermectin B1a (10E,14E,16E)-(1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R,24S)-6'-[(S)-sec-butyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo [15.6.1.14,8.020,24] pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl- α -L-arabino-hexopyranosyl)-3-O-methyl- α -L-arabino-hexopyranoside	≥ 850 g/kg abamectin (sum of avermectin B1a and avermectin B1b), min. 800 g/kg avermectin B1a and max. 200 g/kg avermectin B1b	1 April 2023	31 March 2038	Only uses which allow controlled exchange of material and energy with the surroundings and prevent release of plant protection products into the environment may be authorised, in particular uses in permanent greenhouses.
Avermectin B1a CAS No 65195-55-3					
Avermectin B1b CAS No 65195-56-4					For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on Abamectin, and in particular Appendices I and II thereto, shall be taken into account.
Abamectin CIPAC No 495	Avermectin B1b (10E,14E,16E)-(1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R,24S)-21,24--dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo [15.6.1.14,8.020,24] pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl- α -L-arabino-hexopyranosyl)-3-O-methyl- α -L-arabino-hexopyranoside				In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, such as the the use of gloves; — the effect of photolysis on the levels of pesticide residues in crops. Particular attention is required to ensure that available residue trials on crops reflect the most critical residue situation. Where appropriate, depending on the zone, seasonal restrictions for the timing of application shall be applied (cf. representative uses excluded application from November till February).

⁽¹⁾ Further details on the identity and the specification of the active substance are provided in the renewal report.

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 210 on Abamectin is deleted;

(2) in Part B, the following entry is added:

No.	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'157	Abamectin CAS No 71751-41-2 Avermectin B1a CAS No 65195-55-3 Avermectin B1b CAS No 65195-56-4 Abamectin CIPAC No 495	Avermectin B1a (10E,14E,16E)-(1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R,24S)-6'-[(S)-sec-butyl]-21,24-dihydroxy-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo [15.6.1.14,8.020,24] pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabino-hexopyranoside Avermectin B1b (10E,14E,16E)-(1R,4S,5'S,6S,6'R,8R,12S,13S,20R,21R,24S)-21,24-dihydroxy-6'-isopropyl-5',11,13,22-tetramethyl-2-oxo-(3,7,19-trioxatetracyclo [15.6.1.14,8.020,24] pentacosa-10,14,16,22-tetraene)-6-spiro-2'-(5',6'-dihydro-2'H-pyran)-12-yl 2,6-dideoxy-4-O-(2,6-dideoxy-3-O-methyl-α-L-arabino-hexopyranosyl)-3-O-methyl-α-L-arabino-hexopyranoside	≥ 850 g/kg abamectin (sum of avermectin B1a and avermectin B1b), min. 800 g/kg avermectin B1a and max. 200 g/kg avermectin B1b	1 April 2023	31 March 2038	Only uses which allow controlled exchange of material and energy with the surroundings and prevent release of plant protection products into the environment may be authorised, in particular uses in permanent greenhouses. For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on Abamectin, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: — the protection of operators and workers, ensuring that conditions of use include the application of adequate personal protective equipment, such as the use of gloves; — The effect of photolysis on the levels of pesticide residues in crops. Particular attention is required to ensure that available residue trials on crops reflect the most critical residue situation. Where appropriate, depending on the zone, seasonal restrictions for the timing of application shall be applied (cf. representative uses excluded application from November till February).'

⁽¹⁾ Further details on the identity and the specification of the active substance are provided in the renewal report.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/516**of 8 March 2023****amending Implementing Regulation (EU) 2020/2236 as regards the model animal health certificate for the entry into the Union of consignments of aquatic animals intended for certain aquaculture establishments, for release into the wild or for other purposes, excluding direct 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) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ⁽¹⁾, and in particular Articles 238(3), points (a) and (c), 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 90 thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2020/2236 ⁽³⁾ sets out the model animal health certificates for the entry into the Union and movements within the Union of consignments of aquatic animals and of certain products of animal origin from aquatic animals.
- (2) In particular, Annex II to Implementing Regulation (EU) 2020/2236 sets out the model animal health certificate for the entry into the Union of consignments of aquatic animals intended for certain aquaculture establishments, for release into the wild or for other purposes, excluding direct human consumption (model 'AQUA-ENTRY-ESTAB/RELEASE/OTHER'). Article 166 of Commission Delegated Regulation (EU) 2020/692 ⁽⁴⁾ was recently amended by Delegated Regulation (EU) 2023/119 ⁽⁵⁾ in order to permit aquatic animal health professionals to perform clinical

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ OJ L 95, 7.4.2017, p. 1.

