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

⁽¹⁾ Text with EEA relevance.

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⁽¹) Text with EEA relevance.

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

Information concerning the entry into force of Agreement between the European Community and the Government of Australia on certain aspects of air services

The Agreement between the European Community and the Government of Australia on certain aspects of air services, signed in Brussels on 29 April 2008, entered into force on 2 July 2009, in accordance with Article 7 of the Agreement, as the last notification was deposited on 25 June 2009.

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2020/22

of 31 October 2019

amending Annexes I and III to Regulation (EU) 2019/631 of the European Parliament and of the Council as regards the monitoring of CO₂ emissions from new light commercial vehicles type-approved in a multi-stage process

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/631 of the European Parliament and of the Council of 17 April 2019 setting CO_2 emission performance standards for new passenger cars and for new light commercial vehicles, and repealing Regulations (EC) No 443/2009 and (EU) No 510/2011 (1), and in particular Articles 7(8) and 15(8) thereof,

Whereas:

- (1) Since 1 September 2019 all light commercial vehicles are subject to a new regulatory test procedure for measuring CO₂ emissions and fuel consumption, the Worldwide Harmonised Light Vehicles Test Procedure (WLTP) set out in Commission Regulation (EU) 2017/1151 (²), replacing the New European Driving Cycle (NEDC) set out in Commission Regulation (EC) No 692/2008 (³). A new methodology for determining the CO₂ emissions and fuel consumption from category N1 vehicles which are type-approved in a multi-stage process has therefore been established and is set out in Annexes I and II to Regulation (EU) No 510/2011 of the European Parliament and of the Council (⁴).
- (2) In view of the repeal of Regulation (EU) No 510/2011 from 1 January 2020, it is necessary to ensure that the same methodology is set out in Regulation (EU) 2019/631.
- (3) According to point 2 of Part B of Annex III to Regulation (EU) 2019/631, the specific emissions of CO₂ of a multistage vehicle are to be allocated to the manufacturer of the base vehicle. In order to allow the base vehicle manufacturer to plan effectively and with sufficient certainty its compliance with its specific emissions targets, a methodology should be set up that ensures that the CO₂ emissions and mass of the completed vehicles that will be allocated to that manufacturer are known at the moment of the production and sale of the base vehicle whether complete or incomplete, and not only at the moment when the final stage manufacturer places the completed vehicle on the market.

⁽¹⁾ OJ L 111, 25.4.2019, p. 13.

^(*) Commission Regulation (EU) 2017/1151 of 1 June 2017 supplementing Regulation (EC) No 715/2007 of the European Parliament and of the Council on type-approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information, amending Directive 2007/46/EC of the European Parliament and of the Council, Commission Regulation (EC) No 692/2008 and Commission Regulation (EU) No 1230/2012 and repealing Commission Regulation (EC) No 692/2008 (OJ L 175, 7.7.2017, p. 1).

⁽³⁾ Commission Regulation (EC) No 692/2008 of 18 July 2008 implementing and amending Regulation (EC) No 715/2007 of the European Parliament and of the Council on type-approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information (OJ L 199, 28.7.2008, p. 1).

^(*) Regulation (EU) No 510/2011 of the European Parliament and of the Council of 11 May 2011 setting emission performance standards for new light commercial vehicles as part of the Union's integrated approach to reduce CO₂ emissions from light-duty vehicles (OJ L 145, 31.5.2011, p. 1).

- (4) A specific methodology for determining the CO₂ emissions of an incomplete base vehicle is therefore provided according to which the interpolation method provided for in Regulation (EU) 2017/1151 should be used. The CO₂ emissions and the mass values thus determined should be as representative as possible of the specific CO₂ emissions and mass in running order that will be determined for the completed vehicle. In order to ensure consistency, the calculation of the base vehicle manufacturer's specific emission target should therefore take into account the mass values determined pursuant to this methodology.
- (5) The base vehicle manufacturer should report the input values used for the interpolation method as well as the resulting CO₂ emissions and mass of incomplete base vehicles to the Commission. At the same time, Member States should continue to report to the Commission the specific emissions of CO₂ and mass in running order of the completed vehicles.
- (6) On the basis of those reported data, the Commission should continuously assess the representativeness of the monitoring CO₂ emissions of the base vehicle and inform the manufacturers of any divergences found. In the case of a significant and continued divergence between the average of the monitoring CO₂ values of the base vehicles and the average of the specific emissions of CO₂ of the completed vehicles, the values for the completed vehicles should be used for the purposes of determining whether manufacturers comply with their specific emissions targets.
- (7) In order to take into account that Regulation (EU) No 510/2011 is repealed with effect from 1 January 2020, it is appropriate to ensure that this Regulation enters into force as close as possible to that date.
- (8) Annexes I and III to Regulation (EU) 2019/631 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I and III to Regulation (EU) 2019/631 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the seventh 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, 31 October 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Annexes I and III to Regulation (EU) 2019/631 are amended as follows:

(1) in point 4 of Part B of Annex I, the definition of ${}^{\circ}M_{o}$ is replaced by the following:

'Mø is the average of the mass (M) of the new light commercial vehicles of the manufacturer registered in the relevant target year in kilograms (kg);

Where.

- in the case of a complete vehicle, M is the mass in running order of that vehicle
- in the case of a complete base vehicle related to a completed vehicle, M is the mass in running order of that base vehicle
- in the case of an incomplete base vehicle related to a completed vehicle, M is the monitoring mass (M_{mon}) of that base vehicle, determined in accordance with the following formula:

$$M_{mon} = MRO_{base} \times B_0$$

Where,

MRO_{base} is the mass in running order of the base vehicle concerned

B₀ is as defined in point 1.2.4(a) of Part A of Annex III.';

- (2) in Annex III, Part A is amended as follows:
 - (a) point 1.2 is replaced by the following:
 - '1.2. Completed vehicles registered as N1 vehicles
 - 1.2.1. Reporting by Member States

The format set out in Section 2 of Part C shall be used for the reporting of data relating to completed N1 vehicles.

The vehicle identification number referred to in point (o) of point 1.1 shall not be made public.

1.2.1.1. Completed vehicles type-approved in accordance with Regulation (EC) No 692/2008

Member States shall for calendar year 2020 record the following detailed data with regard to:

- (a) the incomplete base vehicle: the data specified in points (a), (b), (c), (d), (e), (g), (h), (i), (n) and (o) of point 1.1, or, instead of the data specified in points (h) and (i), the default added mass provided as part of the type-approval information specified in point 2.17.2 of Annex I to Directive 2007/46/EC;
- (b) the complete base vehicle: the data specified in points (a), (b), (c), (d), (e), (g), (h), (i), (n) and (o) of point 1.1;
- (c) the completed vehicle: the data specified in points (a), (f), (g), (h), (j), (k), (l), (m) and (o) of point 1.1.

Where any of the data referred to in points (a) and (b) of the first subparagraph cannot be provided for the base vehicle, Member States shall provide data with regard to the completed vehicle instead.

1.2.1.2. Completed vehicles of category N1 type-approved in accordance with Annex XXI to Regulation (EU) 2017/1151

For each new completed vehicle registered in 2020 and subsequent calendar years, Member States shall as a minimum report the detailed data specified in points (a), (f), (g), (h), (o), (p) and (r) of point 1.1.

1.2.2. Reporting by manufacturers

For each new completed vehicle of category N1, type-approved in accordance with Annex XXI to Regulation (EU) 2017/1151 registered in 2020 and subsequent calendar years, the manufacturer of the related base vehicle shall report to the Commission by 28 February each year, starting from 2021, the following data relating to the base vehicle:

- (a) where the completed vehicle is based on an incomplete base vehicle:
 - (i) vehicle identification number;
 - (ii) vehicle family identifier as referred to in paragraph 5.0 of Annex XXI to Regulation (EU) 2017/1151;

- (iii) monitoring CO₂ emissions determined in accordance with point 1.2.4;
- (iv) frontal area, specifying the applicable option as referred to in point 1.2.4(c);
- (v) rolling resistance, as referred to in point 1.2.4(b);
- (vi) monitoring mass, determined in accordance with point 4.1 of Part B of Annex I;
- (vii) mass in running order;
- (viii) mass representative of the vehicle load as defined in point 1.2.4(a);
- (b) where the completed vehicle is based on a complete base vehicle:
 - (i) vehicle identification number;
 - (ii) vehicle family identifier as referred to in point (a)(ii) of this paragraph;
 - (iii) specific CO₂ emissions of the base vehicle;
 - (iv) mass in running order.
- 1.2.3. Calculation of the average specific emissions of CO₂ and the specific emission target

The Commission shall use the values reported by a base vehicle manufacturer in accordance with point 1.2.2 to calculate its average specific emissions of CO₂ and the specific emission target in the calendar year in which the related completed vehicle is registered, except where the conditions referred to in point 1.2.5 are met in which case the data for the completed vehicles shall be used.

Where the data referred to in point 1.2.2 is not reported by the manufacturer of the base vehicle, the specific CO_2 emissions reported by the Member States in accordance with point 1.2.1 with regard to the related completed vehicle shall be used for the calculation of the average specific emissions of CO_2 and the specific emissions target of the manufacturer concerned.

1.2.4. Calculation of the monitoring CO2 emissions in the case of incomplete base vehicles

A manufacturer shall, starting from calendar year 2020, calculate the monitoring CO_2 emissions for each of its individual incomplete base vehicles in accordance with the interpolation method referred to in points 3.2.3.2 or 3.2.4 of Sub-Annex 7 to Annex XXI to Regulation (EU) 2017/1151, using the same method as that applied for the EC type-approval of the base vehicle with regard to its emissions, where the terms shall be as defined in those points with the following exceptions:

(a) Mass of the individual vehicle

The term ' TM_{ind} ' referred to in points 3.2.3.2.2.1 or 3.2.4.1.1.1 of Sub-Annex 7 to Annex XXI to Regulation (EU) 2017/1151 shall be replaced by the base vehicle default mass, DM_{base} . Where DM_{base} is lower than the test mass of vehicle low, TM_L , of the interpolation family, TM_{ind} shall be replaced by TM_L . Where DM_{base} is higher than the test mass of vehicle high, TM_H , of the interpolation family, TM_{ind} shall be replaced by TM_H .

DM_{base} shall be determined in accordance with the following formula:

$$DM_{base} = MRO_{base} \times B_0 + 25 \text{ kg} + M_{VL}$$

Where,

MRO_{base} is the mass in running order of the base vehicle as defined in point

3.2.5 of Annex XXI to Regulation (EU) 2017/1151;

 B_0 is the body mass value of 1,375;

 M_{VL} is the mass representative of the vehicle load, which means 28 per

cent of the maximum vehicle load, where maximum vehicle load is defined as the technically permissible maximum laden mass minus the mass in running order of the base vehicle multiplied by B_0 ,

minus 25 kg.

