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Contents



[1] Text with EEA relevance.

EN

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

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

II

*(Non-legislative acts)*

# REGULATIONS

## COMMISSION DELEGATED REGULATION (EU) 2021/457

## of 13 January 2021

## amending Delegated Regulation (EU) 2016/161 as regards a derogation from the obligation of wholesalers to decommission the unique identifier of products exported to the United Kingdom

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ([1]), and in particular Article 54a(2)(d) thereof,

Whereas:

(1) Article 54a(1) of Directive 2001/83/EC provides that medical products subject to prescription shall bear safety features.

(2) Pursuant to Article 22(a) of Commission Delegated Regulation (EU) 2016/161 ([2]), a wholesaler is to decommission the unique identifier of medicinal products which he intends to distribute outside of the Union.

(3) On 1 February 2020, the United Kingdom withdrew from the European Union and from the European Atomic Energy Community. Pursuant to Articles 126 and 127 of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (the 'Withdrawal Agreement'), Union law is applicable to and in the United Kingdom during a transition period that is to end on 31 December 2020 ('transition period').

(4) In accordance with Article 185 of the Withdrawal Agreement and Article 5(4) of the Protocol on Ireland/Northern Ireland, Union legislation on medicinal products apply in Northern Ireland after the end of the transition period.

(5) The withdrawal of the United Kingdom from the Union would, in the absence of a derogation from the applicable rules, thus have the effect that the unique identifiers must be decommissioned for medicinal products intended to be distributed in the United Kingdom.

(6) A number of medicinal products are supplied to Cyprus, Ireland, Malta or Northern Ireland through Great Britain. After the end of the transition period, in accordance with Article 54a(1) of Directive 2001/83/EC, it would be for importers holding a manufacturing authorisation in those areas to affix a new unique identifier on the medicinal products when they are placed on the market. However, there are currently no importers holding a manufacturing

([1]) OJ L 311, 28.11.2001, p. 67.

([2]) Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).

authorisation in Cyprus, Ireland, Malta and Northern Ireland and therefore no importers in those areas that could meet that obligation from 1 January 2021. In order to ensure supplies in compliance with the obligation to affix a new unique identifier, the supply chains need to be redesigned.

(7) In order to ensure that medicinal products are marketed with a unique identifier in the small markets currently dependent on the United Kingdom for their supplies of medicinal products, it is therefore necessary to grant a temporary derogation from the obligation of wholesalers to decommission the unique identifier of the products which they intend to distribute in the United Kingdom as those products may be re-exported to the Union. This derogation should not affect the application of Union law to and in the United Kingdom in respect of Northern Ireland in accordance with Article 5(4) of the Protocol on Ireland/Northern Ireland to the Withdrawal Agreement in conjunction with Annex 2 to that Protocol.

(8) Delegated Regulation (EU) 2016/161 should therefore be amended accordingly.

(9) Having regard to the imminent end of the transition period, this Regulation should enter into force as a matter of urgency. As the transition period of the withdrawal agreement ends on 31 December 2020, this Regulation should apply from 1 January 2021,

HAS ADOPTED THIS REGULATION:

*Article 1*

In Article 22 of Delegated Regulation (EU) 2016/161, the following paragraph is added:

'By way of derogation from point (a), from 1 January 2021 to 31 December 2021 the obligation to decommission the unique identifier of medicinal products which the wholesaler intends to distribute outside of the Union shall not apply to products which he intends to distribute in the United Kingdom (*).

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

*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 2021.

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

Done at Brussels, 13 January 2021.

*For the Commission*
*The President*
Ursula VON DER LEYEN

# COMMISSION IMPLEMENTING REGULATION (EU) 2021/458

## of 10 March 2021

## approving non-minor amendments to the product specification for a name entered in the register of protected designations of origin and protected geographical indications 'Πατάτα Νάξου' (Patata Naxou) (PGI)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ([1]), and in particular Article 52(2) thereof,

Whereas:

(1) Pursuant to the first subparagraph of Article 53(1) of Regulation (EU) No 1151/2012, the Commission has examined Greece's application for the approval of amendments to the specification for the protected geographical indication 'Πατάτα Νάξου' (Patata Naxou), registered under Commission Implementing Regulation (EU) No 1250/2011 ([2]).

