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⁽¹⁾ Text with EEA relevance.

EN

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2022/474

of 17 January 2022

amending Annex II to Regulation (EU) 2018/848 of the European Parliament and of the Council as regards specific requirements for the production and use of non-organic, in-conversion and organic seedlings and other plant reproductive material

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to 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 ⁽¹⁾, and in particular Article 12(2), points (b) and (e), thereof,

Whereas:

- (1) Regulation (EU) 2018/848, and in particular Part I of Annex II thereto, lays down certain requirements with regard to the use of in-conversion and non-organic plant reproductive material.
- (2) In view of the phasing out of the derogations from the use of organic plant reproductive material laid down in Article 53 of Regulation (EU) 2018/848, it is important to increase the production and placing on the market of organic and in-conversion plant reproductive material.
- (3) However, for some horticultural species, the current availability of organic and in-conversion seeds is limited, and the use of non-organic seeds for the production of seedlings as plant reproductive material, grown under organic conditions, is a common technique.
- (4) The databases and systems referred to in Article 26(1) and (2) of Regulation (EU) 2018/848, in which the Member States are required to make public information on the availability of organic and in-conversion plant reproductive material, do not include seedlings. Considering the particular nature of seedlings and the variable duration of their production cycles, it is necessary to clarify the rules on their use in organic production. The availability of organic and in-conversion seeds for the species and variety concerned should be taken into account to determine the potential availability on the market of organic and in-conversion seedlings.
- (5) In accordance with Article 10(4), second subparagraph, point (a), of Regulation (EU) 2018/848, non-organic plant reproductive material can also be marketed as in-conversion, provided that such material has completed a conversion period of at least 12 months. The use of in-conversion plant reproductive material should be prioritised over the use of non-organic plant reproductive material. In that context, it is necessary to clarify that 'in-conversion seedlings' may be used when their cultivation cycle has lasted at least 12 months on a land parcel that has completed a conversion period of 12 months or when cultivated in containers or on a land parcel, provided that the seedlings originate from in-conversion seeds that were harvested from plants grown on a land parcel that completed a conversion period of 12 months.

⁽¹⁾ OJ L 150, 14.6.2018, p. 1.

- (6) Nevertheless, as regards seedlings, it is necessary to prohibit the use of non-organic seedlings for crops that have completed a production cycle within one growing season from the transplantation of seedlings to the first harvest of the final product in order to ensure the integrity of organic products which could be undermined in case of presence of residues in the non-organic seeds used as starting material.
- (7) For certain fruit, grapevine and ornamental species or varieties, the availability of mother plants or, where relevant, other plants intended for the production of plant reproductive material, grown in compliance with point 1.8.2 of Part I of Annex II to Regulation (EU) 2018/848, is insufficient. Moreover, there are few organic fruit and grapevine nurseries that work currently with mother plants grown in compliance with point 1.8.2 due to the long term investments and technical difficulties to ensure full compliance with quality certification and phytosanitary requirements.
- (8) In order to promote the further development of this highly specialised production sector, it is appropriate to introduce the possibility to authorise the use of non-organic plant reproductive material grown under organic conditions for the production of plant reproductive material to be marketed and used for organic crops, provided that certain specific conditions are met.
- (9) Operators producing such plant reproductive material should be allowed to make public, on a voluntary basis, information on the availability of such material in the national systems established in accordance with Article 26(2) of Regulation (EU) 2018/848. This will allow operators to choose organically grown plant reproductive material when organic or in-conversion plant reproductive material is not available.
- (10) In order to ensure coherence, the authorisations to use non-organic plant reproductive material grown under organic conditions for the production of plant reproductive material should expire at the same time as the derogations to the use of organic plant reproductive material. The Commission should monitor the availability of organic plant reproductive material and will end or extend such authorisations in the light of the conclusions as regards availability of organic plant reproductive material presented in the report provided for in Article 53(7) of Regulation (EU) 2018/848 and in accordance with Article 53(2) of that Regulation.
- (11) Annex II to Regulation (EU) 2018/848 should therefore be amended accordingly.
- (12) In order to avoid a legal vacuum, this Regulation should apply retroactively from the date of application of Regulation (EU) 2018/848,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EU) 2018/848 is amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from 1 January 2022.

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

Done at Brussels, 17 January 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Part I of Annex II to Regulation (EU) 2018/848 is amended as follows:

(a) point 1.8.5.1 is amended as follows:

(i) the first paragraph is replaced by the following:

'By way of derogation from point 1.8.1, where the data collected in the database referred to in Article 26(1) or the systems referred to in Article 26(2) show that the qualitative or quantitative needs of the operator regarding relevant organic plant reproductive material are not met, the operator may use in-conversion plant reproductive material in accordance with Article 10(4), second subparagraph, point (a), or plant reproductive material authorised in accordance with point 1.8.6.';

(ii) the following paragraph is inserted after the first paragraph:

'In addition, in case of a lack of availability of organic seedlings, "in-conversion seedlings", marketed in compliance with Article 10(4), second subparagraph, point (a), may be used when grown as follows:

- (a) through a cultivation cycle from seeds to final seedling lasting at least 12 months on a land parcel that, during that same period, has completed a conversion period of at least 12 months; or
- (b) on an organic or in-conversion land parcel or in containers if covered by the derogation referred to in point 1.4, provided that the seedlings have originated from in-conversion seeds, harvested from a plant grown on a land parcel that has completed a conversion period of at least 12 months.';

(iii) the second, third and fourth paragraphs are replaced by the following:

'Where organic or in-conversion plant reproductive material or plant reproductive material authorised in accordance with point 1.8.6 is not available in sufficient quality or quantity to fulfil the operator's needs, competent authorities may authorise the use of non-organic plant reproductive material subject to points 1.8.5.3 to 1.8.5.8.

Such individual authorisation shall be issued only in one of the following situations:

- (a) where no variety of the species that the operator wants to obtain is registered in the database referred to in Article 26(1) or the systems referred to in Article 26(2);
- (b) where no operator who markets plant reproductive material, is able to deliver the relevant organic or in-conversion plant reproductive material or plant reproductive material authorised in accordance with point 1.8.6 in time for sowing or planting in situations where the user has ordered the plant reproductive material in reasonable time to allow the preparation and supply of organic or in-conversion plant reproductive material or of plant reproductive material authorised in accordance with point 1.8.6;
- (c) where the variety that the operator wants to obtain is not registered as organic or in-conversion plant reproductive material or as plant reproductive material authorised in accordance with point 1.8.6 in the database referred to in Article 26(1) or the systems referred to Article 26(2) and the operator is able to demonstrate that none of the registered alternatives of the same species are appropriate in particular to the agronomic and pedo-climatic conditions and necessary technological properties for the production to be obtained;
- (d) where it is justified for use in research, test in small-scale field trials, for variety conservation purposes or for product innovation and agreed by the competent authorities of the Member State concerned.

Prior to requesting any such authorisation, operators shall consult the database referred to in Article 26(1) or the systems referred to in Article 26(2) in order to verify whether relevant organic or in-conversion plant reproductive material or plant reproductive material authorised in accordance with point 1.8.6 is available and thus whether their request is justified.';

(b) point 1.8.5.2 is amended as follows:

(i) the first paragraph is replaced by the following:

‘By way of derogation from point 1.8.1, operators in third countries may use in-conversion plant reproductive material in accordance with Article 10(4), second subparagraph, point (a), or plant reproductive material authorised in accordance with point 1.8.6 when organic plant reproductive material is justified to be not available in sufficient quality or quantity in the territory of the third country in which the operator is located.’;

(ii) the third paragraph is replaced by the following:

‘Control authorities or control bodies recognised in accordance with Article 46(1) may authorise operators in third countries to use non-organic plant reproductive material in an organic production unit, when organic or in-conversion plant reproductive material or plant reproductive material authorised in accordance with point 1.8.6 is not available in sufficient quality or quantity in the territory of the third country in which the operator is located, under the conditions laid down in points 1.8.5.3, 1.8.5.4, 1.8.5.5 and 1.8.5.8.’;

(c) the following points 1.8.5.8 and 1.8.6 are inserted:

‘1.8.5.8. Competent authorities shall not authorise the use of non-organic seedlings in the case of seedlings of species that have a cultivation cycle completed in one growing season, from the transplantation of the seedling to the first harvest of product.

1.8.6. Competent authorities or, where appropriate, control authorities or control bodies recognised in accordance with Article 46(1) may authorise operators producing plant reproductive material for use in organic production to use non-organic plant reproductive material, when mother plants or, where relevant, other plants intended for the production of plant reproductive material and produced in compliance with point 1.8.2 are not available in sufficient quantity or quality, and to place such material on the market for use in organic production provided that the following conditions are met:

- (a) the non-organic plant reproductive material used has not been treated after harvest with plant protection products other than those authorised in accordance with Article 24(1) of this Regulation, unless chemical treatment has been prescribed in accordance with Regulation (EU) 2016/2031 for phytosanitary purposes by the competent authorities of the Member State concerned for all varieties and heterogeneous material of a given species in the area in which the plant reproductive material is to be used. Where non-organic plant reproductive material treated with such prescribed chemical treatment is used, the land parcel on which the treated plant reproductive material is growing shall be subject, where appropriate, to a conversion period as provided in points 1.7.3 and 1.7.4;
- (b) the non-organic plant reproductive material used is not a seedling of species that have a cultivation cycle completed in one growing season, from the transplantation of the seedling to the first harvest of product;
- (c) the plant reproductive material is grown in compliance with all other relevant organic plant production requirements;
- (d) the authorisation to use non-organic plant reproductive material shall be obtained before that material is sown or planted;
- (e) the competent authority, control authority or control body responsible for the authorisation shall grant the authorisation only to individual users and for one season at a time, and shall list the quantities of the authorised plant reproductive material;
- (f) by way of derogation from point (e), the competent authorities of the Member States may annually grant a general authorisation for the use of a given species or subspecies or variety of non-organic plant reproductive material and make the list of species, subspecies or varieties publicly available and keep it updated on an annual basis. In that case, those competent authorities shall list the quantities of authorised non-organic plant reproductive material;
- (g) the authorisations granted in accordance with this paragraph shall expire on 31 December 2036.

By 30 June of each year, and for the first time by 30 June 2023, the competent authorities of the Member States shall notify the Commission and the other Member States of the information on the authorisations granted in accordance with the first paragraph.

Operators who produce and market the plant reproductive material produced in accordance with the first paragraph shall be allowed to make public, on a voluntary basis, the relevant specific information on the availability of such plant reproductive material in the national systems established in accordance with Article 26(2). Operators that opt to include such information shall ensure that the information is updated regularly, and is withdrawn from the national systems once the plant reproductive material is no longer available. When relying on the general authorisation referred to in point (f), operators shall keep records of the quantity used.'

COMMISSION IMPLEMENTING REGULATION (EU) 2022/475**of 23 March 2022****amending Regulation (EC) No 1484/95 as regards fixing representative prices in the poultrymeat and egg sectors and for egg albumin**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ⁽¹⁾, and in particular Article 183(b) thereof,

Having regard to Regulation (EU) No 510/2014 of the European Parliament and of the Council of 16 April 2014 laying down the trade arrangements applicable to certain goods resulting from the processing of agricultural products and repealing Council Regulations (EC) No 1216/2009 and (EC) No 614/2009 ⁽²⁾, and in particular Article 5(6)(a) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1484/95 ⁽³⁾ lays down detailed rules for implementing the system of additional import duties and fixes representative prices in the poultrymeat and egg sectors and for egg albumin.
- (2) Regular monitoring of the data used to determine representative prices for poultrymeat and egg products and for egg albumin shows that the representative import prices for certain products should be amended to take account of variations in price according to origin.
- (3) Regulation (EC) No 1484/95 should therefore be amended accordingly.
- (4) Given the need to ensure that this measure applies as soon as possible after the updated data have been made available, this Regulation should enter into force on the day of its publication,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 1484/95 is replaced by the text set out in the Annex to this Regulation.

Article 2

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

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ OJ L 150, 20.5.2014, p. 1.

⁽³⁾ Commission Regulation (EC) No 1484/95 of 28 June 1995 laying down detailed rules for implementing the system of additional import duties and fixing representative prices in the poultrymeat and egg sectors and for egg albumin, and repealing Regulation No 163/67/EEC (OJ L 145, 29.6.1995, p. 47).

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

Done at Brussels, 23 March 2022.

*For the Commission,
On behalf of the President,
Wolfgang BURTSCHER
Director-General
Directorate-General for Agriculture and Rural
Development*

ANNEX

‘ANNEX I

CN code	Description of goods	Representative price (EUR/100 kg)	Security under Article 3 (EUR/100 kg)	Origin ⁽¹⁾
0207 14 10	Fowls of the species <i>Gallus domesticus</i> , boneless cuts, frozen	220,7	24	BR

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7).

COMMISSION REGULATION (EU) 2022/476**of 24 March 2022****amending Annexes II, III and IV to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for acetic acid, azoxystrobin, benzovindiflupyr, cyantraniliprole, cyflufenamid, emamectin, flutolanil, lime sulphur, maltodextrin and proquinazid in or on certain products****(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 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC ⁽¹⁾, and in particular Article 5(1) and Article 14(1)(a) thereof,

Whereas:

- (1) For azoxystrobin, benzovindiflupyr, cyantraniliprole, cyflufenamid, flutolanil and proquinazid maximum residue levels ('MRLs') were set in Annex II to Regulation (EC) No 396/2005. For emamectin, MRLs were set in Part A of Annex III to that Regulation. Acetic acid, lime sulphur and maltodextrin are included in Annex IV to Regulation (EC) No 396/2005.
- (2) In the context of a procedure for the authorisation of the use of a plant protection product containing the active substance benzovindiflupyr on 'herbs and edible flowers', spring onions/green onions, Welsh onions and leeks, two applications pursuant to Article 6(1) of Regulation (EC) No 396/2005 requesting a modification of the existing MRLs were submitted.
- (3) As regards cyantraniliprole, an application pursuant to Article 6(1) of Regulation (EC) No 396/2005 requesting a modification of the existing MRLs was submitted for table olives and olives for oil production. As regards cyflufenamid, such an application was submitted for blackberries and raspberries (red and yellow). As regards emamectin, such an application was submitted for pome fruits, apricots, cherries (sweet), 'spinaches and similar leaves' and 'herbal infusions from leaves and herbs'. As regards proquinazid, such an application was submitted for blueberries and cranberries.
- (4) As regards azoxystrobin, two applications for import tolerances pursuant to Article 6(2) and (4) of Regulation (EC) No 396/2005 were submitted as regards the use of that substance in Brazil on mangoes and in Colombia on oil palms fruits as well as regards the use of flutolanil in the United States on peanuts/groundnuts. The applicants stated that the authorised uses of those substances on these crops in those countries lead to residues exceeding the MRLs contained in Regulation (EC) No 396/2005 and that higher MRLs are necessary to avoid trade barriers for the importation of those crops.
- (5) In accordance with Article 8 of Regulation (EC) No 396/2005, all applications mentioned above were evaluated by the Member States concerned and the evaluation reports were forwarded to the Commission.

⁽¹⁾ OJ L 70, 16.3.2005, p. 1.

- (6) The European Food Safety Authority ('the Authority') assessed the applications and the evaluation reports, examining in particular the risks to consumers and, where relevant, to animals, and gave reasoned opinions on the proposed MRLs ⁽²⁾. It forwarded those opinions to the applicants, the Commission and the Member States and made them available to the public.
- (7) As regards emamectin, the Authority concluded that for 'pome fruits' the submitted data was insufficient to set new MRLs. As regards all other applications, the Authority concluded that all requirements with respect to completeness of data submission were met, and that the modifications to the MRLs requested by the applicants were acceptable with regard to consumer safety on the basis of a consumer exposure assessment for 27 specific European consumer groups. The Authority took into account the most recent information on the toxicological properties of the substances. Neither the lifetime exposure to these substances via consumption of all food products that may contain them, nor the short-term exposure due to high consumption of the relevant products showed that there is a risk that the acceptable daily intake or the acute reference dose is exceeded.
- (8) Acetic acid, lime sulphur and maltodextrin were temporarily included in Annex IV to Regulation (EC) No 396/2005 pending the finalisation of their evaluation under Council Directive 91/414/EEC ⁽³⁾ or Regulation (EC) No 1107/2009 of the European Parliament and of the Council ⁽⁴⁾. The Authority evaluated those substances and concluded that no MRLs are required for acetic acid, lime sulphur and maltodextrin and that it is therefore appropriate to retain these substances in Annex IV to Regulation (EC) No 396/2005 permanently ⁽⁵⁾.
- (9) Based on the reasoned opinions and the conclusion of the Authority and taking into account the factors relevant to the matter under consideration, the modifications to the MRLs proposed by this Regulation fulfil the requirements of Article 14(2) of Regulation (EC) No 396/2005.
- (10) Regulation (EC) No 396/2005 should therefore be amended accordingly.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes II, III and IV to Regulation (EC) No 396/2005 are amended in accordance with the Annex to this Regulation.

- ⁽²⁾ EFSA scientific reports available online: <http://www.efsa.europa.eu>:
Reasoned opinion on the setting of import tolerances for azoxystrobin in mangoes and oil palm fruits. EFSA Journal 2021;19(8):6821.
Reasoned opinion on the modification of the existing maximum residue levels for benzovindiflupyr in fresh herbs and edible flowers. EFSA Journal 2021;19(9):6839.
Reasoned opinion on the modification of the existing maximum residue levels for benzovindiflupyr leeks and spring onions/green onions/Welsh onions. EFSA Journal 2021;19(7):6774.
Reasoned opinion on the modification of the existing maximum residue levels for cyantraniliprole in olives. EFSA Journal 2021;19(8):6805.
Reasoned opinion on the modification of the existing maximum residue levels for cyflufenamid in blackberries and raspberries. EFSA Journal 2021;19(8):6831.
Reasoned opinion on the modification of the existing maximum residue levels for emamectin in various crops. EFSA Journal 2021;19(8):6824.
Reasoned opinion on the setting of import tolerance for flutolanil in peanuts. EFSA Journal 2021;19(8):6717.
Reasoned opinion on the modification of the existing maximum residue levels for proquinazid in blueberries and cranberries. EFSA Journal 2021;19(9):6835.
- ⁽³⁾ Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).
- ⁽⁴⁾ 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 (OJ L 309, 24.11.2009, p. 1).
- ⁽⁵⁾ Statement on pesticide active substances that do not require a review of the existing maximum residue levels under Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2020;18(12):6318.

Article 2

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

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

Done at Brussels, 24 March 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes II, III and IV to Regulation (EC) No 396/2005 are amended as follows:

- (1) in Annex II, the columns for azoxystrobin, benzovindiflupyr, cyantraniliprole, cyflufenamid, flutolanil and proquinazid are replaced by the following:

“Pesticide residues and maximum residue levels (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply ^(A)	Azoxystrobin	Benzovindiflupyr	Cyantraniliprole	Cyflufenamid (sum of cyflufenamid (Z-isomer) and its E-isomer, expressed as cyflufenamid) (R) (A)	Flutolanil (R)	Proquinazid (R) (F)
0100000	FRUITS, FRESH or FROZEN; TREE NUTS					0,01 (*)	
0110000	Citrus fruits	15	0,01 (*)	0,9	0,01 (*)		0,01 (*)
0110010	Grapefruits						
0110020	Oranges						
0110030	Lemons						
0110040	Limes						
0110050	Mandarins						
0110990	Others (2)						
0120000	Tree nuts		0,01 (*)	0,04	0,01 (*)		0,02 (*)
0120010	Almonds	0,01					
0120020	Brazil nuts	0,01					
0120030	Cashew nuts	0,01					
0120040	Chestnuts	0,01					
0120050	Coconuts	0,01					
0120060	Hazelnuts/cobnuts	0,01					
0120070	Macadamias	0,01					
0120080	Pecans	0,01					
0120090	Pine nut kernels	0,01					
0120100	Pistachios	1					
0120110	Walnuts	0,01					
0120990	Others (2)	0,01					
0130000	Pome fruits	0,01 (*)	0,2	0,8	0,06		
0130010	Apples						0,08
0130020	Pears						0,08

0130030	Quinces						0,01 (*)
0130040	Medlars						0,01 (*)
0130050	Loquats/Japanese medlars						0,01 (*)
0130990	Others (2)						0,01 (*)
0140000	Stone fruits	2	0,01 (*)				0,01 (*)
0140010	Apricots			0,01 (*)	0,06		
0140020	Cherries (sweet)			6	0,1		
0140030	Peaches			1,5	0,06		
0140040	Plums			0,7	0,07		
0140990	Others (2)			0,01 (*)	0,06		
0150000	Berries and small fruits						
0151000	(a) grapes	3	1	1,5	0,2		0,5
0151010	Table grapes						
0151020	Wine grapes						
0152000	(b) strawberries	10	0,01 (*)	1,5	0,04		2
0153000	(c) cane fruits	5	0,01 (*)	0,01 (*)			0,01 (*)
0153010	Blackberries				0,07		
0153020	Dewberries				0,01 (*)		
0153030	Raspberries (red and yellow)				0,07		
0153990	Others (2)				0,01 (*)		
0154000	(d) other small fruits and berries				0,01 (*)		
0154010	Blueberries	5	0,01 (*)	4			1,5
0154020	Cranberries	0,5	0,01 (*)	0,08			1,5
0154030	Currants (black, red and white)	5	0,01 (*)	4			1,5
0154040	Gooseberries (green, red and yellow)	5	0,01 (*)	4			1,5
0154050	Rose hips	5	0,01 (*)	4			0,01 (*)
0154060	Mulberries (black and white)	5	0,01 (*)	0,01 (*)			0,01 (*)
0154070	Azaroles/ Mediterranean medlars	5	0,2	0,8			0,01 (*)
0154080	Elderberries	5	0,01 (*)	0,01 (*)			0,01 (*)
0154990	Others (2)	5	0,01 (*)	0,01 (*)			0,01 (*)

0160000	Miscellaneous fruit with				0,01 (*)		
0161000	(a) edible peel						
0161010	Dates	0,01 (*)	0,01 (*)	0,01 (*)			0,01 (*)
0161020	Figs	0,01 (*)	0,01 (*)	0,01 (*)			0,01 (*)
0161030	Table olives	0,01 (*)	0,01 (*)	3			0,02 (*)
0161040	Kumquats	0,01 (*)	0,01 (*)	0,01 (*)			0,01 (*)
0161050	Carambolas	0,1	0,01 (*)	0,01 (*)			0,01 (*)
0161060	Kaki/Japanese persimmons	0,01 (*)	0,2	0,8			0,01 (*)
0161070	Jambuls/jambolans	0,01 (*)	0,01 (*)	0,01 (*)			0,01 (*)
0161990	Others (2)	0,01 (*)	0,01 (*)	0,01 (*)			0,01 (*)
0162000	(b) inedible peel, small		0,01 (*)	0,01 (*)			0,01 (*)
0162010	Kiwi fruits (green, red, yellow)	0,01 (*)					
0162020	Litchis/lychees	0,01 (*)					
0162030	Passionfruits/ maracujas	4					
0162040	Prickly pears/cactus fruits	0,3					
0162050	Star apples/cainitos	0,01 (*)					
0162060	American persimmons/Virginia kaki	0,01 (*)					
0162990	Others (2)	0,01 (*)					
0163000	(c) inedible peel, large		0,01 (*)				
0163010	Avocados	0,01 (*)		0,01 (*)			0,02 (*)
0163020	Bananas	2		0,01 (*)			0,01 (*)
0163030	Mangoes	4		0,7			0,01 (*)
0163040	Papayas	0,3		0,01 (*)			0,01 (*)
0163050	Granate apples/ pomegranates	0,01 (*)		0,01 (*)			0,01 (*)
0163060	Cherimoyas	0,01 (*)		0,01 (*)			0,01 (*)
0163070	Guavas	0,01 (*)		0,01 (*)			0,01 (*)
0163080	Pineapples	0,01 (*)		0,01 (*)			0,01 (*)
0163090	Breadfruits	0,01 (*)		0,01 (*)			0,01 (*)
0163100	Durians	0,01 (*)		0,01 (*)			0,01 (*)
0163110	Soursops/ guanabanas	0,01 (*)		0,01 (*)			0,01 (*)

0163990	Others (2)	0,01 (*)		0,01 (*)			0,01 (*)
0200000	VEGETABLES, FRESH or FROZEN						
0210000	Root and tuber vegetables			0,05	0,01 (*)		0,01 (*)
0211000	(a) potatoes	7	0,02			0,1	
0212000	(b) tropical root and tuber vegetables	1	0,02			0,01 (*)	
0212010	Cassava roots/manioc						
0212020	Sweet potatoes						
0212030	Yams						
0212040	Arrowroots						
0212990	Others (2)						
0213000	(c) other root and tuber vegetables except sugar beets					0,01 (*)	
0213010	Beetroots	1	0,01 (*)				
0213020	Carrots	1	0,01 (*)				
0213030	Celeriacs/turnip rooted celeries	1	0,01 (*)				
0213040	Horseradishes	1	0,01 (*)				
0213050	Jerusalem artichokes	1	0,02				
0213060	Parsnips	1	0,01 (*)				
0213070	Parsley roots/Hamburg roots parsley	1	0,01 (*)				
0213080	Radishes	1,5	0,01 (*)				
0213090	Salsifies	1	0,01 (*)				
0213100	Swedes/rutabagas	1	0,01 (*)				
0213110	Turnips	1	0,01 (*)				
0213990	Others (2)	1	0,01 (*)				
0220000	Bulb vegetables	10			0,01 (*)	0,01 (*)	0,01 (*)
0220010	Garlic		0,01 (*)	0,05			
0220020	Onions		0,01 (*)	0,05			
0220030	Shallots		0,01 (*)	0,05			
0220040	Spring onions/green onions and Welsh onions		0,09	8			