⁽³⁾ Commission Implementing Regulation (EU) 2020/2236 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 for the entry into the Union and movements within the Union of consignments of aquatic animals and of certain products of animal origin from aquatic animals, official certification regarding such certificates and repealing Regulation (EC) No 1251/2008 (OJ L 442, 30.12.2020, p. 410).

⁽⁴⁾ 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).

⁽⁵⁾ Commission Delegated Regulation (EU) 2023/119 of 9 November 2022 amending Delegated Regulation (EU) 2020/692 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 16, 18.1.2023, p. 5).

inspections on consignments of aquatic animals prior to export to the Union, provided they are authorised to do so under the law of the exporting third country or territory. Those new requirements for the entry into the Union of those consignments should be reflected in point II.3.2. of that model animal health certificate. Annex II to Implementing Regulation (EU) 2020/2236 should therefore be amended accordingly.

- (3) In order to avoid any disruption to trade as regards the entry into the Union of consignments of aquatic animals intended for certain aquaculture establishments, for release into the wild or for other purposes, excluding direct human consumption, the use of animal health certificate issued in accordance with Implementing Regulation (EU) 2020/2236, as applicable prior to the amendments made by this Implementing Regulation, should continue to be authorised during a transitional period subject to certain conditions.
- (4) As Implementing Regulation (EU) 2020/2236 applies from 21 April 2021, in the interest of legal certainty and to facilitate trade, the amendments to be made to Implementing Regulation (EU) 2020/2236 by this Regulation should take effect as a matter of urgency.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Implementing Regulation (EU) 2020/2236 is amended in accordance with the Annex to this Regulation.

Article 2

For a transitional period until 15 December 2023, consignments of aquatic animals intended for certain aquaculture establishments, for release into the wild or for other purposes, excluding direct human consumption, accompanied by the animal health certificate issued in accordance with the model set out in Annex II to Implementing Regulation (EU) 2020/2236, as applicable before the amendments made to that Implementing Regulation by this Implementing Regulation, shall continue to be authorised for entry into the Union provided that the certificate was issued no later than 15 September 2023.

Article 3

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

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

Done at Brussels, 8 March 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annex II to Implementing Regulation (EU) 2020/2236 is replaced by the following:

'ANNEX II

Annex II contains the following model animal health certificate:

Model

AQUA-ENTRY-ESTAB/RELEASE/ OTHER	Model animal health certificate for the entry into the Union of aquatic animals intended for certain aquaculture establishments, for release into the wild or for other purposes, excluding direct human consumption
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MODEL ANIMAL HEALTH CERTIFICATE FOR THE ENTRY INTO THE UNION OF AQUATIC ANIMALS INTENDED FOR CERTAIN AQUACULTURE ESTABLISHMENTS, FOR RELEASE INTO THE WILD OR FOR OTHER PURPOSES, EXCLUDING DIRECT HUMAN CONSUMPTION (MODEL 'AQUA-ENTRY-ESTAB/RELEASE/OTHER')

COUNTRY		Animal health certificate to the EU	
Part I: Description of consignment	I.1 Consignor/Exporter Name Address Country ISO country code	I.2 Certificate reference	I.2a IMSOC reference
		I.3 Central Competent Authority	QR CODE
		I.4 Local Competent Authority	
	I.5 Consignee/Importer Name Address Country ISO country code	I.6 Operator responsible for the consignment Name Address Country ISO country code	
	I.7 Country of origin ISO country code	I.9 Country of destination ISO country code	
	I.8 Region of origin Code	I.10 Region of destination Code	
	I.11 Place of dispatch Name Registration/Approval No Address Country ISO country code	I.12 Place of destination Name Registration/Approval No Address Country ISO country code	
	I.13 Place of loading	I.14 Date and time of departure	
	I.15 Means of transport ☐ Aircraft ☐ Vessel ☐ Railway ☐ Road vehicle Identification	I.16 Entry Border Control Post	
		I.17 Accompanying documents Type Code Country ISO country code Commercial document reference	
	I.18 Transport conditions	☐ Ambient	☐ Chilled
I.19 Container number/Seal number			
Container No		Seal No	
I.20 Certified as or for			
☐ Further keeping ☐ Confined establishment ☐ Release into the wild ☐ Quarantine establishment ☐ Other ☐ Ornamental aquaculture establishment ☐ Relaying area			
I.21 For transit Third country ISO country code	I.22 For internal market		
	I.23		