(2) Since the amendments in question are not minor within the meaning of Article 53(2) of Regulation (EU) No 1151/2012, the Commission published the amendment application in the *Official Journal of the European Union* ([3]) as required by Article 50(2)(a) of that Regulation.

(3) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the amendments to the specification should be approved,

HAS ADOPTED THIS REGULATION:

*Article 1*

The amendments to the product specification published in the *Official Journal of the European Union* regarding the name 'Πατάτα Νάξου' (Patata Naxou) (PGI) are hereby approved.

*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, 10 March 2021.

*For the Commission,*
*On behalf of the President,*
Janusz WOJCIECHOWSKI
*Member of the Commission*

([1]) OJ L 343, 14.12.2012, p. 1.
([2]) Commission Implementing Regulation (EU) No 1250/2011 of 29 November 2011 entering a name in the register of protected designations of origin and protected geographical indications (Πατάτα Νάξου (Patata Naxou) (PGI)) (OJ L 319, 2.12.2011, p. 41).
([3]) OJ C 383, 13.11.2020, p. 12.

# COMMISSION IMPLEMENTING REGULATION (EU) 2021/459

## of 16 March 2021

## amending Implementing Regulation (EU) No 540/2011 as regards the conditions of approval of the active substance fenpyrazamine

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ([1]), and in particular the second alternative of Article 21(3) and Article 78(2) thereof,

Whereas:

(1) Commission Implementing Regulation (EU) No 595/2012 ([2]) approved fenpyrazamine as an active substance in accordance with Regulation (EC) No 1107/2009 subject to certain conditions, requiring, in particular, the examining Member State to inform the Commission in accordance with Article 38 of Regulation (EC) No 1107/2009 on the specification of the technical material as commercially manufactured.

(2) In December 2013, the applicant submitted an updated dossier intended to provide the information on specification of the technical material as commercially manufactured to the rapporteur Member State Austria within the time period provided for its submission. The updated dossier was evaluated by the rapporteur Member State in the form of an Addendum to the Draft Assessment Report.

(3) On 23 April 2014, Austria distributed the addendum to the Member States, the applicant and the European Food Safety Authority ('the Authority') for comments, collated together with all comments in the format of a reporting table, which was submitted to the Authority on 7 July 2014. The Authority added its scientific views on the specific points raised during the commenting phase in the reporting table.

(4) On 13 August 2014, the Authority published a technical report ([3]) summarising the outcome of this consultation process for fenpyrazamine.

(5) The draft assessment report, the addendum and the technical report were reviewed by the Member States and the Commission within the Standing Committee on Plants, Animals, Food and Feed and finalised on 18 May 2020 in the format of the Commission review report for fenpyrazamine.

(6) The Commission invited the applicant to submit its comments on the Commission review report for fenpyrazamine.

(7) In its review report the Commission considered that the technical specification proposed in the approval of fenpyrazamine needs to be changed from pilot to commercial production. The impurity hydrazine, a starting material, has been identified during the assessment as a relevant impurity, since it was detected in the reanalysed pilot plant batches as well as in the commercial plant batches. Bearing in mind that the relevant impurity hydrazine is of toxicological concern, the Commission has concluded that a maximum content of this impurity in the technical material should not exceed 0,0001 % (1 mg/kg).

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Implementing Regulation (EU) No 595/2012 of 5 July 2012 approving the active substance fenpyrazamine, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 (OJ L 176, 6.7.2012, p. 46).

([3]) EFSA (European Food Safety Authority), 2015. Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment of confirmatory data for the active substance fenpyrazamine. EFSA supporting publication 2014:EN-630.

(8) In order to ensure a high level of protection for consumers it is, therefore, appropriate to establish a maximum level for this impurity in the commercially manufactured active substance.

(9) The Annex to Commission Implementing Regulation (EU) No 540/2011 ([4]) should therefore be amended accordingly.

(10) Member States should be allowed sufficient time to amend or withdraw authorisations for plant protection products containing fenpyrazamine, which are not complying with the specification of the technical material as commercially manufactured and the restricted conditions of approval.