0220990	Others (2)		0,01 (*)	0,05			
0230000	Fruiting vegetables					0,01 (*)	
0231000	(a) Solanaceae and Malvaceae	3					
0231010	Tomatoes		0,9	1	0,04		0,15
0231020	Sweet peppers/bell peppers		1	1,5	0,06	(+)	0,01 (*)
0231030	Aubergines/eggplants		0,9	1	0,02 (*)		0,15
0231040	Okra/lady's fingers		1	1,5	0,01 (*)		0,01 (*)
0231990	Others (2)		1	1,5	0,01 (*)		0,01 (*)
0232000	(b) cucurbits with edible peel	1	0,08	0,4	0,05		0,05
0232010	Cucumbers						
0232020	Gherkins						
0232030	Courgettes						
0232990	Others (2)						
0233000	(c) cucurbits with inedible peel	1	0,01 (*)	0,3	0,05		0,01 (*)
0233010	Melons						
0233020	Pumpkins						
0233030	Watermelons						
0233990	Others (2)						
0234000	(d) sweet corn	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)		0,01 (*)
0239000	(e) other fruiting vegetables	0,01 (*)	0,9	0,01 (*)	0,01 (*)		0,01 (*)
0240000	Brassica vegetables (excluding brassica roots and brassica baby leaf crops)		0,01 (*)		0,01 (*)		0,01 (*)
0241000	(a) flowering brassica	5		2		0,05	
0241010	Broccoli						
0241020	Cauliflowers						
0241990	Others (2)						
0242000	(b) head brassica	5		2		0,05	
0242010	Brussels sprouts						
0242020	Head cabbages						

0242990	Others (2)						
0243000	(c) leafy brassica	6		0,01 (*)		0,01 (*)	
0243010	Chinese cabbages/pe-tsai						
0243020	Kales						
0243990	Others (2)						
0244000	(d) kohlrabies	5		2		0,01 (*)	
0250000	Leaf vegetables, herbs and edible flowers						
0251000	(a) lettuces and salad plants	15	0,01 (*)		0,01 (*)	0,01 (*)	0,01 (*)
0251010	Lamb's lettuces/corn salads	(+)		0,01 (*)			
0251020	Lettuces			5			
0251030	Escaroles/broad-leaved endives	(+)		0,01 (*)			
0251040	Cresses and other sprouts and shoots	(+)		0,01 (*)			
0251050	Land cresses	(+)		0,01 (*)			
0251060	Roman rocket/rucola	(+)		0,01 (*)			
0251070	Red mustards	(+)		0,01 (*)			
0251080	Baby leaf crops (including brassica species)	(+)		0,01 (*)			
0251990	Others (2)			0,01 (*)			
0252000	(b) spinaches and similar leaves	15	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)
0252010	Spinaches						
0252020	Purslanes						
0252030	Chards/beet leaves						
0252990	Others (2)						
0253000	(c) grape leaves and similar species	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)
0254000	(d) watercresses	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)
0255000	(e) witloofs/Belgian endives	0,3	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)
0256000	(f) herbs and edible flowers	70	1	0,02 (*)	0,02 (*)	0,02 (*)	0,02 (*)
0256010	Chervil						
0256020	Chives						
0256030	Celery leaves						

0256040	Parsley						
0256050	Sage						
0256060	Rosemary						
0256070	Thyme						
0256080	Basil and edible flowers						
0256090	Laurel/bay leaves						
0256100	Tarragon						
0256990	Others (2)						
0260000	Legume vegetables	3	0,01 (*)		0,01 (*)	0,01 (*)	0,01 (*)
0260010	Beans (with pods)			1,5			
0260020	Beans (without pods)			0,3			
0260030	Peas (with pods)			2			
0260040	Peas (without pods)			0,3			
0260050	Lentils			0,01 (*)			
0260990	Others (2)			0,01 (*)			
0270000	Stem vegetables					0,01 (*)	0,01 (*)
0270010	Asparagus	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)		
0270020	Cardoons	15	0,01 (*)	0,01 (*)	0,01 (*)		
0270030	Celeries	15	0,01 (*)	15	0,01 (*)		
0270040	Florence fennels	10	0,01 (*)	0,01 (*)	0,01 (*)		
0270050	Globe artichokes	5	0,01 (*)	0,1	0,04		
0270060	Leeks	10	0,09	0,01 (*)	0,01 (*)		
0270070	Rhubarbs	0,6	0,01 (*)	0,01 (*)	0,01 (*)		
0270080	Bamboo shoots	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)		
0270090	Palm hearts	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)		
0270990	Others (2)	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)		
0280000	Fungi, mosses and lichens	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)
0280010	Cultivated fungi						
0280020	Wild fungi						
0280990	Mosses and lichens						
0290000	Algae and prokaryotes organisms	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)	0,01 (*)
0300000	PULSES	0,15	0,2		0,01 (*)	0,01 (*)	0,01 (*)
0300010	Beans			0,3			
0300020	Lentils			0,01 (*)			

0300030	Peas			0,01 (*)			
0300040	Lupins/lupini beans			0,01 (*)			
0300990	Others (2)			0,01 (*)			
0400000	OILSEEDS AND OIL FRUITS				0,01 (*)		0,02 (*)
0401000	Oilseeds						
0401010	Linseeds	0,4	0,15	0,01 (*)		0,01 (*)	
0401020	Peanuts/groundnuts	0,2	0,04	0,01 (*)		0,02	
0401030	Poppy seeds	0,5	0,15	0,01 (*)		0,01 (*)	
0401040	Sesame seeds	0,01 (*)	0,01 (*)	0,01 (*)		0,01 (*)	
0401050	Sunflower seeds	0,5	0,01 (*)	0,5		0,01 (*)	
0401060	Rapeseeds/canola seeds	0,5	0,2	0,8		0,01 (*)	
0401070	Soyabeans	0,5	0,08	0,4		0,01 (*)	
0401080	Mustard seeds	0,5	0,15	0,01 (*)		0,01 (*)	
0401090	Cotton seeds	0,7	0,15	1,5		0,01 (*)	
0401100	Pumpkin seeds	0,01 (*)	0,01 (*)	0,01 (*)		0,01 (*)	
0401110	Safflower seeds	0,4	0,01 (*)	0,01 (*)		0,01 (*)	
0401120	Borage seeds	0,4	0,01 (*)	0,01 (*)		0,01 (*)	
0401130	Gold of pleasure seeds	0,5	0,15	0,01 (*)		0,01 (*)	
0401140	Hemp seeds	0,01 (*)	0,01 (*)	0,01 (*)		0,01 (*)	
0401150	Castor beans	0,01 (*)	0,01 (*)	0,01 (*)		0,01 (*)	
0401990	Others (2)	0,01 (*)	0,01 (*)	0,01 (*)		0,01 (*)	
0402000	Oil fruits		0,01 (*)			0,01 (*)	
0402010	Olives for oil production	0,01 (*)		3			
0402020	Oil palms kernels	0,01 (*)		0,01 (*)			
0402030	Oil palms fruits	0,03		0,01 (*)			
0402040	Kapok	0,01 (*)		0,01 (*)			
0402990	Others (2)	0,01 (*)		0,01 (*)			
0500000	CEREALS			0,01 (*)			
0500010	Barley	1,5	1,5		0,1	0,01 (*)	0,04(+)
0500020	Buckwheat and other pseudocereals	0,01 (*)	0,01 (*)		0,1	0,01 (*)	0,01 (*)
0500030	Maize/corn	0,02	0,02		0,01 (*)	0,01 (*)	0,01 (*)

0500040	Common millet/proso millet	0,01 (*)	0,01 (*)		0,01 (*)	0,01 (*)	0,01 (*)
0500050	Oat	1,5	1,5		0,1	0,01 (*)	0,04(+)
0500060	Rice	5	0,01 (*)		0,01 (*)	2	0,01 (*)
0500070	Rye	0,5	0,1		0,04	0,01 (*)	0,02
0500080	Sorghum	10	0,01 (*)		0,01 (*)	0,01 (*)	0,01 (*)
0500090	Wheat	0,5	0,1		0,04(+)	0,01 (*)	0,02
0500990	Others (2)	0,01 (*)	0,01 (*)		0,01 (*)	0,01 (*)	0,01 (*)
0600000	TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS				0,05 (*)	0,05 (*)	0,05 (*)
0610000	Teas	0,05 (*)	0,05 (*)	0,05 (*)			
0620000	Coffee beans	0,03	0,15	0,05			
0630000	Herbal infusions from		0,05 (*)				
0631000	(a) flowers	60		0,05 (*)			
0631010	Chamomile						
0631020	Hibiscus/roselle						
0631030	Rose						
0631040	Jasmine						
0631050	Lime/linden						
0631990	Others (2)						
0632000	(b) leaves and herbs	60		0,05 (*)			
0632010	Strawberry						
0632020	Rooibos						
0632030	Mate/maté						
0632990	Others (2)						
0633000	(c) roots	0,3		0,2			
0633010	Valerian						
0633020	Ginseng						
0633990	Others (2)						
0639000	(d) any other parts of the plant	0,05 (*)		0,05 (*)			
0640000	Cocoa beans	0,05 (*)	0,05 (*)	0,05 (*)			
0650000	Carobs/Saint John's breads	0,05 (*)	0,05 (*)	0,05 (*)			
0700000	HOPS	30	0,05 (*)	0,05 (*)	5	0,05 (*)	0,05 (*)
0800000	SPICES						
0810000	Seed spices	0,3	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)
0810010	Anise/aniseed						

0810020	Black caraway/black cumin						
0810030	Celery						
0810040	Coriander						
0810050	Cumin						
0810060	Dill						
0810070	Fennel						
0810080	Fenugreek						
0810090	Nutmeg						
0810990	Others (2)						
0820000	Fruit spices	0,3	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)
0820010	Allspice/pimento						
0820020	Sichuan pepper						
0820030	Caraway						
0820040	Cardamom						
0820050	Juniper berry						
0820060	Peppercorn (black, green and white)						
0820070	Vanilla						
0820080	Tamarind						
0820990	Others (2)						
0830000	Bark spices	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)
0830010	Cinnamon						
0830990	Others (2)						
0840000	Root and rhizome spices						
0840010	Liquorice	0,05 (*)	0,05 (*)	0,2	0,05 (*)	0,05 (*)	0,05 (*)
0840020	Ginger (10)						
0840030	Turmeric/curcuma	0,05 (*)	0,15	0,2	0,05 (*)	0,05 (*)	0,05 (*)
0840040	Horseradish (11)						
0840990	Others (2)	0,05 (*)	0,05 (*)	0,2	0,05 (*)	0,05 (*)	0,05 (*)
0850000	Bud spices	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)
0850010	Cloves						
0850020	Capers						
0850990	Others (2)						
0860000	Flower pistil spices	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)
0860010	Saffron						
0860990	Others (2)						

0870000	Aril spices	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)
0870010	Mace						
0870990	Others (2)						
0900000	SUGAR PLANTS				0,01 (*)	0,01 (*)	0,01 (*)
0900010	Sugar beet roots	5	0,01 (*)	0,05			
0900020	Sugar canes	0,05	0,04	0,01 (*)			
0900030	Chicory roots	0,09	0,01 (*)	0,05			
0900990	Others (2)	0,01 (*)	0,01 (*)	0,01 (*)			
1000000	PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS						
1010000	Commodities from				0,02 (*)		0,02 (*)
1011000	(a) swine						
1011010	Muscle	0,01 (*) (+)	0,01 (*)	0,2		0,05 (*)	
1011020	Fat	0,05 (+)	0,03	0,5		0,05 (*)	
1011030	Liver	0,07 (+)	0,1	1,5		0,5	
1011040	Kidney	0,07 (+)	0,1	1,5		0,5	
1011050	Edible offals (other than liver and kidney)	0,07 (+)	0,1	1,5		0,5	
1011990	Others (2)	0,01 (*) (+)	0,01 (*)	0,01		0,05 (*)	
1012000	(b) bovine						
1012010	Muscle	0,01 (*) (+)	0,01 (*)	0,2		0,05 (*)	(+)
1012020	Fat	0,05 (+)	0,03	0,5		0,05 (*)	(+)
1012030	Liver	0,07 (+)	0,1	1,5		0,5	(+)
1012040	Kidney	0,07 (+)	0,1	1,5		0,5	(+)
1012050	Edible offals (other than liver and kidney)	0,07 (+)	0,1	1,5		0,5	
1012990	Others (2)	0,01 (*) (+)	0,01 (*)	0,01		0,05 (*)	
1013000	(c) sheep						
1013010	Muscle	0,01 (*) (+)	0,01 (*)	0,2		0,05 (*)	(+)
1013020	Fat	0,05 (+)	0,03	0,5		0,05 (*)	(+)
1013030	Liver	0,07 (+)	0,1	1,5		0,5	(+)
1013040	Kidney	0,07 (+)	0,1	1,5		0,5	(+)
1013050	Edible offals (other than liver and kidney)	0,07 (+)	0,1	1,5		0,5	
1013990	Others (2)	0,01 (*) (+)	0,01 (*)	0,01		0,05 (*)	

1014000	(d) goat						
1014010	Muscle	0,01 (*) (+)	0,01 (*)	0,2		0,05 (*)	(+)
1014020	Fat	0,05 (+)	0,03	0,5		0,05 (*)	(+)
1014030	Liver	0,07 (+)	0,1	1,5		0,5	(+)
1014040	Kidney	0,07 (+)	0,1	1,5		0,5	(+)
1014050	Edible offals (other than liver and kidney)	0,07 (+)	0,1	1,5		0,5	
1014990	Others (2)	0,01 (*) (+)	0,01 (*)	0,01		0,05 (*)	
1015000	(e) equine						
1015010	Muscle	0,01 (*)	0,01 (*)	0,2		0,05 (*)	(+)
1015020	Fat	0,05	0,03	0,5		0,05 (*)	(+)
1015030	Liver	0,07	0,1	1,5		0,5	(+)
1015040	Kidney	0,07	0,1	1,5		0,5	(+)
1015050	Edible offals (other than liver and kidney)	0,07	0,1	1,5		0,5	
1015990	Others (2)	0,01 (*)	0,01 (*)	0,01		0,05 (*)	
1016000	(f) poultry	0,01 (*) (+)	0,01 (*)			0,05 (*)	
1016010	Muscle	(+)		0,02			
1016020	Fat	(+)		0,04			
1016030	Liver	(+)		0,15			
1016040	Kidney	(+)		0,15			
1016050	Edible offals (other than liver and kidney)	(+)		0,15			
1016990	Others (2)	(+)		0,01			
1017000	(g) other farmed terrestrial animals						
1017010	Muscle	0,01 (*)	0,01 (*)	0,2		0,05 (*)	
1017020	Fat	0,05	0,03	0,5		0,05 (*)	
1017030	Liver	0,07	0,1	1,5		0,5	
1017040	Kidney	0,07	0,1	1,5		0,5	
1017050	Edible offals (other than liver and kidney)	0,07	0,1	1,5		0,5	
1017990	Others (2)	0,01 (*)	0,01 (*)	0,01		0,05 (*)	
1020000	Milk	0,01 (*) (+)	0,01 (*)	0,02	0,02 (*)	0,05 (*)	0,02 (*)
1020010	Cattle	(+)					(+)
1020020	Sheep	(+)					(+)

1020030	Goat	(+)					(+)
1020040	Horse	(+)					(+)
1020990	Others (2)	(+)					
1030000	Birds eggs	0,01 (*) (+)	0,01 (*)	0,15	0,02 (*)	0,05 (*)	0,02 (*)
1030010	Chicken	(+)					
1030020	Duck	(+)					
1030030	Geese	(+)					
1030040	Quail	(+)					
1030990	Others (2)	(+)					
1040000	Honey and other apiculture products (7)	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)	0,05 (*)
1050000	Amphibians and Reptiles	0,01 (*)	0,01 (*)	0,01	0,02 (*)	0,05 (*)	0,02 (*)
1060000	Terrestrial invertebrate animals	0,01 (*)	0,01 (*)	0,01	0,02 (*)	0,05 (*)	0,02 (*)
1070000	Wild terrestrial vertebrate animals	0,01 (*)	0,01 (*)	0,01	0,02 (*)	0,05 (*)	0,02 (*)
1100000	PRODUCTS OF ANIMAL ORIGIN - FISH, FISHPRODUCTS AND ANY OTHER MARINE AND FRESHWATER FOOD PRODUCTS (8)						
1200000	PRODUCTS OR PART OF PRODUCTS EXCLUSIVELY USED FOR ANIMAL FEED PRODUCTION (8)						
1300000	PROCESSED FOOD PRODUCTS (9)						

(*) Indicates lower limit of analytical determination

(^e) For the complete list of products of plant and animal origin to which MRL's apply, reference should be made to Annex I

Azoxystrobin

The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 1 July 2017, or, if that information is not submitted by that date, the lack of it.

0251010 Lamb's lettuces/corn salads

0251030 Escaroles/broad-leaved endives

0251040 Cresses and other sprouts and shoots

0251050 Land cresses

0251060 Roman rocket/rucola

0251070 Red mustards

0251080 Baby leaf crops (including brassica species)

The European Food Safety Authority identified some information on toxicity of metabolites as unavailable. When reviewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 1 July 2017, or, if that information is not submitted by that date, the lack of it.

1011000 (a) swine

1011010 Muscle

1011020 Fat

1011030 Liver

1011040 Kidney

1011050 Edible offals (other than liver and kidney)

1011990 Others (2)

1012000 (b) bovine

1012010 Muscle

1012020 Fat

1012030 Liver

1012040 Kidney

1012050 Edible offals (other than liver and kidney)

1012990 Others (2)

1013000 (c) sheep

1013010 Muscle

1013020 Fat

1013030 Liver

1013040 Kidney

1013050 Edible offals (other than liver and kidney)

1013990 Others (2)

1014000 d) goat

1014010 Muscle

1014020 Fat

1014030 Liver

1014040 Kidney

1014050 Edible offals (other than liver and kidney)

1014990 Others (2)

1016000 (f) poultry

1016010 Muscle

1016020 Fat

1016030 Liver

1016040 Kidney

1016050 Edible offals (other than liver and kidney)

1016990 Others (2)

1020000 Milk

1020010 Cattle

1020020 Sheep

1020030 Goat

1020040 Horse

1020990 Others (2)

1030000 Birds eggs

1030010 Chicken

1030020 Duck

1030030 Geese

1030040 Quail

1030990 Others (2)

Cyflufenamid (sum of cyflufenamid (Z-isomer) and its E-isomer, expressed as cyflufenamid) (R) (A)

(R) The residue definition differs for the following combinations pesticide-code number: Cyflufenamid - code 1000000 except 1040000: sum of cyflufenamid (Z-isomer), its E-isomer and metabolite 149-F1, expressed as cyflufenamid

(A) The EU reference laboratories identified the reference standard for the E-isomer and for metabolite 149-F1 as commercially not available. When reviewing the MRLs, the Commission will take into account the commercial availability of the reference standard referred to it in the first sentence by 17 September 2020, or, if that reference standard is not commercially available by that date, the unavailability of it.

The European Food Safety Authority identified some information on feeding studies for poultry as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 17 September 2021, or, if that information is not submitted by that date, the lack of it.

0500090 Wheat

Flutolanil (R)

(R) The residue definition differs for the following combinations pesticide-code number: code 1000000 except 1040000: Flutolanil (Flutolanil and metabolites containing the 2-trifluoromethylbenzoic acid moiety, expressed as flutolanil)

The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 17 April 2017, or, if that information is not submitted by that date, the lack of it.

0231020 Sweet peppers/bell peppers

Proquinazid (R) (F)

(R) The residue definition differs for the following combinations pesticide-code number: Proquinazid - code 1000000 except 1040000 : Sum of proquinazid and metabolite 3-[(6-iodo-4-oxo-3-propyl-3,4-dihydroquinazolin-2-yl)oxy] propanoic acid (IN-MU210) expressed as proquinazid

(F) Fat soluble

The European Food Safety Authority identified some information on residue trials as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 16 April 2023, or, if that information is not submitted by that date, the lack of it.

0500010 Barley

0500050 Oat

The European Food Safety Authority identified some information on residue trials on grass (major component of the livestock dietary burden), as unavailable. When re-viewing the MRL, the Commission will take into account the information referred to in the first sentence, if it is submitted by 16 April 2023, or, if that information is not submitted by that date, the lack of it.

1012010 Muscle

1012020 Fat

1012030 Liver

1012040 Kidney

1013010 Muscle

1013020 Fat

1013030 Liver

1013040 Kidney

1014010 Muscle

1014020 Fat

1014030 Liver

1014040 Kidney

1015010 Muscle

1015020 Fat

1015030 Liver

1015040 Kidney

1020010 Cattle
1020020 Sheep
1020030 Goat
1020040 Horse"

(2) in Part A of Annex III, the column for emamectin is replaced by the following:

"Pesticide residues and maximum residue levels (mg/kg)

Code number	Groups and examples of individual products to which the MRLs apply ^(a)	Emamectin benzoate B1a, expressed as emamectin
0100000	FRUITS, FRESH or FROZEN; TREE NUTS	
0110000	Citrus fruits	0,01 (*)
0110010	Grapefruits	
0110020	Oranges	
0110030	Lemons	
0110040	Limes	
0110050	Mandarins	
0110990	Others (2)	
0120000	Tree nuts	0,01 (*)
0120010	Almonds	
0120020	Brazil nuts	
0120030	Cashew nuts	
0120040	Chestnuts	
0120050	Coconuts	
0120060	Hazelnuts/cobnuts	
0120070	Macadamias	
0120080	Pecans	
0120090	Pine nut kernels	
0120100	Pistachios	
0120110	Walnuts	
0120990	Others (2)	
0130000	Pome fruits	0,02
0130010	Apples	
0130020	Pears	
0130030	Quinces	
0130040	Medlars	
0130050	Loquats/Japanese medlars	

0130990	Others (2)	
0140000	Stone fruits	
0140010	Apricots	0,05
0140020	Cherries (sweet)	0,04
0140030	Peaches	0,15
0140040	Plums	0,02
0140990	Others (2)	0,01 (*)
0150000	Berries and small fruits	
0151000	(a) grapes	0,05
0151010	Table grapes	
0151020	Wine grapes	
0152000	(b) strawberries	0,05
0153000	(c) cane fruits	0,01 (*)
0153010	Blackberries	
0153020	Dewberries	
0153030	Raspberries (red and yellow)	
0153990	Others (2)	
0154000	(d) other small fruits and berries	0,01 (*)
0154010	Blueberries	
0154020	Cranberries	
0154030	Currants (black, red and white)	
0154040	Gooseberries (green, red and yellow)	
0154050	Rose hips	
0154060	Mulberries (black and white)	
0154070	Azaroles/Mediterranean medlars	
0154080	Elderberries	
0154990	Others (2)	
0160000	Miscellaneous fruitswith	
0161000	(a) edible peel	0,01 (*)
0161010	Dates	
0161020	Figs	
0161030	Table olives	
0161040	Kumquats	
0161050	Carambolas	
0161060	Kaki/Japanese persimmons	
0161070	Jambuls/jambolans	
0161990	Others (2)	
0162000	(b) inedible peel, small	
0162010	Kiwi fruits (green, red, yellow)	0,15

0162020	Litchis/lychees	0,01 (*)
0162030	Passionfruits/maracujas	0,01 (*)
0162040	Prickly pears/cactus fruits	0,01 (*)
0162050	Star apples/cainitos	0,01 (*)
0162060	American persimmons/Virginia kaki	0,01 (*)
0162990	Others (2)	0,01 (*)
0163000	(c) inedible peel, large	0,01 (*)
0163010	Avocados	
0163020	Bananas	
0163030	Mangoes	
0163040	Papayas	
0163050	Granate apples/pomegranates	
0163060	Cherimoyas	
0163070	Guavas	
0163080	Pineapples	
0163090	Breadfruits	
0163100	Durians	
0163110	Soursops/guanabanas	
0163990	Others (2)	
0200000	VEGETABLES, FRESH or FROZEN	
0210000	Root and tuber vegetables	0,01 (*)
0211000	(a) potatoes	
0212000	(b) tropical root and tuber vegetables	
0212010	Cassava roots/manioc	
0212020	Sweet potatoes	
0212030	Yams	
0212040	Arrowroots	
0212990	Others (2)	
0213000	(c) other root and tuber vegetables except sugar beets	
0213010	Beetroots	
0213020	Carrots	
0213030	Celeriacs/turnip rooted celeries	
0213040	Horseradishes	
0213050	Jerusalem artichokes	
0213060	Parsnips	
0213070	Parsley roots/Hamburg roots parsley	
0213080	Radishes	
0213090	Salsifies	
0213100	Swedes/rutabagas	

0213110	Turnips	
0213990	Others (2)	
0220000	Bulb vegetables	0,01 (*)
0220010	Garlic	
0220020	Onions	
0220030	Shallots	
0220040	Spring onions/green onions and Welsh onions	
0220990	Others (2)	
0230000	Fruiting vegetables	
0231000	(a) Solanaceae and Malvaceae	0,02
0231010	Tomatoes	
0231020	Sweet peppers/bell peppers	
0231030	Aubergines/eggplants	
0231040	Okra/lady's fingers	
0231990	Others (2)	
0232000	(b) ucurbits with edible peel	0,01 (*)
0232010	Cucumbers	
0232020	Gherkins	
0232030	Courgettes	
0232990	Others (2)	
0233000	(c) cucurbits with inedible peel	0,01 (*)
0233010	Melons	
0233020	Pumpkins	
0233030	Watermelons	
0233990	Others (2)	
0234000	(d) sweet corn	0,01 (*)
0239000	(e) other fruiting vegetables	0,02
0240000	Brassica vegetables(excluding brassica roots and brassica baby leaf crops)	
0241000	(a) flowering brassica	0,01 (*)
0241010	Broccoli	
0241020	Cauliflowers	
0241990	Others (2)	
0242000	(b) head brassica	0,01 (*)
0242010	Brussels sprouts	
0242020	Head cabbages	
0242990	Others (2)	
0243000	(c) leafy brassica	0,03
0243010	Chinese cabbages/pe-tsai	