The value of B_0 shall be adjusted by 31 October 2021 on the basis of the mass in running order of the incomplete base vehicles for all completed vehicles registered in calendar years 2018, 2019, and 2020, calculated in accordance with the below formulas. The new B_0 value shall apply from 1 January 2022 until 31 December 2024.

Formula 1:

$$B_0 = \frac{\sum_{i=2018}^{2020} A_i n_i}{\sum_{i=2018}^{2020} n_i}$$

Where,

 A_{i} is the value A_{y} as calculated in Formula 2 for the relevant calendar

n_i is the number of incomplete base vehicles related to completed vehicles registered in the calendar year

Formula 2:

$$A_{y} = \frac{\sum_{i=1}^{n} M_{fi}}{\sum_{i=1}^{n} M_{bi}}$$

Where,

 A_v is the average of the ratio between M_{fi} and M_{bi} for each of the calendar years 2018 to 2020;

 $M_{\rm fi}$ is the mass in running order of the incomplete base vehicle increased by the default added mass as defined in Section 5 of Annex XII to Regulation (EC) No 692/2008;

M_{bi} is the mass in running order of the incomplete base vehicle;

n is the number of incomplete base vehicles related to completed vehicles registered in the calendar year.

(b) Rolling resistance of the individual vehicle

The rolling resistance of the base vehicle shall be used for the purposes of point 3.2.3.2.2.2 or 3.2.4.1.1.2 of Sub-Annex 7 to Annex XXI to Regulation (EU) 2017/1151.

(c) Frontal area

In the case of an incomplete base vehicle that belongs to a road load matrix family, the manufacturer shall determine the term 'Af' referred to in point 3.2.3.2.2.3 of Sub-Annex 7 to Annex XXI to Regulation (EU) 2017/1151 in accordance with one of the following options:

- (i) frontal area of the representative vehicle of the road load matrix family, in m²;
- (ii) the mean value of the frontal area of vehicle high and vehicle low of the interpolation family, in m²:
- (iii) the frontal area of the vehicle high of the interpolation family, in case the interpolation method is not used, in m².

In the case of an incomplete base vehicle that does not belong to a road load matrix family, the frontal area value of vehicle high of the interpolation family shall be used.

1.2.5. Representativeness of the monitoring CO2 value

The Commission shall each year assess the representativeness of the average of the monitoring CO_2 emissions reported by the base vehicle manufacturer as compared to the average of the specific emissions of CO_2 of the related completed vehicles registered in the relevant calendar year. The Commission shall inform the manufacturer of the base vehicle of the divergence found between those values.

In case a divergence by 4 % or more is found during each of two successive calendar years, the Commission shall use the average of the specific emissions of CO₂ of the completed vehicles in the following calendar year to calculate the average specific emissions of CO₂ of the base vehicle manufacturer or the pool in that year.';

- (b) point 2 is replaced by the following:
 - '2. The details referred to in point 1 shall be taken from the certificate of conformity issued by the manufacturer of the relevant light commercial vehicle or be consistent with it. For those details that are not available in the certificate of conformity, details shall be taken from the type approval documentation or from the information reported by the base vehicle manufacturer pursuant to point 1.2.3. Member States shall put the necessary measures in place to ensure adequate accuracy in the monitoring procedure. Where the certificate of conformity specifies both a minimum and a maximum mass for a light commercial vehicle, the Member States shall use only the maximum figure for the purpose of this Regulation. In the case of bi-fuelled vehicles (petrol/gas) the certificates of conformity of which bear specific CO₂ emission figures for both types of fuel, Member States shall use only the figure measured for gas.'

COMMISSION IMPLEMENTING REGULATION (EU) 2020/23

of 13 January 2020

concerning the non-renewal of the approval of the active substance thiacloprid, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to 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) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2004/99/EC (²) included thiacloprid 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 thiacloprid as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 April 2020.
- (4) An application for the renewal of the approval of thiacloprid was submitted 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 required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2004/99/EC of 1 October 2004 amending Council Directive 91/414/EEC to include acetamiprid and thiacloprid as active substances (OJ L 309, 6.10.2004, p. 6).

⁽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).

^(*) 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).

- (6) The rapporteur Member State prepared a renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 31 October 2017.
- (7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the renewal assessment report to the applicant and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.
- (8) On 22 January 2019 the Authority communicated to the Commission its conclusion (6) on whether thiacloprid can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The Authority identified a critical concern in relation to the contamination of groundwater by metabolites of thiacloprid. In particular, metabolites M30, M34 and M46 are predicted to occur above the parametric drinking water limit of 0,1 μg/L in all pertinent scenarios for all proposed uses of thiacloprid. These metabolites are considered *a priori* of concern since it cannot be excluded that they share the same carcinogenic properties of the parent active substance thiacloprid, which is classified in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council (⁷) as carcinogenic category 2. Therefore, it cannot currently be established that the presence of metabolites of thiacloprid in groundwater will not result in unacceptable effects on groundwater and in harmful effects on human health. The Authority also concluded that the assessment of the risks to aquatic organisms, bees and non-target terrestrial plants could not be finalised based on the information provided in the dossier.
- (10) Additionally, thiacloprid is classified in accordance with Regulation (EC) No 1272/2008 also as toxic for reproduction category 1B. The applicant provided information attempting to demonstrate that exposure of humans to thiacloprid can be considered negligible. The Authority presented the outcome of the assessment of that information in its conclusion. Nevertheless, given the concerns identified in recital 9, a conclusion on whether exposure to humans is negligible for the purposes of point 3.6.4 of Annex II to Regulation (EC) No 1107/2009, is not necessary for the decision on whether the approval of thiacloprid can be renewed.
- (11) Furthermore, given the concerns identified, it is also not possible to provide for an approval in accordance with Article 4(7) to Regulation (EC) No 1107/2009.
- (12) The Commission invited the applicant to submit its comments on the conclusion of the Authority. Furthermore, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, the Commission invited the applicant to submit comments on the draft renewal report. The applicant submitted its comments, which have been carefully examined.
- (13) However, despite the arguments put forward by the applicant, the concerns regarding the active substance could not be eliminated.
- (14) Consequently, it has not been established with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to renew the approval of the active substance thiacloprid in accordance with Article 20(1)(b) of that Regulation.
- (15) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (16) Member States should be given sufficient time to withdraw authorisations for plant protection products containing thiacloprid.

^(°) EFSA Journal (2019). Conclusion on the peer review of the pesticide risk assessment of the active substance thiacloprid. EFSA Journal 2019;17(3):5595. doi: 10.2903/j.efsa.2019.5595.

⁽⁷⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

- (17) For plant protection products containing thiacloprid, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should not exceed 12 months.
- (18) Commission Implementing Regulation (EU) 2019/168 (8) extended the approval period of thiacloprid to 30 April 2020 in order to allow the renewal process to be completed before the expiry of the approval period of that substance. However, given that a decision on the non-renewal of the approval is taken ahead of the expiry of that extended approval period, this Regulation should apply as soon as possible.
- (19) This Regulation does not prevent the submission of a further application for the approval of thiacloprid pursuant to Article 7 of Regulation (EC) No 1107/2009.
- (20) 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

Non-renewal of the approval of the active substance

The approval of the active substance thiacloprid is not renewed.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011 row 92, on thiacloprid, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing thiacloprid as active substance by 3 August 2020.

Article 4

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire by 3 February 2021.

⁽⁸⁾ Commission Implementing Regulation (EU) 2019/168 of 31 January 2019 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, Bacillus thuringiensis subsp. israeliensis, Bacillus thuringiensis subsp. kurstaki, Beauveria bassiana, benfluralin, clodinafop, clopyralid, Cydia pomonella Granulovirus (CpGV), cyprodinil, dichlorprop-P, epoxiconazole, fenpyroximate, fluazinam, flutolanil, fosetyl, Lecanicillium muscarium, mepanipyrim, mepiquat, Metarhizium anisopliae var. Anisopliae, metconazole, metrafenone, Phlebiopsis gigantea, pirimicarb, Pseudomonas chlororaphis strain: MA 342, pyrimethanil, Pythium oligandrum, rimsulfuron, spinosad, Streptomyces K61, thiacloprid, tolclofos-methyl, Trichoderma asperellum, Trichoderma atroviride, Trichoderma gamsii, Trichoderma harzianum, triclopyr, trinexapac, triticonazole, Verticillium albo-atrum and ziram (OJ L 33, 5.2.2019, p. 1).

Article 5

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, 13 January 2020.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2020/24

of 13 January 2020

authorising an extension of use of chia seeds (Salvia hispanica) as a novel food and the change of the conditions of use and the specific labelling requirements of chia seeds (Salvia hispanica) under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001 (¹), and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 (²) establishing a Union list of authorised novel foods was adopted.
- (3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to submit a draft implementing act authorising placing on the Union market of a novel food and on the updating of the Union list.
- (4) Commission Decision 2009/827/EC (3) authorised, in accordance with Regulation (EC) No 258/97, the placing on the market in the Union of chia seeds (*Salvia hispanica*) as a novel food to be used in bread products.
- (5) Commission Implementing Decision 2013/50/EU (4) authorised, in accordance with Regulation (EC) No 258/97, an extension of use of chia seeds (*Salvia hispanica*) as a novel food to be used in additional food categories as follows: baked products; breakfast cereals; fruit, nut and seed mixes, and pre-packed chia seeds as such.
- (6) On 18 September 2015, an authorisation letter was issued by the competent authority of Ireland (5), in accordance with Regulation (EC) No 258/97 of the European Parliament and of the Council (6), for an extension of use of the novel food chia seeds (Salvia hispanica) to be used in additional food categories, namely, in fruit juice and fruit/vegetable blend beverages.
- (7) On 17 October 2017, an authorisation letter was issued by the competent authority of Austria (7), in accordance with Regulation (EC) No 258/97, for an extension of use of the novel food chia seeds (*Salvia hispanica*) to be used in additional food category, namely, fruit spreads.

- (2) Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).
- (3) Commission Decision 2009/827/EC of 13 October 2009 authorising the placing on the market of Chia seed (*Salvia hispanica*) as novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 294, 11.11.2009, p. 14).
- (4) Commission Implementing Decision 2013/50/EU of 22 January 2013 authorising an extension of use of Chia (*Salvia hispanica*) seed as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 21, 24.1.2013, p. 34).
- (5) Letter of 18 September 2015 (https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_authorisation_2015_auth-letter_chiaseeds-2_en.pdf).
- (6) Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).
- (7) Letter of 17 October 2017 (https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_authorisation_2017_auth-letter_chia-seeds_en.pdf).