(11) For plant protection products containing fenpyrazamine, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should expire, at the latest, 15 months after the entry into force of this Regulation.

(12) 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*

**Amendment to Implementing Regulation (EU) No 540/2011**

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

*Article 2*

**Transitional measures**

Member States shall, where necessary, amend or withdraw existing authorisations for plant protection products containing fenpyrazamine as active substance by 6 July 2021 at the latest.

*Article 3*

**Grace period**

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall be as short as possible and shall expire by 6 July 2022 at the latest.

*Article 4*

**Entry into force**

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

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

Done at Brussels, 16 March 2021.

*For the Commission*
*The President*
Ursula VON DER LEYEN

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

*ANNEX*

The column 'Purity' of row 25, fenpyrazamine, of Part B of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

'≥ 960 g/kg

The following manufacturing impurity is of toxicological concern and must not exceed the following amount in the technical material:

Hydrazine: maximum content: < 0,0001 % (1 mg/kg)'

The column 'Specific provisions' of row 25, fenpyrazamine, of Part B of the Annex to Implementing Regulation (EU) No 540/2011 is replaced by the following:

'PART B

For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on fenpyrazamine, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 1 June 2012 and the Standing Committee on Plants, Animals, Food and Feed on 18 May 2020 shall be taken into account. The purity given in this entry is based on a commercial plant production.'

# COMMISSION IMPLEMENTING REGULATION (EU) 2021/460

## of 16 March 2021

## amending Annex I to Regulation (EC) No 798/2008 as regards the entry for Ukraine in the list of third countries, territories, zones or compartments from which certain poultry commodities may be imported into and transit through the Union in relation to highly pathogenic avian influenza

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption ([1]), and in particular the introductory phrase of Article 8, the first subparagraph of paragraph 1 of Article 8, paragraph 4 of Article 8 and Article 9(4) thereof,

Having regard to Council Directive 2009/158/EC of 30 November 2009 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs ([2]), and in particular Articles 23(1), 24(2) and 25(2) thereof,

Whereas:

(1) Commission Regulation (EC) No 798/2008 ([3]) lays down veterinary certification requirements for imports into and transit, including storage during transit, through the Union of poultry and poultry products ('the commodities'). It provides that the commodities are only to be imported into and transit through the Union from the third countries, territories, zones or compartments listed in columns 1 and 3 of the table in Part 1 of Annex I thereto.

(2) Regulation (EC) No 798/2008 also lays down the conditions for a third country, territory, zone or compartment to be considered as free from highly pathogenic avian influenza (HPAI).

(3) Ukraine is listed in the table in Part 1 of Annex I to Regulation (EC) No 798/2008 as a third country from which imports into and transit through the Union of certain poultry commodities are authorised from certain parts of its territory depending on the presence of HPAI. That regionalisation was set out in Part 1 of Annex I to Regulation (EC) No 798/2008, as amended by Implementing Regulation (EU) 2020/352 ([4]), following the confirmation of an outbreak of HPAI of subtype H5N8 on 19 January 2020.

(4) Following the outbreak of HPAI, Ukraine has implemented a stamping out policy in order to control and limit the spread of that disease. In addition, Ukraine completed the requisite cleaning and disinfection measures following the implementation of the stamping out policy on the poultry holding where the HPAI outbreak was confirmed in January 2020. Ukraine has submitted updated information on the epidemiological situation on its territory and the measures it has taken to prevent the further spread of HPAI, which were evaluated by the Commission.

(5) On the basis of that evaluation it is concluded that that outbreak has been cleared and that there is no risk associated with the introduction into the Union of poultry commodities from the areas of Ukraine listed in Part 1 of Annex I to Regulation (EC) No 798/2008 from where imports have been suspended by that Regulation, as amended by Implementing Regulation (EU) 2020/352.

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([1]) OJ L 18, 23.1.2003, p. 11.

([2]) OJ L 343, 22.12.2009, p. 74.

([3]) Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements (OJ L 226, 23.8.2008, p. 1).