0243020	Kales	
0243990	Others (2)	
0244000	(d) kohlrabies	0,01 (*)
0250000	Leaf vegetables, herbs and edible flowers	
0251000	(a) lettuces and salad plants	
0251010	Lamb's lettuces/corn salads	1
0251020	Lettuces	1
0251030	Escaroles/broad-leaved endives	0,2
0251040	Cresses and other sprouts and shoots	1
0251050	Land cresses	1
0251060	Roman rocket/rucola	1
0251070	Red mustards	1
0251080	Baby leaf crops (including brassica species)	1
0251990	Others (2)	1
0252000	(b) spinaches and similar leaves	0,2
0252010	Spinaches	
0252020	Purslanes	
0252030	Chards/beet leaves	
0252990	Others (2)	
0253000	(c) grape leaves and similar species	0,01 (*)
0254000	(d) watercresses	0,01 (*)
0255000	(e) witloofs/Belgian endives	0,01 (*)
0256000	(f) herbs and edible flowers	1
0256010	Chervil	
0256020	Chives	
0256030	Celery leaves	
0256040	Parsley	
0256050	Sage	
0256060	Rosemary	
0256070	Thyme	
0256080	Basil and edible flowers	
0256090	Laurel/bay leaves	
0256100	Tarragon	
0256990	Others (2)	
0260000	Legume vegetables	
0260010	Beans (with pods)	0,03
0260020	Beans (without pods)	0,01 (*)
0260030	Peas (with pods)	0,03
0260040	Peas (without pods)	0,01 (*)

0260050	Lentils	0,01 (*)
0260990	Others (2)	0,01 (*)
0270000	Stem vegetables	
0270010	Asparagus	0,01 (*)
0270020	Cardoons	0,01 (*)
0270030	Celeries	0,01 (*)
0270040	Florence fennels	0,01 (*)
0270050	Globe artichokes	0,1
0270060	Leeks	0,01 (*)
0270070	Rhubarbs	0,01 (*)
0270080	Bamboo shoots	0,01 (*)
0270090	Palm hearts	0,01 (*)
0270990	Others (2)	0,01 (*)
0280000	Fungi, mosses and lichens	0,01 (*)
0280010	Cultivated fungi	
0280020	Wild fungi	
0280990	Mosses and lichens	
0290000	Algae and prokaryotes organisms	0,01 (*)
0300000	PULSES	0,01 (*)
0300010	Beans	
0300020	Lentils	
0300030	Peas	
0300040	Lupins/lupini beans	
0300990	Others (2)	
0400000	OILSEEDS AND OIL FRUITS	0,01 (*)
0401000	Oilseeds	
0401010	Linseeds	
0401020	Peanuts/groundnuts	
0401030	Poppy seeds	
0401040	Sesame seeds	
0401050	Sunflower seeds	
0401060	Rapeseeds/canola seeds	
0401070	Soyabeans	
0401080	Mustard seeds	
0401090	Cotton seeds	
0401100	Pumpkin seeds	
0401110	Safflower seeds	
0401120	Borage seeds	
0401130	Gold of pleasure seeds	

0401140	Hemp seeds	
0401150	Castor beans	
0401990	Others (2)	
0402000	Oil fruits	
0402010	Olives for oil production	
0402020	Oil palms kernels	
0402030	Oil palms fruits	
0402040	Kapok	
0402990	Others (2)	
0500000	CEREALS	0,01 (*)
0500010	Barley	
0500020	Buckwheat and other pseudocereals	
0500030	Maize/corn	
0500040	Common millet/proso millet	
0500050	Oat	
0500060	Rice	
0500070	Rye	
0500080	Sorghum	
0500090	Wheat	
0500990	Others (2)	
0600000	TEAS, COFFEE, HERBAL INFUSIONS, COCOA AND CAROBS	
0610000	Teas	0,02 (*)
0620000	Coffee beans	0,02 (*)
0630000	Herbal infusions from	
0631000	(a) flowers	0,02 (*)
0631010	Chamomile	
0631020	Hibiscus/roselle	
0631030	Rose	
0631040	Jasmine	
0631050	Lime/linden	
0631990	Others (2)	
0632000	(b) leaves and herbs	2
0632010	Strawberry	
0632020	Rooibos	
0632030	Mate/maté	
0632990	Others (2)	
0633000	(c) roots	0,02 (*)
0633010	Valerian	

0633020	Ginseng	
0633990	Others (2)	
0639000	(d) any other parts of the plant	0,02 (*)
0640000	Cocoa beans	0,02 (*)
0650000	Carobs/Saint John's breads	0,02 (*)
0700000	HOPS	0,02 (*)
0800000	SPICES	
0810000	Seed spices	0,02 (*)
0810010	Anise/aniseed	
0810020	Black caraway/black cumin	
0810030	Celery	
0810040	Coriander	
0810050	Cumin	
0810060	Dill	
0810070	Fennel	
0810080	Fenugreek	
0810090	Nutmeg	
0810990	Others (2)	
0820000	Fruit spices	0,02 (*)
0820010	Allspice/pimento	
0820020	Sichuan pepper	
0820030	Caraway	
0820040	Cardamom	
0820050	Juniper berry	
0820060	Peppercorn (black, green and white)	
0820070	Vanilla	
0820080	Tamarind	
0820990	Others (2)	
0830000	Bark spices	0,02 (*)
0830010	Cinnamon	
0830990	Others (2)	
0840000	Root and rhizome spices	
0840010	Liquorice	0,02 (*)
0840020	Ginger (10)	
0840030	Turmeric/curcuma	0,02 (*)
0840040	Horseradish (11)	
0840990	Others (2)	0,02 (*)
0850000	Bud spices	0,02 (*)
0850010	Cloves	
0850020	Capers	

0850990	Others (2)	
0860000	Flower pistil spices	0,02 (*)
0860010	Saffron	
0860990	Others (2)	
0870000	Aril spices	0,02 (*)
0870010	Mace	
0870990	Others (2)	
0900000	SUGAR PLANTS	0,01 (*)
0900010	Sugar beet roots	
0900020	Sugar canes	
0900030	Chicory roots	
0900990	Others (2)	
1000000	PRODUCTS OF ANIMAL ORIGIN -TERRESTRIAL ANIMALS	
1010000	Commodities from	
1011000	(a) swine	
1011010	Muscle	0,01 (*)
1011020	Fat	0,02
1011030	Liver	0,08
1011040	Kidney	0,08
1011050	Edible offals (other than liver and kidney)	0,08
1011990	Others (2)	0,01 (*)
1012000	(b) bovine	
1012010	Muscle	0,01 (*)
1012020	Fat	0,02
1012030	Liver	0,08
1012040	Kidney	0,08
1012050	Edible offals (other than liver and kidney)	0,08
1012990	Others (2)	0,01 (*)
1013000	(c) sheep	
1013010	Muscle	0,01 (*)
1013020	Fat	0,02
1013030	Liver	0,08
1013040	Kidney	0,08
1013050	Edible offals (other than liver and kidney)	0,08
1013990	Others (2)	0,01 (*)
1014000	(d) goat	
1014010	Muscle	0,01 (*)
1014020	Fat	0,02

1014030	Liver	0,08
1014040	Kidney	0,08
1014050	Edible offals (other than liver and kidney)	0,08
1014990	Others (2)	0,01 (*)
1015000	(e) equine	
1015010	Muscle	0,01 (*)
1015020	Fat	0,02
1015030	Liver	0,08
1015040	Kidney	0,08
1015050	Edible offals (other than liver and kidney)	0,08
1015990	Others (2)	0,01 (*)
1016000	(f) poultry	0,01 (*)
1016010	Muscle	
1016020	Fat	
1016030	Liver	
1016040	Kidney	
1016050	Edible offals (other than liver and kidney)	
1016990	Others (2)	
1017000	(g) other farmed terrestrial animals	
1017010	Muscle	0,01 (*)
1017020	Fat	0,02
1017030	Liver	0,08
1017040	Kidney	0,08
1017050	Edible offals (other than liver and kidney)	0,08
1017990	Others (2)	0,01 (*)
1020000	Milk	0,01 (*)
1020010	Cattle	
1020020	Sheep	
1020030	Goat	
1020040	Horse	
1020990	Others (2)	
1030000	Birds eggs	0,01 (*)
1030010	Chicken	
1030020	Duck	
1030030	Geese	
1030040	Quail	
1030990	Others (2)	
1040000	Honey and other apiculture products (7)	0,05 (*)
1050000	Amphibians and Reptiles	0,01 (*)

1060000	Terrestrial invertebrate animals	0,01 (*)
1070000	Wild terrestrial vertebrate animals	0,01 (*)
1100000	PRODUCTS OF ANIMAL ORIGIN - FISH, FISHPRODUCTS AND ANY OTHER MARINE AND FRESHWATER FOOD PRODUCTS (8)	
1200000	PRODUCTS OR PART OF PRODUCTS EXCLUSIVELY USED FOR ANIMAL FEED PRODUCTION (8)	
1300000	PROCESSED FOOD PRODUCTS (9)	

(*) Indicates lower limit of analytical determination

(8) For the complete list of products of plant and animal origin to which MRL's apply, reference should be made to Annex I"

- (3) in Annex IV, the entries for 'acetic acid (1)', 'lime sulphur (1)' and 'maltodextrin (1)' are replaced by 'acetic acid', 'lime sulphur' and 'maltodextrin', respectively.
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COMMISSION REGULATION (EU) 2022/477**of 24 March 2022****amending Annexes VI to X to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)****(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 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ⁽¹⁾, and in particular Article 131 thereof,

Whereas:

- (1) Regulation (EC) No 1907/2006 lays down specific registration duties and obligations on manufacturers, importers and downstream users to generate data on substances they manufacture, import or use, to assess the risks related to those substances and to develop and recommend appropriate risk management measures.
- (2) Annex VI to Regulation (EC) No 1907/2006 sets out information requirements referred to in Article 10, point (a)(i) to (v) and (x), of that Regulation. Annexes VII to X to that Regulation set out standard information requirements for substances manufactured or imported in quantities of 1 tonne or more, 10 tonnes or more, 100 tonnes or more and 1 000 tonnes or more.
- (3) In June 2019, the Commission and the European Chemicals Agency ('the Agency') concluded in the REACH Evaluation Joint Action Plan ⁽²⁾ that certain information requirements in the Annexes to Regulation (EC) No 1907/2006 should be amended to provide more clarity on the obligations of registrants regarding the submission of information.
- (4) To increase clarity of the registrants' obligations, a number of information requirements in Annexes VII to X to Regulation (EC) No 1907/2006 and the general rules for adaptation of the standard testing regime in Annex XI to that Regulation have been amended by Commission Regulation (EU) 2021/979 ⁽³⁾ but in line with the objectives of the REACH Evaluation Joint Action Plan a number of information requirements remain to be clarified.
- (5) Requirements concerning the general registrant information and substance identification information which a registrant is to submit for general registration purposes, laid down in Annex VI, sections 1 and 2, to Regulation (EC) No 1907/2006 should therefore be amended.

⁽¹⁾ OJ L 396, 30.12.2006, p. 1.

⁽²⁾ European Commission and European Chemicals Agency REACH Evaluation Joint Action Plan of June 2019 (https://echa.europa.eu/documents/10162/21877836/final_echa_com_reach_evaluation_action_plan_en.pdf/0003c9fc-652e-5f0b-90f9-dff9d5371d17).

⁽³⁾ Commission Regulation (EU) 2021/979 of 17 June 2021 amending Annexes VII to XI to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 216, 18.6.2021, p. 121).

- (6) Certain specific rules for adaptation from the standard information requirements set out in Annexes VII to X to Regulation (EC) No 1907/2006 should be amended to align the terminology of the classification of hazardous substances to that used in Annex I, parts 2 to 5, to Regulation (EC) No 1272/2008 of the European Parliament and the Council ⁽⁴⁾.
- (7) Specific rules for adaptation from the standard information laid down in Annex VII to Regulation (EC) No 1907/2006 on mutagenicity and aquatic toxicity should be amended for reasons of clarity and to ensure that useful information is provided. In particular, subsection 8.4 should be amended to clarify the consequences of a positive result in the *in vitro* gene mutation study, as well as the situations when the study required under point 8.4.1 does not need to be conducted. In addition, parts not referring to standard information required should be removed from column 1 of point 9.1.1, while column 2 of that point should describe more accurately the situations where the study does not need to be conducted and where long-term aquatic toxicity testing is required. Point 9.1.2 should also be modified to clarify when the study does not need to be conducted.
- (8) The information requirements on testing for mutagenicity and for reproductive toxicity, and on ecotoxicological information in Annex VIII to Regulation (EC) No 1907/2006 should be amended in order to clarify the obligations of registrants. In particular, the rules on testing for mutagenicity in subsection 8.4 should specify the situations that do not require testing referred to in that Annex and the situations that require further testing referred to in Annex IX. Furthermore, the nomenclature of the studies in point 8.4.2 should be aligned with that of the corresponding technical guidance documents of the Organisation for Economic Cooperation and Development (OECD) ⁽⁵⁾. In addition, to ensure that useful information on reproductive and developmental toxicity is generated, the preferred animal species and the preferred administration routes for testing should be added to point 8.7.1, while certain specific rules for adaptation from the standard information requirements should be clarified. Finally, a subsection heading 9.1 for aquatic toxicity that was missing should be added and the information requirement on short-term toxicity testing on fish in point 9.1.3 should be amended in order to remove the parts that do not list standard information from column 1 and to clarify the situations when the test is not required in column 2. Subsections 9.2 on degradation and 9.3 on fate and behaviour in the environment should also be modified in order to better describe the situations requiring further information on degradation and bioaccumulation as well as further degradation and bioaccumulation studies.
- (9) Information requirements on testing for mutagenicity in Annex IX to Regulation (EC) No 1907/2006 should be amended to specify in points 8.4.4 and 8.4.5 the studies to be conducted in mammalian somatic cells and, when relevant, in mammalian germ cells, as well as the cases where such studies need to be conducted. In addition, the information requirements in point 8.7.2 on testing for pre-natal developmental toxicity in a first and second species and in point 8.7.3 for Extended One-Generation Reproductive Toxicity studies should be clarified with regard to the preferred animal species and the preferred administration routes for testing, as well as with regard to the possible deviations from the general rules. Finally, as regards the section on ecotoxicological information, certain information requirements on long-term toxicity testing on fish should be removed due to animal welfare reasons. The subsection 9.2 on degradation should also be amended to align the wording of point 9.2.3 concerning identification of degradation products with that of the related provision in Annex XIII, and to reflect the amended requirement on further degradation testing accordingly. The subsection 9.4 on effects on terrestrial organisms should also be amended to clarify that a long-term toxicity study should be proposed by the registrant or may be required by the Agency for substances that have a high potential to adsorb to soil or that are very persistent.
- (10) Annex X to Regulation (EC) No 1907/2006 should be amended to clarify certain information requirements on mutagenicity, developmental and reproductive toxicity and ecotoxicological information. In particular, the amendments should describe the situations meeting the requirement for a second *in-vivo* somatic cell study or a second *in-vivo* germ cell study and specify the need to conduct such studies in mammalian species. Those studies should be listed together with the mutagenicity concerns they are to address. In addition, the information requirements on pre-natal developmental toxicity and Extended One-Generation Reproductive Toxicity studies should be amended to clarify the need for a study in, and the choice of, a second species, as well as the preferred administration routes for testing and the deviations from the general rules. Furthermore, the reference to a specific requirement on biotic degradation in point 9.2.1 is no longer necessary and should therefore be deleted, while

⁽⁴⁾ 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).

⁽⁵⁾ OECD TG 473 and 487.

relevant specific rules for adaptation in subsection 9.2 should be amended accordingly. Finally, it should be clarified in subsection 9.4, as well as point 9.5.1 that in addition to degradation products, long-term toxicity testing of transformation products is required to investigate their effects on terrestrial and sediment organisms.

- (11) Regulation (EC) No 1907/2006 should therefore be amended accordingly.
- (12) The proposed amendments aim at providing clarifications of certain standard information requirements and specific rules for their adaptation, as well as at increasing the legal certainty of the evaluation practices already applied by the Agency. Nevertheless, it cannot be discarded that as a result of the amendments, certain registration dossiers will need to be updated. The application of this Regulation should therefore be deferred.
- (13) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes VI to X to Regulation (EC) No 1907/2006 are amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from 14 October 2022.

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

Done at Brussels, 24 March 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Regulation (EC) No 1907/2006 is amended as follows:

(1) Annex VI is amended as follows:

(a) point 1.1.1 is replaced by the following:

‘1.1.1. Name, address, telephone number and email address’;

(b) the following point 1.1.4 is added:

‘1.1.4. Where an only representative has been appointed in accordance with Article 8(1), the following information regarding the natural or legal person established outside the Union who appointed the only representative: name, address, telephone number, email address, contact person, location of the production site(s) or formulation site(s), as appropriate, company website, as appropriate and national company identification number(s), as appropriate.’;

(c) subsection 1.2 is replaced by the following:

‘1.2. Joint submission of data

Articles 11 and 19 provide for the possibility for the lead registrant to submit parts of the registration information on behalf of other member registrants.

When, in accordance with Article 11(1), the lead registrant submits information referred to in Article 10, point (a)(iv), (vi), (vii) and (ix), the lead registrant shall describe the composition(s), nanoform or set of similar nanoforms to which this information relates in accordance with points 2.3.1 to 2.3.4 and subsection 2.4 of this Annex. Each member registrant relying on information submitted by the lead registrant shall indicate which information thus submitted pertains to which composition, nanoform or set of similar nanoforms of the substance that the registrant identifies in accordance with Article 10, point (a)(ii), and Article 11(1).

When, in accordance with Article 11(3), a registrant submits information referred to in Article 10, point (a)(iv), (vi), (vii) or (ix), separately, this registrant shall describe the composition(s), nanoform or set of similar nanoforms of the substance to which this information relates in accordance with points 2.3.1 to 2.3.4 and subsection 2.4 of this Annex.’;

(d) point 1.3.1 is replaced by the following:

‘1.3.1. Name, address, telephone number and email address’;

(e) subsection 2.1 is replaced by the following:

‘2.1. Name and any other identifier of each substance’;

(f) point 2.1.1 is replaced by the following:

‘2.1.1. Name(s) in the IUPAC nomenclature. If unavailable, other international chemical name(s)’;

(g) point 2.1.3 is replaced by the following:

‘2.1.3. EC number, i.e. EINECS, ELINCS or NLP number, or the number assigned by the Agency (if available and appropriate)’;

(h) point 2.1.5 is replaced by the following:

‘2.1.5. Other identity code, such as customs number (if available)’;

(i) subsection 2.2 is replaced by the following:

‘2.2. Information related to molecular and structural formula or crystal structure of each substance’;

(j) point 2.2.1 is replaced by the following:

‘2.2.1. Molecular formula and structural formula (including SMILES notation and other representation if available) and description of crystal structure(s)’;

(k) points 2.3.1 to 2.3.7 are replaced by the following:

‘2.3.1. Degree of purity (%), if applicable

2.3.2. Names of constituents and impurities

In the case of a substance of unknown or variable composition, complex reaction products or biological materials (UVCB):

- names of constituents present at a concentration of $\geq 10\%$;
- names of known constituents present at a concentration of $< 10\%$;
- for constituents that cannot be identified individually, description of groups of constituents based on chemical nature;
- description of the origin or source and the manufacturing process

2.3.3. Typical concentration and concentration range (in percentage) of constituents, groups of constituents that cannot be identified individually and impurities as specified in point 2.3.2

2.3.4. Names and typical concentration and concentration range (in percentage) of additives

2.3.5. All necessary qualitative analytical data specific for the identification of the substance, such as ultra-violet, infra-red, nuclear magnetic resonance, mass spectrum or diffraction data

2.3.6. All necessary quantitative analytical data specific for the identification of the substance, such as chromatographic, titrimetric, elemental analysis or diffraction data

2.3.7. Description of the analytical methods or the appropriate bibliographical references that are necessary for the identification of the substance (including the identification and quantification of its constituents and, where appropriate, its impurities and additives). The description shall consist of the experimental protocols followed and the relevant interpretation of the results reported under points 2.3.1 to 2.3.6. This information shall be sufficient to allow the methods to be reproduced.;

(l) point 2.4.6 is replaced by the following:

‘2.4.6. Description of the analytical methods or the appropriate bibliographical references for the information elements in this subsection (2.4). The description shall consist of the experimental protocols followed and the relevant interpretation of the results reported under points 2.4.2 to 2.4.5. This information shall be sufficient to allow the methods to be reproduced.’;

(m) the following subsection 2.5 is added:

‘2.5. Any other available information relevant for the identification of the substance’;

(n) subsection 3.5 is replaced by the following:

‘3.5. General description of the identified use(s)’;

(2) Annex VII is amended as follows:

(a) in subsection 8.4, in column 2, the text is replaced by the following:

	‘8.4. In case of a positive result in the <i>in vitro</i> gene mutation study in bacteria referred to in point 8.4.1 of this Annex, which gives rise to concern, the registrant shall perform an <i>in vitro</i> study referred to in Annex VIII, point 8.4.2. Based on the positive result of any of those <i>in vitro</i> genotoxicity studies, the registrant shall propose, or the Agency may require, an appropriate <i>in vivo</i> study referred to in Annex IX, point 8.4.4. The <i>in vivo</i> study shall address the chromosomal aberration concern or the gene mutation concern or both, as appropriate. The <i>in vitro</i> gene mutation study in bacteria does not need to be conducted if this test is not applicable for the substance. In this case, the registrant shall provide a justification and perform an <i>in vitro</i> study referred to in Annex VIII, point 8.4.3. In case of a positive result in that study the registrant shall perform an <i>in vitro</i> cytogenicity study referred to in Annex VIII, point 8.4.2. Based on the positive result in any of those <i>in vitro</i> genotoxicity studies, or in case one of the Annex VIII <i>in vitro</i> tests is not applicable for the substance, the
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	registrant shall propose, or the Agency may require, an appropriate <i>in vivo</i> study referred to in Annex IX, point 8.4.4. The <i>in vivo</i> study shall address the chromosomal aberration concern or the gene mutation concern or both, as appropriate. The <i>in vitro</i> gene mutation study in bacteria referred to in point 8.4.1 and follow-up testing do not need to be conducted in any of the following cases: — the substance is known to cause germ cell mutagenicity, meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B, and appropriate risk management measures are implemented, — the substance is known to be a genotoxic carcinogen, meeting the criteria for classification both in the hazard class germ cell mutagenicity category 1A, 1B or 2 and in the hazard class carcinogenicity category 1A or 1B, and appropriate risk management measures are implemented.;
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(b) in point 8.4.1, in column 2, the text is replaced by the following:

	'8.4.1. The <i>in vitro</i> gene mutation study in bacteria does not need to be conducted for nanoforms where it is not appropriate. In such case, an <i>in vitro</i> study referred to in Annex VIII, point 8.4.3, shall be provided.;
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(c) in point 9.1.1, in column 1, the second paragraph is deleted.