I.24 Total number of packages			I.25 Total quantity		I.26 Total net weight/gross weight (kg)		
I.27 Description of consignment							
CN code	Species	Subspecies/Category		Nature of commodity	Type of packaging		Age Quantity
					Number of packages		Net weight
					Approval or registration number of establishment		

COUNTRY

Certificate model AQUA-ENTRY-
ESTAB/RELEASE/OTHER

Part II: Certification	II. Health information	II.a Certificate reference	II.b IMSOC reference
	I, the undersigned official veterinarian, hereby certify: II.1. According to official information, the aquatic animals of the consignment described in Box I.27 meet the following animal health requirements: II.1.1. The aquatic animals originate from [an establishment] ⁽¹⁾ [a habitat] ⁽¹⁾ which is not subject to national restriction measures for animal health reasons or because of the occurrence of abnormal mortalities with an undetermined cause, including the listed diseases referred to in Annex I to Commission Delegated Regulation (EU) 2020/692 ^A relevant for the species and emerging diseases. II.1.2. The aquatic animals are not intended to be killed under a national programme for the eradication of diseases, including the listed diseases referred to in Annex I to Delegated Regulation (EU) 2020/692 relevant for the species and emerging diseases. ⁽¹⁾ [II.2. The aquaculture animals of the consignment described in Box I.27 meet the following requirements: II.2.1. They come from an aquaculture establishment which is [registered] ⁽¹⁾ [approved] ⁽¹⁾ by, and under the control of, the competent authority of the third country or territory of origin and has a system in place to maintain and to keep for a period of at least three years, up-to-date records containing information regarding: (i) the species, categories and number of aquaculture animals on the aquaculture establishment; (ii) movements of aquatic animals into, and aquaculture animals out of, the aquaculture establishment; (iii) mortality in the aquaculture establishment. II.2.2. They come from an aquaculture establishment which receives regular animal health visits from a veterinarian for the purpose of the detection of, and information on, signs indicative of the listed diseases referred to in Annex I to Delegated Regulation (EU) 2020/692 relevant for the species and of emerging diseases, at a frequency that is proportionate to the risk posed by the aquaculture establishment.] II.3. General health requirements The aquatic animals of the consignment described in Box I.27 meet the following animal health requirements: II.3.1. The aquatic animals originate from a [country] ⁽¹⁾ [territory] ⁽¹⁾, [zone] ⁽¹⁾ [compartment] ⁽¹⁾ with code: __ - __ ⁽²⁾ which, at the date of issuing this animal health certificate is listed in Part 1 of Annex XXI to Commission Implementing Regulation (EU) 2021/404 ^B for the entry into the Union of certain species of aquatic animals. II.3.2. They have undergone clinical inspection in accordance with Article 166 of Delegated Regulation (EU) 2020/692 within a period of 72 hours prior to the time of loading. During the inspection, the aquatic animals showed no clinical symptoms of transmissible disease and, according to the relevant records of the aquaculture establishment, there was no indication of disease problems. II.3.3. They will be dispatched to the Union directly from the establishment of origin. II.3.4. They have not been in contact with aquatic animals of a lower health status. ⁽¹⁾ either II.4. Specific health requirements		