 $[\]begin{tabular}{ll} (\begin{tabular}{ll} (\begin{tabular}{ll} 1) & OJ~L~327,~11.12.2015,~p.~1. \end{tabular}$

- (8) On 02 November 2017, an authorisation letter was issued by the competent authority of Spain (8), in accordance with Regulation (EC) No 258/97, for an extension of use of the novel food chia seeds (*Salvia hispanica*) to be used in additional food categories, namely, sterilised ready meals based on cereal grains, pseudocereal grains and/or pulses.
- (9) Commission Implementing Decision (EU) 2017/2354 (*) authorised, in accordance with Regulation (EC) No 258/97, an extension of use of the novel food chia seeds (*Salvia hispanica*) to be used in additional food category, namely, in yoghurt.
- (10) On 13 April 2017, the company Zentis GmbH & Co. KG submitted a request in accordance with Article 4 of Regulation (EC) No 258/97 to the competent authority of Germany to change the conditions of use of the novel food chia seeds (Salvia hispanica). The application requested to extend the use of chia seeds (Salvia hispanica) in additional food categories, namely, fruit desserts, mixed fruits with coconut milk for a twin pot, fruit-preparations to underlay dairy products and fruit-preparations to be mixed with dairy products, and to increase maximum use level of chia seeds (Salvia hispanica) in an already authorised food category, namely fruit spreads.
- (11) On 12 September 2017, the company Sanchis Mira S.A. submitted a request in accordance with Article 4 of Regulation (EC) No 258/97 to the competent authority of Spain for an extension of use of the novel food chia seeds (Salvia hispanica) in chocolate. On 25 September 2017, the competent authority of Spain issued its initial assessment report. In that report, it came to the conclusion that the extension of use and proposed maximum use level of chia seeds (Salvia hispanica) meet the criteria for novel foods set out in Article 3(1) of Regulation (EC) No 258/97.
- (12) On 17 October 2017, the Commission forwarded the initial assessment report to the other Member States. One Member State raised objections, questioning the overall safety of the novel food in light of the 2009 European Food Safety Authority ('the Authority') NDA Panel assessment (10) as a result of the increasing dietary intake of chia seeds (Salvia hispanica) from the growing number of authorised uses. The objecting Member State underlined that while individual uses, including the proposed use in chocolate at 3 %, may be safe, there is a need to assess the overall dietary intake from all authorised uses since 2009 including the current request for the extension of use and if necessary, revise the 2009 NDA Panel safety assessment.
- (13) Pursuant to Article 35(1) of Regulation (EU) 2015/2283, any request for placing a novel food on the market within the Union submitted to a Member State in accordance with Article 4 of Regulation (EC) No 258/97 and for which the final decision has not been taken before 1 January 2018 shall be treated as an application submitted under Regulation (EU) 2015/2283.
- (14) While the requests for an extension of use of chia seeds (*Salvia hispanica*) were submitted to the Member States in accordance with Article 4 of Regulation (EC) No 258/97, the applications also meet the requirements laid down in Regulation (EU) 2015/2283.
- (15) On 2 February 2018, the company Parry's Pots Limited (PPL) submitted a request to the Commission to change the conditions of use of the novel food chia seeds (Salvia hispanica) within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requested to increase maximum use level of chia seeds (Salvia hispanica) in an already authorised food category, namely fruit spreads.
- (16) On 12 June 2018, the company Naturkost Übelhör GmbH & Co. KG submitted a request to the Commission to change the conditions of use of the novel food chia seeds (*Salvia hispanica*) within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requested to extend the use of chia seeds (*Salvia hispanica*) in additional food categories, namely, chocolate and chocolate products.

⁽⁸⁾ Letter of 2 November 2017 (https://ec.europa.eu/food/sites/food/files/safety/docs/novel-food_authorisation_2017_auth-letter_chia-seeds-ext-steri_en.pdf).

^(°) Commission Implementing Decision (EU) 2017/2354 of 14 December 2017 authorising an extension of use of Chia seeds (Salvia hispanica) as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 336, 16.12.2017, p. 49).

⁽¹⁰⁾ EFSA Journal 2009;7(4):996.

- (17) On 15 June 2018, the company Majami Sp.zo.o.Sp.k. submitted a request to the Commission to change the conditions of use of the novel food chia seeds (*Salvia hispanica*) within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requested to extend the use of chia seeds (*Salvia hispanica*) in additional food category, namely, confectionery.
- (18) On 16 July 2018, the company The Chia Co submitted a request to the Commission to change the conditions of use of the novel food chia seeds (*Salvia hispanica*) within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requested to extend the use of chia seeds (*Salvia hispanica*) in additional food categories as follows: confectionery, excluding chewing gums; dairy products and analogues; edible ices; fruit and vegetable products; cereal and cereal products; bakery wares; herbs, spices, seasonings, soups and broths, sauces, salads and savoury based sandwich spreads and protein products; total diet replacement foods for weight control; foods bearing statements on the absence or reduced presence of gluten; non-alcoholic beverages; ready-to-eat savouries and snacks; and desserts.
- (19) On 3 August 2018, the company Materne SAS submitted a request to the Commission to change the conditions of use of the novel food chia seeds (*Salvia hispanica*) within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requested to extend the use of chia seeds (*Salvia hispanica*) in additional food categories, namely, compotes from fruit and/or vegetables and/or with cereals.
- (20) On 9 January 2019, the company RFH Produktion AB submitted a request to the Commission to change the conditions of use of the novel food chia seeds (*Salvia hispanica*) within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requested to extend the use of chia seeds (*Salvia hispanica*) in additional food category, namely, puddings.
- (21) In accordance with Article 10(3) of Regulation (EU) 2015/2283 and in the light of the growing number of requests for the authorisation of a number of extended uses of chia seeds (*Salvia hispanica*), the new authorised uses in recent years, and the resulting potential increase in the dietary intake of chia seeds (*Salvia hispanica*), the Commission consulted the Authority on 16 July 2018, asking it to carry out an assessment on the overall dietary exposure for all the potential extensions of use of chia seeds (*Salvia hispanica*) as a novel food.
- (22) On 14 March 2019, the Authority adopted the scientific opinion 'Safety of chia seeds (*Salvia hispanica* L.) as a novel food for extended uses pursuant to Regulation (EU) 2015/2283' (11). That opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- In that opinion the Authority concluded, in reply to the Commission's request for a general assessment of the safety without restrictions or precautions regarding the use levels, that the use of chia seeds (Salvia hispanica) in foods which do not require heat treatment at or above 120 °C in their manufacture, processing or preparation, including chocolate, fruit spreads, fruit desserts, mixed fruit with coconut milk in twin pot, fruit-preparations to underlay dairy products, fruit-preparations to be mixed with dairy products, confectionery (excluding chewing gums), dairy products and analogues, edible ices, fruit and vegetables products, non-alcoholic beverages and compotes from fruit and/or vegetables and/or with cereals, are safe without any specific restrictions and precautions regarding their use levels. Therefore, that scientific opinion gives sufficient grounds to establish that the above-mentioned uses of chia seeds (Salvia hispanica) comply with the requirements of Article 12(1) of Regulation (EU) 2015/2283. It is therefore appropriate that the conditions of use of chia seeds (Salvia hispanica) as listed in the Union list of authorised novel foods are amended by including all of the above food categories and to remove the setting of maximum levels and the corresponding specific labelling requirement relating to the maximum daily intake. In addition, although the use of chia seeds (Salvia hispanica) in puddings was not explicitly included in the assessment of the Authority, the opinion gives sufficient grounds to also authorise the extension of use of chia seeds (Salvia hispanica) to puddings that do not require heat treatment at or above 120 °C in their manufacture, processing or preparation. Puddings are to be understood as a subcategory of products commonly known as desserts, which are usually flavoured and sweet in taste.

⁽¹¹⁾ EFSA Journal 2019;17(4):5657.

- (24) In the same opinion, the Authority considered one study, retrieved by the Authority itself from the publicly available scientific literature, and which was not part of the evidence submitted by applicants in support of the proposed extensions of use of chia seeds (*Salvia hispanica*), which pointed to the possible formation of acrylamide when chia seeds (*Salvia hispanica*) are used in foods which require heat treatment at or above 120 °C in their manufacture, processing or preparation.
- (25) In that opinion, the Authority considered that additional information is needed from applicants and/or from the public domain, to address the potential for acrylamide formation when foods containing chia seeds (Salvia hispanica) undergo heat treatment at or above 120 °C. In accordance with Article 11(4) of Regulation (EU) 2015/2283 the Authority has requested additional information from the relevant applicant relating to potential formation of process contaminants which may be formed during processing and production of a food (at the level of the manufacturer) and/or when a food with added chia seeds (Salvia hispanica) is subjected to cooking (heat treatment at consumer level). The period set established for the provision of the additional information ends in March 2020. In the absence of such information in the submitted applications, the Authority deferred the evaluation of those extensions of use of chia seeds (Salvia hispanica) in foods which require heat treatment at or above 120 °C in their manufacture, processing or preparation (bakery wares, cereal and cereal products, herbs, spices, seasonings, soups and broths, sauces, salads and savoury based sandwich spreads and protein products, total diet replacement foods for weight control as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council (12), foods bearing statements on the absence or reduced presence of gluten in accordance with the requirements of Commission Implementing Regulation (EU) No 828/2014 (13), ready to eat savouries and snacks and desserts) to when the additional information becomes available. It follows, that the Commission, at this stage, does not dispose of the opinion of the Authority necessary pursuant to Article 12(1)(a) and (c) of Regulation (EU) 2015/2283 for the approval of the extension of uses involving the treatment of chia seeds (Salvia hispanica) at or above 120 °C. Therefore, a further decision about such uses will be taken after the publication of the relevant opinion of the Authority.
- (26) The opinion of the Authority also identified two case reports from the available scientific literature which linked the consumption of chia seeds (*Salvia hispanica*) to allergic reactions and concluded on the basis of this evidence that allergic reactions upon consumption of chia seeds (*Salvia hispanica*) may occur. Considering that, to date, only those two allergic cases have been reported, in light of the widespread consumption of chia seeds (*Salvia hispanica*) and their presence on the Union and global market for many years, the Commission considers that no specific labelling requirements concerning potential allergic reactions upon consumption of chia seeds (*Salvia hispanica*) should be included in the Union list of authorised novel foods, until further scientific evidence on the allergenic potential of chia seeds (*Salvia hispanica*) is obtained and assessed by the Authority.
- (27) 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

- 1. The entry in the Union list of authorised novel foods as provided for in Article 6 of Regulation (EU) 2015/2283 and included in Implementing Regulation (EU) 2017/2470, referring to the novel food chia seeds (*Salvia hispanica*) is amended as specified in the Annex to this Regulation.
- 2. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

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

⁽¹³⁾ Commission Implementing Regulation (EU) No 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food (OJ L 228, 31.7.2014, p. 5).