(d) in point 9.1.1, in column 2, the text is replaced by the following:

	'9.1.1. The study does not need to be conducted in any of the following cases: — there are factors indicating that short-term aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes, — a long-term aquatic toxicity study on invertebrates is available. For nanoforms, the study may not be waived on the basis of high insolubility in water alone. The registrant may propose long-term toxicity testing instead of short-term toxicity testing. Long-term toxicity testing on invertebrates (preferred species <i>Daphnia</i>), (Annex IX, point 9.1.5) shall be proposed by the registrant or may be required by the Agency when it is unlikely that short-term toxicity testing can provide a true measure of the intrinsic aquatic toxicity of the substance, for instance: — if the substance is poorly water soluble (solubility below 1 mg/L), or — for nanoforms with low dissolution rate in the relevant test media.;
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- (e) in point 9.1.2, in column 2, the text is replaced by the following:

	'9.1.2. The study does not need to be conducted if there are factors indicating that aquatic toxicity is unlikely to occur for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes. For nanoforms, the study may not be waived on the basis of high insolubility in water alone.';
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- (3) Annex VIII is amended as follows:

- (a) in subsection 8.4, in column 2, the following text is added:

	'8.4. The studies referred to in points 8.4.2 and 8.4.3 do not need to be conducted in any of the following cases: — adequate data from the corresponding <i>in vivo</i> study, (namely <i>in vivo</i> chromosomal aberration (or micronucleus) study regarding point 8.4.2 or <i>in vivo</i> mammalian gene mutation study regarding point 8.4.3), are available, — the substance is known to cause germ cell mutagenicity, meeting the criteria for classification as germ cell mutagen category 1A or 1B, and appropriate risk management measures are implemented, — the substance is known to be a genotoxic carcinogen, meeting the criteria for classification both in the hazard class germ cell mutagenicity category 1A, 1B or 2 and in the hazard class carcinogenicity category 1A or 1B, and appropriate risk management measures are implemented. In case of a positive result in any of the <i>in vitro</i> genotoxicity studies referred to in Annex VII or this Annex, which gives rise to concern, the registrant shall propose, or the Agency may require, an appropriate <i>in vivo</i> study referred to in Annex IX, point 8.4. The <i>in vivo</i> study shall address the chromosomal aberration concern or the gene mutation concern or both as appropriate. In case an <i>in vitro</i> mutagenicity study referred to in points 8.4.2 or 8.4.3 is not applicable for the substance, the registrant shall provide a justification and shall propose or the Agency may require an appropriate <i>in vivo</i> study referred to in Annex IX, point 8.4.4. The <i>in vivo</i> study shall address the chromosomal aberration concern or the gene mutation concern or both as appropriate.';
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- (b) in point 8.4.2, in column 1, the text is replaced by the following:

'8.4.2. <i>In vitro</i> mammalian chromosomal aberration study or <i>in vitro</i> mammalian micronucleus study';	
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- (c) in point 8.4.2, the text in column 2 is deleted;

- (d) in point 8.4.3, the text in column 2 is deleted;

- (e) in point 8.6.1, in column 2, the introductory wording of the sixth paragraph is replaced by the following:

	'Further studies shall be proposed by the registrant or may be required by the Agency in case of:';
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(f) point 8.7.1 is replaced by the following:

‘8.7.1. Screening for reproductive/developmental toxicity (OECD TG 421 or TG 422); the preferred species is the rat. The route of administration shall be oral if the substance is a solid or liquid, and inhalation if the substance is a gas; deviations may be made if scientifically justified, for example through evidence of equivalent or higher systemic exposure via another relevant route of human exposure or route-specific toxicity.	8.7.1. This study does not need to be conducted in any of the following cases: — the substance is known to be a genotoxic carcinogen, meeting the criteria for classification both in the hazard class germ cell mutagenicity category 1A, 1B or 2 and in the hazard class carcinogenicity category 1A or 1B, and appropriate risk management measures are implemented, — the substance is known to be a germ cell mutagen, meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B and appropriate risk management measures are implemented, — relevant human exposure can be excluded in accordance with Annex XI, Section 3, — a pre-natal developmental toxicity study (OECD TG 414) referred to in Annex IX, point 8.7.2 or an Extended One-Generation Reproductive Toxicity Study (OECD TG 443) referred to in Annex IX, point 8.7.3 is available or proposed by the registrant; or a Two-Generation Reproductive Toxicity Study (OECD TG 416) is available, — a substance is known to have an adverse effect on sexual function or fertility, meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B: May damage fertility (H360F), and the available data are adequate to support a robust risk assessment, — a substance is known to cause developmental toxicity, meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B: May damage the unborn child (H360D), and the available data are adequate to support a robust risk assessment. In case of serious concerns about potential adverse effects on sexual function, fertility or development, the registrant shall propose, or the Agency may require either an Extended One-Generation Reproductive Toxicity Study (OECD TG 443), referred to in Annex IX, point 8.7.3, or a pre-natal developmental toxicity study (OECD TG 414), referred to in Annex IX, point 8.7.2, instead of the screening study (OECD TG 421 or 422) to address those concerns. Those serious concerns include among others: — adverse effects related to sexual function, fertility or development based on available information, not meeting the criteria for classification as reproductive toxicity category 1A or 1B, — possible developmental or reproductive toxicity of the substance predicted from information on structurally related substances, (Q)SAR estimates or <i>in vitro</i> methods.’;
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- (g) in point 8.8.1, in column 2, the first paragraph is replaced by the following:

	‘For nanoforms without high dissolution rate in biological media a toxicokinetics study shall be proposed by the registrant or may be required by the Agency in case such an assessment cannot be performed on the basis of relevant available information, including from the study conducted in accordance with 8.6.1’;
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- (h) the following subsection 9.1 is inserted:

‘9.1. Aquatic toxicity	9.1. Long-term aquatic toxicity testing referred to in Annex IX, subsection 9.1, in addition to short-term toxicity testing shall be proposed by the registrant or may be required by the Agency if the chemical safety assessment performed in accordance with Annex I indicates that it is needed to further investigate the effects on aquatic organisms, for example when further information is needed for the refinement of the PNEC or if additional toxicity information as set out in Annex XIII, point 3.2.3, would be necessary to assess PBT or vPvB properties of the substance. The choice of the appropriate test(s) shall be made on the basis of the results of the chemical safety assessment.’;
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- (i) point 9.1.3 is replaced by the following:

‘9.1.3. Short-term toxicity testing on fish	9.1.3. The study does not need to be conducted in any of the following cases: — there are factors indicating that short-term aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water or the substance is unlikely to cross biological membranes, — a long-term aquatic toxicity study on fish is available. For nanoforms, the study may not be waived on the basis of high insolubility in water alone. The registrant may propose long-term toxicity testing instead of short-term toxicity testing. Long-term toxicity testing on fish referred to in Annex IX, point 9.1.6, shall be proposed by the registrant or may be required by the Agency when it is unlikely that short-term toxicity testing can provide a true measure of the intrinsic aquatic toxicity of the substance, for instance: — if the substance is poorly water soluble (below 1 mg/L), or — for nanoforms with low dissolution rate in the relevant test media.’;
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- (j) in subsection 9.2, in column 2, the text is replaced by the following:

	‘9.2. Further information on degradation shall be generated or further degradation testing as described in Annex IX shall be proposed if the chemical safety assessment performed in accordance with Annex I indicates that it is needed to further investigate the degradation of the substance. That could for example be the case if additional information on degradation as set out in Annex XIII, point 3.2.1, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex. For nanoforms that are not soluble, nor have high dissolution rate, such test(s) shall consider morphological transformation (e.g. irreversible changes in particle size, shape and surface properties, loss of coating), chemical transformation (e.g. oxidation, reduction) and other abiotic degradation (e.g. photolysis). The choice of the appropriate test(s) shall be made on the basis of the results of the chemical safety assessment. In case the generation of additional information requires further testing in accordance with Annex IX, the registrant shall propose or the Agency may require such testing.’;
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- (k) in subpoint 9.2.2.1, in column 2, the text is replaced by the following:

	‘9.2.2.1. The study does not need to be conducted in any of the following cases: — the substance is readily biodegradable, — the substance is highly insoluble in water, — based on the structure, the substance does not have chemical groups that can hydrolyse. For nanoforms, the study may not be waived on the basis of high insolubility in water alone.’;
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- (l) in subsection 9.3, in column 2, the following text is added:

	‘9.3. Further information on bioaccumulation shall be generated if additional information on bioaccumulation as set out in Annex XIII, point 3.2.2, is required to assess PBT or vPvB properties of the substance in accordance with subsection 2.1 of that Annex. In case the generation of additional information requires further testing in accordance with Annex IX or Annex X, the registrant shall propose or the Agency may require such testing.’;
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- (4) Annex IX is amended as follows:

- (a) in point 7.16, the second bullet point in column 2 is deleted;

- (b) subsection 8.4 is replaced by the following:

8.4. Mutagenicity	8.4. The studies referred to in points 8.4.4 and 8.4.5 do not need to be conducted in any of the following cases: — the substance is known to cause germ cell mutagenicity, meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B, and appropriate risk management measures are implemented, — the substance is known to be a genotoxic carcinogen, meeting the criteria for classification both in the hazard class germ cell mutagenicity category 1A, 1B or 2 and in the hazard class carcinogenicity category 1A or 1B, and appropriate risk management measures are implemented.;
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- (c) the following points 8.4.4 and 8.4.5 are added:

8.4.4. An appropriate <i>in vivo</i> mammalian somatic cell genotoxicity study, if there is a positive result in any of the <i>in vitro</i> genotoxicity studies referred to in Annex VII or Annex VIII, which gives rise to concern. The <i>in vivo</i> mammalian somatic cell genotoxicity study shall address the chromosomal aberration concern or the gene mutation concern or both, as appropriate.	8.4.4. The <i>in vivo</i> mammalian somatic cell genotoxicity study does not need to be conducted if there are adequate results available from an appropriate <i>in vivo</i> mammalian somatic cell genotoxicity study.
8.4.5. An appropriate <i>in vivo</i> mammalian germ cell genotoxicity study, if there is a positive result in an available <i>in vivo</i> mammalian somatic cell genotoxicity study, which gives rise to concern. The <i>in vivo</i> mammalian germ cell genotoxicity study shall address the chromosomal aberration concern or the gene mutation concern or both, as appropriate.	8.4.5. The study does not need to be conducted if there is clear evidence that neither the substance nor its metabolites reach the germ cells.;

- (d) point 8.7.2 is replaced by the following:

8.7.2. Pre-natal developmental toxicity study (OECD TG 414) on one species; the preferred species is the rat or the rabbit. The route of administration shall be oral if the substance is a solid or liquid, and inhalation if the substance is a gas; deviations may be made if scientifically justified, for example through evidence of equivalent or higher systemic exposure via another relevant route of human exposure or route-specific toxicity.	8.7.2. An additional pre-natal developmental toxicity study in a second species, that is the other preferred species to the one used in the first study, shall be proposed by the registrant or may be required by the Agency if there is a concern for developmental toxicity based on the outcome of the first study and all other relevant data. That could be the case for example if the study on the first species shows developmental toxicity not meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B; May damage the unborn child (H360D). Deviations from the default route of administration and deviations in the choice of species shall be scientifically justified.;
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- (e) in point 8.7.3, in column 1, the text is replaced by the following:

‘8.7.3. Extended One-Generation Reproductive Toxicity Study (OECD TG 443), basic test design (cohorts 1A and 1B without extension to include an F2 generation), one species, if the available repeated dose toxicity studies (e.g. 28-day or 90-day studies, or OECD TG 421 or 422 screening studies) indicate adverse effects on reproductive organs or tissues or reveal other concerns in relation with reproductive toxicity. The route of administration shall be oral if the substance is a solid or liquid, and inhalation if the substance is a gas; deviations may be made if scientifically justified, for example through evidence of equivalent or higher systemic exposure via another relevant route of human exposure or route-specific toxicity.’;	
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- (f) in point 8.7.3, in column 2, the introductory wording of the first paragraph is replaced by the following:

	‘8.7.3. An Extended One-Generation Reproductive Toxicity Study with the extension of cohort 1B to include the F2 generation shall be proposed by the registrant or may be required by the Agency if:’;
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- (g) in point 8.7.3, in column 2, the introductory wording of the second paragraph is replaced by the following:

	‘An Extended One-Generation Reproductive Toxicity Study including cohorts 2A/2B (developmental neurotoxicity) and/or cohort 3 (developmental immunotoxicity) shall be proposed by the registrant or may be required by the Agency in case of particular concerns on (developmental) neurotoxicity or (developmental) immunotoxicity justified by any of the following:’;
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- (h) in subsection 9.1, in column 2, the text is replaced by the following:

	‘9.1. Long-term toxicity testing other than the tests referred to in points 9.1.5 and 9.1.6 shall be proposed by the registrant or may be required by the Agency if the chemical safety assessment performed in accordance with Annex I indicates that it is needed to further investigate the effects of the substance on aquatic organisms. The choice of the test(s) shall be made on the basis of the results of the chemical safety assessment.’;
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- (i) point 9.1.6 is replaced by the following:

‘9.1.6. Long-term toxicity testing on fish, (unless already provided as part of Annex VIII requirements).	9.1.6. Fish short-term toxicity tests on embryo and sac-fry stages (OECD TG 212) that were initiated before 14 April 2022 shall be considered appropriate to address this standard in-
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The information shall be provided for subpoint 9.1.6.1 or subpoint 9.1.6.3.	formation requirement provided that the substance is not highly lipophilic (log Kow > 4) or there is no indication of endocrine disrupting properties or any other specific mode of action.’;
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- (j) subpoint 9.1.6.1 is replaced by the following:

‘9.1.6.1. Fish early-life stage (FELS) toxicity test (OECD TG 210)’;	
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- (k) subpoint 9.1.6.2 is deleted.

- (l) subpoint 9.1.6.3 is replaced by the following:

‘9.1.6.3. Fish juvenile growth test (OECD TG 215)’;	
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- (m) in subsection 9.2, in column 2, the text is replaced by the following:

	‘9.2. Further degradation testing shall be proposed by the registrant or may be required by the Agency if the chemical safety assessment performed in accordance with Annex I indicates that it is needed to further investigate the degradation of the substance and its transformation or degradation products. The choice of the appropriate test(s) and test media shall be made on the basis of the results of the chemical safety assessment.’;
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- (n) in point 9.2.3, in column 1, the text is replaced by the following:

‘9.2.3. Identification of transformation and abiotic and biotic degradation products’;	
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- (o) in subsection 9.4, in column 2, the text is replaced by the following:

	‘9.4. These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. In the absence of toxicity data for soil organisms, the equilibrium partitioning method may be applied to assess the hazard to soil organisms. Where the equilibrium partitioning method is applied to nanoforms, this shall be scientifically justified. The choice of the appropriate test(s) shall be made on the basis of the results of the chemical safety assessment. In particular for substances that have a high potential to adsorb to soil or that are very persistent, the registrant shall propose or the Agency may require long-term toxicity testing as referred to in Annex X instead of short-term toxicity testing.’;
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(5) Annex X is amended as follows:

(a) subsection 8.4. is replaced by the following:

‘8.4. Mutagenicity	8.4. The studies referred to in points 8.4.6 and 8.4.7 do not need to be conducted in any of the following cases: — the substance is known to cause germ cell mutagenicity, meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B, and appropriate risk management measures are implemented, — the substance is known to be a genotoxic carcinogen, meeting the criteria for classification both in the hazard class germ cell mutagenicity category 1A or 1B or 2 and in the hazard class carcinogenicity category 1A or 1B, and appropriate risk management measures are implemented.’;
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(b) the following points 8.4.6 and 8.4.7 are added:

‘8.4.6. A second <i>in vivo</i> mammalian somatic cell genotoxicity study, if there is a positive result in any of the <i>in vitro</i> genotoxicity studies referred to in Annex VII or Annex VIII, which gives rise to both chromosomal aberration concern and gene mutation concern. The second study shall address chromosomal aberration or gene mutation, as appropriate, which has not been addressed by the first <i>in vivo</i> mammalian somatic cell genotoxicity study.	
8.4.7. A second <i>in vivo</i> mammalian germ cell genotoxicity study, if there is a positive result in <i>in vivo</i> mammalian somatic cell genotoxicity studies, which gives rise to both chromosomal aberration concern and gene mutation concern. The second study shall address the chromosomal aberration or gene mutation, as appropriate, which has not been addressed by the first <i>in vivo</i> mammalian germ cell genotoxicity study.	8.4.7. The study does not need to be conducted if there is clear evidence that neither the substance nor its metabolites reach the germ cells.’;

(c) point 8.7.2 is replaced by the following:

‘8.7.2. Pre-natal developmental toxicity study (OECD TG 414) in a second species, the preferred species is the rat or the rabbit, whichever was not used in the first study under Annex IX. The route of administration shall be oral if the substance is a solid or liquid, and inhalation if the substance is a gas; deviations may be made if scientifically justified, for example through evidence of equivalent or higher systemic exposure via another relevant route of human exposure or route-specific toxicity.	Deviations from the default route of administration and deviations in the choice of species shall be scientifically justified.’;
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- (d) in point 8.7.3, in column 1, the text is replaced by the following:

'8.7.3. Extended One-Generation Reproductive Toxicity Study (OECD TG 443), basic test design (cohorts 1A and 1B without extension to include an F2 generation), one species, unless already provided as part of Annex IX requirements. The route of administration shall be oral if the substance is a solid or liquid, and inhalation if the substance is a gas; deviations may be made if scientifically justified, for example through evidence of equivalent or higher systemic exposure via another relevant route of human exposure or route-specific toxicity.'	
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- (e) in point 8.7.3, in column 2, the introductory wording of the first paragraph is replaced by the following:

	'An Extended One-Generation Reproductive Toxicity Study with the extension of cohort 1B to include the F2 generation shall be proposed by the registrant or may be required by the Agency if:'
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- (f) in point 8.7.3, in column 2, the introductory wording of the second paragraph is replaced by the following:

	'An Extended One-Generation Reproductive Toxicity Study including cohorts 2A/2B (developmental neurotoxicity) and/or cohort 3 (developmental immunotoxicity) shall be proposed by the registrant or may be required by the Agency in case of particular concerns on (developmental) neurotoxicity or (developmental) immunotoxicity justified by any of the following:'
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- (g) in subsection 9.2, in column 2, the text is replaced by the following:

	'9.2. Further degradation testing shall be proposed by the registrant or may be required by the Agency, if the chemical safety assessment performed in accordance with Annex I indicates that it is needed to further investigate the degradation of the substance and its transformation and degradation products. The choice of the appropriate test(s) and test media shall be made on the basis of the results of the chemical safety assessment.'
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- (h) point 9.2.1 is deleted;

- (i) in subsection 9.4, in column 2, the text is replaced by the following:

	'9.4. Long-term toxicity testing shall be proposed by the registrant or may be required by the Agency if the results of the chemical safety assessment performed in accordance with Annex I indicates that it is needed to further investigate the effects of the substance or of transformation and degradation products on terrestrial organisms. The choice of the appropriate test(s) shall be made on the basis of the outcome of the chemical safety assessment.'
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	These studies do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely.’;
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(j) in point 9.5.1, in column 2, the text is replaced by the following:

	‘9.5.1. Long-term toxicity testing shall be proposed by the registrant or may be required by the Agency if the results of the chemical safety assessment performed in accordance with Annex I indicates that it is needed to further investigate the effects of the substance or of relevant transformation and degradation products on sediment organisms. The choice of the appropriate test(s) shall be made on the basis of the results of the chemical safety assessment.’.
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COMMISSION IMPLEMENTING REGULATION (EU) 2022/478**of 24 March 2022****on maintaining protective measures on imports of bivalve molluscs from Turkey intended for human consumption****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ⁽¹⁾, and in particular Article 128(1) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) No 743/2013 ⁽²⁾ was adopted as Commission audits identified deficiencies in the implementation of official controls by the Turkish competent authorities on the production of bivalve molluscs intended for entry into the Union, and as Member States reported non-compliant consignments of bivalve molluscs originating in Turkey which were not fulfilling Union microbiological standards.
- (2) The most recent Commission audit which took place in September 2015, found that significant deficiencies in the control system for bivalve molluscs intended for entry into the Union, remained.
- (3) In January 2020, the Turkish competent authorities have presented information regarding the corrective measures initiated to address those deficiencies. Whilst that initially has been assessed favourably on paper, an audit on the spot to verify the implementation of those actions has not been possible yet due to COVID-19 pandemic restrictions. Until the outcomes of this audit have been considered favourably, the measures imposed by Implementing Regulation (EU) No 743/2013 should remain in place.
- (4) Implementing Regulation (EU) No 743/2013 expired on 31 December 2021. In addition, given that Council Directive 97/78/EC ⁽³⁾, constituting the basis for the above Regulation, is no longer applicable, the legal basis of the Commission Implementing Regulation should be updated to refer to Article 128 of Regulation (EU) 2017/625.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 95, 7.4.2017, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) No 743/2013 of 31 July 2013 on introducing protective measures on imports of bivalve molluscs from Turkey intended for human consumption (OJ L 205, 1.8.2013, p. 1).

⁽³⁾ Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries (OJ L 24, 30.1.1998, p. 9).

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation shall apply to live, chilled, frozen and processed bivalve molluscs intended for human consumption (CN Codes: 0307, 1605) and originating in or dispatched from Turkey.

Article 2

Prohibition of entry of live and chilled bivalve molluscs

Member States shall not allow entry into the Union of live and chilled bivalve molluscs originating in or dispatched from Turkey.

Article 3

Measures concerning frozen and processed bivalve molluscs

1. Member States shall, using appropriate sampling plans and detection methods, carry out tests on consignments of frozen and processed bivalve molluscs originating in or dispatched from Turkey as provided for in paragraph 2.

Those tests shall take place at the border control post of entry into the Union of the consignments concerned.

2. Member States shall carry out the tests necessary to identify:

- (a) the contamination level of *Escherichia coli* in all consignments of frozen bivalve molluscs;
- (b) the presence of marine biotoxins in all consignments of frozen or processed bivalve molluscs.

3. The consignments subjected to tests referred to in paragraphs 1 and 2 shall stay under supervision of the competent authorities at the border control post concerned until the results of those tests are received and assessed.

4. If the tests referred to in paragraphs 1 and 2 indicate that a consignment is likely to be injurious to human health, the competent authority shall immediately seize and either destroy the consignment or subject it to special treatment as provided for by Article 67 of Regulation (EU) 2017/625 and in accordance with Article 71(1) and (2) of that same Regulation.

Article 4

Expenditures

All expenditures incurred by the Member States in the application of this Regulation shall be charged to the operator or his/her representative responsible for the consignment at the time of presentation of that consignment to the border control post of entry into the Union.

Article 5

Entry into force and period of application

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

It shall apply until 31 December 2023.

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

Done at Brussels, 24 March 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2022/479**of 24 March 2022****amending Annexes V and XIV to Implementing Regulation (EU) 2021/404 as regards the entries for the United Kingdom and the United States in the lists of third countries authorised for the entry into the Union of consignments of poultry, germinal products of poultry and fresh meat of poultry and game birds****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') ⁽¹⁾, and in particular Articles 230(1) and 232(1) thereof.

Whereas:

- (1) Regulation (EU) 2016/429 requires that consignments of animals, germinal products and products of animal origin must come from a third country or territory, or zone or compartment thereof, listed in accordance with Article 230(1) of that Regulation in order to enter the Union.
- (2) Commission Delegated Regulation (EU) 2020/692 ⁽²⁾ lays down the animal health requirements with which consignments of certain species and categories of animals, germinal products and products of animal origin from third countries or territories, or zones thereof, or compartments thereof, in the case of aquaculture animals, must comply with in order to enter the Union.
- (3) Commission Implementing Regulation (EU) 2021/404 ⁽³⁾ establishes the lists of third countries, or territories, or zones or compartments thereof, from which the entry into the Union of the species and categories of animals, germinal products and products of animal origin falling within the scope of Delegated Regulation (EU) 2020/692 is permitted.
- (4) More particularly, Annexes V and XIV to Implementing Regulation (EU) 2021/404 set out the lists of third countries, or territories, or zones thereof authorised for the entry into the Union, respectively, of consignments of poultry, germinal products of poultry, and of fresh meat from poultry and game birds.
- (5) The United Kingdom notified the Commission of an outbreak of highly pathogenic avian influenza in poultry. The outbreak is located near Collieston, Aberdeenshire, Scotland, and was confirmed on 11 March 2022 by laboratory analysis (RT-PCR).
- (6) In addition, the United Kingdom notified the Commission of outbreaks of highly pathogenic avian influenza in poultry. The outbreaks are located in a second establishment near Redgrave, Mid Suffolk, Suffolk, England and near Market Weston, West Suffolk, Suffolk, England, and were confirmed on 12 March 2022 by laboratory analysis (RT-PCR).

⁽¹⁾ OJ L 84, 31.3.2016, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

⁽³⁾ Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 1).

- (7) Additionally, the United States notified the Commission of outbreaks of highly pathogenic avian influenza in poultry. The outbreaks are located in a second establishment in the already affected Cecil county, state of Maryland, United States, and in Taylor county, state of Iowa, United States and were confirmed on 10 March 2022 by laboratory analysis (RT-PCR).
- (8) Furthermore, the United States notified the Commission of an outbreak of highly pathogenic avian influenza in poultry. The outbreak is located in Franklin county, state of Kansas, United States and was confirmed on 11 March 2022 by laboratory analysis (RT-PCR).
- (9) Moreover, the United States notified the Commission of an outbreak of highly pathogenic avian influenza in poultry. The outbreak is located in a second establishment in the already affected Charles Mix county, state of South Dakota, United States and was confirmed on 12 March 2022 by laboratory analysis (RT-PCR).
- (10) In addition, the United States notified the Commission of an outbreak of highly pathogenic avian influenza in poultry. The outbreak is located in Jefferson county, state of Wisconsin, United States and was confirmed on 14 March 2022 by laboratory analysis (RT-PCR).
- (11) Additionally, the United States notified the Commission of outbreaks of highly pathogenic avian influenza in poultry. The outbreaks are located in Kent county, state of Delaware, United States and in a second poultry establishment in the already affected Buena Vista county, state of Iowa, United States and were confirmed on 17 March 2022 by laboratory analysis (RT-PCR).
- (12) Furthermore, the United States notified the Commission of outbreaks of highly pathogenic avian influenza in poultry. The outbreaks are located in Dickinson county, state of Kansas, United States and in a third poultry establishment in the already affected Cecil county, state of Maryland, United States and were confirmed on 18 March 2022 by laboratory analysis (RT-PCR).
- (13) The veterinary authorities of the United Kingdom and the United States established a 10 km control zone around the affected establishments and implemented a stamping-out policy in order to control the presence of highly pathogenic avian influenza and limit the spread of that disease.
- (14) The United Kingdom and the United States have submitted information to the Commission on the epidemiological situation on their territory and the measures they have taken to prevent the further spread of highly pathogenic avian influenza. That information has been evaluated by the Commission. On the basis of that evaluation and in order to protect the animal health status of the Union, the entry into the Union of consignments of poultry, germinal products of poultry, and fresh meat from poultry and game birds from the areas under restrictions established by the veterinary authorities of the United Kingdom and the United States due to the recent outbreaks of highly pathogenic avian influenza should no longer be authorised.
- (15) Moreover, the United Kingdom has submitted updated information on the epidemiological situation on its territory in relation to an outbreak of HPAI confirmed in a poultry establishment on 21 November 2021 near Silecroft, Copeland, Cumbria, England. The United Kingdom has also submitted the measures it has taken to prevent the further spread of that disease. In particular, following this outbreak of HPAI, the United Kingdom has implemented a stamping out policy in order to control and limit the spread of that disease. In addition, the United Kingdom completed the requisite cleaning and disinfection measures following the implementation of the stamping out policy on the infected poultry establishment on its territory.
- (16) The Commission has evaluated the information submitted by the United Kingdom and concluded that the HPAI outbreak near Silecroft, Copeland, Cumbria, England in a poultry establishment has been cleared and that there is no longer any risk associated with the entry into the Union of poultry commodities from the zone of the United Kingdom from which the entry into the Union of poultry commodities has been suspended due to this outbreak.
- (17) Annexes V and XIV to Implementing Regulation (EU) 2021/404 should be therefore amended accordingly.

- (18) Taking into account the current epidemiological situation in the United Kingdom and the United States as regards highly pathogenic avian influenza and the serious risk of its introduction into the Union, the amendments to be made to Implementing Regulation (EU) 2021/404 by this Regulation should take effect as a matter of urgency.
- (19) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 24 March 2022.