COUNTRY

Certificate model AQUA-ENTRY-
ESTAB/RELEASE/OTHER

	⁽¹⁾ [II.4.1. Requirements for listed ⁽³⁾ species for Epizootic haematopoietic necrosis, Infection with <i>Mikrocytos mackini</i>, Infection with <i>Perkinsus marinus</i>, Infection with Taura syndrome virus and Infection with yellow head virus The aquatic animals of the consignment described in Box I.27 originate from a [country] ⁽¹⁾ [territory] ⁽¹⁾ [zone] ⁽¹⁾ [compartment] ⁽¹⁾ declared free from [Epizootic haematopoietic necrosis] ⁽¹⁾ [Infection with <i>Mikrocytos mackini</i>] ⁽¹⁾ [Infection with <i>Perkinsus marinus</i>] ⁽¹⁾ [Infection with Taura syndrome virus] ⁽¹⁾ [Infection with yellow head virus] ⁽¹⁾ in accordance with conditions which are at least as stringent as those set out in Article 66 or in Article 73(1) and Article 73(2), point (a), of Commission Delegated Regulation (EU) 2020/689 ^C and where all listed ⁽³⁾ species for the relevant disease(s): (i) are introduced from another country or territory, or zone or compartment thereof which has been declared free from the same disease(s); (ii) are not vaccinated against [that] ⁽¹⁾ [those] ⁽¹⁾ disease(s).] ⁽¹⁾⁽⁴⁾ [II.4.2. Requirements for listed ⁽³⁾ species for Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN), infection with HPR-deleted infectious salmon anaemia virus (ISAV), infection with <i>Marteilia refringens</i>, infection with <i>Bonamia exitiosa</i>, infection with <i>Bonamia ostreae</i>, and infection with White spot syndrome virus The aquatic animals of the consignment described in Box I.27 originate from a [country] ⁽¹⁾ [territory] ⁽¹⁾ [zone] ⁽¹⁾ [compartment] ⁽¹⁾ declared free from [Viral haemorrhagic septicaemia (VHS)] ⁽¹⁾ [Infectious haematopoietic necrosis (IHN)] ⁽¹⁾ [infection with HPR-deleted infectious salmon anaemia virus (ISAV)] ⁽¹⁾ [infection with <i>Marteilia refringens</i>] ⁽¹⁾ [infection with <i>Bonamia exitiosa</i>] ⁽¹⁾ [infection with <i>Bonamia ostreae</i>] ⁽¹⁾ [infection with White spot syndrome virus] ⁽¹⁾ in accordance with Part II, Chapter 4, of Delegated Regulation (EU) 2020/689 and where all listed ⁽³⁾ species for the relevant disease(s): (i) are introduced from another country or territory, or zone or compartment thereof which has been declared free from the same disease(s); (ii) are not vaccinated against [that] ⁽¹⁾ [those] ⁽¹⁾ disease(s).] ⁽¹⁾⁽⁵⁾ [II.4.3. Requirements for species ⁽⁶⁾ susceptible to infection with Spring viraemia of carp virus (SVC), Bacterial Kidney disease (BKD), infection with Infectious pancreatic necrosis virus (IPN), infection with <i>Gyrodactylus salaris</i> (GS), infection with Salmonid alphavirus (SAV) infection with Ostreid herpes virus 1 μvar (OsHV-1 μvar) and species ⁽³⁾ susceptible to Koi herpes virus disease The aquatic animals of the consignment described in Box I.27 originate from a [country] ⁽¹⁾ [territory] ⁽¹⁾ [zone] ⁽¹⁾ [compartment] ⁽¹⁾ which fulfils the health guarantees as regards [SVC,] ⁽¹⁾ [BKD,] ⁽¹⁾ [IPN,] ⁽¹⁾ [GS,] ⁽¹⁾ [SAV,] ⁽¹⁾ [OsHV-1 μvar,] ⁽¹⁾ [KHV,] ⁽¹⁾ which are necessary to comply with the national measures which apply in the Member State of destination in accordance with Article 175 of Delegated Regulation (EU) 2020/692, and for which the Member State or part thereof, is listed in [Annex I] ⁽¹⁾ [Annex II] ⁽¹⁾ to Commission Implementing Decision (EU) 2021/260 ^D.] ^{(1) or} [II.4. Specific health requirements The aquatic animals of the consignment described in Box I.27 are aquatic animals destined for a confined establishment fulfilling the requirements of Article 9 of Commission Delegated Regulation (EU) 2020/691 ^E where they are to be used for research purposes.]
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COUNTRY

Certificate model AQUA-ENTRY-
ESTAB/RELEASE/OTHER⁽¹⁾ or **II.4. Specific health requirements**

The aquatic animals of the consignment described in Box I.27 are wild aquatic animals which, [have been subject to quarantine in an establishment approved for that purpose by the competent authority in the [country] ⁽¹⁾ [territory] ⁽¹⁾ of origin in accordance with Article 15 of Delegated Regulation (EU) 2020/691.] ⁽¹⁾ [will be subject to quarantine in an establishment which is approved for that purpose in accordance with Article 15 of Delegated Regulation (EU) 2020/691.] ⁽¹⁾

II.5. To the best of my knowledge, and as declared by the operator, the aquatic animals of the consignment described in Box I.27 show no symptoms of disease and come from [an establishment] ⁽¹⁾ [a habitat] ⁽¹⁾ where:

- (i) there were no abnormal mortalities with an undetermined cause; and
- (ii) the aquatic animals have not been in contact with kept animals of listed ⁽³⁾ species which did not comply with the requirements referred to in point II.1.