Article 2

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 3

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, 13 January 2020.

For the Commission The President Ursula VON DER LEYEN

ANNEX

The entry for 'Chia seeds (Salvia hispanica)' in Table 1 (Authorised novel foods) of the Annex to Implementing Regulation (EU) 2017/2470 is replaced by the following:

Authorised novel food	Conditions under which the	e novel food may be used	Additional specific labelling requirements	Other requirements
'Chia seeds (Salvia hispanica)	Specified food category	Maximum levels	The designation of the novel food on the	
	Bread products	5 % (whole or ground chia seeds)	labelling of the foodstuffs containing it shall be "Chia seeds (Salvia hispanica)"	
	Baked products	10 % whole chia seeds]	
	Breakfast cereals	10 % whole chia seeds		
	Sterilised ready to eat meals based on cereal grains, pseudocereals grains and/ or pulses	5 % whole chia seeds		
	Fruit, nut and seed mixes			
	Pre-packaged Chia seed as such			
	Confectionery (including chocolate and chocolate products), excluding chewing gums			
	Dairy products (including yoghurt) and analogues			
	Edible ices			
	Fruit and vegetables products (including fruit spreads, compotes with/without cereals, fruit-preparations to underlay or to be mixed with dairy products, fruit desserts, mixed fruits with coconut milk for a twin pot)			
	Non-alcoholic beverages (including fruit juice and fruit/vegetable blend beverages)			
	Puddings that do not require heat treatment at or above 120 °C in their manufacture, processing or preparation			

COMMISSION IMPLEMENTING REGULATION (EU) 2020/25

of 13 January 2020

amending and correcting Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 (¹), and in particular Article 33(2) and (3) and Article 38(d), thereof,

Whereas:

- (1) Regulation (EU) 2018/848 of the European Parliament and of the Council (²), establishes that the scheme of control bodies and control authorities recognised by the Commission on the basis of Article 33(3) of Regulation (EC) No 834/2007 to carry out controls and to issue certificates in third countries for the purpose of importing products with equivalent guarantees will be replaced by a scheme of control bodies and control authorities recognised by the Commission for the purpose of importing compliant products. The new import scheme provided in Regulation (EU) 2018/848 will apply from 1 January 2021. In order to ensure that the necessary administrative capacities are available to provide for a timely recognition of control bodies and control authorities under the new scheme, it is appropriate to introduce a final date for receiving new requests for the recognition of control bodies and control authorities for the purpose of equivalence pursuant to Article 10 of Commission Regulation (EC) No 1235/2008 (³) and the inclusion of such control bodies and control authorities in the list set out in Annex IV to that Regulation. Requests received after that date should no longer be admissible.
- (2) Products imported from a third country can be placed on the Union market as organic if they are covered by a certificate of inspection issued by the competent authorities, control authorities or control bodies of a recognised third country or by a recognised control authority or control body. In order to ensure compliance with the second subparagraph of Article 33(1) of Regulation (EC) No 834/2007, which requires the certificate of inspection to accompany the goods to the premises of the first consignee, and with a view to ensuring the traceability of the imported products during distribution, including transport form third countries, it should be clarified that the certificate of inspection is to be issued by the relevant control authority or control body at the moment the consignment leaves the third country of export or origin.
- (3) Annex III to Regulation (EC) No 1235/2008 sets out the list of third countries whose systems of production and control measures for organic production of agricultural products are recognised as equivalent to those laid down in Regulation (EC) No 834/2007.
- (4) Japan has informed the Commission that its competent authority has added the control body 'Akatonbo' to the list of control bodies recognised by Japan.
- (5) The Republic of Korea has informed the Commission that its competent authority has changed the name of 'Neo environmentally-friendly' and the name and internet address of 'Association for Agricultural Products Quality Evaluation'. The Republic of Korea has also informed the Commission that the recognition of the control body 'Korea Agricultural Product and Food Certification' has been withdrawn.

⁽¹⁾ OJ L 189, 20.7.2007, p. 1.

⁽²⁾ Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007 (OJ L 150, 14.6.2018, p. 1).

⁽³⁾ Commission Regulation (EC) No 1235/2008 of 8 December 2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (OJ L 334 12.12.2008, p. 25).

- (6) The United States has informed the Commission that its competent authority has added seven control bodies to the list of control bodies recognised by the United States for the purpose of the equivalence under Article 33(2) of Regulation (EC) No 834/2007, namely 'CERES', 'EcoLOGICA S.A', 'Food Safety S.A.', 'IBD Certifications', 'Istituto per la Certificazione Etica e Ambientale (ICEA)', 'OnMark' and 'Perry Johnson Registrar Food Safety, Inc.'. The United States has also requested the removal of 'Global Culture', 'Global Organic Certification Services', 'Stellar Certification Services, Inc.', 'Institute for Marketecology (IMO)', and 'Basin and Range Organics (BARO)' from the list in Annex III to Regulation (EC) No 1235/2008.
- (7) Annex IV to Regulation (EC) No 1235/2008 sets out the list of control authorities and control bodies competent to carry out controls and issue certificates in third countries for the purpose of equivalence.
- (8) The Commission has received and examined a request from 'A CERT European Organization for Certification S.A' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the scope of its recognition for product categories A and D to Armenia, Ghana, Kosovo (3), Kuwait, Oman, Peru, Sudan, the United Arab Emirates, Uzbekistan and Vietnam.
- (9) The Commission has received and examined a request from 'Argencert SA' to be removed from the list in Annex IV to Regulation (EC) No 1235/2008. Based on the information received, the Commission has concluded that it is justified to remove that control body from that list.
- (10) The Commission has received and examined a request from 'Balkan Biocert Skopje' to amend its legal status. Based on the information received, the Commission has concluded that it is justified to replace the name of that control body by 'Balkan Biocert Macedonia DOOEL Skopje'.
- (11) The Commission has received a request from 'Başak Ekolojik Ürünler Kontrol ve Sertifikasyon Hizmetleri Tic. Ltd' to amend its address.
- (12) The Commission has received and examined a request from 'Bioagricert S.r.l.' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the scope of its recognition for product categories A, B, D and E to Paraguay and Uruguay, for product categories A, B and D to Bolivia and Sri Lanka, for product categories A, D and E to Cameroon, and for product categories A and D to Fiji.
- (13) The Commission has received and examined a request from 'Biocert International Pvt Ltd' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the scope of its recognition to Afghanistan, Bangladesh, Bhutan, Myanmar/Burma, Egypt, Malaysia, Mauritius, Nepal, Oman, Pakistan, the Philippines, Tanzania, Thailand, the United Arab Emirates and Vietnam for product categories A and D, to Benin, Ethiopia, Mozambique, Nigeria, Qatar, Russia, Sudan, Togo, Uganda and Ukraine for product categories A, D and E, and to Georgia for product categories D and E, and to extend its recognition for Sri Lanka to product category E.
- (14) The Commission has received and examined a request from 'Bio.inspecta AG' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the scope of its recognition to Montenegro, North Macedonia and Serbia for product categories A, B, D, E and F, and to extend the scope of its recognition for Albania, Bosnia and Herzegovina, Georgia, Iran, Kazakhstan, Kosovo (*), Moldova, Russia, Tajikistan, Ukraine, Uzbekistan and Vietnam to product categories B, E and F, for Armenia, Lebanon and Tanzania to product categories B and E, for Algeria and Kyrgyzstan to product category B, for Turkey to product categories E and F, and for Azerbaijan to product category E.
- (15) The Commission has received and examined a request from 'Bureau Veritas Certification France SAS' to amend its internet address and its specifications. Based on the information received, the Commission has concluded that it is justified to withdraw its recognition for product category E in respect of Mauritius.

⁽³⁾ 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

⁽⁴⁾ 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

- (16) The Commission has received and examined a request from 'CCPB Srl' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the scope of its recognition to Burkina Faso, Cameroon, Comoros and Madagascar for product categories A, C and D, and to extend the scope of its recognition for Côte d'Ivoire to product categories C and D.
- (17) The Commission has received and examined a request from 'CERES Certification of Environmental Standards GmbH' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the scope of its recognition to the United States for product category C, and to extend the scope of its recognition for the United Arab Emirates to product category A, for Chile to product category C, and for South Africa to product category F.
- (18) The Commission has received and examined a request from 'DQS Polska sp. z o.o.' to be included in the list in Annex IV to Regulation (EC) No 1235/2008. Based on the information received, the Commission has concluded that it is justified to recognise that control body for Bosnia and Herzegovina, China and Madagascar for product categories A, B and D.
- (19) The Commission has received and examined a request from 'Ecocert SA' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the scope of its recognition for the United Arab Emirates, Cuba, Kuwait and Malawi to product category B, for Serbia and Zimbabwe to product category E, and for Moldova to product category F.
- (20) The Commission has received and examined a request from 'FairCert Certification Services Pvt Ltd' to be included in the list in Annex IV to Regulation (EC) No 1235/2008. Based on the information received, the Commission has concluded that it is justified to recognise that control body for Bhutan and Nepal for product categories A, B, D and E, and for India for product categories B, D and E.
- (21) The Commission has received and examined a request from 'IBD Certificações Ltda.' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the scope of its recognition to Bolivia and Paraguay for product category A and D, and to Mongolia for product categories A and E.
- (22) The Commission has received and examined a request from 'Kiwa BCS Öko-Garantie GmbH' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the scope of its recognition to Seychelles for product categories A and D, and to the United States for product category C, and to extend the scope of its recognition for Armenia, Georgia, Tajikistan, Uzbekistan and Zambia to product category B, for Guatemala to product categories C and F, and for the Dominican Republic, Ecuador, Honduras, Paraguay, Peru, Serbia, and Turkey to product category F.
- (23) The Commission has received and examined a request from 'Mayacert' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the scope of its recognition to Panama and Sri Lanka for product categories A and D.
- (24) The Commission has received and examined a request from 'OneCert International PVT Ltd' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the scope of its recognition to Egypt, Jordan, Malaysia and Qatar for product categories A and D, and to extend the scope of its recognition for the United Arab Emirates to product category A, and for Ethiopia, India, Mozambique, Tanzania and Uganda to product category E.
- (25) The Commission has received and examined a request from 'Organización International Agropecuaria' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the scope of its recognition to Colombia for product categories A and D, and to extend the scope of its recognition for Chile and Uruguay to product category E, except for those products already covered by Annex III to Regulation (EC) No 1235/2008.
- (26) The Commission has received and examined a request from 'Servicio de Certificación CAAE S.L.U' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the scope of its recognition to Colombia, the Dominican Republic, El Salvador, Guatemala, Honduras, Nicaragua and Panama for product categories A and D.