For the Commission
The President
Ursula VON DER LEYEN

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

(1) Annex V is amended as follows:

(a) Part 1 is amended as follows:

(i) in the entry for the United Kingdom, the row for the zone GB-2.26 is replaced by the following:

‘GB United Kingdom	GB-2.26	Breeding poultry other than ratites and productive poultry other than ratites	BPP	N, P1		21.11.2021	14.3.2022
		Breeding ratites and productive ratites	BPR	N, P1		21.11.2021	14.3.2022
		Poultry intended for slaughter other than ratites	SP	N, P1		21.11.2021	14.3.2022
		Ratites intended for slaughter	SR	N, P1		21.11.2021	14.3.2022
		Day-old chicks other than ratites	DOC	N, P1		21.11.2021	14.3.2022
		Day-old chicks of ratites	DOR	N, P1		21.11.2021	14.3.2022
		Less than 20 heads of poultry other than ratites	POU-LT20	N, P1		21.11.2021	14.3.2022
		Hatching eggs of poultry other than ratites	HEP	N, P1		21.11.2021	14.3.2022
		Hatching eggs of ratites	HER	N, P1		21.11.2021	14.3.2022
		Less than 20 hatching eggs of poultry other than ratites	HE-LT20	N, P1		21.11.2021	14.3.2022’

(ii) in the entry for the United Kingdom, the following rows for the zones GB-2.105 to GB-2.107 are added after the row for the zone GB-2.104:

‘GB United Kingdom	GB-2.105	Breeding poultry other than ratites and productive poultry other than ratites	BPP	N, P1		11.3.2022	
		Breeding ratites and productive ratites	BPR	N, P1		11.3.2022	
		Poultry intended for slaughter other than ratites	SP	N, P1		11.3.2022	
		Ratites intended for slaughter	SR	N, P1		11.3.2022	
		Day-old chicks other than ratites	DOC	N, P1		11.3.2022	
		Day-old chicks of ratites	DOR	N, P1		11.3.2022	
		Less than 20 heads of poultry other than ratites	POU-LT20	N, P1		11.3.2022	

		Hatching eggs of poultry other than ratites	HEP	N, P1		11.3.2022	
		Hatching eggs of ratites	HER	N, P1		11.3.2022	
		Less than 20 hatching eggs of poultry other than ratites	HE-LT20	N, P1		11.3.2022	
	GB-2.106	Breeding poultry other than ratites and productive poultry other than ratites	BPP	N, P1		12.3.2022	
		Breeding ratites and productive ratites	BPR	N, P1		12.3.2022	
		Poultry intended for slaughter other than ratites	SP	N, P1		12.3.2022	
		Ratites intended for slaughter	SR	N, P1		12.3.2022	
		Day-old chicks other than ratites	DOC	N, P1		12.3.2022	
		Day-old chicks of ratites	DOR	N, P1		12.3.2022	
		Less than 20 heads of poultry other than ratites	POU-LT20	N, P1		12.3.2022	
		Hatching eggs of poultry other than ratites	HEP	N, P1		12.3.2022	
		Hatching eggs of ratites	HER	N, P1		12.3.2022	
		Less than 20 hatching eggs of poultry other than ratites	HE-LT20	N, P1		12.3.2022	
	GB-2.107	Breeding poultry other than ratites and productive poultry other than ratites	BPP	N, P1		12.3.2022	
		Breeding ratites and productive ratites	BPR	N, P1		12.3.2022	
		Poultry intended for slaughter other than ratites	SP	N, P1		12.3.2022	
		Ratites intended for slaughter	SR	N, P1		12.3.2022	
		Day-old chicks other than ratites	DOC	N, P1		12.3.2022	
		Day-old chicks of ratites	DOR	N, P1		12.3.2022	
		Less than 20 heads of poultry other than ratites	POU-LT20	N, P1		12.3.2022	
		Hatching eggs of poultry other than ratites	HEP	N, P1		12.3.2022	
		Hatching eggs of ratites	HER	N, P1		12.3.2022	
		Less than 20 hatching eggs of poultry other than ratites	HE-LT20	N, P1		12.3.2022'	

(iii) in the entry for the United States, the following rows for the zones US-2.21 to US-2.29 are added after the row for the zone US-2.20:

US United States	US-2.21	Breeding poultry other than ratites and productive poultry other than ratites	BPP	N, P1		10.3.2022	
		Breeding ratites and productive ratites	BPR	N, P1		10.3.2022	
		Poultry intended for slaughter other than ratites	SP	N, P1		10.3.2022	
		Ratites intended for slaughter	SR	N, P1		10.3.2022	
		Day-old chicks other than ratites	DOC	N, P1		10.3.2022	
		Day-old chicks of ratites	DOR	N, P1		10.3.2022	
		Less than 20 heads of poultry other than ratites	POU-LT20	N, P1		10.3.2022	
		Hatching eggs of poultry other than ratites	HEP	N, P1		10.3.2022	
		Hatching eggs of ratites	HER	N, P1		10.3.2022	
		Less than 20 hatching eggs of poultry other than ratites	HE-LT20	N, P1		10.3.2022	
	US-2.22	Breeding poultry other than ratites and productive poultry other than ratites	BPP	N, P1		10.3.2022	
		Breeding ratites and productive ratites	BPR	N, P1		10.3.2022	
		Poultry intended for slaughter other than ratites	SP	N, P1		10.3.2022	
		Ratites intended for slaughter	SR	N, P1		10.3.2022	
		Day-old chicks other than ratites	DOC	N, P1		10.3.2022	
		Day-old chicks of ratites	DOR	N, P1		10.3.2022	
		Less than 20 heads of poultry other than ratites	POU-LT20	N, P1		10.3.2022	
		Hatching eggs of poultry other than ratites	HEP	N, P1		10.3.2022	
		Hatching eggs of ratites	HER	N, P1		10.3.2022	
		Less than 20 hatching eggs of poultry other than ratites	HE-LT20	N, P1		10.3.2022	
	US-2.23	Breeding poultry other than ratites and productive poultry other than ratites	BPP	N, P1		11.3.2022	
		Breeding ratites and productive ratites	BPR	N, P1		11.3.2022	

		Poultry intended for slaughter other than ratites	SP	N, P1		11.3.2022	
		Ratites intended for slaughter	SR	N, P1		11.3.2022	
		Day-old chicks other than ratites	DOC	N, P1		11.3.2022	
		Day-old chicks of ratites	DOR	N, P1		11.3.2022	
		Less than 20 heads of poultry other than ratites	POU-LT20	N, P1		11.3.2022	
		Hatching eggs of poultry other than ratites	HEP	N, P1		11.3.2022	
		Hatching eggs of ratites	HER	N, P1		11.3.2022	
		Less than 20 hatching eggs of poultry other than ratites	HE-LT20	N, P1		11.3.2022	
	US-2.24	Breeding poultry other than ratites and productive poultry other than ratites	BPP	N, P1		12.3.2022	
		Breeding ratites and productive ratites	BPR	N, P1		12.3.2022	
		Poultry intended for slaughter other than ratites	SP	N, P1		12.3.2022	
		Ratites intended for slaughter	SR	N, P1		12.3.2022	
		Day-old chicks other than ratites	DOC	N, P1		12.3.2022	
		Day-old chicks of ratites	DOR	N, P1		12.3.2022	
		Less than 20 heads of poultry other than ratites	POU-LT20	N, P1		12.3.2022	
		Hatching eggs of poultry other than ratites	HEP	N, P1		12.3.2022	
		Hatching eggs of ratites	HER	N, P1		12.3.2022	
		Less than 20 hatching eggs of poultry other than ratites	HE-LT20	N, P1		12.3.2022	
	US-2.25	Breeding poultry other than ratites and productive poultry other than ratites	BPP	N, P1		14.3.2022	
		Breeding ratites and productive ratites	BPR	N, P1		14.3.2022	
		Poultry intended for slaughter other than ratites	SP	N, P1		14.3.2022	
		Ratites intended for slaughter	SR	N, P1		14.3.2022	
		Day-old chicks other than ratites	DOC	N, P1		14.3.2022	
		Day-old chicks of ratites	DOR	N, P1		14.3.2022	

		Less than 20 heads of poultry other than ratites	POU-LT20	N, P1		14.3.2022	
		Hatching eggs of poultry other than ratites	HEP	N, P1		14.3.2022	
		Hatching eggs of ratites	HER	N, P1		14.3.2022	
		Less than 20 hatching eggs of poultry other than ratites	HE-LT20	N, P1		14.3.2022	
	US-2.26	Breeding poultry other than ratites and productive poultry other than ratites	BPP	N, P1		17.3.2022	
		Breeding ratites and productive ratites	BPR	N, P1		17.3.2022	
		Poultry intended for slaughter other than ratites	SP	N, P1		17.3.2022	
		Ratites intended for slaughter	SR	N, P1		17.3.2022	
		Day-old chicks other than ratites	DOC	N, P1		17.3.2022	
		Day-old chicks of ratites	DOR	N, P1		17.3.2022	
		Less than 20 heads of poultry other than ratites	POU-LT20	N, P1		17.3.2022	
		Hatching eggs of poultry other than ratites	HEP	N, P1		17.3.2022	
		Hatching eggs of ratites	HER	N, P1		17.3.2022	
		Less than 20 hatching eggs of poultry other than ratites	HE-LT20	N, P1		17.3.2022	
	US-2.27	Breeding poultry other than ratites and productive poultry other than ratites	BPP	N, P1		17.3.2022	
		Breeding ratites and productive ratites	BPR	N, P1		17.3.2022	
		Poultry intended for slaughter other than ratites	SP	N, P1		17.3.2022	
		Ratites intended for slaughter	SR	N, P1		17.3.2022	
		Day-old chicks other than ratites	DOC	N, P1		17.3.2022	
		Day-old chicks of ratites	DOR	N, P1		17.3.2022	
		Less than 20 heads of poultry other than ratites	POU-LT20	N, P1		17.3.2022	
		Hatching eggs of poultry other than ratites	HEP	N, P1		17.3.2022	

		Hatching eggs of ratites	HER	N, P1		17.3.2022	
		Less than 20 hatching eggs of poultry other than ratites	HE-LT20	N, P1		17.3.2022	
US-2.28		Breeding poultry other than ratites and productive poultry other than ratites	BPP	N, P1		18.3.2022	
		Breeding ratites and productive ratites	BPR	N, P1		18.3.2022	
		Poultry intended for slaughter other than ratites	SP	N, P1		18.3.2022	
		Ratites intended for slaughter	SR	N, P1		18.3.2022	
		Day-old chicks other than ratites	DOC	N, P1		18.3.2022	
		Day-old chicks of ratites	DOR	N, P1		18.3.2022	
		Less than 20 heads of poultry other than ratites	POU-LT20	N, P1		18.3.2022	
		Hatching eggs of poultry other than ratites	HEP	N, P1		18.3.2022	
		Hatching eggs of ratites	HER	N, P1		18.3.2022	
		Less than 20 hatching eggs of poultry other than ratites	HE-LT20	N, P1		18.3.2022	
US-2.29		Breeding poultry other than ratites and productive poultry other than ratites	BPP	N, P1		18.3.2022	
		Breeding ratites and productive ratites	BPR	N, P1		18.3.2022	
		Poultry intended for slaughter other than ratites	SP	N, P1		18.3.2022	
		Ratites intended for slaughter	SR	N, P1		18.3.2022	
		Day-old chicks other than ratites	DOC	N, P1		18.3.2022	
		Day-old chicks of ratites	DOR	N, P1		18.3.2022	
		Less than 20 heads of poultry other than ratites	POU-LT20	N, P1		18.3.2022	
		Hatching eggs of poultry other than ratites	HEP	N, P1		18.3.2022	
		Hatching eggs of ratites	HER	N, P1		18.3.2022	
		Less than 20 hatching eggs of poultry other than ratites	HE-LT20	N, P1		18.3.2022'	

(b) Part 2 is amended as follows:

(i) in the entry for the United Kingdom, the following descriptions of the zones GB-2.105 to GB-2.107 are added after the description for the zone GB-2.104:

United Kingdom	GB-2.105	Near Collieston, Aberdeenshire, Scotland. The area contained with a circle of a radius of 10km, centred on WGS84 dec, coordinates N57.38 and W1.92.
	GB-2.106	Near Redgrave, Mid Suffolk, Suffolk, England: The area contained within a circle of a radius of 10km, centred on WGS84 dec, coordinates N52.33 and E1.02.
	GB-2.107	Near Market Weston, West Suffolk, Suffolk, England: The area contained within a circle of a radius of 10km, centred on WGS84 dec, coordinates N52.37 and E0.96.'

(ii) in the entry for the United States, the following descriptions of the zones US-2.21 to US-2.29 are added after the description of the zone US-2.20:

United States	US-2.21	State of Maryland Cecil 02 Cecil County: A zone of a 10 km radius starting with North point (GPS coordinates: 75.7817424°W 39.5011636°N) and extending in a circular clockwise fashion: (a) North: 2.5km North-Northeast from intersection of Cayots Corner Rd and N St Augustine Rd. (b) Northeast: 0.9km North-Northeast from the intersection of N Broad St Cedar Ln Rd. (c) East: 0.9km Southwest from the intersection of Main St and Summit Bridge Rd. (d) Southeast: 0.7km North-Northwest from the intersection of McKays Corner Rd and Sawmill Rd. (e) South: 1.4km Northeast from the intersection of 301 and 313. (f) Southwest: 2.6km Southwest from the intersection of 213 and Sandy Bottom Rd. (g) West: 3.4km Northeast from intersection of Stemmer's Run Rd and Pond Neck Rd. (h) Northwest: 1.8km West from intersection of Cayots Corner Rd and Aufustine Herman Hwy.
	US-2.22	State of Iowa Taylor County: A zone of a 10 km radius starting with North point (GPS coordinates: 94.4900604°W 40.8972542°N) and extending in a circular clockwise fashion: (a) North: 1.3km North from intersection of 110th St and Yellowstone Ave. (b) Northeast: 1.0km East from the intersection of 120th St and 140th Ave. (c) East: 0.8km Southwest from the intersection of County Hwy J23 and 155th Ave.

		(d) Southeast: 1.2km East-Northeast from the intersection of 210th St and 140th Ave. (e) South: 0.8km North-Northeast from the intersection of 230th St and Winchester Ave. (f) Southwest: 0.9km North-Northwest from the intersection of 210th St and Tennessee Ave. (g) West: 0.7km Southwest from intersection of 160th St and Rockwood Ave. (h) Northwest: 0.7km North-Northwest from intersection of 120th St and Tennessee Ave.
	US-2.23	State of Kansas Franklin County: A zone of a 10 km radius starting with North point (GPS coordinates: 95.0792521°W 38.7130278°N) and extending in a circular clockwise fashion: (a) North: 0.5km Northwest from intersection of Stafford Rd and Poplar St. (b) Northeast: 0.9km Northwest from the intersection of W 247th St and Bethel Church Rd. (c) East: 0.8km East from the intersection of W 279th St and Crescent Hill Rd. (d) Southeast: 0.9km Southwest from the intersection of W 311th St and Bethel Church Rd. (e) South: 0.4km Northwest from the intersection of Jackson Rd and Virginia Rd. (f) Southwest: 1.5km Northeast from the intersection of Rock Creek Rd and Oregon Rd. (g) West: 0.2km West-Northwest from intersection of Highway K68 and Ohio Rd. (h) Northwest: 0.8km Northwest from intersection of Tennessee Rd and Riley Rd.
	US-2.24	State of South Dakota Charles Mix 02 Charles Mix County: A zone of a 10 km radius starting with North point (GPS coordinates: 98.6493004°W 43.2818237°N) and extending in a circular clockwise fashion: (a) North: 1.7km Northeast from intersection of 376th Avenue and 284th Street. (b) Northeast: 0.3km North Northeast from the intersection of 381st Avenue and 285th Street. (c) East: 1.4km South Southwest from the intersection of 289th Street and 384th Avenue. (d) Southeast: 0.9km Northwest from the intersection of 294th Avenue and US 18; US 281. (e) South: 0.6km Northeast from the intersection of 296th Street and 377th Avenue. (f) Southwest: 1.7km West from the intersection of 294th Street and SD 1804. (g) West: 1.1km South from intersection of 371st Avenue and 289th Street. (h) Northwest: 0.6km South Southwest from intersection of 373rd Avenue and 285th Street.

	US-2.25	State of Wisconsin Jefferson County: A zone of a 10 km radius starting with North point (GPS coordinates: 88.6351537°W 42.9712343°N) and extending in a circular clockwise fashion: (a) North: 0.5km Northeast from intersection of Bente Road and Turner Road. (b) Northeast: 1.7km Northwest from the intersection of County Road CI and CTH Z. (c) East: 1.7km East-Southeast from the intersection of CTH Z and WI 59. (d) Southeast: 0.6km Southwest from the intersection of Greening Road and WI 67. (e) South: 1.3km Northwest from the intersection of CTH 0 and Kettle Moraine Drive. (f) Southwest: 0.5km North from the intersection of South Franklin Street and US 12;WI 59. (g) West: 1.2km Southwest from intersection of Findlay Road and Fremont Road. (h) Northwest: 0.9km South from intersection of Schmidt Road and Gnube Lane.
	US-2.26	State of Delaware Kent County: A zone of a 10 km radius starting with North point (GPS coordinates: 75.4180689°W 39.0474609°N) and extending in a circular clockwise fashion: (a) North: 0.7km Southeast from intersection of Bowers Beach Road and Old Bowers Road. (b) Northeast: 2.1km East-Northeast from the intersection of Brockam Bridge Road and Bennetts Pier Road. (c) East: 0.6km Northwest from the intersection of DE 36 and Lighthouse Road. (d) Southeast: 0.6km North from the intersection of Johnson Road and DE 30. (e) South: 0.5km East from the intersection of DE 36 and Fitzgeralds Road. (f) Southwest: 0.8km Southeast from the intersection of Hunting Quarter Road and Messicks Road. (g) West: 1.5km Northwest from intersection of Paradise Alley Road and Campground Road. (h) Northwest: 0.5km Southeast from intersection of Barratts Chapel Road and McGinnis Pond Road.
	US-2.27	State of Iowa Buena Vista 02 Buena Vista County: A zone of a 10 km radius starting with North point (GPS coordinates: 95.1270827°W 42.9155545°N) and extending in a circular clockwise fashion: (a) North: 1.2km Southeast from intersection of 500th Street and 230th Avenue. (b) Northeast: 1.1km Southeast from the intersection of 180th Avenue and 430th Street. (c) East: 1.15km Northwest from the intersection of 480th Street and CR M54. (d) Southeast: 0.9km Southwest from the intersection of 520th Street and 190th Avenue.

		(e) South: 0.2km Northeast from the intersection of 540th Street and 140th Avenue. (f) Southwest: 0.4km Southwest from the intersection of 520th Street and 100th Avenue. (g) West: 0.4m North from intersection of C-25 and 80th Avenue. (h) Northwest: 0.4km Northwest from intersection of 100th Avenue and 435th Street.
	US-2.28	State of Kansas Dickinson County: A zone of a 10 km radius starting with North point (GPS coordinates: 96.9485550°W 38.7273195°N) and extending in a circular clockwise fashion: (a) North: 0.3km Northwest from intersection of 900 Avenue and Vane Road. (b) Northeast: 0.8km Northeast from the intersection of Q Avenue and South 2900 Road. (c) East: 0.5km East from the intersection of V avenue and 2700 Road. (d) Southeast: 1.2km Northeast from the intersection of Bb Avenue and South 2900 Road. (e) South: 0.5km Southeast from the intersection of 330th Street and Wagonwheel Road. (f) Southwest: 0.8km North-northwest from the intersection of Sunflower Road and 340th Street. (g) West: 0.4km Southwest from intersection of Paint Road and 300 Avenue. (h) Northwest: 0.7km Northwest from intersection of KS 4 and Rain Road.
	US-2.29	State of Maryland Cecil 04 Cecil County: A zone of a 10 km radius starting with North point (GPS coordinates: 75.7934265°W 39.4839828°N) and extending in a circular clockwise fashion: (a) North: 0.6km North from intersection of Stallion Row and Myrtle Wilson Road. (b) Northeast: 0.2km Southeast from the intersection of Industrial Road and Haveg Road. (c) East: 1.0km Northwest from the intersection of Gears Corner Road and Dexter Corner Road. (d) Southeast: 1.3km Southeast from the intersection of Delaware Line Road and McKays Corner Road. (e) South: 1.0km South-Southeast from the intersection of US 301 and MD. 313. (f) Southwest: 1.6km Northwest from the intersection of MD213 and Starkey Farm Lane. (g) West: 0.8km North-Northeast from intersection of Grove Neck Road and Woodlawn Lane. (h) Northwest: 0.8km North from intersection of Park Lane and Beachview Avenue.'

(2) in Annex XIV, Part 1 is amended as follows:

(i) in the entry for the United Kingdom, the row for the zone GB-2.26 is replaced by the following:

'GB United Kingdom	GB-2.26	Fresh meat of poultry other than ratites	POU	N, P1		21.11.2021	14.3.2022
		Fresh meat of ratites	RAT	N, P1		21.11.2021	14.3.2022
		Fresh meat of game birds	GBM	P1		21.11.2021	14.3.2022'

(ii) in the entry for the United Kingdom, the following rows for the zones GB-2.105 to GB-2.107 are added after the row for the zone GB-2.104:

'GB United Kingdom	GB-2.105	Fresh meat of poultry other than ratites	POU	N, P1		11.3.2022	
		Fresh meat of ratites	RAT	N, P1		11.3.2022	
		Fresh meat of game birds	GBM	P1		11.3.2022	
	GB-2.106	Fresh meat of poultry other than ratites	POU	N, P1		12.3.2022	
		Fresh meat of ratites	RAT	N, P1		12.3.2022	
		Fresh meat of game birds	GBM	P1		12.3.2022	
	GB-2.107	Fresh meat of poultry other than ratites	POU	N, P1		12.3.2022	
		Fresh meat of ratites	RAT	N, P1		12.3.2022	
		Fresh meat of game birds	GBM	P1		12.3.2022'	

(iii) in the entry for the United States, the following rows for the zones US-2.21 to US-2.29 are added after the row for the zone US-2.20:

'US United States	US-2.21	Fresh meat of poultry other than ratites	POU	N, P1		10.3.2022	
		Fresh meat of ratites	RAT	N, P1		10.3.2022	
		Fresh meat of game birds	GBM	P1		10.3.2022	
	US-2.22	Fresh meat of poultry other than ratites	POU	N, P1		10.3.2022	
		Fresh meat of ratites	RAT	N, P1		10.3.2022	
		Fresh meat of game birds	GBM	P1		10.3.2022	
	US-2.23	Fresh meat of poultry other than ratites	POU	N, P1		11.3.2022	
		Fresh meat of ratites	RAT	N, P1		11.3.2022	
		Fresh meat of game birds	GBM	P1		11.3.2022	

	US-2.24	Fresh meat of poultry other than ratites	POU	N, P1		12.3.2022	
		Fresh meat of ratites	RAT	N, P1		12.3.2022	
		Fresh meat of game birds	GBM	P1		12.3.2022	
	US-2.25	Fresh meat of poultry other than ratites	POU	N, P1		14.3.2022	
		Fresh meat of ratites	RAT	N, P1		14.3.2022	
		Fresh meat of game birds	GBM	P1		14.3.2022	
	US-2.26	Fresh meat of poultry other than ratites	POU	N, P1		17.3.2022	
		Fresh meat of ratites	RAT	N, P1		17.3.2022	
		Fresh meat of game birds	GBM	P1		17.3.2022	
	US-2.27	Fresh meat of poultry other than ratites	POU	N, P1		17.3.2022	
		Fresh meat of ratites	RAT	N, P1		17.3.2022	
		Fresh meat of game birds	GBM	P1		17.3.2022	
	US-2.28	Fresh meat of poultry other than ratites	POU	N, P1		18.3.2022	
		Fresh meat of ratites	RAT	N, P1		18.3.2022	
		Fresh meat of game birds	GBM	P1		18.3.2022	
	US-2.29	Fresh meat of poultry other than ratites	POU	N, P1		18.3.2022	
		Fresh meat of ratites	RAT	N, P1		18.3.2022	
		Fresh meat of game birds	GBM	P1		18.3.2022'	

DECISIONS

DECISION (EU) 2022/480 OF THE EUROPEAN PARLIAMENT

of 10 March 2022

on setting up a committee of inquiry to investigate the use of the Pegasus and equivalent surveillance spyware, and defining the subject of the inquiry, as well as the responsibilities, numerical strength and term of office of the committee

The European Parliament,

- having regard to the request presented by 290 Members for a committee of inquiry to be set up to look into and investigate alleged contraventions, or maladministration in implementation of Union law as regards the use of the Pegasus and equivalent surveillance spyware that is installed on mobile devices by exploiting IT vulnerabilities ('equivalent surveillance spyware'),
- having regard to the proposal from the Conference of Presidents,
- having regard to Article 226 of the Treaty on the Functioning of the European Union (TFEU),
- having regard to Decision 95/167/EC, Euratom, ECSC of the European Parliament, the Council and the Commission of 19 April 1995 on the detailed provisions governing the exercise of the European Parliament's right of inquiry ⁽¹⁾,
- having regard to the European Union's attachment to the values and principles of liberty, democracy and respect for human rights and fundamental freedoms and of the rule of law as outlined in the preamble to the Treaty on European Union (TEU) and notably in Articles 2, 6 and 21 of that Treaty,
- having regard to Article 4(2) TEU, which reaffirms Member States' exclusive competence in maintaining law and order and safeguarding national security,
- having regard to Articles 16 and 223 TFEU,
- having regard to the Charter of Fundamental Rights of the European Union (the 'Charter'), and in particular Articles 7, 8, 11, 21 and 47 thereof, that recognise the specific rights, freedoms and principles set out in it, such as respect for private and family life and the protection of personal data, freedom of expression and information, right to non-discrimination, as well as the right to effective remedy and fair trial, and which fully apply to Member States when they are implementing Union law, and Article 52(1) thereof that allows for certain limitation on the exercise of fundamental rights and freedoms,
- having regard to Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications) ⁽²⁾,
- having regard to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) ⁽³⁾,
- having regard to Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA ⁽⁴⁾,

⁽¹⁾ OJ L 113, 19.5.1995, p. 1.

⁽²⁾ OJ L 201, 31.7.2002, p. 37.

⁽³⁾ OJ L 119, 4.5.2016, p. 1.

⁽⁴⁾ OJ L 119, 4.5.2016, p. 89.