II.6. Transport requirements

Arrangements have been made to transport the aquatic animals of the consignment described in Box I.27 in accordance with the requirements laid down in Articles 167 and 168 of Delegated Regulation (EU) 2020/692 and specifically that:

- II.6.1. the aquatic animals are dispatched to the Union directly from the establishment of origin and are not unloaded from their container when transported by air, sea, railway or by road;
- II.6.2. the water in which they are transported is not changed in a third country or territory, or zone, or compartment thereof which is not listed for entry into the Union of the particular species and category of aquatic animals;
- II.6.3. the animals are not transported under conditions that jeopardise their health status, in particular:
 - (i) when the aquatic animals are transported in water, it does not alter their health status;
 - (ii) the means of transport and the containers are constructed in such a way that the health status of the aquatic animals is not jeopardised during transportation;
 - (iii) the [container] ⁽¹⁾ [well-boat] ⁽¹⁾ is previously unused or cleaned and disinfected, in accordance with a protocol and with products approved by the competent authority of the third country or territory of origin, prior to loading for dispatch to the Union;
- II.6.4. from the time of loading at the establishment of origin until the time of arrival in the Union, the aquatic animals of the consignment described in Box I.27 are not transported in the same water or [container] ⁽¹⁾ [well-boat] ⁽¹⁾ together with aquatic animals which are of a lower health status or which are not intended for entry into the Union;
- II.6.5. where a water exchange is necessary in a [country] ⁽¹⁾ [territory] ⁽¹⁾ [zone] ⁽¹⁾ [compartment] ⁽¹⁾ which is listed for entry into the Union of the particular species and category of aquatic animals, it only occurs [in the case of transport on land, at water exchange points approved by the competent authority of the third country or territory where the water exchange takes place.] ⁽¹⁾ [in the case of transport by well-boat, at a distance which is at least 10 km from any aquaculture establishments which are located *en-route* from the place of origin to the place of destination in the Union.] ⁽¹⁾

COUNTRY

Certificate model AQUA-ENTRY-
ESTAB/RELEASE/OTHER**II.7. Labelling requirements**

Arrangements have been made to identify and label the [means of transport] ⁽¹⁾ [containers] ⁽¹⁾ in accordance with Article 169(1) and (2) of Delegated Regulation (EU) 2020/692 and specifically that:

- II.7.1. the consignment is identified by [a legible and visible label on the exterior of the container] ⁽¹⁾ [an entry in the ships manifest when transported by well-boat,] ⁽¹⁾ which clearly links the consignment to this animal health certificate;
- II.7.2. the legible and visible label will contain at least the following information:
 - (a) the number of containers in the consignment;
 - (b) the name of the species present in each container;
 - (c) the number of aquatic animals in each container for each of the species present;
 - (d) the purpose for which the aquatic animals are intended.

II.8. Validity of the animal health certificate

This animal health certificate is valid for a period of 10 days from the date of issuing. In the case of transport by waterway/sea of aquatic animals, this period of 10 days may be extended by the duration of the journey by waterway/sea.

Notes

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, references to the Union in this animal health certificate include the United Kingdom in respect of Northern Ireland.

‘Aquatic animals’ are animals as defined in Article 4, point (3), of Regulation (EU) 2016/429.

‘Aquaculture animals’ are aquatic animals which are subject to aquaculture as defined in Article 4, point (7), of Regulation (EU) 2016/429.

This animal health certificate is intended for entry into the Union of aquatic animals for the purposes indicated in the title of the certificate, including when the Union is not the final destination of those animals.

This animal health certificate shall not be used for the entry into the Union of aquatic animals intended for human consumption in accordance with Regulation (EC) No 853/2004 of the European Parliament and of the Council ^H and Commission Regulation (EC) No 2073/2005 ^I, including those animals which are intended for the following aquaculture establishments:

- (i) a disease control aquatic food establishment as defined in Article 4, point (52), of Regulation (EU) 2016/429, or
- (ii) a dispatch centre as defined in Article 2, point (3), of Delegated Regulation (EU) 2020/691.

For those aquatic animals, the model certificate FISH-CRUST-HC as set out in Chapter 28 of Annex III to Commission Implementing Regulation (EU) 2020/2235 ^F, or MOL-HC as set out in Chapter 31 of Annex III to that Regulation, must be used, as relevant.

This animal health certificate shall be completed in accordance with the notes for the completion of certificates provided for in Chapter 4 of Annex I to Implementing Regulation (EU) 2020/2235.