([4]) Commission Implementing Regulation (EU) 2020/352 of 3 March 2020 amending Annex I to Regulation (EC) No 798/2008 as regards the entry for Ukraine in the lists of third countries, territories, zones or compartments from which certain poultry commodities may be imported into and transit through the Union in relation to highly pathogenic avian influenza (OJ L 65, 4.3.2020, p. 4).

(6) On 4 December 2020, however, Ukraine confirmed the presence of HPAI of subtype H5 in a poultry holding on its territory. Due to that confirmed outbreak of HPAI, the whole territory of Ukraine can no longer be considered as free from that disease and the veterinary authorities of Ukraine can, therefore, no longer certify consignments of poultry commodities for import into, or transit through, the Union from the areas concerned by that outbreak. Following that outbreak, Ukraine has confirmed further HPAI outbreaks of subtype H5 in poultry holdings on its territory.

(7) The veterinary authorities of Ukraine have confirmed that following the outbreak in December 2020, they suspended issuing certificates for consignments of commodities intended for import into, or transit through, the Union and implemented a stamping-out policy in order to control HPAI and limit the spread of that disease.

(8) Furthermore, Ukraine has submitted information to the Commission on the epidemiological situation on its territory and indicated the areas placed under restrictions as well as the measures it has taken to prevent the further spread of HPAI outside those restricted areas. That information has now been evaluated by the Commission and on the basis of that evaluation, as well as the guarantees provided by Ukraine, it should be concluded that limiting the restrictions on the introduction into the Union of consignments of poultry commodities to the areas affected by HPAI, which the veterinary authorities of Ukraine have placed under restrictions due to the current outbreaks, should be sufficient to cover the risks associated with the introduction into the Union of such commodities.

(9) The entry for Ukraine in the table in Part 1 of Annex I to Regulation (EC) No 798/2008 should, therefore, be amended to take account of the current epidemiological situation in that third country.

(10) Annex I to Regulation (EC) No 798/2008 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*

Part 1 of Annex I to Regulation (EC) No 798/2008 is amended in accordance with the Annex to this Regulation.

*Article 2*

This Regulation shall enter into force on the third 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, 16 March 2021.

*For the Commission*
*The President*
Ursula VON DER LEYEN

*ANNEX*

In Part 1 of Annex I to Regulation (EC) No 798/2008, the entry for Ukraine is replaced by the following:

| ISO code and name of third country or territory | Code of third country, territory, zone or compartment | Description of third country, territory, zone or compartment | Veterinary certificate | | Specific conditions | Specific conditions | | Avian influenza surveillance status | Avian influenza vaccination status | Salmonella control status |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | Model(s) | Additional guarantees | | Closing date | Opening date | | | |
| 1 | 2 | 3 | 4 | 5 | 6 | 6A | 6B | 7 | 8 | 9 |
| 'UA – Ukraine | UA-0 | Whole country | EP, E | | | | | | | |
| | UA-1 | The whole country of Ukraine excluding area UA-2 | WGM | | | | | | | |
| | | | POU, RAT | | | | | | | |
| | UA-2 | Area of Ukraine corresponding to: | | | | | | | | |
| | UA-2.1 | Kherson Oblast (region) | WGM | | P2 | 30.11.2016 | 7.3.2020 | | | |
| | | | POU, RAT | | P2 | 30.11.2016 | 7.3.2020 | | | |
| | UA-2.2 | Odessa Oblast (region) | WGM | | P2 | 4.1.2017 | 7.3.2020 | | | |
| | | | POU, RAT | | P2 | 4.1.2017 | 7.3.2020 | | | |
| | UA-2.3 | Chernivtsi Oblast (region) | WGM | | P2 | 4.1.2017 | 7.3.2020 | | | |
| | | | POU, RAT | | P2 | 4.1.2017 | 7.3.2020 | | | |
| | UA-2.4 | Vinnytsia Oblast (region), Nemyriv Raion (district), municipalities:<br>Berezivka village<br>Bratslav village<br>Budky village<br>Bugakiv village<br>Chervone village<br>Chukiv village<br>Danylky village<br>Dovzhok village<br>Horodnytsia village<br>Hrabovets village | WGM | | P2 | 19.1.2020 | 20.3.2021 | | | |
| | | | POU, RAT | | P2 | 19.1.2020 | 20.3.2021' | | | |