- having regard to Council Decision (CFSP) 2019/797 of 17 May 2019 concerning restrictive measures against cyber-attacks threatening the Union or its Member States ⁽⁵⁾ as amended by Council Decision (CFSP) 2021/796 of 17 May 2021 ⁽⁶⁾,
- having regard to Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items ⁽⁷⁾,
- having regard to the Act concerning the election of the members of the European Parliament by direct universal suffrage ⁽⁸⁾,
- having regard to the European Convention for the Protection of Human Rights and Fundamental Freedoms, and in particular Articles 8, 9, 13 and 17 thereof, and the Protocols to that Convention,
- having regard to the United Nations Guiding Principles on Business and Human Rights ⁽⁹⁾,
- having regard to its resolution of 12 March 2014 on the US NSA surveillance programme, surveillance bodies in various Member States and their impact on EU citizens' fundamental rights and on transatlantic cooperation in Justice and Home Affairs ⁽¹⁰⁾ and to its recommendations regarding the strengthening of IT security in the EU's institutions, bodies and agencies,
- having regard to Rule 208 of its Rules of Procedure,

A. whereas there have been recent revelations that several countries, including Member States, have used the Pegasus surveillance spyware against journalists, politicians, law enforcement officials, diplomats, lawyers, business people, civil society actors and other actors, and that such practices are extremely alarming and appear to confirm the dangers of the misuse of surveillance technology to undermine human rights and democracy;

1. Decides to set up a committee of inquiry to investigate alleged contraventions, or maladministration in the implementation, of Union law as regards the use of the Pegasus and equivalent surveillance spyware, without prejudice to the jurisdiction of national or Union courts;

2. Decides that the committee of inquiry shall:

- investigate the scope of alleged contraventions, or maladministration in the implementation, of Union law, resulting from the use of the Pegasus and equivalent surveillance spyware, collect information on the extent to which Member States, including but not limited to Hungary and Poland, or third countries use intrusive surveillance in a way that violates the rights and freedoms enshrined in the Charter, as well as assess the level of risk this poses to the values enshrined in Article 2 TEU, such as democracy, the rule of law and respect for human rights;
- for the performance of its duties, collect and analyse information to ascertain:
 - the use and the functioning of the Pegasus and equivalent surveillance spyware and its alleged negative impact on fundamental rights under the Charter, in cases where Member States were implementing Union law;
 - the existing legal framework in which Member States have acquired and used the Pegasus and equivalent surveillance spyware;
 - whether Member States' authorities have used the Pegasus and equivalent surveillance spyware for political, economic or other unjustified purposes to spy on journalists, politicians, law enforcement officials, diplomats, lawyers, business people, civil society actors or other actors, in violation of Union law and of the values enshrined in Article 2 TEU, or the rights enshrined in the Charter;

⁽⁵⁾ OJ L 129 I, 17.5.2019, p. 13.

⁽⁶⁾ OJ L 174 I, 18.5.2021, p. 1.

⁽⁷⁾ OJ L 206, 11.6.2021, p. 1.

⁽⁸⁾ OJ L 278, 8.10.1976, p. 5.

⁽⁹⁾ https://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf

⁽¹⁰⁾ OJ C 378, 9.11.2017, p. 104.

- whether the use, in contravention of Union law, of the Pegasus and equivalent surveillance spyware had an adverse impact on democratic processes in the Member States concerning elections on local, national and European levels;
- the alleged contraventions or maladministration by Member States, resulting from the use of the Pegasus and equivalent surveillance spyware, of Directive 2002/58/EC, in particular regarding the principle of confidentiality of communications and the prohibition of listening, tapping, storage or other kinds of interception or surveillance of communications and the related traffic data of persons;
- whether the use of the Pegasus and equivalent surveillance spyware by Member States have constituted, resulted in or revealed violations of Directive (EU) 2016/680 and Regulation (EU) 2016/679;
- whether the Commission had evidence of the use of the Pegasus and equivalent surveillance spyware against persons;
- whether the Member States have ensured sufficient institutional and legal safeguards to avoid the illegal use of spyware, and whether persons who suspect that their rights have been violated by the use of spyware have access to effective remedy;
- the alleged failure of Member States to act in respect of the involvement of entities in the EU in the development, dissemination, or financing of the Pegasus and equivalent surveillance spyware, including the supply chain in terms of technology and its exploitation, in so far as it is in breach of Union law, including Regulation (EU) 2021/821, and including where surveillance software marketed for a certain purpose (e.g. fight against terrorism) is used in another context;
- the role of the government of Israel and of other third countries in supplying the Pegasus and equivalent surveillance spyware to Member States;
- whether the use of the Pegasus or equivalent surveillance spyware by Member State authorities has resulted in the transfer of personal data to third countries, in particular but not limited to it, to the NSO Group, as well as to third countries' governments;
- whether the use of the Pegasus or equivalent surveillance spyware, directly or indirectly involving entities linked to the EU, contributed to illegal spying on journalists, politicians, law enforcement officials, diplomats, lawyers, business people, civil society actors or other actors in third countries and whether it led to human rights violations or abuses that are of serious concern as regards the objectives of the EU's common foreign and security policy, and whether such use was in contravention of the values enshrined in Article 21 TEU and in the Charter, also with due regard to the United Nations Guiding Principles on Business and Human Rights and other rights enshrined in international human rights law;
- whether there were sufficient grounds for the Council to adopt restrictive measures or sanctions in the framework of the EU common foreign and security policy against one or more third countries where a decision, adopted in accordance with Chapter 2 of Title V TEU provided for the interruption or reduction of economic or financial relation, in accordance with Article 215(1) TFEU;
- whether the use of the Pegasus or equivalent surveillance spyware by third countries had an impact on fundamental rights ensured under Union law and whether, there were sufficient grounds for the Council to reassess any international cooperation agreements in the Area of Freedom, Security and Justice concluded with third countries pursuant to Article 218 TFEU;
- make any recommendations that it deems necessary in this matter;
- make recommendations for protecting EU institutions and its Members and staff against such surveillance spyware;

3. Decides that the committee of inquiry shall submit its final report within 12 months of the adoption of this decision;
 4. Decides that the committee of inquiry should take account in its work of any relevant developments within the remit of the committee that emerge during its term;
 5. Underlines that in order to ensure good cooperation and information flow between the committee of inquiry and the relevant standing committees and sub-committees, the Chair and the Rapporteur of the committee of inquiry could be involved in relevant debates of the standing committees and sub-committees, and vice versa, in particular for hearings of the committee of inquiry;
 6. Decides that any recommendations drawn up by the committee of inquiry should be referred to the relevant standing committees and subcommittees in their respective fields of competences as defined by Annex VI to the Rules of Procedure;
 7. Decides that the committee of inquiry shall have 38 members;
 8. Instructs its President to arrange for publication of this decision in the *Official Journal of the European Union*.
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COUNCIL DECISION (EU) 2022/481**of 22 March 2022****on the position to be taken on behalf of the European Union within the General Council of the World Trade Organization as regards the adoption of a decision on the review of the Understanding on Tariff Rate Quota Administration Provisions of Agricultural Products**

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the European Commission,

Whereas:

- (1) On 22 December 1994, the Marrakesh Agreement Establishing the World Trade Organization ('the WTO Agreement') was concluded by the Union by means of Council Decision 94/800/EC ⁽¹⁾ and entered into force on 1 January 1995.
- (2) Pursuant to paragraph 1 of Article IV of the WTO Agreement, the Ministerial Conference of the World Trade Organization (WTO) has the authority to take decisions on all matters under any of the Multilateral Trade Agreements.
- (3) Pursuant to paragraph 2 of Article IV of the WTO Agreement, in the intervals between meetings of the Ministerial Conference, the functions of the Ministerial Conference are to be conducted by the General Council of the WTO.
- (4) Pursuant to paragraph 1 of Article IX of the WTO Agreement, WTO bodies usually take decisions by consensus.
- (5) In December 2013, the Ninth Session of the WTO Ministerial Conference adopted a Ministerial Decision on Understanding on Tariff Rate Quota Administration Provisions of Agricultural Products, as defined in Article 2 of the Agreement on Agriculture (WT/MIN(13)/39) ('the TRQ Understanding'). The TRQ Understanding governs the management of tariff-rate quotas of agricultural products.
- (6) Pursuant to paragraph 13 of the TRQ Understanding, a review of the operation of the TRQ Understanding is to commence no later than 4 years following its adoption, taking into account experience gained up to that time. The objective of the review is to promote a continuing process of improvement in the utilisation of tariff-rate quotas.
- (7) In accordance with paragraph 13 of the TRQ Understanding, the Committee on Agriculture proceeded with the review of the TRQ Understanding in 2018. In December 2019, the review findings were presented to the meeting of the General Council of the WTO in the form of a report issued by the Committee on Agriculture (document G/AG/29 of 31 October 2019).
- (8) On 9 November 2021, the Chair of the Committee on Agriculture presented his report on the negotiations and a draft decision, as contained in document G/AG/32. At the same time, the Committee on Agriculture submitted the draft decision set out in the annex to the report contained in document G/AG/32 ('the draft decision') for the consideration of the General Council and for its subsequent transmission to the 12th Ministerial Conference for final adoption, noting, however, that some WTO Members had not yet finalised the internal consultations on this matter.

⁽¹⁾ Council Decision 94/800/EC of 22 December 1994 concerning the conclusion on behalf of the European Community, as regards matters within its competence, of the agreements reached in the Uruguay Round multilateral negotiations (1986-1994) (OJ L 336, 23.12.1994, p. 1).

- (9) Due to the postponement of the 12th WTO Ministerial Conference, the Committee on Agriculture agreed to propose a three-month extension of the deadline (namely, up to 31 March 2022) in order to finalise a decision on the review.
- (10) At the special meeting of the General Council on 15 December 2021, the WTO Members agreed on the three-month extension of the deadline, up to 31 March 2022.
- (11) It is expected that the General Council of the WTO will be invited, by 31 March 2022, or possibly by a later date in 2022, if a further extension is agreed, to consider the adoption of the draft decision, possibly with some amendments following negotiations.
- (12) It is appropriate to establish the position to be taken on the Union's behalf in the General Council of the WTO, as the decision to be adopted will be binding on the Union.
- (13) The draft decision contains recommendations for the future operation of the TRQ Underfill Mechanism which, if acceptable to all WTO Members, could conclude the review. The adoption of the draft decision would mean that the provisions of the TRQ Understanding that exempt the US and developing countries from the Underfill Mechanism would become obsolete, which is clearly in the Union's interest.
- (14) In the General Council of the WTO, the Union is to be represented by the Commission, in accordance with Article 17(1) of the Treaty on European Union,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf within the General Council of the World Trade Organization at any meeting to be held by 31 March 2022, or thereafter if a further extension is agreed, shall be to support a consensus-based outcome with a view to adopting a decision concluding the review of the operation of the Decision of the WTO Ministerial Conference of 7 December 2013 on the Understanding of Tariff Rate Quota Administration Provisions of Agricultural Products, as defined in Article 2 of the Agreement on Agriculture (WT/MIN(13)/39), and rendering paragraphs 13 to 15 of that Decision, along with Annex B to that Decision, non-operational, as set out in the draft decision set out in the annex to the report contained in document G/AG/32, which is attached to this Decision.

Article 2

Minor changes to the draft decision set out in the annex to the report contained in document G/AG/32 may be agreed to by the representatives of the Union in the General Council of the WTO without a further decision of the Council.

Article 3

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

Done at Brussels, 22 March 2022.

For the Council
The President
C. BEAUNE

COMMITTEE ON AGRICULTURE

G/AG/32

11 November 2021

REVIEW OF THE OPERATION OF THE BALI DECISION ON TRQ ADMINISTRATION

REPORT BY THE CHAIRPERSON TO THE GENERAL COUNCIL

- 1.1. At the Ninth Session of the Ministerial Conference in December 2013 at Bali, Ministers adopted the Decision on 'Understanding of Tariff Rate Quota Administration Provisions of Agricultural Products, as defined in Article 2 of the Agreement on Agriculture' (WT/MIN(13)/39) (hereinafter referred to as the 'Decision'). The Decision also required a review of its operation commencing no later than end-2017 with a view to improving the rate of TRQ utilization. The future operation of paragraph 4 of the Underfill Mechanism in Annex A of the Decision was specifically mandated to be taken up under the Review as per paragraphs 13-14 of the Decision.
- 1.2. The Review was concluded when the General Council, at its meeting on 9-10 December 2019, approved the recommendations by the Committee on Agriculture (CoA) contained in Annex 2 to G/AG/29. However, there was no substantive agreement on the issue of the future operation of paragraph 4 of the Underfill Mechanism during the 2017-19 review exercise. Instead, as per paragraph 1 of the approved recommendations in Annex 2 to G/AG/29, Members agreed to defer the timeline for a decision on paragraph 4 of the Underfill Mechanism by two years, i.e. to end-2021.
- 1.3. The recommendations also allude to a potential fragmentation of the Decision by offering the right to select Members, listed in Annex B of the Decision, to discontinue the application of paragraph 4, should there be no agreement among Members on the future operation of this paragraph. Avoidance of a carve out for certain Members, which the lack of an agreement on the future operation of paragraph 4 within the agreed deadline could potentially trigger, remained an important motivation for several Members to find an agreeable solution on this paragraph in the post-2019 CoA discussions on this matter.
- 1.4. In these discussions, Members examined in detail as to how current paragraph 4 would operate in practice during the final stage of the Underfill Mechanism. It was noted that the importing Member in the final stage of the Underfill Mechanism under current paragraph 4 is obliged to change the TRQ administration method to either first-come first-served at customs (FCFS) or an automatic unconditional license on demand system - with the option to be chosen based on consultations with the concerned exporting Member(s). The selected administration method would then be maintained for a minimum of two years after which, and provided timely fill rates were notified for those two years, the matter would be 'closed' and marked accordingly on the Secretariat Tracking Register.
- 1.5. Developing importing Members in the final stage of the Underfill Mechanism, under the latter part of current paragraph 4, may choose an alternative TRQ administration method or maintain the current method. The choice of an alternative TRQ administration method would need to be notified to the CoA within the operation of the Underfill Mechanism. The method selected would be maintained for a minimum of two years and the matter would be 'closed' provided the fill rate had increased by two-thirds of the annual increments described in paragraph 3(b) of the Underfill Mechanism.
- 1.6. Based on these discussions, Members achieved a better appreciation of the main sticking point identified in relation to the future operation of paragraph 4 of the Underfill Mechanism, where a developing importing Member does not achieve the required increase in the fill rate while either retaining the current TRQ administration method or using an alternative administration method.
- 1.7. Members' efforts in reaching an agreement on paragraph 4 principally focussed on finding possible approaches to address this potential outstanding situation for developing importing Members in order to achieve a 'closure' of the underfill matter raised.
- 1.8. There was a wide support for an approach along a textual suggestion made informally by Costa Rica according to which an importing developing Member that fails to meet the required fill rate standard (i.e. two-thirds of the annual increments described in paragraph 3 (b) of the Underfill Mechanism) after two years in the final stage of the Underfill Mechanism, having used an alternative administration method or maintained the current method in place,

would be subject to the standard requirement in the first sentence of paragraph 4, if so requested by interested exporting Member(s). In the absence of such request, the concern would be marked as 'closed' after two years in the final stage even if the required increase on the fill rate was not achieved. This suggestion seeks to ensure that a matter in the final stage of the Mechanism will eventually reach a 'closure' or 'resolution'.

- 1.9. One additional issue that was raised more recently in this discussion concerned the relationship between the obligations arising from the Underfill Mechanism and specific provisions on TRQ administration an importing Member may have in its Schedule of Concessions. Members generally acknowledged the primacy of concessions and commitments in the Schedules, and that the role of the Decision and its Underfill Mechanism was to promote an effective implementation of scheduled commitments, rather than to modify them. Here, Members were specifically guided by paragraph 5 of the Underfill Mechanism, which explicitly establishes a hierarchy between the obligations under the covered agreements (which, as per Article II:7 of the GATT 1994, include Members' goods schedules) and the provisions of the Underfill Mechanism, by stating that 'in the event of any conflict, the provisions of the covered agreements shall prevail'.
- 1.10. Based on discussions, the proposed draft Decision on the future operation of paragraph 4 of the Underfill Mechanism (as shown in Annex to this report) contains the following elements:
 - i. Splitting of current paragraph 4 of the Underfill Mechanism into two sub-paragraphs to offer clarity with regard to the 'standard' requirement as in the proposed sub-paragraph 4a), and the special and differential treatment (S&DT) in sub-paragraph 4b);
 - ii. The content of the S&DT element in current paragraph 4 is reproduced, without any alteration, in the proposed sub-paragraph 4b);
 - iii. In order to address the outstanding situation where a developing importing Member does not meet the required fill rate standard after two years while either retaining the current TRQ administration method or using an alternative administration method, the draft decision proposes to add an additional option in the latter part of sub-paragraph 4 (b) in order to reach the 'closure' of the matter. This would require the concerned developing importing Member to implement the 'standard' requirement in the first part of the current paragraph 4;
 - iv. A new footnote 6 is proposed to address the potential concerns that a few Members expressed on the relationship between the obligations arising from the Underfill Mechanism and those contained in importing Members' schedules of concessions. Paragraph 5 of the Underfill Mechanism already clarifies the relationship between the obligations arising from the Underfill Mechanism and Members' rights and obligations under the 'covered agreements';
 - v. As an agreement on the future operation of paragraph 4 of the Underfill Mechanism would also lead to the conclusion of the review of the operation of the Bali TRQ Decision pursuant to paragraphs 13-15 of Decision, the draft decision accordingly proposes that these three paragraphs, along with Annex B of the Decision, are rendered non-operational.
- 1.11. Paragraph 14 of the Decision requires that the General Council recommendations in relation to paragraph 4 of the Underfill Mechanism shall provide for S&DT. In this regard, the draft Decision containing recommendations for the future operation of paragraph 4 retains the current S&DT provision under the proposed sub-paragraph 4b), as it states that a developing importing Member in the final stage of the Underfill Mechanism may maintain the current TRQ administration method or use an alternative administration method, and achieve a resolution of the matter by showing the required increase in the fill rate. This option, as in current paragraph 4 of the Decision, remains unchanged. When, in the following two years, the importing developing Member does not achieve the required increase in the fill rate under these circumstances, the proposed Decision may require that Member to apply the 'standard' requirement as in the first part of current paragraph 4 (i.e. first-come first-served at the customs or automatic licensing). It should be noted that the requirement to apply that provision is not automatic even after those two years. Instead, the proposed obligation would apply only based on request by the concerned exporting Member(s). In case no request is made, despite the importing developing Member not meeting the required fill rate standard, the underfill matter would be marked as 'closed'.

- 1.12. The Committee on Agriculture reconvened its 99th regular meeting on 9 November 2021 to take up the suspended agenda item 2 D(i) on the implementation of the Bali Decision on TRQ administration. **At that meeting, the Committee agreed to forward the draft Decision ⁽¹⁾ in Annex to this report to the General Council for consideration and for its subsequent submission to the Twelfth Ministerial Conference (MC-12) for a decision by Ministers.**
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⁽¹⁾ Some Members indicated that they would need additional time to consult with their capitals.

ANNEX

The Ministerial Conference,

Having regard to paragraph 1 of Article IX of the Marrakesh Agreement establishing the World Trade Organization (the 'WTO Agreement');

Noting the Ministerial Decision of 7 December 2013 on Understanding on Tariff Rate Quota Administration Provisions of Agricultural Products, as Defined in Article 2 of the Agreement on Agriculture (WT/MIN(13)/39-WT/L/914) dated 11 December 2013 (hereinafter referred to as the 'Bali Decision on TRQ Administration');

Recalling the recommendations of the Review of the operation of the Bali Decision on TRQ Administration in Annex 2 to G/AG/29 approved by the General Council at its meeting on 9-10 December 2019;

Recognizing that paragraph 1 of the aforementioned recommendations set the deadline of 31 December 2021 for a decision on the future operation of paragraph 4 of Annex A of the Bali Decision on TRQ Administration;

Decides that:

1. Paragraph 4 of Annex A of the Bali Decision on TRQ Administration shall be read as follows:

4.a. The importing Member shall then promptly provide unencumbered access via one of the following tariff quota administration methods ⁽²⁾, ⁽³⁾: a first-come, first-served only basis (at the border); or an automatic, unconditional license on demand system within the tariff quota. In taking a decision on which of these two options to implement, the importing Member will consult with interested exporting Members. The method selected shall be maintained by the importing Member for a minimum of two years, after which time – provided that timely notifications for the two years have been submitted – it will be noted on the Secretariat's tracking register and the concern marked "closed".

4.b. Developing country Members may choose an alternative tariff quota administration method or maintain the current method in place. This choice of an alternative tariff quota administration method shall be notified to the Committee on Agriculture under the provisions of this mechanism. The method selected shall be maintained by the importing Member for a minimum of two years, after which time, if the fill rate has increased by two-thirds of the annual increments described in paragraph 3(b), it will be noted on the Secretariat's tracking register and the concern marked "closed". At the request of an interested Member, the provisions under paragraph 4(a) shall apply if after the two years the fill rate has not increased at least by two-thirds of the annual increments described in paragraph 3(b). If no request is made, the concern shall be marked as "closed".

2. Henceforth, paragraphs 13-15 of the Bali Decision on TRQ Administration, along with Annex B, are rendered non-operational.

⁽²⁾ The actions and remedies taken by the importing Member shall not modify or impede the rights of a Member holding a country-specific allocation for that tariff quota with respect to their country-specific allocation.

⁽³⁾ In the event of a conflict, the specific provisions on tariff quota import arrangements specified in the importing Member's Schedule of Concessions shall prevail to the extent of the conflict.

COMMISSION IMPLEMENTING DECISION (EU) 2022/482**of 16 March 2022****on the request for registration of the European citizens' initiative entitled 'Fur Free Europe' pursuant to Regulation (EU) 2019/788 of the European Parliament and of the Council***(notified under document C(2022) 1530)***(Only the English text is authentic)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/788 of the European Parliament and of the Council of 17 April 2019 on the European citizens' initiative ⁽¹⁾, and in particular Article 6(2) and (3) thereof,

Whereas:

- (1) A request for registration of a European citizens' initiative entitled 'Fur Free Europe' was submitted to the Commission on 25 January 2022.
- (2) The objectives of the initiative as expressed by the organisers in the annex to the initiative are 'to achieve an EU-wide ban on: (a) keeping and killing of animals for the sole or main purpose of fur production; (b) placing farmed animal fur, and products containing such fur, on the EU market'.
- (3) An annex and an additional document provide further details on the subject matter, objectives and background to the initiative, by setting out and detailing the reasons to support the end of fur farming. The organisers claim that fur farming is inherently cruel, since the vast majority of animals kept for its production are still essentially wild, while a clear majority of Union citizens wants to see fur farming banned. Fur farming poses a risk to animal and human health as well as to native biodiversity. The organisers refer to some Member States' initiatives to eliminate fur production at national level. At the same time those national divergences lead to a distortion in the Union's internal market, justifying in their view, an EU-wide outright ban under Article 114 TFEU. They also claim that the marketing of farmed fur and products containing such fur should not be allowed in the Union.
- (4) As regards the objectives of the initiative to achieve an EU-wide ban on both fur farming and fur commercialization in the Union, insofar as they aim at improving the functioning of the internal market, the Commission has the power to present proposals for legal acts on the basis of Article 114 TFEU. In addition, as regards the objective to achieve an EU-wide ban on fur farming, a legal act of the Union for the purpose of implementing the Treaties can be adopted for provisions necessary for the pursuit of the objectives of the common agricultural policy on the basis of Article 43(2) TFEU.
- (5) For those reasons, none of the parts of the initiative manifestly falls outside the framework of the Commission's powers to submit a proposal for a legal act of the Union for the purpose of implementing the Treaties.
- (6) This conclusion is without prejudice to the assessment of whether the concrete factual and substantive conditions required for the Commission to act, including compliance with the principles of proportionality and subsidiarity and compatibility with fundamental rights, would be met in this case.

⁽¹⁾ OJ L 130, 17.5.2019, p. 55.

- (7) The group of organisers has provided appropriate evidence that it fulfils the requirements laid down in Article 5(1) and (2) of Regulation (EU) 2019/788 and has designated the contact persons in accordance with Article 5(3), first subparagraph, of that Regulation.
- (8) The initiative is not manifestly abusive, frivolous or vexatious, nor is it manifestly contrary to the values of the Union as set out in Article 2 of the Treaty on European Union and rights enshrined in the Charter of Fundamental Rights of the European Union.
- (9) The initiative entitled 'Fur Free Europe' should therefore be registered.
- (10) The conclusion that the conditions for registration under Article 6(3) of Regulation (EU) 2019/788 are fulfilled does not imply that the Commission in any way confirms the factual correctness of the content of the initiative, which is the sole responsibility of the group of organisers of the initiative. The content of the initiative only expresses the views of the group of organisers, and can in no way be taken to reflect the views of the Commission,

HAS ADOPTED THIS DECISION:

Article 1

The European citizens' initiative entitled 'Fur Free Europe' shall be registered.

Article 2

This Decision is addressed to the group of organisers of the citizens' initiative entitled 'Fur Free Europe', represented by Ms Elise FLEURY and Ms Agnese MARCON acting as contact persons.

Done at Brussels, 16 March 2022.