COUNTRY

Certificate model AQUA-ENTRY-
ESTAB/RELEASE/OTHER

Part II: (1) (2) (3) (4) (5) (6)	Keep if appropriate/delete if not applicable. In the case of Part II.4.1., deletion is not permitted if the consignment contains listed species for Epizootic haematopoietic necrosis, Infection with <i>Mikrocytos mackini</i>, Infection with <i>Perkinsus marinus</i>, Infection with Taura syndrome virus or Infection with yellow head virus. Code of the third country or territory, or zone or compartment thereof as it appears in column 2 of the table in Part 1 of Annex XXI to Implementing Regulation (EU) 2021/404. Listed species as referred to in columns 3 and 4 of the table in the Annex to Commission Implementing Regulation (EU) 2018/1882^G. Vector species listed in column 4 of that table shall only be regarded as vectors if they fulfil the conditions set out in Annex XXX to Delegated Regulation (EU) 2020/692. Applicable in all cases when aquatic animals are to be released into the wild in the Union or when the Member State of destination either has disease-free status for a category C disease as defined in Article 1, point (3), of Implementing Regulation (EU) 2018/1882 or is subject to an optional eradication programme established in accordance with Article 31(2) of Regulation (EU) 2016/429. Only applicable when the Member State of destination or part thereof, has approved national measures for a specific disease as listed in Annex I or Annex II to Implementing Decision (EU) 2021/260, otherwise delete. Species listed in column 2 of the table in Annex III to Implementing Decision (EU) 2021/260.				
Official veterinarian Name (in capital letters) <table border="0" style="width: 100%;"> <tr> <td style="width: 50%;">Date</td> <td style="width: 50%;">Qualification and title</td> </tr> <tr> <td>Stamp</td> <td>Signature</td> </tr> </table>		Date	Qualification and title	Stamp	Signature
Date	Qualification and title				
Stamp	Signature				

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

^B 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).

^C Commission Delegated Regulation (EU) 2020/689 of 17 December 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (OJ L 174, 3.6.2020, p. 211).

^D Commission Implementing Decision (EU) 2021/260 of 11 February 2021 approving national measures designed to limit the impact of certain diseases of aquatic animals in accordance with Article 226(3) of Regulation (EU) 2016/429 of the European Parliament and of the Council and repealing Commission Decision 2010/221/EU (OJ L 59, 19.2.2021, p. 1).

^E Commission Delegated Regulation (EU) 2020/691 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for aquaculture establishments and transporters of aquatic animals (OJ L 174, 3.6.2020, p. 345).

^F 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).

^G Commission Implementing Regulation (EU) 2018/1882 of 3 December 2018 on the application of certain disease prevention and control rules to categories of listed diseases and establishing a list of species and groups of species posing a considerable risk for the spread of those listed diseases (OJ L 308, 4.12.2018, p. 21).

^H 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).

^I Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).'

CORRIGENDA

Corrigendum to Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

(Official Journal of the European Union L 20 of 31 January 2022)

1. On page 11, Article 1, point (a):

for: 'a) preparing for, preventing, coordinating and managing the impact of public health emergencies on medicinal products and on medical devices and the impact of major events on medicinal products and on medical devices at Union level;'

read: 'a) preparing for, preventing, coordinating and managing the impact of public health emergencies on medicinal products and on medical devices and the impact of major events on medicinal products at Union level;'

2. On page 14, Article 4(2):

for: '2. To facilitate the monitoring referred to in paragraph 1, the national competent authorities for medicinal products, acting through the single points of contact referred to in Article 3(6), or the platform referred to in Article 13 (the 'ESMP'), once it is fully functional, shall report in a timely manner to the Agency [...].'

read: '2. To facilitate the monitoring referred to in paragraph 1, the national competent authorities for medicinal products, acting through the single points of contact referred to in Article 3(6), second subparagraph, or the platform referred to in Article 13 (the 'ESMP'), once it is fully functional, shall report in a timely manner to the Agency [...].'

3. On page 16, Article 8(1):

for: '1. For the duration of a public health emergency, or following the recognition of a major event as referred to in Article 4(3) until it has been confirmed that the major event has been sufficiently addressed pursuant to Article 4(4), the MSSG shall regularly report the results of the monitoring referred to in Article 7 to the Commission and the single points of contact referred to in Article 3(6), and, in particular, shall signal any actual or potential shortages of medicinal products included on the critical medicines lists or any event that is likely to lead to a major event.'

read: '1. For the duration of a public health emergency, or following the recognition of a major event as referred to in Article 4(3) until it has been confirmed that the major event has been sufficiently addressed pursuant to Article 4(4), the MSSG shall regularly report the results of the monitoring referred to in Article 7 to the Commission and the single points of contact referred to in Article 3(6), second subparagraph, and, in particular, shall signal any actual or potential shortages of medicinal products included on the critical medicines lists or any event that is likely to lead to a major event.'

4. On page 16, Article 8(2):

for: '2. Where requested by the Commission or one or more single point of contact as referred to in Article 3(6), the MSSG shall provide aggregated data and demand forecasts to support its findings and conclusions. In that regard, the MSSG shall: [...]',

read: '2. Where requested by the Commission or one or more single point of contact as referred to in Article 3(6), second subparagraph, the MSSG shall provide aggregated data and demand forecasts to support its findings and conclusions. In that regard, the MSSG shall: [...]'.