- (27) The Commission has received and examined a request from 'Suolo e Salute srl' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the scope of its recognition for Egypt to product category D.
- (28) The Commission has received and examined a request from 'Tse-Xin Organic Certification Corporation' to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the scope of its recognition to the Republic of Korea for product category A, to Hong Kong and Singapore for product category D, and to Cambodia, Indonesia, Laos, Malaysia, Myanmar/Burma, the Philippines, Thailand and Vietnam for product categories A and D.
- (29) The Commission has received and examined a request from 'Valsts SIA "Sertifikācijas un testēšanas centrs" to amend its legal status. Based on the information received, the Commission has concluded that it is justified to replace the name of that control body by 'SIA "Sertifikācijas un testēšanas centrs". In addition, the Commission has received and examined a request from that control body to amend its specifications. Based on the information received, the Commission has concluded that it is justified to extend the scope of its recognition for Belarus to product categories B, D, E and F, and for Uzbekistan to product categories D, E and F, and to extend the scope of its recognition to Kazakhstan, Moldova and Tajikistan for product categories A, B, D, E and F, and to Kyrgyzstan for product categories A, B, D and E.
- (30) On the basis of the dossier submitted by 'Agricert Certificação de Produtos Alimentares Ida', the scope of its recognition was extended to Guinea for product categories A and D by Commission Implementing Regulation (EU) 2019/39 (5). However, in that dossier that control body had wrongly requested an extension for Guinea instead of Guinea Bissau. Based on the information received, the Commission has concluded that it is justified to correct Annex IV to Regulation (EC) No 1235/2008 accordingly. In the interest of clarity and legal certainty, this correction should apply from the date of entry into force of Implementing Regulation (EU) 2019/39.
- (31) Regulation (EC) No 1235/2008 should therefore be amended and corrected accordingly.
- (32) The measures provided for in this Regulation are in accordance with the opinion of the Committee on organic production,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 1235/2008

Regulation (EC) No 1235/2008 is amended as follows:

- (1) in Article 11, paragraph 1 is replaced by the following:
 - '1. The Commission shall consider whether to include a control body or control authority in the list provided for in Article 10 upon receipt of a request thereto from the representative of the control body or control authority concerned on the basis of the model of application made available by the Commission in accordance with Article 17(2). Only complete requests that have been submitted by 30 June 2020 shall be taken into account for updating the list.';
- (2) in Article 13(2), the first subparagraph is replaced by the following:

'The certificate of inspection shall be issued by the relevant control authority or control body before the consignment leaves the third country of export or origin. It shall be endorsed by the relevant Member State's competent authority and completed by the first consignee on the basis of the model and the notes set out in Annex V and using the electronic Trade Control and Expert System (TRACES) established by Commission Decision 2003/24/EC (*).

- (*) Commission Decision 2003/24/EC of 30 December 2002 concerning the development of an integrated computerised veterinary system (OJ L 8, 14.1.2003, p. 44).';
- (5) Commission Implementing Regulation (EU) 2019/39 of 10 January 2019 amending Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (OJ L 9, 11.1.2019, p. 106).

- (3) Annex III is amended in accordance with Annex I to this Regulation;
- (4) Annex IV is amended in accordance with Annex II to this Regulation.

Article 2

Correction of Regulation (EC) No 1235/2008

Annex IV to Regulation (EC) No 1235/2008 is corrected in accordance with Annex III to this Regulation.

Article 3

Entry into force and application

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

Article 2 shall apply from 31 January 2019.

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

Done at Brussels, 13 January 2020.

For the Commission The President Ursula VON DER LEYEN

ANNEX I

Annex III to Regulation (EC) No 1235/2008 is amended as follows:

(1) in the entry relating to Japan, the following row is added:

JP-BIO-038	Akatonbo	http://www.akatonbo.or.jp/
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- (2) in the entry relating to the **Republic of Korea**, point 5 is amended as follows:
 - (a) the rows relating to code numbers KR-ORG-019 and KR-ORG-026 are replaced by the following:

'KR-ORG-019	Neo environmentally-friendly Certification Center	http://neoefcc.modoo.at
KR-ORG-026	Agricultural Products Quality Service	http://apqs.kr'

- (b) the row relating to code number KR-ORG-001 is deleted;
- (3) in the entry relating to the **United States**, point 5 is amended as follows:
 - (a) the following rows are added:

'US-ORG-62	CERES	http://www.ceres-cert.com/
US-ORG-63	EcoLOGICA S.A.	http://www.eco-logica.com/
US-ORG-64	Food Safety S.A.	http://www.foodsafety.com.ar/
US-ORG-65	IBD Certifications	http://www.ibd.com.br/
US-ORG-66	Istituto per la Certificazione Etica e Ambientale (ICEA)	http://www.icea.info/
US-ORG-67	OnMark	http://onmarkcertification.com/
US-ORG-68	Perry Johnson Registrar Food Safety, Inc.	http://www.pjrfsi.com/

(b) the rows relating to code numbers US-ORG-12, US-ORG-14, US-ORG-54, US-ORG-60 and US-ORG-61 are deleted.

ANNEX II

Annex IV to Regulation (EC) No 1235/2008 is amended as follows:

(1) in the entry relating to 'A CERT European Organization for Certification S.A', in point 3, the following rows are inserted in the order of the code numbers:

'AE-BIO-171	United Arab Emirates	X	-	-	X	-	-
AM-BIO-171	Armenia	X	-	-	X	-	-
GH-BIO-171	Ghana	X	1	-	X	-	-
KW-BIO-171	Kuwait	X	1	-	X	-	-
OM-BIO-171	Oman	X	1	-	X	-	-
PE-BIO-171	Peru	X	1	-	X	-	-
SD-BIO-171	Sudan	X	1	-	X	-	-
UZ-BIO-171	Uzbekistan	X	-	-	X	-	-
VN-BIO-171	Vietnam	X	-	-	X	-	-
XK-BIO-171	Kosovo (*)	X	-	-	X	-	-

^(*) 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.'

- (2) the entry relating to 'Argencert SA' is deleted;
- (3) in the entry relating to 'Balkan Biocert Skopje', the name of the control body is replaced by 'Balkan Biocert Macedonia DOOEL Skopje';
- (4) in the entry relating to 'Başak Ekolojik Ürünler Kontrol ve Sertifikasyon Hizmetleri Tic. Ltd', point 1 is replaced by the following:
 - '1. Address: Çinarli Mahallesi Şehit Polis Fethi Sekin Cad. No:3/1006 Konak/İZMİR, Turkey';
- (5) in the entry relating to 'Bioagricert S.r.l.', in point 3, the following rows are inserted in the order of the code numbers:

'BO-BIO-132	Bolivia	X	X	-	X	-	-
CM-BIO-132	Cameroon	X	-	-	X	X	-
FJ-BIO-132	Fiji	X	-	-	X	-	-
LK-BIO-132	Sri Lanka	X	X	-	X	-	-
PY-BIO-132	Paraguay	Х	X	-	X	X	-
UY-BIO-132	Uruguay	X	X	-	X	X	_',

- (6) in the entry relating to 'Biocert International Pvt Ltd', point 3 is amended as follows:
 - (a) the following rows are inserted in the order of the code numbers:

'AE-BIO-177	United Arab Emirates	X	-	-	X	-	-
AF-BIO-177	Afghanistan	X	-	-	X	-	-
BD-BIO-177	Bangladesh	X	-	-	X	-	-
BJ-BIO-177	Benin	X	-	-	X	X	-
BT-BIO-177	Bhutan	X	-	-	X	-	-
EG-BIO-177	Egypt	X	-	-	X	-	-

ET-BIO-177	Ethiopia	X	-	-	x	x	-
GE-BIO-177	Georgia	-	-	-	x	x	-
MM-BIO-177	Myanmar/Bur- ma	х	-	-	X	-	-
MU-BIO-177	Mauritius	x	-	-	x	-	-
MY-BIO-177	Malaysia	X	-	-	x	-	-
MZ-BIO-177	Mozambique	X	-	-	X	X	-
NP-BIO-177	Nepal	х	-	-	х	-	-
NG-BIO-177	Nigeria	х	-	-	х	X	-
OM-BIO-177	Oman	х	-	-	х	-	-
PH-BIO-177	Philippines	х	-	-	х	-	-
PK-BIO-177	Pakistan	х	-	-	х	-	-
QA-BIO-177	Qatar	х	-	-	x	x	-
RU-BIO-177	Russia	X	-	-	X	X	-
SD-BIO-177	Sudan	х	-	-	х	X	-
TG-BIO-177	Togo	х	-	-	х	X	-
TH-BIO-177	Thailand	х	-	-	х	-	-
TZ-BIO-177	Tanzania	х	-	-	х	-	-
UA-BIO-177	Ukraine	Х	-	-	х	х	-
UG-BIO-177	Uganda	Х	-	-	х	x	-
VN-BIO-177	Vietnam	х	-	-	X	-	_'

(b) the row relating to Sri Lanka is replaced by the following:

'LK-BIO-177 Sri Lanka	X	-	-	X	X	_',
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- (7) in the entry relating to 'Bio.inspecta AG', point 3 is amended as follows:
 - (a) the following rows are inserted in the order of the code numbers:

'ME-BIO-161	Montenegro	x	X	_	x	X	X
MK-BIO-161	North Mace- donia	X	X	_	х	X	X
RS-BIO-161	Serbia	X	X	_	X	X	x'

(b) the rows relating to Albania, Algeria, Armenia, Azerbaijan, Bosnia and Herzegovina, Georgia, Iran, Kazakhstan, Kosovo, Kyrgyzstan, Lebanon, Moldova, Russia, Tajikistan, Tanzania, Turkey, Ukraine, Uzbekistan and Vietnam are replaced by the following:

'AL-BIO-161	Albania	X	X	_	X	X	X
AM-BIO-161	Armenia	x	X		X	X	_
AZ-BIO-161	Azerbaijan	х		_	X	X	_
BA-BIO-161	Bosnia and Herzegovina	X	X	_	X	X	Х

DZ-BIO-161	Algeria	x	X	_	X	_	_
GE-BIO-161	Georgia	x	X	_	X	X	X
IR-BIO-161	Iran	x	X	_	X	X	X
KG-BIO-161	Kyrgyzstan	x	X	_	X	_	_
KZ-BIO-161	Kazakhstan	x	X	_	X	X	Х
LB-BIO-161	Lebanon	x	X	_	X	X	_
MD-BIO-161	Moldova	x	X	_	X	X	х
RU-BIO-161	Russia	х	X	_	X	X	х
TJ-BIO-161	Tajikistan	х	X	_	X	X	Х
TR-BIO-161	Turkey	x	_	_	X	X	х
TZ-BIO-161	Tanzania	x	X	_	X	X	_
UA-BIO-161	Ukraine	x	X	_	X	X	Х
UZ-BIO-161	Uzbekistan	x	X	_	X	X	Х
VN-BIO-161	Vietnam	х	X		X	X	Х
XK-BIO-161	Kosovo (*)	X	X	-	X	X	х

^(*) 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.'