For the Commission
Věra JOUROVÁ
Vice-President

COMMISSION IMPLEMENTING DECISION (EU) 2022/483**of 21 March 2022****amending Implementing Decision (EU) 2021/1073 laying down technical specifications and rules for the implementation of the trust framework for the EU Digital COVID Certificate established by Regulation (EU) 2021/953 of the European Parliament and of the Council****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic ⁽¹⁾, and in particular Article 9(1) thereof,

Whereas:

- (1) Regulation (EU) 2021/953 sets out the EU Digital COVID Certificate which provides proof that a person has received a COVID-19 vaccine, a negative test result or has recovered from infection for the purpose of facilitating the holders' exercise of their right to free movement during the COVID-19 pandemic.
- (2) Regulation (EU) 2021/954 of the European Parliament and of the Council ⁽²⁾ provides that Member States are to apply the rules laid down in Regulation (EU) 2021/953 to third-country nationals who do not fall within the scope of that Regulation, but who are legally staying or residing in their territory and who are entitled to travel to other Member States in accordance with Union law.
- (3) Council Recommendation (EU) 2022/290 amending Recommendation (EU) 2020/912 on the temporary restriction on non-essential travel into the EU and the possible lifting of such restriction ⁽³⁾ provides that third-country nationals wishing to undertake non-essential travel from a third countries to the Union should be in the possession valid proof of vaccination or recovery, such as a EU Digital COVID Certificate or a COVID-19 certificate issued by a third country covered by an implementing act adopted pursuant to Article 8(2) of Regulation (EU) 2021/953.
- (4) In order for the EU Digital COVID Certificate to be operational throughout the Union, the Commission adopted Implementing Decision (EU) 2021/1073 ⁽⁴⁾, laying down technical specifications and rules to populate, securely issue and verify EU Digital COVID Certificates, ensure the protection of personal data, lay down the common structure of the unique certificate identifier and issue a valid, secure and interoperable barcode.
- (5) In accordance with Article 4 of Regulation (EU) 2021/953, the Commission and the Member States were to set up and maintain a trust framework for the EU Digital COVID Certificate. That trust framework is able to support the bilateral exchange of certificate revocation lists containing the unique certificate identifiers of revoked certificates.

⁽¹⁾ OJ L 211, 15.6.2021, p. 1.

⁽²⁾ Regulation (EU) 2021/954 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) with regard to third-country nationals legally staying or residing in the territories of Member States during the COVID-19 pandemic (OJ L 211, 15.6.2021, p. 24).

⁽³⁾ Council Recommendation (EU) 2022/290 of 22 February 2022 amending Council Recommendation (EU) 2020/912 on the temporary restriction on non-essential travel into the EU and the possible lifting of such restriction (OJ L 43, 24.2.2022, p. 79).

⁽⁴⁾ Commission Implementing Decision (EU) 2021/1073 of 28 June 2021 laying down technical specifications and rules for the implementation of the trust framework for the EU Digital COVID Certificate established by Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 230, 30.6.2021, p. 32).

- (6) On 1 July 2021, the EU Digital COVID Certificate gateway (the 'gateway'), which is the central part of the trust framework and which allows for the secure and trusted exchange between Member States of public keys used to verify EU Digital COVID Certificates, became operational.
- (7) Due to their successful and large-scale rollout, EU Digital COVID Certificates have become a target for fraudsters seeking to find ways to issue fraudulent certificates. Those fraudulent certificates need therefore to be revoked. In addition, certain EU Digital COVID Certificates may be revoked by Member States at national level for medical and public health reasons, for example because a batch of vaccines administered was later found to be defective.
- (8) While the EU Digital COVID Certificate system is capable of immediately revealing forged certificates, authentic certificates that are unlawfully issued on the basis of false documentation, unauthorised access or with fraudulent intent cannot be detected in other Member States unless the lists of revoked certificates generated at national level are exchanged between Member States. The same applies for certificates that have been revoked for medical and public health reasons. Failure by Member States' verification applications to detect certificates revoked by other Member States poses a threat to public health and undermines citizens' trust and confidence in the EU Digital COVID Certificate system.
- (9) As noted in Recital 19 of Regulation (EU) 2021/953, Member States should, for medical and public health reasons and in the event of fraudulently issued or obtained certificates, be able to establish and exchange with other Member States for the purpose of that Regulation certificate revocation lists in limited cases, in particular as regards certificates that have been issued erroneously, as a result of fraud or following the suspension of a COVID-19 vaccine batch found to be defective. Member States should not be able to revoke certificates issued by other Member States. Certificate revocation lists exchanged should not contain any personal data other than unique certificate identifiers. In particular, they should not include the reason why a certificate has been revoked.
- (10) In addition to the general information about the possibility of revocation of certificates and the possible reasons for that, holders of revoked certificates should be promptly informed by the responsible issuing authority about the revocation of their certificates and the reasons for the revocation. However, it may in some cases, and in particular in the case of EU Digital COVID Certificates issued on paper, prove impossible or could involve a disproportionate effort to trace and inform the holder of the revocation. Member States should not collect additional personal data not needed for the issuance process only to be able to inform certificate holders in case their certificates are revoked.
- (11) It is thus necessary to enhance the EU Digital COVID Certificate trust framework by supporting the bilateral exchange of certificate revocation lists between Member States.
- (12) This Decision does not cover temporary suspension of certificates for national use cases outside the scope of the EU Digital COVID Certificate Regulation, for example because the holder of a vaccination certificate has tested positive for SARS-CoV-2. It is without prejudice to established procedures for checking the business rules for the validity of certificates.
- (13) While, from a technical point of view, different architectures for the exchange of revocation lists are feasible, exchanging them via the gateway is the most appropriate one as it limits data exchanges to the trust framework already established and as it minimises the number of both possible points of failure and exchanges between Member States compared to an alternative peer-to-peer system.
- (14) Accordingly, the EU Digital COVID Certificate gateway should be enhanced to support the secure exchange of revoked EU Digital COVID Certificates for the purpose of their secure verification via the Gateway. In this regard, appropriate security measures to protect the personal data processed in the gateway should be implemented. To ensure a high level of protection, Member States should pseudonymise certificate attributes by means of an irreversible hash to be included in the revocation lists. Indeed, the unique identifier should be considered as pseudonymised data for the processing operations carried out within the framework of the gateway.

- (15) In addition provisions on the role of the Member States and of the Commission as regards the exchange of certificate revocation lists should be laid down.
- (16) The processing of personal data of certificate holders, which is done under the responsibility of the Member States or other public organisations or official bodies in the Member States, should be carried out in accordance with Regulation (EU) 2016/679 of the European Parliament and of the Council ⁽⁵⁾. Processing of personal data under the responsibility of the Commission for the purpose of managing and ensuring the security of the EU Digital COVID Certificate Gateway should comply with Regulation (EU) 2018/1725 of the European Parliament and of the Council ⁽⁶⁾.
- (17) The Member States, represented by the designated national authorities or official bodies, determine together the purpose and means of processing of personal data through the EU Digital COVID Certificate gateway and are therefore joint controllers. Article 26 of Regulation (EU) 2016/679 places an obligation on joint controllers of personal data processing operations to determine, in a transparent manner, their respective responsibilities for compliance with the obligations under that Regulation. It also provides for the possibility to have those responsibilities determined by Union or Member State law to which the controllers are subject. The arrangement referred to in Article 26 should be included in Annex III to this Decision.
- (18) Regulation (EU) 2021/953 assigns a task to the Commission to support such exchanges. The most appropriate way to fulfil that mandate is to collate the submitted certificate revocation lists on behalf of the Member States. Therefore a data processor role should be assigned to the Commission to support these exchanges by facilitating the exchange of lists via the EU Digital COVID Certificate gateway on behalf of the Member States.
- (19) The Commission, as a provider of technical and organisational solutions for the EU Digital COVID Certificate gateway, processes the personal data in the revocation lists in the gateway on behalf of the Member States as joint controllers. Therefore, it acts as their processor. Pursuant to Article 28 of Regulation (EU) 2016/679 and Article 29 of Regulation (EU) 2018/1725, the processing by a processor is to be governed by a contract or a legal act under Union or Member State law which is binding on the processor with regard to the controller and which specifies the processing. Therefore it is necessary to lay down rules on processing by the Commission as a data processor.
- (20) The Commission's supporting task does not involve the establishment of a central database as referred to in Recital 52 of Regulation (EU) 2021/953. That prohibition is intended to avoid a central repository of all EU Digital COVID Certificates issued and does not preclude the Member States from exchanging revocation lists, which is expressly provided for in Article 4(2) of Regulation (EU) 2021/953.
- (21) When processing personal data in the EU Digital COVID Certificate gateway, the Commission is bound by Commission Decision (EU, Euratom) 2017/46 ⁽⁷⁾.
- (22) Article 3(10) of Regulation (EU) 2021/953 allows the Commission to adopt implementing acts establishing that COVID-19 certificates issued by a third country with which the Union and the Member States have concluded an agreement on the free movement of persons allowing the contracting parties to restrict such free movement on grounds of public health in a non-discriminatory manner and which does not contain a mechanism of incorporation of Union legal acts are equivalent to those issued in accordance with this Regulation. On that basis, the Commission adopted, on 8 July 2021, Implementing Decision (EU) 2021/1126 ⁽⁸⁾ establishing the equivalence of COVID-19 certificates issued by Switzerland.

⁽⁵⁾ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

⁽⁶⁾ Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

⁽⁷⁾ The Commission publishes further information on Security standards applying to all European Commission information systems on https://ec.europa.eu/info/publications/security-standards-applying-all-european-commission-information-systems_en

⁽⁸⁾ Commission Implementing Decision (EU) 2021/1126 of 8 July 2021 establishing the equivalence of COVID-19 certificates issued by Switzerland to the certificates issued in accordance with Regulation (EU) 2021/953 of the European Parliament and of the Council (OJ L 243, 9.7.2021, p. 49).

- (23) Article 8(2) of Regulation (EU) 2021/953 allows the Commission to adopt implementing acts establishing that COVID-19 certificates issued by a third country in accordance with standards and technological systems that are interoperable with the trust framework for the EU Digital COVID Certificate and that allow for the verification of the authenticity, validity and integrity of the certificate, and which contain the data set out in the Annex to the Regulation, are to be considered as equivalent to EU Digital COVID Certificates for the purpose of facilitating the holders' exercise of their right to free movement within the Union. As noted in Recital 28 of Regulation (EU) 2021/953, Article 8(2) of that Regulation concerns the acceptance of certificates issued by third countries to Union citizens and their family members. The Commission has already adopted several such implementing acts.
- (24) To avoid gaps in the detection of revoked certificates covered by such implementing acts, it should also be possible for third countries whose COVID-19 certificates have been deemed equivalent pursuant to Article 3(10) and Article 8(2) of Regulation (EU) 2021/953 to submit relevant certificate revocation lists to the EU Digital COVID Certificate gateway.
- (25) Some third-country nationals who hold revoked COVID-19 certificates issued by a third country whose COVID-19 certificates have been deemed equivalent pursuant to Regulation (EU) 2021/953 may fall outside the scope of either that Regulation or Regulation (EU) 2021/954 at the moment a revocation list including their certificates is generated by the third country concerned. However, whether all third country nationals holders of revoked certificates fall within the scope of either Regulation cannot be known at the time when a certificate revocation list is generated by a third country concerned. Seeking to exclude persons not covered by the scope of either regulation at the moment when those countries' certificate revocation lists are generated is thus not feasible, and attempting to do so would result in Member States being unable to detect revoked certificates held by third-country nationals travelling to the Union for the first time. However, even the revoked certificates of those third country nationals would be verified by Member States when their holders travel to the Union, and subsequently, when they travel within the Union. The third countries whose certificates have been deemed equivalent pursuant to Regulation (EU) 2021/953 are not involved in the governance of the gateway and thus do not qualify as joint controllers.
- (26) In addition, the EU Digital COVID Certificate system has proven to be the only COVID-19 certificate system operational at international level on a large scale. As a result, the EU Digital COVID Certificate has gained increasing global significance and has contributed to addressing the pandemic at the international level by facilitating safe international travel and global recovery. In the process of adopting additional implementing acts pursuant to Article 8(2) of Regulation (EU) 2021/953, new needs regarding populating the EU Digital COVID Certificate arise. According to the rules set out in Implementing Decision (EU) 2021/1073, the surname is a mandatory field in the technical contents of the certificate. It is necessary to amend that requirement to promote inclusion and interoperability with other systems, given that, in some third countries, there are persons without a surname. In cases where the certificate holder's name cannot be divided into two parts, the name should be placed in the same field (surname or forename) of the EU Digital COVID Certificate as would be done the holder's travel or identity document. This change would also better align the technical contents of the certificates with the currently valid specifications on machine-readable travel documents published by the International Civil Aviation Organization.
- (27) Implementing Decision (EU) 2021/1073 should therefore be amended accordingly.
- (28) The European Data Protection Supervisor was consulted in accordance with Article 42(1) of Regulation (EU) 2018/1725 and delivered an opinion on 11 March 2022.
- (29) To allow Member States and the Commission sufficient time to implement the changes needed to enable the exchange of certificate revocation lists via the EU Digital COVID Certificate gateway, this Decision should start to apply four weeks after its entry into force.
- (30) The measures provided for in this Decision are in accordance with the opinion of the Committee set up under Article 14 of Regulation (EU) 2021/953,

HAS ADOPTED THIS DECISION:

Article 1

Implementing Decision (EU) 2021/1073 is amended as follows:

(1) the following Articles 5a, 5b and 5c are inserted:

Article 5a

Exchange of certificate revocation lists

1. The EU Digital COVID Certificate trust framework shall enable the exchange of certificate revocation lists via the central EU Digital COVID Certificate gateway (the 'gateway') in accordance with the technical specifications in Annex I.
2. Where Member States revoke EU Digital COVID Certificates they may submit certificate revocation lists to the gateway.
3. Where Member States submit certificate revocation lists, the issuing authorities shall keep a list of revoked certificates.
4. Where personal data is exchanged via the gateway, the processing shall be limited to the purpose of supporting the exchange of revocation information. Such personal data shall only be used for the purpose of verifying the revocation status of EU Digital COVID Certificates issued within the scope of Regulation (EU) 2021/953.
5. The information submitted to the gateway shall comprise the following data in accordance with the technical specifications in Annex I:
 - (a) the pseudonymised unique certificate identifiers of revoked certificates,
 - (b) an expiry date for the submitted certificate revocation list;
6. Where an issuing authority revokes EU Digital COVID Certificates it has issued pursuant to Regulation (EU) 2021/953 or Regulation (EU) 2021/954 and intends to exchange relevant information through the gateway, it shall transmit the information referred to in paragraph 5 in the form of certificate revocation lists to the gateway in a secure format in accordance with the technical specifications in Annex I.
7. Issuing authorities shall, to the extent possible, provide a solution to inform the holders of revoked certificates about the revocation status of their certificates and the reason for the revocation at the time of revocation.
8. The gateway shall collect the certificate revocation lists received. It shall provide tools for distributing the lists to the Member States. It shall automatically delete lists in accordance with the expiry dates indicated for each submitted list by the submitting authority.
9. The designated national authorities or official bodies of the Member States processing personal data in the gateway shall be joint controllers of the data processed. The respective responsibilities of the joint controllers shall be allocated in accordance with Annex VI.
10. The Commission shall be the processor of personal data processed within the gateway. In its capacity as processor on behalf of the Member States, the Commission shall ensure the security of the transmission and of the hosting of personal data within the gateway and shall comply with the obligations of the processor laid down in Annex VII.
11. The effectiveness of the technical and organisational measures for ensuring the security of processing of personal data within the gateway shall be regularly tested, assessed and evaluated by the Commission and by the joint controllers.

Article 5b

Submission of certificate revocation lists by third countries

Third countries issuing COVID-19 certificates in respect of which the Commission has adopted an implementing act pursuant to Article 3(10) or Article 8(2) of Regulation (EU) 2021/953 may submit lists of revoked COVID-19 certificates covered by such an implementing act to be processed by the Commission on behalf of the joint controllers in the gateway referred to in Article 5a, in accordance with the technical specifications set out in Annex I.

Article 5c

Governance of the processing of personal data in the central EU Digital COVID Certificate gateway

1. The decision-making process of the joint controllers shall be governed by a working group established under the Committee referred to in Article 14 of Regulation (EU) 2021/953.

2. The designated national authorities or official bodies of the Member States processing personal data in the gateway as joint controllers shall designate representatives to that group.’;

(2) Annex I is amended in accordance with Annex I to this Decision;

(3) Annex V is amended in accordance with Annex II to this Decision;

(4) the text in Annex III to this Decision is added as Annex VI;

(5) the text in Annex IV to this Decision is added as Annex VII.

Article 2

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

It shall apply from four weeks after its entry into force.

Done at Brussels, 21 March 2022.

For the Commission
The President
Ursula VON DER LEYEN

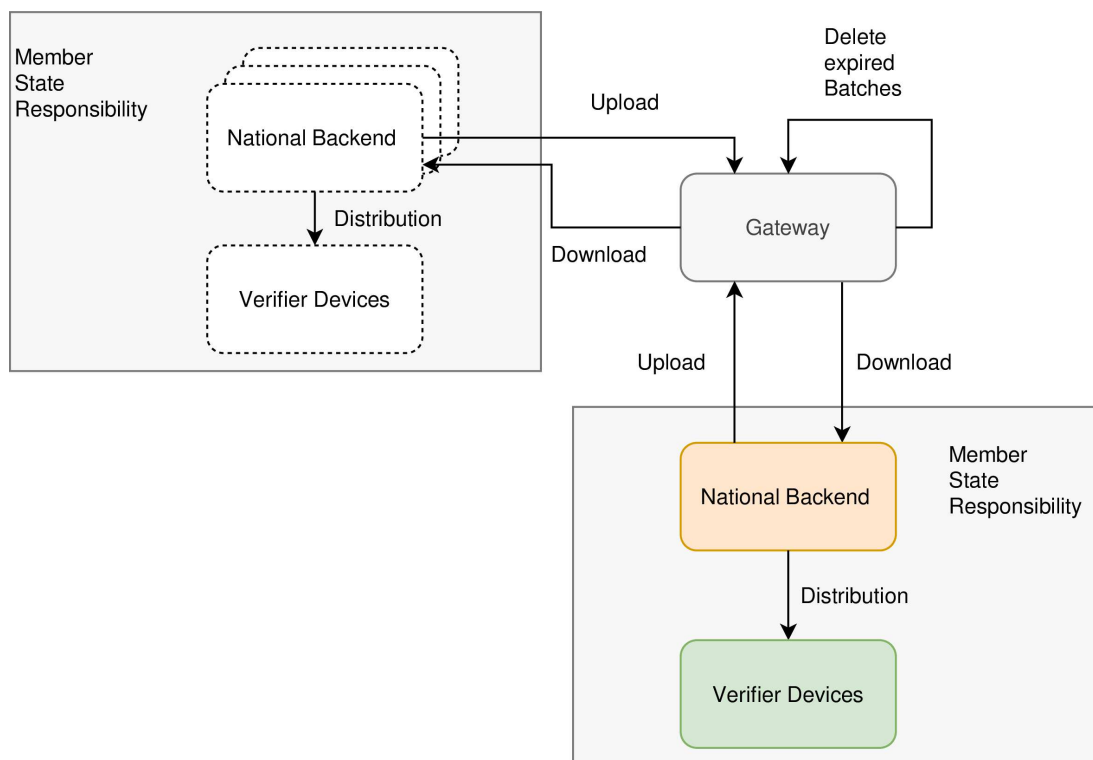
ANNEX I

In Annex I to Implementing Decision (EU) 2021/1073, the following section 9 is added:

‘9. REVOCATION SOLUTION

9.1. DCC Revocation List (DRL) Provision

The Gateway shall provide endpoints and functionality to hold and manage the revocation lists:



9.2. Trust Model

All connections are established by the standard DCCG trust model by the NB_{TLS} and NB_{UP} certificates (see certificate governance). All information is packed and uploaded by CMS messages to ensure the integrity.

9.3. Batch Construction

9.3.1. Batch

Each revocation list shall contain one or multiple entries and shall be packed in batches which contain a set of hashes and their metadata. A batch is immutable and defines an expiration date which indicates when the batch can be deleted. The expiration date of all items in the batch must be exactly the same – meaning that batches must be grouped by expiry date and by signing DSC. Each batch shall contain a maximum of 1 000 entries. If the revocation list consists of more than 1 000 entries, multiple batches shall be created. Any entry may occur in at most one batch. The batch shall be packaged into a CMS structure and signed by the NB_{up} certificate of the uploading country.

9.3.2. Batch Index

When a batch is created it shall be assigned a unique ID by the gateway and shall be automatically added to the index. The index of batches is ordered by the modified date, in ascending chronological order.

9.3.3. Gateway Behaviour

The gateway processes revocation batches without any changes: it can neither update nor remove, nor add any information to the batches. The batches are forwarded to all authorised countries (see chapter 9.6).

The gateway actively observes the expiration dates of batches and removes the expired batches. After the batch is deleted, the gateway returns an "HTTP 410 Gone" response for the deleted batch URL. Therefore, the batch appears in the batch index as "deleted".

9.4. Hash Types

The revocation list contains hashes that can represent different revocation types/attributes. These types or attributes shall be indicated in the provisioning of the revocation lists. The current types are:

Type	Attribute	Hash Calculation
SIGNATURE	DCC Signature	SHA256 of DCC Signature
UCI	UCI (Unique Certificate Identifier)	SHA256 of UCI
COUNTRYCODEUCI	Issuing Country Code + UCI	SHA256 of Issuing CountryCode + UCI

Just the first 128 bits of the hashes encoded as base64 strings are put into the batches and used to identify the revoked DCC ⁽¹⁾.

9.4.1. Hash type: SHA256(DCC Signature)

In this case the hash is calculated over the bytes of the COSE_SIGN1 signature from the CWT. For RSA signatures, the entire signature will be used as input. The formula for the EC-DSA signed certificates is using the r value as an input:

SHA256(r)

[required for all new implementations]

9.4.2. Hash type: SHA256(UCI)

In this case the hash is calculated over the UCI string encoded in UTF-8 and converted to a byte array.

[deprecated ⁽²⁾, but supported for backwards compatibility]

9.4.3. Hash type: SHA256(Issuing CountryCode+UCI)

In this case CountryCode encoded as a UTF-8 string concatenated with the UCI encoded with a UTF-8 string. This is then converted to a byte array and used as input to the hash function.

[deprecated², but supported for backwards compatibility]

9.5. API Structure

9.5.1. Revocation Entry Provisioning API

9.5.1.1. Purpose

The API delivers the revocation list entries in batches including a batch index.

9.5.1.2. Endpoints

⁽¹⁾ Please also consider 9.5.1.2 for the detailed API descriptions.

⁽²⁾ Deprecated means that this feature shall not be considered for new implementations but shall be supported for existing implementations for a well-defined period of time.

9.5.1.2.1. Batch List Download Endpoint

The endpoints follow a simple design, returning a list of batches with a small wrapper providing metadata. The batches are sorted by *date* in *ascending (chronological)* order:

/revocation-list

Verb: GET

Content-Type: application/json

Response: JSON Array

```
{
  'more': true|false,
  'batches':
    [{
      'batchId': '{uuid}',
      'country': 'XY',
      'date': '2021-11-01T00:00:00Z'
      'deleted': true | false
    }, ..
  ]
}
```

Note: The result is limited by default to 1 000. If the flag 'more' is set to true, the response indicates that more batches are available for download. To download more items the client must set the If-Modified-Since header to a date no earlier than the last entry received.

The response contains a JSON array with the following structure:

Field	Definition
more	Boolean Flag which indicates that there are more batches.
batches	Array with the existing batches.
batchId	https://en.wikipedia.org/wiki/Universally_unique_identifier
country	Country Code ISO 3166
date	ISO 8601 Date UTC. Date when the batch was added or deleted.
deleted	boolean. True if deleted. When the deleted flag is set, the entry can be finally removed from the query results after 7 days.

9.5.1.2.1.1. Response Codes

Code	Description
200	All ok.
204	No content, if "If-Modified-Since" Header content has no match.

Request Header

Header	Mandatory	Description
If-Modified-Since	Yes	This header contains the last downloaded date to get just the newest results. On the initial call the header should be the set to the '2021-06-01T00:00:00Z'

9.5.1.2.2. Batch Download Endpoint

The batches contain a list of certificate identifiers:

/revocation-list/{batchId}

Verb: GET

Accepts: application/cms

Response: CMS with Content

```
{
  'country': 'XY',
  'expires': '2022-11-01T00:00:00Z',
  'kid': '23S+33f=',
  'hashType': 'SIGNATURE',
  'entries': [{
    'hash': 'e2e2e2e2e2e2e2e2'
  }, ..]
}
```

The response contains a CMS including a signature which must match to the NB_{UP} certificate of the country. All items in the JSON array contain the following structure:

Field	Mandatory	Type	Definition
expires	Yes	String	Date when the item can be removed. ISO8601 Date/Time UTC
country	Yes	String	Country Code ISO 3166
hashType	Yes	String	Hash Type of the provided entries (see Hash Types)
entries	Yes	JSON Object Array	See Table Entries
kid	Yes	String	base64 encoded KID of the DSC used to sign the DCC. If the KID is not known then the string 'UNKNOWN_KID' (excluding the ') can be used.

Notes:

— Batches shall be grouped by expiry date and DSC – all items shall expire at the same time and have been signed by the same key.

- Expiry time is a date/time in UTC because EU-DCC is a global system and we must use an unambiguous time.
- The expiry date of a permanently revoked DCC shall be set at the expiry date of the corresponding DSC used to sign the DCC or at the Expiration Time of the revoked DCC (in which case the used NumericDate/epoch times shall be treated as being in the UTC time zone).
- National Backend (NB) shall remove items from their revocation list when the **expiration** date is reached.
- NB may remove items from their revocation list in the case that the **kid** used to sign the DCC is revoked.

9.5.1.2.2.1. Entries

Field	Mandatory	Type	Definition
hash	Yes	String	First 128 bits of the SHA256 hash encoded as a base64 string

Note: The entries object contains currently just a hash, but to be compatible with changes in the future an object was chosen, instead of a json array.

9.5.1.2.2.2. Response Codes

Code	Description
200	All ok.
410	Batch gone. Batch can be deleted in the national backend.

9.5.1.2.2.3. Response Headers

Header	Description
ETag	Batch ID.

9.5.1.2.3. Batch Upload Endpoint

The upload is done over the same endpoint via POST Verb:

/revocation-list

Verb: POST

Accepts: application/cms

Request: CMS with Content

ContentType: application/cms

Content:

```
{  
  'country': 'XY',  
  'expires': '2022-11-01T00:00:00Z',  
  'kid': '23S+33f=',
```

```

    'hashType': 'SIGNATURE',
    'entries': [{
        'hash': 'e2e2e2e2e2e2e2e2'
    }, ...]
}

```

The batch shall be signed using the NB_{UP} certificate. The Gateway shall verify that the signature was set by the NB_{UP} for the given *country*. If the signature check fails then the upload shall fail.