5. On page 18, Article 9(2), point (d):

for: '(d) request information on medicinal products on the critical medicines lists from the single points of contact referred to in Article 3(6) on the basis of the set of information referred to in Article 6(4), and set a deadline for the submission of that information, if that information is not available in the ESMP.',

read: '(d) request information on medicinal products on the critical medicines lists from the single points of contact referred to in Article 3(6), second subparagraph, on the basis of the set of information referred to in Article 6(4), and set a deadline for the submission of that information, if that information is not available in the ESMP.'.

6. On page 18, Article 10(2), second subparagraph:

for: 'The marketing authorisation holders referred to in the first subparagraph of this paragraph shall submit the requested information by the deadline set by the Agency, through the single points of contact referred to in Article 9(2), point (b), using the monitoring and reporting methods and systems established pursuant to Article 9(1), points (b) and (c), respectively. Those marketing authorisation holders shall provide updates where necessary.',

read: 'The marketing authorisation holders referred to in the first subparagraph of this paragraph shall submit the requested information by the deadline set by the Agency, through the single points of contact referred to in Article 9(2), point (a), using the monitoring and reporting methods and systems established pursuant to Article 9(1), points (b) and (c), respectively. Those marketing authorisation holders shall provide updates where necessary.'.

7. On page 19, Article 11(1), point (a):

for: '(a) submit the set of information referred to in Article 6(4) including available and estimated data on volume of demand and demand forecasts, through the single point of contact referred to in Article 3(6) and using the reporting methods and systems established pursuant to Article 9(1), points (b) and (c), respectively';,

read: ‘(a) submit the set of information referred to in Article 9(2), point (d), including available and estimated data on volume of demand and demand forecasts, through the single point of contact referred to in Article 3(6), second subparagraph, using the reporting methods and systems established pursuant to Article 9(1), points (b) and (c), respectively;’.

8. On page 20, Article 11(3):

for: ‘3. Where Member States have any information in addition to the information to be provided in accordance with paragraphs 1 and 2 of this Article on volumes of sales of and volumes of prescriptions for medicinal products which provides evidence of an actual or potential shortage of a medicinal product included on the critical medicines lists, including data referred to in Article 23a, third paragraph, of Directive 2001/83/EC, they shall immediately provide such information to the MSSG through their respective single points of contact referred to in Article 3(6) of this Regulation.’.

read: ‘3. Where Member States have any information in addition to the information to be provided in accordance with paragraphs 1 and 2 of this Article on volumes of sales of and volumes of prescriptions for medicinal products which provides evidence of an actual or potential shortage of a medicinal product included on the critical medicines lists, including data referred to in Article 23a, third paragraph, of Directive 2001/83/EC, they shall immediately provide such information to the MSSG through their respective single points of contact referred to in Article 3(6), second subparagraph, of this Regulation.’.

9. On page 21, Article 13(3), point (b):

for: ‘(b) Member States shall use the ESMP to report information relating to medicinal products on the critical medicines lists to the Agency, through the single points of contact referred to in Article 9(1), point (d), in accordance with Articles 9 and 11.’.

read: ‘(b) Member States shall use the ESMP to report information relating to medicinal products on the critical medicines lists to the Agency, through the single points of contact referred to in Article 3(6), second subparagraph, in accordance with Articles 9 and 11.’.

10. On page 21, Article 13(4), point (b):

for: ‘(b) Member States shall use the ESMP to report to the Agency on shortages of medicinal products that are likely to lead to a public health emergency or major event in accordance with Article 4(2), through the single points of contact referred to in Article 9(1), point (e).’.

read: ‘(b) Member States shall use the ESMP to report to the Agency on shortages of medicinal products that are likely to lead to a public health emergency or major event in accordance with Article 4(2), through the single points of contact referred to in Article 3(6), second subparagraph.’.

11. On page 28, Article 22(2):

for: '2. For the purposes of Article 25(2), the MDSSG shall adopt and make publicly available the set of information referred to in Article 25(2), points (b) and (c), that is necessary to monitor the supply of and demand for medical devices included on the public health emergency critical devices list, and inform the working party referred to in Article 21(5) of that set of information.'

read: '2. For the purposes of Article 25(2), the MDSSG shall adopt and make publicly available the set of information referred to in Article 25(2), points (c) and (d), that is necessary to monitor the supply of and demand for medical devices included on the public health emergency critical devices list, and inform the working party referred to in Article 21(5) of that set of information.'