(8) the entry relating to 'Bureau Veritas Certification France SAS' is amended as follows:

- (a) in point 2, the internet address is replaced by the following: 'https://filiereagro.bureauveritas.fr/';
- (b) in point 3, the row relating to Mauritius is replaced by the following:

'MU-BIO-165 Mauritius	X	_	_	X	_	
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- (9) in the entry relating to 'CCPB Srl', point 3 is amended as follows:
 - (a) the following rows are inserted in the order of the code numbers:

'BF-BIO-102	Burkina Faso	X	-	X	X	1	-
CM-BIO-102	Cameroon	X	-	X	X	-	-
KM-BIO-102	Comoros	X	-	X	X	-	-
MG-BIO-102	Madagascar	X	-	X	X	1	_'

(b) the row relating to Côte d'Ivoire is replaced by the following:

'CI-BIO-102	Côte d'Ivoire	X	-	X	X	-	_',

- (10) in the entry relating to 'CERES Certification of Environmental Standards GmbH', point 3 is amended as follows:
 - (a) the following row is inserted in the order of the code numbers:

'US-BIO-140	United States	_	_	X	_	_	'

(b) the rows relating to Chile, South Africa and the United Arab Emirates are replaced by the following:

'AE-BIO-140	United Arab Emirates	X	_	_	X	_	_
CL-BIO-140	Chile	X	X	X	X	_	_
ZA-BIO-140	South Africa	X	X	_	X	_	x'

(11) after the entry relating to 'Control Union Certification', the following entry is inserted:

"DQS Polska sp. z o.o."

- 1. Address: ul. Domaniewska 45, 02-672 Warszawa, Poland
- 2. Internet address: www.dqs.pl
- 3. Code numbers, third countries and product categories concerned:

Code number Th	Third country		Category of products						
	Third country	A	В	С	D	E	F		
BA-BIO-181	Bosnia and Herzegovina	X	X	-	X	-	-		
CN-BIO-181	China	X	X	-	X	-	-		
MG-BIO-181	Madagascar	x	x	-	x	-	-		

- 4. Exceptions: in-conversion products and wine
- 5. Duration of inclusion: until 30 June 2021'
- (12) in the entry relating to 'Ecocert SA', in point 3, the rows relating to Cuba, Kuwait, Malawi, Moldova, Serbia, the United Arad Emirates and Zimbabwe are replaced by the following:

'AE-BIO-154	United Arab Emirates	X	X	_	X	х	_
CU-BIO-154	Cuba	X	X	_	X	X	_
KW-BIO-154	Kuwait	X	X	_	X	_	_
MD-BIO-154	Moldova	X	X	_	X	_	X
MW-BIO-154	Malawi	X	X	_	X	_	_
RS-BIO-154	Serbia	X	X	_	X	X	X
ZW-BIO-154	Zimbabwe	X	X	_	X	X	x'

(13) after the entry relating to 'Ekoagros', the following entry is inserted:

"FairCert Certification Services Pvt Ltd'

- 1. Address: C 122, GAURIDHAM COLONY, 451001-KHARGONE, India
- 2. Internet address: www.faircert.com
- 3. Code numbers, third countries and product categories concerned:

Code number Third of	Th:1		Category of products						
	Third country	A	В	С	D	E	F		
BT-BIO-180	Bhutan	X	X	-	X	X	-		
IN-BIO-180	India	-	X	-	X	X	-		
NP-BIO-180	Nepal	X	X	-	Х	X	-		

- 4. Exceptions: in-conversion products and wine
- 5. Duration of inclusion: until 30 June 2021'
- (14) in the entry relating to 'IBD Certificações Ltda.', in point 3, the following rows are inserted in the order of the code numbers:

'BO-BIO-122	Bolivia	X	-	-	х	-	-
MN-BIO-122	Mongolia	X	-	-	-	X	-
PY-BIO-122	Paraguay	X	-	-	X	-	_'

- (15) in the entry relating to 'Kiwa BCS Öko-Garantie GmbH', point 3 is amended as follows:
 - (a) the following rows are inserted in the order of the code numbers:

'SC-BIO-141	Seychelles	X			X	_	_
US-BIO-141	United States	_	_	X	_	_	_'

(b) the rows relating to Armenia, the Dominican Republic, Ecuador, Georgia, Guatemala, Honduras, Paraguay, Peru, Serbia, Tajikistan, Turkey, Uzbekistan and Zambia are replaced by the following:

'AM-BIO-141	Armenia	x	X	_	X	_	_
DO-BIO-141	Dominican Republic	X	_	_	X	_	Х
EC-BIO-141	Ecuador	X	X	X	X	X	X
GE-BIO-141	Georgia	x	X	_	X	X	_
GT-BIO-141	Guatemala	x	X	X	X	X	X
HN-BIO-141	Honduras	X	_	_	X	X	X
PE-BIO-141	Peru	x	X	_	X	X	X
PY-BIO-141	Paraguay	x	X	_	X	X	X
RS-BIO-141	Serbia	х	_	_	X	_	Х
TJ-BIO-141	Tajikistan	x	X	_	X	_	_
TR-BIO-141	Turkey	х	X	_	X	X	Х
UZ-BIO-141	Uzbekistan	х	X	_	X	_	_
ZM-BIO-141	Zambia	x	X	_	X	_	

(16) in the entry relating to 'Mayacert', in point 3, the following rows are inserted in the order of the code numbers:

'LK-BIO-169	Sri Lanka	X	1	1	X	ı	-
PA-BIO-169	Panama	X	1	1	X	ı	_'

- (17) in the entry relating to 'OneCert International PVT Ltd', point 3 is amended as follows:
 - (a) the following rows are inserted in the order of the code numbers:

'EG-BIO-152	Egypt	Х	-	-	Х	-	-
JO-BIO-152	Jordan	X	-	-	X	-	-

MY-BIO-152	Malaysia	Х	-	-	Х	-	-
QA-BIO-152	Qatar	Х	-	-	X	-	_'

(b) the rows relating to the United Arab Emirates, Ethiopia, India, Mozambique, Tanzania and Uganda are replaced by the following:

'AE-BIO-152	United Arab Emirates	X	-	-	X	1	-
ET-BIO-152	Ethiopia	X	-	-	X	X	-
IN-BIO-152	India	-	-	-	X	X	-
MZ-BIO-152	Mozambique	x	-	-	X	X	-
TZ-BIO-152	Tanzania	X	-	-	X	X	-
UG-BIO-152	Uganda	X	-	-	X	X	_'

- (18) in the entry relating to 'Organización International Agropecuaria', point 3 is amended as follows:
 - (a) the following row is inserted in the order of the code numbers:

'CO-BIO-110 Co	Colombia	X	-	-	X	-	_'
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(b) the row relating to Chile and Uruguay is replaced by the following:

'CL-BIO-110	Chile	Х	-	X	X	x	-
UY-BIO-110	Uruguay	X	X	X	X	X	_',

(19) in the entry relating to 'Servicio de Certificación CAAE S.L.U', in point 3, the following entries are inserted in the order of the code numbers:

'CO-BIO-178	Colombia	X	-	1	x	-	-
DO-BIO-178	Dominican Republic	X	-	-	X	-	-
GT-BIO-178	Guatemala	Х	-	-	х	-	-
HN-BIO-178	Honduras	X	-	1	x	-	-
NI-BIO-178	Nicaragua	X	-	-	x	-	-
PA-BIO-178	Panama	X	-	-	x	-	-
SV-BIO-178	El Salvador	X	-	-	x	-	_'

(20) in the entry relating to 'Suolo e Salute srl', in point 3, the row relating to Egypt is replaced by the following:

EG-BIO-150 Egypt	Х	-	-	X	-	_'
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(21) in the entry relating to 'Tse-Xin Organic Certification Corporation', in point 3, the following rows are inserted in the order of the code numbers:

'НК-ВІО-174	Hong Kong	-	-	-	X	-	-
ID-BIO-174	Indonesia	X	-	-	X	-	-
KH-BIO-174	Cambodia	X	-	-	X	-	-

KR-BIO-174	Republic of Korea	х	-	-	-	-	-
LA-BIO-174	Laos	Х	-	1	X	-	-
MM-BIO-174	Myan- mar/Burma	X	1	1	X	-	-
MY-BIO-174	Malaysia	X	-	ı	X	-	-
PH-BIO-174	Philippines	X	-	ı	X	-	-
SG-BIO-174	Singapore	-	-	-	X	-	-
TH-BIO-174	Thailand	Х	-	-	X	-	-
VN-BIO-174	Vietnam	Х	-	-	X	-	_'

- (22) the entry relating to 'Valsts SIA "Sertifikācijas un testēšanas centrs" is amended as follows:
 - (a) the name of the control body is replaced by 'SIA "Sertifikācijas un testēšanas centrs";
 - (b) point 3 is amended as follows:
 - (i) the following rows are inserted in the order of the code numbers:

'KG-BIO-173	Kyrgyzstan	X	X	_	X	X	_
KZ-BIO-173	Kazakhstan	X	X	_	X	X	X
MD-BIO-173	Moldova	X	X	_	X	X	X
TJ-BIO-173	Tajikistan	X	X	_	X	X	x'

(ii) the rows relating to Belarus and Uzbekistan are replaced by the following:

BY-BIO-173	Belarus	Х	Х	_	Х	Х	Х
UZ-BIO-173	Uzbekistan	X	X		X	X	x'

ANNEX III

In Annex IV to Regulation (EC) No 1235/2008, in the entry relating to 'Agricert — Certificação de Produtos Alimentares lda', in point 3, the row relating to Guinea is replaced by the following:

	1		1	1	1		
'GW-BIO-172	Guinea Bissau	X	_	_	X	_	'

DECISIONS

COMMISSION DECISION (EU) 2020/26

of 13 January 2020

updating Annex A to the Monetary Agreement between the European Union and the Principality of Monaco

THE EUROPEAN COMMISSION,

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

Having regard to the Monetary Agreement of 29 November 2011 between the European Union and the Principality of Monaco (¹), and in particular Article 11(3) thereof,

Whereas:

- (1) Article 11(2) of the Monetary Agreement between the European Union and the Principality of Monaco (hereinafter 'the Monetary Agreement') requires the Principality of Monaco to apply the same rules as those established in the French Republic for the purposes of transposing European legal acts concerning the activities and prudential regulation of credit institutions and the prevention of systemic risks to payment and securities settlement systems contained in Annex A,
- (2) The update of the Annex A is made according to Article 11(3) of the Monetary Agreement which foresees that Annex A needs to be updated by the Commission upon amendment of any relevant texts and also each time a new text is adopted by the European Union,
- (3) New texts have been adopted by the European Union and amendments have been made to the texts already existing in Annex A.
- (4) Annex A to the Monetary Agreement should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Sole Article

Annex A to the Monetary Agreement between the European Union and the Principality of Monaco is replaced by the Annex to this Decision.