NOTE: Every batch is immutable and can't be changed after uploading. It can be deleted, though. The ID of every deleted batch is stored, and an upload of a new batch with the same ID is rejected.

9.5.1.2.4. Batch Delete Endpoint

A batch can be deleted over the same endpoint via DELETE Verb:

/revocation-list

Verb: DELETE

Accepts: application/cms

ContentType: application/cms

Request: CMS with Content

Content:

```

{
    'batchId': '...'
}

```

or, for compatibility reasons, to the following endpoint with the POST verb:

/revocation-list/delete

Verb: POST

Accepts: application/cms

ContentType: application/cms

Request: CMS with Content

Content:

```

{
    'batchId': '...'
}

```

9.6. API Protection/GDPR

This section specifies measures for the implementation to comply with the provisions of the Regulation 2021/953 as regards to the processing of personal data.

9.6.1. Existing Authentication

The Gateway currently uses the NB_{TLS} certificate to authenticate the countries connecting to the Gateway. This authentication can be used to determine the identity of the country connected to Gateway. That identity can then be used to implement access control.

9.6.2. *Access Control*

To be able to lawfully process personal data the Gateway shall implement an access control mechanism.

The gateway implements an Access Control List combined with Role Based Security. In that scheme, two tables shall be maintained – one table describing which Roles can apply which Operations to which Resources, the other table describing which Roles are assigned to which Users.

To implement the controls required by this document, three Roles are required, and that is:

RevocationListReader

RevocationUploader

RevocationDeleter

The following endpoints shall check to see if the User has the Role RevocationListReader; if they do then access shall be granted, if they do not then an HTTP 403 Forbidden shall be returned:

GET/revocation-list/

GET/revocation-list/{batchId}

The following endpoints shall check to see if the User has the Role RevocationUploader; if they do then access shall be granted, if they do not then an HTTP 403 Forbidden shall be returned:

POST/revocation-list

The following endpoints shall check to see if the User has the Role RevocationDeleter; if they do then access shall be granted, if they do not then an HTTP 403 Forbidden shall be returned:

DELETE/revocation-list

POST/revocation-list/delete

The Gateway shall also provide a reliable method whereby the administrators can manage the Roles that are linked to the Users in such a way as to reduce the chance of human errors whilst also not burdening the functional administrators.'

ANNEX II

Section 3 of Annex V to Implementing Decision 2021/1073 is replaced by the following:

3. Common structures and general requirements

An EU Digital COVID Certificate shall not be issued if not all data fields can be correctly populated in accordance with this specification due to missing information. ***This shall not be understood as affecting the obligation of Member States to issue EU Digital COVID Certificates.***

Information in all fields may be provided using the full set of UNICODE 13.0 characters encoded using UTF-8, unless specifically restricted to value sets or narrower sets of characters.

The common structure shall be as follows:

```
"JSON":{
  "ver":<version information>,
  "nam":{
    <person name information>
  },
  "dob":<date of birth>,
  "v" or "t" or "r":[
    {<vaccination dose or test or recovery information, one entry>}
  ]
}
```

Detailed information on individual groups and fields is provided in next sections.

Where the rules indicate that a field shall be skipped, this means that its content shall be empty and that neither the name nor the value of the field are allowed in the contents.

3.1. Version

Version information shall be provided. Versioning is following Semantic Versioning (semver: <https://semver.org>). In production, it shall be one of the officially released (current or one of the older officially released) versions. See Section JSON Schema location for more details.

Field id	Field name	Instructions
ver	Schema version	Shall match the identifier of the schema version used for producing the EUDCC. Example: "ver": "1.3.0"

3.2. Person name and date of birth

Person name is the official full name of the person, matching the name stated on travel documents. The identifier of the structure is *nam*. Exactly 1 (one) person name shall be provided.

Field id	Field name	Instructions
nam/fn	Surname(s)	Surname(s) of the holder. If the holder has no surnames and has a forename, the field shall be skipped. In all other cases, exactly 1 (one) non-empty field shall be provided, with all surnames included in it. In case of multiple surnames, these shall be separated by a space. Combination names including hyphens or similar characters must however stay the same.

		Examples: "fn": "Musterfrau-Gößinger" "fn": "Musterfrau-Gößinger Müller"
nam/fnt	Standardised surname(s)	Surname(s) of the holder transliterated using the same convention as the one used in the holder's machine readable travel documents (such as the rules defined in ICAO Doc 9303 Part 3). If the holder has no surnames and has a forename, the field shall be skipped. In all other cases, exactly 1 (one) non-empty field shall be provided, only including characters A-Z and <. Maximum length: 80 characters (as per ICAO 9303 specification). Examples: "fnt": "MUSTERFRAU<GOESSINGER" "fnt": "MUSTERFRAU<GOESSINGER<MUELLER"
nam/gn	Forename(s)	Forename(s), such as given name(s), of the holder. If the holder has no forenames and has a surname, the field shall be skipped. In all other cases, exactly 1 (one) non-empty field shall be provided, with all forenames included in it. In case of multiple forenames, these shall be separated by a space. Example: "gn": "Isolde Erika"
nam/gnt	Standardised forename(s)	Forename(s) of the holder transliterated using the same convention as the one used in the holder's machine-readable travel documents (such as the rules defined in ICAO Doc 9303 Part 3). If the holder has no forenames and has a surname, the field shall be skipped. In all other cases, exactly 1 (one) non-empty field shall be provided, only including characters A-Z and <. Maximum length: 80 characters. Example: "gnt": "ISOLDE<ERIKA"
dob	Date of birth	Date of birth of the DCC holder. Complete or partial date without time restricted to the range from 1900-01-01 to 2099-12-31. Exactly 1 (one) non-empty field shall be provided if the complete or partial date of birth is known. If the date of birth is not known even partially, the field shall be set to an empty string "". This should match the information as provided on travel documents. One of the following ISO 8601 formats shall be used if information on date of birth is available. Other options are not supported. YYYY-MM-DD YYYY-MM YYYY (The verifier app may show missing parts of the date of birth using the XX convention as the one used in machine-readable travel documents, e.g. 1990-XX-XX.) Examples: "dob": "1979-04-14" "dob": "1901-08" "dob": "1939" "dob": ""

3.3. *Groups for certificate type specific information*

The JSON Schema supports three groups of entries encompassing certificate type specific information. Each EUDCC shall contain exactly 1 (one) group. Empty groups are not allowed.

Group identifier	Group name	Entries
v	Vaccination group	If present, shall contain exactly 1 (one) entry describing exactly 1 (one) vaccination dose (one dose).
t	Test group	If present, shall contain exactly 1 (one) entry describing exactly 1 (one) test result.
r	Recovery group	If present, shall contain exactly 1 (one) entry describing 1 (one) recovery statement.'

ANNEX III

‘ANNEX VI

**RESPONSIBILITIES OF THE MEMBER STATES AS JOINT CONTROLLERS FOR THE EU DIGITAL COVID
CERTIFICATE GATEWAY FOR THE EXCHANGE OF EU DCC REVOCATION LISTS**

SECTION 1

*Subsection 1****Division of responsibilities***

- (1) The joint controllers shall process personal data through the trust framework gateway in accordance with the technical specifications in Annex I.
- (2) The Member States' issuing authorities remain the sole controller for the collection, use, disclosure and any other processing of revocation information outside the gateway, including for the procedure leading to the revocation of a certificate.
- (3) Each controller shall be responsible for the processing of personal data in the trust framework gateway in accordance with Articles 5, 24 and 26 of the General Data Protection Regulation.
- (4) Each controller shall set up a contact point with a functional mailbox that will serve for the communication between the joint controllers themselves and between the joint controllers and the processor.
- (5) A working group set up by the Committee referred to in Article 14 of Regulation (EU) 2021/953 shall be mandated to decide any issues arising from the exchange of revocation lists and from the joint controllership of related processing of personal data and to facilitate coordinated instructions to the Commission as a processor. The decisions making process of the Joint Controllers is governed by that working group and the rules of procedure to be adopted by it. As a baseline rule, non-participation by any of the joint controllers in a meeting of this working group, that has been announced at least seven (7) days before it has been convened in writing, results in a tacit agreement with the outcomes of that working group meeting. Any of the joint controllers can convene a meeting of this working group.
- (6) Instructions to the processor shall be sent by any of the joint controllers' contact points, in agreement with the other joint controllers, as per the working group decision making process outlined in (5) above. The joint controller who provides the instruction should provide them to the processor in writing, and inform all other joint controllers of this. If the matter at hand is sufficiently time-critical that it does not allow for a meeting of the working group as referred to in (5) above, an instruction may be provided nonetheless, but may be rescinded by the working group. This instruction should be given in writing, and all other joint controllers should be informed of this at the time of giving the instruction.
- (7) The working group as set up per (5) above does not preclude any of the joint controllers' individual competence to inform their competent supervisory authority in accordance with article 33 and 24 of the General Data Protection Regulation. Such notification does not require the consent of any of the other joint controllers.
- (8) In the scope of the trust framework gateway only persons authorised by the designated national authorities or official bodies may access the personal data exchanged.
- (9) Each issuing authority shall maintain a record of the processing activities under its responsibility. The joint controllership may be indicated in the record.

*Subsection 2****Responsibilities and roles for handling requests of and informing data subjects***

- (1) Each controller in its role as issuing authority shall provide natural persons whose certificate(s) it has revoked ('the data subjects') with information about said revocation and the processing of their personal data in the EU Digital COVID Certificate Gateway for the purposes of supporting the exchange of revocation lists, in accordance with Article 14 of the General Data Protection Regulation, unless this proves impossible or would involve a disproportionate effort.
- (2) Each controller shall act as the contact point for natural persons whose certificate it has revoked and shall handle the requests submitted by data subjects or their representatives in the exercise of their rights in accordance with the General Data Protection Regulation. If a joint controller receives a request from a data subject, which relates to a certificate issued by another joint controller, it shall inform the data subject of the identity and contact details of that responsible joint controller. If requested by another joint controller, the joint controllers shall assist each other in handling data subjects' requests and shall reply to each other without undue delay and at the latest within 1 month from receiving a request for assistance. If a request is related to data submitted by a third country, the controller that receives the request shall handle it and inform the data subject of the identity and contact details of the issuing authority in the third country.
- (3) Each controller shall make available to the data subjects the content of this Annex including the arrangements laid down in points 1 and 2.

SECTION 2

Management of security incidents, including personal data breaches

- (1) The joint controllers shall assist each other in the identification and handling of any security incidents, including personal data breaches, linked to the processing in the EU Digital COVID Certificate Gateway.
- (2) In particular, the joint controllers shall notify each other of the following:
 - (a) any potential or actual risks to the availability, confidentiality and/or integrity of the personal data undergoing processing in the trust framework gateway;
 - (b) any personal data breach, the likely consequences of the personal data breach and the assessment of the risk to the rights and freedoms of natural persons, and any measures taken to address the personal data breach and mitigate the risk to the rights and freedoms of natural persons;
 - (c) any breach of the technical and/or organisational safeguards of the processing operation in the trust framework gateway.
- (3) The joint controllers shall communicate any personal data breaches related to the processing operation in the trust framework gateway to the Commission, to the competent supervisory authorities and, where required so, to data subjects, in accordance with Articles 33 and 34 of the General Data Protection Regulation or following notification by the Commission.
- 4) Each issuing authority shall implement appropriate technical and organisational measures, designed to:
 - a) ensure and protect the availability, integrity and confidentiality of the personal data jointly processed;
 - b) protect against any unauthorised or unlawful processing, loss, use, disclosure or acquisition of or access to any personal data in its possession;
 - c) ensure that access to the personal data is not disclosed or allowed to anyone other than the recipients or processors.

SECTION 3

Data Protection Impact Assessment

- (1) If a controller, in order to comply with its obligations specified in Articles 35 and 36 of Regulation (EU) 2016/679, needs information from another controller, it shall send a specific request to the functional mailbox referred to in Subsection 1(4) of Section 1. The latter shall use its best efforts to provide such information.'
-

ANNEX IV

ANNEX VII

RESPONSIBILITIES OF THE COMMISSION AS DATA PROCESSOR FOR THE EU DIGITAL COVID CERTIFICATE GATEWAY FOR SUPPORTING THE EXCHANGE OF EU DCC REVOCATION LISTS

The Commission shall:

- (1) Set up and ensure a secure and reliable communication infrastructure on behalf of the Member States that supports the exchange of revocation lists submitted to the Digital COVID Certificate Gateway.
- (2) To fulfil its obligations as data processor of the trust framework gateway for the Member States, the Commission may engage third parties as sub-processors; the Commission shall inform the joint controllers of any intended changes concerning the addition or replacement of other sub-processors thereby giving the controllers the opportunity to jointly object to such changes. The Commission shall ensure that the same data protection obligations as set out in this Decision apply to these sub-processors.
- (3) Process the personal data, only based on documented instructions from the controllers, unless required to do so by Union or Member State law; in such a case, the Commission shall inform the joint controllers of that legal requirement before carrying on the processing activity, unless that law prohibits submitting such information on important grounds of public interest.

The processing by the Commission entails the following:

- (a) Authentication of national backend servers, based on national backend server certificates;
 - (b) Reception of the data referred to in Article 5a(3) of the Decision uploaded by national backend servers by providing an application programming interface that allows national backend servers to upload the relevant data;
 - (c) Storage of the data in the EU Digital COVID certificate gateway;
 - (d) Making the data available for download by national backend servers;
 - (e) Deletion of the data at their expiration date or upon instruction of the controller that submitted them;
 - (f) After the end of the provision of service, delete any remaining data unless Union or Member State law requires storage of the personal data.
- (4) Take all state of the art organisational, physical and logical security measures to maintain the EU Digital COVID Certificate Gateway. To this end, the Commission shall:
 - (a) designate a responsible entity for the security management at the level of the EU Digital COVID Certificate Gateway, communicate to the joint controllers its contact information and ensure its availability to react to security threats;
 - (b) assume the responsibility for the security of the EU Digital COVID Certificate Gateway, including regularly carrying out tests, evaluations and assessments of the security measures;
 - (c) ensure that all individuals that are granted access to the EU Digital COVID Certificate Gateway are subject to contractual, professional or statutory obligation of confidentiality.
- (5) Take all necessary security measures to avoid compromising the smooth operational functioning of the national backend servers. To this end, the Commission shall put in place specific procedures related to the connection from the backend servers to the EU Digital COVID Certificate Gateway. This includes:
 - (a) risk assessment procedure, to identify and estimate potential threats to the system;
 - (b) audit and review procedure to:
 - i. check the correspondence between the implemented security measures and the applicable security policy;
 - ii. control on a regular basis the integrity of system files, security parameters and granted authorisations;

- iii. monitor to detect security breaches and intrusions;
 - iv. implement changes to mitigate existing security weaknesses;
 - v. define the conditions under which to authorise, including at the request of controllers, and contribute to, the performance of independent audits, including inspections, and reviews on security measures subject to conditions that respect Protocol (No 7) to the TFEU on the Privileges and Immunities of the European Union;
- (c) changing the control procedure to document and measure the impact of a change before its implementation and keep the joint controllers informed of any changes that can affect the communication with and/or the security of their infrastructures;
- (d) laying down a maintenance and repair procedure to specify the rules and conditions to be respected when maintenance and/or repair of equipment should be performed;
- (e) laying down a security incident procedure to define the reporting and escalation scheme, inform without delay the controllers affected, inform without delay the controllers for them to notify the national data protection supervisory authorities, of any personal data breach and define a disciplinary process to deal with security breaches.
- (6) Take state of the art physical and/or logical security measures for the facilities hosting the EU Digital COVID Certificate Gateway equipment and for the controls of logical data and security access. To this end, the Commission shall:
- (a) enforce physical security to establish distinct security perimeters and allowing detection of breaches;
 - (b) control access to the facilities and maintain a visitor register for tracing purposes;
 - (c) ensure that external people granted access to the premises are escorted by duly authorised staff;
 - (d) ensure that equipment cannot be added, replaced or removed without prior authorisation of the designated responsible bodies;
 - (e) control access from and to the national backend servers to the trust framework gateway;
 - (f) ensure that individuals who access the EU Digital COVID Certificate Gateway are identified and authenticated;
 - (g) review the authorisation rights related to the access to the EU Digital COVID Certificate Gateway in case of a security breach affecting this infrastructure;
 - (h) keep the integrity of the information transmitted through the EU Digital COVID Certificate Gateway;
 - (i) implement technical and organisational security measures to prevent unauthorised access to personal data;
 - (j) implement, whenever necessary, measures to block unauthorised access to the EU Digital COVID Certificate Gateway from the domain of the issuing authorities (i.e.: block a location/IP address).
- (7) Take steps to protect its domain, including the severing of connections, in the event of substantial deviation from the principles and concepts for quality or security.
- (8) Maintain a risk management plan related to its area of responsibility.
- (9) Monitor – in real time – the performance of all the service components of its trust framework gateway services, produce regular statistics and keep records.
- (10) Provide support for all trust framework gateway services in English, 24/7 via phone, mail or Web Portal and accept calls from authorised callers: the EU Digital COVID Certificate Gateway's coordinators and their respective helpdesks, Project Officers and designated persons from the Commission.
- (11) Assist the joint controllers by appropriate technical and organisational measures, insofar as it is possible in accordance with Article 12 of Regulation (EU) 2018/1725, for the fulfilment of the controller's obligation to respond to requests for exercising the data subject's rights laid down in Chapter III of the General Data Protection Regulation.

- (12) Support the joint controllers by providing information concerning the EU Digital COVID Certificate Gateway, to implement the obligations pursuant to Articles 32, 33, 34, 35 and 36 of the General Data Protection Regulation.
 - (13) Ensure that data processed within the EU Digital COVID Certificate Gateway is unintelligible to any person who is not authorised to access it.
 - (14) Take all relevant measures to prevent that the EU Digital COVID Certificate Gateway's operators have unauthorised access to transmitted data.
 - (15) Take measures in order to facilitate the interoperability and the communication between EU Digital COVID Certificate Gateway's designated controllers.
 - (16) Maintain a record of processing activities carried out on behalf of the joint controllers in accordance with Article 31(2) of Regulation (EU) 2018/1725.'
-

COMMISSION IMPLEMENTING DECISION (EU) 2022/484**of 23 March 2022****providing for derogations from Regulation (EU) No 1307/2013 of the European Parliament and of the Council and from Commission Delegated Regulation (EU) No 639/2014 as regards the implementation of certain conditions relating to the greening payment for claim year 2022***(notified under document C(2022) 1875)*

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009 ⁽¹⁾, and in particular Article 69(1) thereof,

Whereas:

- (1) Title III, Chapter 3, of Regulation (EU) No 1307/2013 provides for payment for agricultural practices beneficial for the climate and the environment ('greening payment'). Those practices include crop diversification pursuant to Article 43(2), point (a) and ecological focus areas pursuant to Article 43(2), point (c), of that Regulation. Further rules on those practices are laid down in Chapter 3 of Commission Delegated Regulation (EU) No 639/2014 ⁽²⁾.
- (2) Article 44(4) of Regulation (EU) No 1307/2013 establishes that, for the purposes of crop diversification, land lying fallow is counted as a different crop from grasses or other herbaceous forage. This implies that land that has been grazed or harvested for production purposes cannot be counted as land lying fallow.
- (3) Article 46(2), first subparagraph, point (a), of Regulation (EU) No 1307/2013, establishes that areas under land lying fallow may be considered as ecological focus areas. Article 45(2) of Delegated Regulation (EU) No 639/2014 requires an absence of agricultural production, and Article 45(10b) of that Regulation prohibits the use of plant protection products, on land lying fallow qualifying as an ecological focus area.
- (4) Russia's invasion of Ukraine on 24 February 2022 has triggered a sharp commodity price surge and has an impact on the supply and demand for agricultural products. In order to address this situation, the Union agricultural production potential both for food and feed supply should be increased.
- (5) Land laying fallow areas remain arable land areas suitable for crop production that, albeit to varying degrees depending on their conditions such as soil quality, could be used immediately to produce food and feed. Therefore, in order to allow farmers to make use as much as possible of their available areas for the purpose of food production and feeding animals, Member States should be authorised to derogate from conditions relating to the greening payment, including the use of plant protection products, for claim year 2022 as regards land lying fallow which has been declared to meet the crop diversification or ecological focus area requirements in accordance with Article 44(4) and Article 46(2), first subparagraph, point (a), of Regulation (EU) No 1307/2013, respectively.
- (6) This Decision should only provide for derogations to the crop diversification and ecological focus area obligations to the extent and for such a period as is strictly necessary. The derogations should be limited to claim year 2022 and aimed at addressing the impact on the supply and demand for agricultural products by allowing for an increase of the total arable land area available for the production of food and feed.

⁽¹⁾ OJ L 347, 20.12.2013, p. 608.

⁽²⁾ Commission Delegated Regulation (EU) No 639/2014 of 11 March 2014 supplementing Regulation (EU) No 1307/2013 of the European Parliament and of the Council establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and amending Annex X to that Regulation (OJ L 81, 20.6.2014, p. 1).

- (7) When deciding on the application of the derogations, those Member States should take due account of the objectives of the agricultural practices beneficial for the climate and the environment and, in particular, the need for sufficient protection of soil quality and quality of natural resources and biodiversity, especially during the most sensitive periods for flowering and nesting birds.
- (8) In order to ensure that the derogations authorised by this Decision are effective with a view to the objectives pursued, i.e. a mitigation of rising commodity prices and the impact on the supply and demand, Member States should take their decisions on the application of the derogations within 21 days from the date of notification of this Decision, and should notify the Commission of those decisions taken within 7 days after the date on which the decisions were taken.
- (9) In order to enable the Commission to monitor the correct application of the derogations provided hereby as well as their impact, Member States should provide information on the number of holdings and hectares covered by the derogations. That information should be made available to the Commission by 15 December 2022 using the existing notification instruments.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Committee for Direct Payments,

HAS ADOPTED THIS DECISION:

Article 1

Decisions derogating from certain conditions relating to the greening payment for claim year 2022

1. By way of derogation from Article 44(4) of Regulation (EU) No 1307/2013, for claim year 2022, Member States may decide that land lying fallow is considered as a distinct crop even though such land has been grazed or harvested for production purpose or has been cultivated.
2. By way of derogation from Article 45(2) of Delegated Regulation (EU) No 639/2014, for claim year 2022, Member States may decide that land lying fallow is considered as ecological focus area pursuant to Article 46(2), first subparagraph, point (a), of Regulation (EU) No 1307/2013 even though such land has been grazed or harvested for production purpose or has been cultivated. The weighting factor set out for land lying fallow in Annex X to Regulation (EU) No 1307/2013 shall apply.

By way of derogation from Article 45(10b) of Delegated Regulation (EU) No 639/2014, where Member States make use of the derogation referred to in the first subparagraph of this paragraph, they may also decide to allow for the use of plant protection products on those areas where grazed or harvested for production purpose or where cultivated.

Article 2

Time limit

The decisions referred to in Article 1 shall be taken within 21 days from the date of notification of this Decision.

Article 3

Notifications

1. Member States shall notify the Commission of the decisions taken pursuant to Article 1 within 7 days after the date on which the decisions were taken.
2. By 15 December 2022, Member States shall notify the Commission of the number of holdings which used the derogations provided for in Article 1 and the number of hectares where those derogations have been applied.

*Article 4***Addressees**

This Decision is addressed to the Member States.

Done at Brussels, 23 March 2022.

For the Commission
Janusz WOJCIECHOWSKI
Member of the Commission

DECISION (EU) 2022/485 OF THE EUROPEAN CENTRAL BANK**of 17 March 2022****amending Decision 2010/624/EU concerning the administration of the borrowing and lending operations concluded by the Union under the European financial stabilisation mechanism****(ECB/2022/11)**

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 122(2) and 132(1) thereof,

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular Articles 17 and 21 and Article 34.1 thereof,

Having regard to Council Regulation (EU) No 407/2010 of 11 May 2010 establishing a European financial stabilisation mechanism ⁽¹⁾, and in particular Article 8 thereof,

Whereas:

- (1) Deposits held with the European Central Bank (ECB) as provided for in Decision 2010/624/EU of the European Central Bank (ECB/2010/17) ⁽²⁾ should be remunerated in accordance with the provisions of Article 2(1) of Decision (EU) 2019/1743 of the European Central Bank (ECB/2019/31) ⁽³⁾ in order to ensure consistency in the remuneration of comparable deposits across the Eurosystem.
- (2) Therefore, Decision 2010/624/EU (ECB/2010/17) should be amended accordingly,

HAS ADOPTED THIS DECISION:

*Article 1***Amendment**

Article 4 of Decision 2010/624/EU (ECB/2010/17) is replaced by the following:

'Article 4

The accounts referred to in Article 2 shall be remunerated in accordance with the provisions of Article 2(1) of Decision (EU) 2019/1743 of the European Central Bank (ECB/2019/31) ^(*).

^(*) Decision (EU) 2019/1743 of the European Central Bank of 15 October 2019 on the remuneration of holdings of excess reserves and of certain deposits (ECB/2019/31) (OJ L 267, 21.10.2019, p. 12).'

*Article 2***Entry into force**

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

⁽¹⁾ OJ L 118, 12.5.2010, p. 1.

⁽²⁾ Decision 2010/624/EU of the European Central Bank of 14 October 2010 concerning the administration of the borrowing and lending operations concluded by the Union under the European financial stabilisation mechanism (ECB/2010/17) (OJ L 275, 20.10.2010, p. 10).

⁽³⁾ Decision (EU) 2019/1743 of the European Central Bank of 15 October 2019 on the remuneration of holdings of excess reserves and of certain deposits (ECB/2019/31) (OJ L 267, 21.10.2019, p. 12).

Done at Frankfurt am Main, 17 March 2022.

The President of the ECB
Christine LAGARDE

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