12. On page 28, Article 24(1):

for: '1. For the duration of the public health emergency, the MDSSG shall regularly report the results of the monitoring referred to in Article 23 to the Commission and the single points of contact referred to in Article 25(2), point (a), and, in particular, shall signal any actual or potential shortages of medical devices included on the public health emergency critical devices list.'

read: '1. For the duration of the public health emergency, the MDSSG shall regularly report the results of the monitoring referred to in Article 23 to the Commission and the single points of contact referred to in Article 21(5), second subparagraph, and, in particular, shall signal any actual or potential shortages of medical devices included on the public health emergency critical devices list.'

13. On page 29, Article 24(5):

for: '5. Where requested by the Commission, the MDSSG may coordinate measures taken by the national competent authorities for medical devices, manufacturers of medical devices, notified bodies, and other entities, as relevant, to prevent or mitigate actual or potential shortages of medical devices in the context of a public health emergency or major event.'

read: '5. Where requested by the Commission, the MDSSG may coordinate measures taken by the national competent authorities for medical devices, manufacturers of medical devices, notified bodies, and other entities, as relevant, to prevent or mitigate actual or potential shortages of medical devices in the context of a public health emergency.'

14. On page 31, Article 27(1), point (a):

for: '(a) submit the set of information referred to in Article 22(2), including available information about needs related to the medical devices included in the public health emergency critical devices list, and available and estimated data on volume of demand and demand forecasts for those medical devices, through the respective single point of contact referred to in Article 25(2), point (a), and using the monitoring and reporting methods and systems established pursuant to Article 25(1), point (b)';

read: ‘(a) submit the set of information referred to in Article 25(2), point (d), including available information about needs related to the medical devices included in the public health emergency critical devices list, and available and estimated data on volume of demand and demand forecasts for those medical devices, through the respective single point of contact referred to in Article 21(5), second subparagraph, using the monitoring and reporting methods and systems established pursuant to Article 25(1), point (b);’.

15. On page 32, Article 27(3):

for: ‘3. Where Member States have any information in addition to the information to be provided in accordance with paragraphs 1 and 2 of this Article, which provides evidence of an actual or potential shortage of medical devices, they shall immediately provide such information to the MDSSG through their respective single point of contact referred to in Article 25(2), point (a).’.

read: ‘3. Where Member States have any information in addition to the information to be provided in accordance with paragraphs 1 and 2 of this Article, which provides evidence of an actual or potential shortage of medical devices, they shall immediately provide such information to the MDSSG through their respective single point of contact referred to in Article 21(5), second subparagraph.’.

16. On page 32, Article 27(4), point (b):

for: ‘(b) take into account any recommendations referred to in Article 24(3) and any guidelines referred to in Article 28, point (b), and coordinate their actions in relation to any actions taken at Union level pursuant to Article 12, point (a);’.

read: ‘(b) take into account any recommendations referred to in Article 24(3) and any guidelines referred to in Article 28, point (b), and coordinate their actions in relation to any actions taken at Union level pursuant to Article 28, point (a);’.

Corrigendum to Council Implementing Regulation (EU) 2023/419 of 24 February 2023 implementing Article 8a of Regulation (EC) No 765/2006 concerning restrictive measures in view of the situation in Belarus and the involvement of Belarus in the Russian aggression against Ukraine

(Official Journal of the European Union L 61 of 27 February 2023)

On page 22, in the Annex, in the introductory wording:

for: 'Annex I to Regulation (EC) No 765/2006 is amended as follows:

- (1) in Table "A. Natural persons referred to in Article 2(1)", entries 10, 17, 20, 22, 35, 39, 41, 42, 64, 65, 71, 73, 75, 78, 85, 87, 89, 90, 123, 125 and 179 are replaced by the following:',

read: 'Annex I to Regulation (EC) No 765/2006 is amended as follows:

- (1) in Table "A. Natural persons referred to in Article 2(1)", entries 10, 17, 20, 22, 35, 39, 41, 42, 64, 65, 71, 73, 75, 78, 85, 87, 89, 90, 104, 123, 125, 129, 131, 179 and 195 are replaced by the following:'.
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Corrigendum to Commission Regulation (EU) 2023/466 of 3 March 2023 amending Annexes II, III and V to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for isoxaben, novaluron and tetraconazole in or on certain products

(Official Journal of the European Union L 68 of 6 March 2023)

On page 78, in the Annex, point (3), in the header of column (3) of the table:

for: '(sum of constituent isomers) (F)',

read: 'Novaluron (sum of constituent isomers) (F)'.

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

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