| 1 | 2 | 3 | 4 | 5 | 6 | 6A | 6B | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Hranitne village<br>Karolina village<br>Korovayna village<br>Korzhiv village<br>Korzhivka village<br>Kryklivtsi village<br>Maryanivka village<br>Melnykivtsi village<br>Monastyrok village<br>Monastyrske village<br>Nemyriv City<br>Novi Obyhody village<br>Ostapkivtsi village<br>Ozero village<br>Perepelychcha village<br>Rachky village<br>Salyntsi village<br>Samchyntsi village<br>Sazhky village<br>Selevintsi village<br>Sholudky village<br>Slobidka village<br>Sorokoduby village<br>Sorokotiazhyntsi village<br>Velyka Bushynka village<br>Vovchok village<br>Vyhnanka village<br>Yosypenky village<br>Zarudyntsi village<br>Zelenianka village | | | | | | | | |
| | UA-2.5 | Mykolaiv Oblast (region)<br>Kherson Oblast (region), Khersonskyi (Bilozerskyi) Raion (district), municipalities:<br>Tavriyske village<br>Nova zoria village | WGM | | P2 | 4.12.2020 | | | | |
| | | | POU, RAT | | P2 | 4.12.2020 | | | | |
| | UA-2.6 | Kyiv Oblast (region):<br>Ivankiv Raion (district), municipalities:<br>Leonivka village<br>Blidcha village<br>Kolentsi village | WGM | | P2 | 24.12.2020 | | | | |
| | | | POU, RAT | | P2 | 24.12.2020 | | | | |

| 1 | 2 | 3 | 4 | 5 | 6 | 6A | 6B | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Zymovyshche village<br>Rudnia-Talska village<br>Sosnivka village<br>Borodianka Raion (district), municipalities:<br>Koblytsia village<br>Talske village<br>Myrcha village<br>Stara Buda village,<br>Velykyi Lis village<br>Krasnyi Rih village<br>Mykhailivskyi small village | | | | | | | | |
| | UA-2.7 | Kyiv Oblast (region):<br>Borodianka Raion (district), municipalities:<br>Borodianka town<br>Kachaly village<br>Shybene village<br>Nebrat village<br>Nove Zalissia village<br>Berestianka village<br>Zdvyzhivka village<br>Babyntsi village<br>Buda-Babynetska village<br>Klavdiyevo-Tarasove town<br>Poroskoten village<br>Pylypovychi village<br>Nova Hreblia village<br>Vablia village<br>Druzhnia village<br>Halynka village<br>Zahaltsi village<br>Mykhailivskyi (Mykhailenkiv) village<br>country estate “Blyzhni sady”<br>Buchanskyi Raion (district), municipalities:<br>Nemishayeve town<br>Mykulychi village<br>Dibrova village<br>Kozyntsi village<br>Chervona hilka village<br>Plakhtianka village | WGM | | P2 | 27.12.2020 | | | | |
| | | | POU, RAT | | P2 | 27.12.2020 | | | | |