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

Done at Brussels, 13 January 2020.

For the Commission The President Ursula VON DER LEYEN

ANNEX

'ANNEX A

	Legislation applicable to the activities and supervision of credit institutions and the prevention of systemic risks to payment and securities settlement systems
1	With regard to the provisions applicable to credit institutions Council Directive 86/635/EEC of 8 December 1986 on the annual accounts and consolidated accounts of banks and other financial institutions (OJ L 372, 31.12.1986, p. 1).
	amended by:
2	Directive 2001/65/EC of the European Parliament and of the Council of 27 September 2001 amending Directives 78/660/EEC, 83/349/EEC and 86/635/EEC as regards the valuation rules for the annual and consolidated accounts of certain types of companies as well as of banks and other financial institutions (OJ L 283, 27.10.2001, p. 28).
3	Directive 2003/51/EC of the European Parliament and of the Council of 18 June 2003 amending Directives 78/660/EEC, 83/349/EEC, 86/635/EEC and 91/674/EEC on the annual and consolidated accounts of certain types of companies, banks and other financial institutions and insurance undertakings (OJ L 178, 17.7.2003, p. 16).
4	Directive 2006/46/EC of the European Parliament and of the Council of 14 June 2006 amending Council Directives 78/660/EEC on the annual accounts of certain types of companies, 83/349/EEC on consolidated accounts, 86/635/EEC on the annual accounts and consolidated accounts of banks and other financial institutions and 91/674/EEC on the annual accounts and consolidated accounts of insurance undertakings (OJ L 224, 16.8.2006, p. 1).
5	Council Directive 89/117/EEC of 13 February 1989 on the obligations of branches established in a Member State of credit institutions and financial institutions having their head offices outside that Member State regarding the publication of annual accounting documents (OJ L 44, 16.2.1989, p. 40).
6	Directive 98/26/EC of the European Parliament and of the Council of 19 May 1998 on settlement finality in payment and securities settlement systems (OJ L 166, 11.6.1998, p. 45).
	amended by:
7	Directive 2009/44/EC of the European Parliament and of the Council of 6 May 2009 amending Directive 98/26/EC on settlement finality in payment and securities settlement systems and Directive 2002/47/EC on financial collateral arrangements as regards linked systems and credit claims (OJ L 146, 10.6.2009, p. 37).
8	Directive 2010/78/EU of the European Parliament and of the Council of 24 November 2010 amending Directives 98/26/EC, 2002/87/EC, 2003/6/EC, 2003/41/EC, 2003/71/EC, 2004/39/EC, 2004/109/EC, 2005/60/EC, 2006/48/EC, 2006/49/EC and 2009/65/EC in respect of the powers of the European Supervisory Authority (European Banking Authority), the European Supervisory Authority (European Insurance and Occupational Pensions Authority) and the European Supervisory Authority (European Securities and Markets Authority) (OJ L 331, 15.12.2010, p. 120).
9	Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories (OJ L 201, 27.7.2012, p. 1).
10	Regulation (EU) No 909/2014 of the European Parliament and of the Council of 23 July 2014 on improving securities settlement in the European Union and on central securities depositories and amending Directives 98/26/EC and 2014/65/EU and Regulation (EU) No 236/2012 (OJ L 257, 28.8.2014, p. 1).



	Legislation applicable to the activities and supervision of credit institutions and the prevention of systemic risks to payment and securities settlement systems
11	Directive 2001/24/EC of the European Parliament and of the Council of 4 April 2001 on the reorganisation and winding up of credit institutions (OJ L 125, 5.5.2001, p. 15).
	amended by:
12	Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014 establishing a framework for the recovery and resolution of credit institutions and investment firms and amending Council Directive 82/891/EEC, and Directives 2001/24/EC, 2002/47/EC, 2004/25/EC, 2005/56/EC, 2007/36/EC, 2011/35/EU, 2012/30/EU and 2013/36/EU, and Regulations (EU) No 1093/2010 and (EU) No 648/2012, of the European Parliament and of the Council (OJ L 173, 12.6.2014, p. 190).
13	Directive 2002/47/EC of the European Parliament and of the Council of 6 June 2002 on financial collateral arrangements (OJ L 168, 27.6.2002, p. 43).
	amended by:
14	Directive 2009/44/EC of the European Parliament and of the Council of 6 May 2009 amending Directive 98/26/EC on settlement finality in payment and securities settlement systems and Directive 2002/47/EC on financial collateral arrangements as regards linked systems and credit claims (OJ L 146, 10.6.2009, p. 37).
15	Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014 establishing a framework for the recovery and resolution of credit institutions and investment firms and amending Council Directive 82/891/EEC, and Directives 2001/24/EC, 2002/47/EC, 2004/25/EC, 2005/56/EC, 2007/36/EC, 2011/35/EU, 2012/30/EU and 2013/36/EU, and Regulations (EU) No 1093/2010 and (EU) No 648/2012, of the European Parliament and of the Council (OJ L 173, 12.6.2014, p. 190).
16	Directive 2002/87/EC of the European Parliament and of the Council of 16 December 2002 on the supplementary supervision of credit institutions, insurance undertakings and investment firms in a financial conglomerate and amending Council Directives 73/239/EEC, 79/267/EEC, 92/49/EEC, 92/96/EEC, 93/6/EEC and 93/22/EEC, and Directives 98/78/EC and 2000/12/EC of the European Parliament and of the Council (OJ L 35, 11.2.2003, p. 1) and the related level 2 measures, where applicable
	amended by:
17	Directive 2005/1/EC of the European Parliament and of the Council of 9 March 2005 amending Council Directives 73/239/EEC, 85/611/EEC, 91/675/EEC, 92/49/EEC and 93/6/EEC and Directives 94/19/EC, 98/78/EC, 2000/12/EC, 2001/34/EC, 2002/83/EC and 2002/87/EC in order to establish a new organisational structure for financial services committees (OJ L 79, 24.3.2005, p. 9).
18	Directive 2008/25/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2002/87/EC on the supplementary supervision of credit institutions, insurance undertakings and investment firms in a financial conglomerate, as regards the implementing powers conferred on the Commission (OJ L 81, 20.3.2008, p. 40).
19	Directive 2010/78/EU of the European Parliament and of the Council of 24 November 2010 amending Directives 98/26/EC, 2002/87/EC, 2003/6/EC, 2003/41/EC, 2003/71/EC, 2004/39/EC, 2004/109/EC, 2005/60/EC, 2006/48/EC, 2006/49/EC and 2009/65/EC in respect of the powers of the European Supervisory Authority (European Banking Authority), the European Supervisory Authority (European Insurance and Occupational Pensions Authority) and the European Supervisory Authority
	(European Securities and Markets Authority) (OJ L 331, 15.12.2010, p. 120).
20	Directive 2011/89/EU of the European Parliament and of the Council of 16 November 2011 amending Directives 98/78/EC, 2002/87/EC, 2006/48/EC and 2009/138/EC as regards the supplementary supervision of financial entities in a financial conglomerate (OJ L 326, 8.12.2011, p. 113).
21	With the exception of Title V: Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338)

	Legislation applicable to the activities and supervision of credit institutions and the prevention of systemic risks to payment and securities settlement systems
22	Directive 2009/110/EC of the European Parliament and of the Council of 16 September 2009 on the taking up, pursuit and prudential supervision of the business of electronic money institutions amending Directives 2005/60/EC and 2006/48/EC and repealing Directive 2000/46/EC (OJ L 267, 10.10.2009, p. 7).
	amended by:
23	With the exception of Title V: Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338).
24	With the exception of Titles III and IV: Directive (EU) 2015/2366 of the European Parliament and of the Council of 25 November 2015 on payment services in the internal market, amending Directives 2002/65/EC, 2009/110/EC and 2013/36/EU and Regulation (EU) No 1093/2010, and repealing Directive 2007/64/EC (OJ L 337, 23.12.2015, p. 35).
25	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).
	amended by:
26	Regulation (EU) No 1022/2013 of the European Parliament and of the Council of 22 October 2013 amending Regulation (EU) No 1093/2010 establishing a European Supervisory Authority (European Banking Authority) as regards the conferral of specific tasks on the European Central Bank pursuant to Council Regulation (EU) No 1024/2013 (OJ L 287, 29.10.2013, p. 5).
27	Directive 2014/17/EU of the European Parliament and of the Council of 4 February 2014 on credit agreements for consumers relating to residential immovable property and amending Directives 2008/48/EC and 2013/36/EU and Regulation (EU) No 1093/2010 (OJ L 60, 28.2.2014, p. 34).
28	Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014 establishing a framework for the recovery and resolution of credit institutions and investment firms and amending Council Directive 82/891/EEC, and Directives 2001/24/EC, 2002/47/EC, 2004/25/EC, 2005/56/EC, 2007/36/EC, 2011/35/EU, 2012/30/EU and 2013/36/EU, and Regulations (EU) No 1093/2010 and (EU) No 648/2012, of the European Parliament and of the Council (OJ L 173, 12.6.2014, p. 190).
29	Regulation (EU) No 806/2014 of the European Parliament and of the Council of 15 July 2014 establishing uniform rules and a uniform procedure for the resolution of credit institutions and certain investment firms in the framework of a Single Resolution Mechanism and a Single Resolution Fund and amending Regulation (EU) No 1093/2010 (OJ L 225, 30.7.2014, p. 1).
30	With the exception of Titles III and IV:
	Directive (EU) 2015/2366 of the European Parliament and of the Council of 25 November 2015 on payment services in the internal market, amending Directives 2002/65/EC, 2009/110/EC and 2013/36/EU and Regulation (EU) No 1093/2010, and repealing Directive 2007/64/EC (OJ L 337, 23.12.2015, p. 35).



	Legislation applicable to the activities and supervision of credit institutions and the prevention of systemic risks to payment and securities settlement systems				
31	Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories (OJ L 201, 27.7.2012, p. 1) and the related level measures, where applicable				
	amended by:				
32	Regulation (EU) No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and investment firms and amending Regulation (EU) No 648/2012 (OJ L 176, 27.6.2013, p. 1).				
33	Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014 establishing a framework for the recovery and resolution of credit institutions and investment firms and amending Council Directive 82/891/EEC, and Directives 2001/24/EC, 2002/47/EC, 2004/25/EC, 2005/56/EC, 2007/36/EC, 2011/35/EU, 2012/30/EU and 2013/36/EU, and Regulations (EU) No 1093/2010 and (EU) No 648/2012, of the European Parliament and of the Council (OJ L 173, 12.6.2014, p. 190).				
34	Regulation (EU) No 600/2014 of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Regulation (EU) No 648/2012 (OJ L 173, 12.6.2014, p. 84) and the related level 2 measures, where applicable				
	amended by:				
35	Regulation (EU) 2016/1033 of the European Parliament and of the Council of 23 June 2016 amending Regulation (EU) No 600/2014 on markets in financial instruments, Regulation (EU) No 596/2014 on market abuse and Regulation (EU) No 909/2014 on improving securities settlement in the European Union and on central securities depositories (OJ L 175, 30.6.2016, p. 1–7)				
36	Directive (EU) 2015/849 of the European Parliament and of the Council of 20 May 2015 on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing, amending Regulation (EU) No 648/2012 of the European Parliament and of the Council, and repealing Directive 2005/60/EC of the European Parliament and of the Council and Commission Directive 2006/70/EC (OJ L 141, 5.6.2015, p. 73).				
37	Regulation (EU) 2015/2365 of the European Parliament and of the Council of 25 November 2015 on transparency of securities financing transactions and of reuse and amending Regulation (EU) No 648/2012 (OJ L 337, 23.12.2015, p. 1), in relation to credit institutions				
38	Regulation (EU) No 575/2013 of the European Parliament and of the Council of 26 June 2013 on prudential requirements for credit institutions and investment firms and amending Regulation (EU) No 648/2012 (OJ L 176, 27.6.2013, p. 1) and the related level 2 measures, where applicable				
	amended by:				
39	Regulation (EU) 2017/2395 of the European Parliament and of the Council of 12 December 2017 amending Regulation (EU) No 575/2013 as regards transitional arrangements for mitigating the impact of the introduction of IFRS 9 on own funds and for the large exposures treatment of certain public sector exposures denominated in the domestic currency of any Member State (OJ L 345, 27.12.2017, p. 27).				
40	Regulation (EU) 2017/2401 of the European Parliament and of the Council of 12 December 2017 amending Regulation (EU) No 575/2013 on prudential requirements for credit institutions and investment firms (OJ L 347, 28.12.2017, p. 1).				
41	Regulation (EU) 2019/630 of the European Parliament and of the Council of 17 April 2019 amending Regulation (EU) No 575/2013 as regards minimum loss coverage for non-performing exposures (OJ L 11, 25.4.2019, p. 4).				



	Legislation applicable to the activities and supervision of credit institutions and the prevention of systemic risks to payment and securities settlement systems
42	With the exception of Title V: Directive 2013/36/EU of the European Parliament and of the Council of 26 June 2013 on access to the activity of credit institutions and the prudential supervision of credit institutions and investment firms, amending Directive 2002/87/EC and repealing Directives 2006/48/EC and 2006/49/EC (OJ L 176, 27.6.2013, p. 338) and the related level 2 measures, where applicable
	amended by:
43	Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014 establishing a framework for the recovery and resolution of credit institutions and investment firms and amending Council Directive 82/891/EEC, and Directives 2001/24/EC, 2002/47/EC, 2004/25/EC, 2005/56/EC, 2007/36/EC, 2011/35/EU, 2012/30/EU and 2013/36/EU, and Regulations (EU) No 1093/2010 and (EU) No 648/2012, of the European Parliament and of the Council (OJ L 173, 12.6.2014, p. 190).
44	Directive 2014/49/EU of the European Parliament and of the Council of 16 April 2014 on deposit-guarantee schemes (recast) (OJ L 173, 12.6.2014, p. 149).
45	Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014 establishing a framework for the recovery and resolution of credit institutions and investment firms and amending Council Directive 82/891/EEC, and Directives 2001/24/EC, 2002/47/EC, 2004/25/EC, 2005/56/EC, 2007/36/EC, 2011/35/EU, 2012/30/EU and 2013/36/EU, and Regulations (EU) No 1093/2010 and (EU) No 648/2012, of the European Parliament and of the Council (OJ L 173, 12.6.2014, p. 190) and the related level 2 measures, where applicable
	amended by:
46	Directive (EU) 2017/2399 of the European Parliament and of the Council of 12 December 2017 amending Directive 2014/59/EU as regards the ranking of unsecured debt instruments in insolvency hierarchy (OJ L 345, 27.12.2017, p. 96).
4 7	With regard to the provisions applicable to credit institutions and with the exception of Articles 34 to 36 and Title III: Directive 2014/65/EU of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Directive 2002/92/EC and Directive 2011/61/EU (recast) (OJ L 173, 12.6.2014, p. 349) and the related level 2 measures, where applicable
	amended by:
48	Regulation (EU) No 909/2014 of the European Parliament and of the Council of 23 July 2014 on improving securities settlement in the European Union and on central securities depositories and amending Directives 98/26/EC and 2014/65/EU and Regulation (EU) No 236/2012 (OJ L 257, 28.8.2014, p. 1).
49	Directive 2016/1034/EC of the European Parliament and of the Council of 23 June 2016 amending Directive 2014/65/EU on markets in financial instruments (OJ L 175, 30.6.2016, p. 8).
50	Regulation (EU) No 909/2014 of the European Parliament and of the Council of 23 July 2014 on improving securities settlement in the European Union and on central securities depositories and amending Directives 98/26/EC and 2014/65/EU and Regulation (EU) No 236/2012 (OJ L 257, 28.8.2014, p. 1).
	amended by:
51	Regulation (EU) 2016/1033 of the European Parliament and of the Council of 23 June 2016 amending Regulation (EU) No 600/2014 on markets in financial instruments, Regulation (EU) No 596/2014 on market abuse and Regulation (EU) No 909/2014 on improving securities settlement in the European Union and on central securities depositories (OJ L 175, 30.6.2016, p. 1).



	Legislation applicable to the activities and supervision of credit institutions and the prevention of systemic risks to payment and securities settlement systems
52	With regard to the provisions applicable to credit institutions Regulation (EU) No 600/2014 of the European Parliament and of the Council of 15 May 2014 on markets in financial instruments and amending Regulation (EU) No 648/2012 (OJ L 173, 12.6.2014, p. 84).
	amended by:
53	Regulation (EU) 2016/1033 of the European Parliament and of the Council of 23 June 2016 amending Regulation (EU) No 600/2014 on markets in financial instruments, Regulation (EU) No 596/2014 on market abuse and Regulation (EU) No 909/2014 on improving securities settlement in the European Union and on central securities depositories (OJ L 175, 30.6.2016, p. 1).
54	Regulation (EU) 2015/2365 of the European Parliament and of the Council of 25 November 2015 on transparency of securities financing transactions and of reuse and amending Regulation (EU) No 648/2012 (OJ L 337, 23.12.2015, p. 1), in relation to credit institutions
55	With the exception of Titles III and IV: Directive (EU) 2015/2366 of the European Parliament and of the Council of 25 November 2015 on payment services in the internal market, amending Directives 2002/65/EC, 2009/110/EC and 2013/36/EU and Regulation (EU) No 1093/2010, and repealing Directive 2007/64/EC (OJ L 337, 23.12.2015, p. 35) and the related level 2 measures, where applicable.'

COMMISSION IMPLEMENTING DECISION (EU) 2020/27

of 13 January 2020

postponing the expiry date of approval of propiconazole for use in biocidal products of product-type 8

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

After consulting the Standing Committee on Biocidal Products,

Whereas:

- (1) The active substance propiconazole was included in Annex I to Directive 98/8/EC of the European Parliament and of the Council (²) for use in biocidal products of product-type 8, and pursuant to Article 86 of Regulation (EU) No 528/2012 is therefore considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.
- (2) The approval of propiconazole for use in biocidal products of product-type 8 will expire on 31 March 2020. On 1 October 2018, an application was submitted in accordance with Article 13(1) of Regulation (EU) No 528/2012 for the renewal of the approval of propiconazole.
- (3) On 8 February 2019, the evaluating competent authority of Finland informed the Commission that it had decided, pursuant to Article 14(1) of Regulation (EU) No 528/2012, that a full evaluation of the application was necessary. Pursuant to Article 8(1) of Regulation (EU) No 528/2012, the evaluating competent authority is to perform a full evaluation of the application within 365 days of its validation.
- (4) The evaluating competent authority may, as appropriate, request the applicant to provide sufficient data to carry out the evaluation, in accordance with Article 8(2) of that Regulation. In such case, the 365-day period is suspended for a period that may not exceed 180 days in total unless a longer suspension is justified by the nature of the data requested or by exceptional circumstances.
- (5) Within 270 days of receipt of a recommendation from the evaluating competent authority, the European Chemicals Agency ('the Agency') is to prepare and submit to the Commission an opinion on renewal of the approval of the active substance in accordance with Article 14(3) of Regulation (EU) No 528/2012.
- (6) Consequently, for reasons beyond the control of the applicant, the approval of propiconazole for use in biocidal products of product-type 8 is likely to expire before a decision has been taken on its renewal. It is therefore appropriate to postpone the expiry date of approval of propiconazole for use in biocidal products of product-type 8 for a period of time sufficient to enable the examination of the application.
- (7) Considering that propiconazole is classified as toxic for reproduction category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council (³), and therefore meets the exclusion criterion set out in point (c) of Article 5(1) of Regulation (EU) No 528/2012, after further discussion with Member States, it is considered appropriate to postpone the expiry date of approval for a shorter period of time. It is therefore proposed to extend the duration of approval until 31 March 2021.
- (8) Except for the expiry date of the approval, propiconazole remains approved for use in biocidal products of producttype 8 subject to the specifications and conditions set out in Annex I to Directive 98/8/EC,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

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

⁽³⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of approval of propiconazole for use in biocidal products of product-type 8 is postponed to 31 March 2021.

Article 2

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

Done at Brussels, 13 January 2020.

For the Commission The President Ursula VON DER LEYEN