| 1 | 2 | 3 | 4 | 5 | 6 | 6A | 6B | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Myrotske village<br>part of Vorzel town restricted by Bilostotskykh and Pushkina str. | | | | | | | | |
| | UA-2.8 | Kherson Oblast (region):<br>Kakhovskyi Raion (district), municipalities:<br>Zaozerne village<br>Skvortsivka village<br>Maryanivka village<br>Slynenko village<br>Olhivka village<br>Novotroyitskyi Raion (district), municipalities:<br>Volodymyro-Ilyinka village<br>Sofiivka village<br>Katerynivka village | WGM | | P2 | 29.12.2020 | | | | |
| | | | POU, RAT | | P2 | 29.12.2020 | | | | |
| | UA-2.9 | Kyiv Oblast (region), Kyiv city:<br>The area contained within a circle of a 10 km radius centred on Hostomel village of Buchanskyi Raion, and extending in a clockwise fashion:<br>(a) North, Northwest, West, Southwest: Kyiv region (oblast), Buchanskyi Raion (district), municipalities: Moshchun village, Hostomel town, Kotsiubynske town, Irpin city, Bucha city, Horenka village.<br>(b) Northeast, East, Southeast, South: Boundary of Kyiv Region (oblast) with Obolonskyi, Podilskyi, Shevchenkivskyi Raions (districts) of Kyiv city from intersection of Polarna str., Avtozavodska Str., Semena Skliarenko str. the intersection with the Oleny Telihy str., Oleksandra Dovzhenko str. to the intersection with Peremohy Avenue | WGM | | P2 | 18.1.2021 | | | | |
| | | | POU, RAT | | P2 | 18.1.2021 | | | | |
| | UA-2.10 | Donetsk Oblast (region):<br>Volnovaskyi (ex Velykonovosilkivskyi) district, municipalities:<br>Vesele village | WGM | | P2 | 3.2.2021 | | | | |
| | | | POU, RAT | | P2 | 3.2.2021 | | | | |

| 1 | 2 | 3 | 4 | 5 | 6 | 6A | 6B | 7 | 8 | 9 |
|---|---|---|---|---|---|---|---|---|---|---|
| | | Fedorivka villageto<br>Skudne village<br>Dniproenerhiia village<br>Velyka Novosilka town<br>Rozdolne village<br>Novyi Komar village<br>Perebudova village<br>Novoocheretuvate village<br>Myrne village<br>Ordadne village<br>Komar village<br>Vremivka village<br>Voskresenka village<br>Vilne Pole village<br>Shevchenko village<br>Burlatske village<br>Pryvilne village<br>Dnipropetrovsk Oblast (region):<br>Prokrovskyi district, municipalities:<br>Maliivka village | | | | | | | | |

# COMMISSION IMPLEMENTING REGULATION (EU) 2021/461

## of 16 March 2021

## amending Regulation (EC) No 1235/2008 as regards the date for receiving requests for the recognition of control authorities and control bodies for the purpose of equivalence under the arrangements for imports of organic products based on Council Regulation (EC) No 834/2007

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) Regulation (EU) 2018/848 of the European Parliament and of the Council ([2]) establishes that the scheme of control authorities and control bodies recognised by the Commission on the basis of Article 33(3) of Regulation (EC) No 834/2007 to carry out controls and to issue certificates in third countries for the purpose of importing products with equivalent guarantees will be replaced by a scheme of control authorities and control bodies recognised by the Commission for the purpose of importing compliant products.

(2) Due to the outbreak of the COVID-19 pandemic and the related public health crisis, the date of application of Regulation (EU) 2018/848 and certain other dates referred to in that Regulation were deferred by one year by Regulation (EU) 2020/1693 of the European Parliament and of the Council ([3]). As a result, Regulation (EU) 2018/848 will apply from 1 January 2022.

(3) In order to ensure that the necessary administrative capacities were available to provide for a timely recognition of control authorities and control bodies under the new scheme, Article 11(1) of Commission Regulation (EC) No 1235/2008 ([4]) was amended by Implementing Regulation (EU) 2020/25 ([5]) in order to introduce a final date for receiving new requests for the recognition of control authorities and control bodies for the purpose of equivalence under the old scheme. That final date is 30 June 2020.

(4) It is therefore necessary to amend Article 11(1) of Regulation (EC) No 1235/2008 once again in order to align the date for receiving new requests for the recognition of control authorities and control bodies for the purpose of equivalence under the old import scheme with the date of the establishment of the new import system in Regulation (EU) 2018/848.

(5) Regulation (EC) No 1235/2008 should therefore be amended accordingly.

([1]) OJ L 189, 20.7.2007, p. 1.

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

([3]) Regulation (EU) 2020/1693 of the European Parliament and of the Council of 11 November 2020 amending Regulation (EU) 2018/848 as regards its date of application and certain other dates referred to in that Regulation (OJ L 381, 13.11.2020, p. 1).

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

([5]) Commission Implementing Regulation (EU) 2020/25 of 13 January 2020 amending and correcting Regulation (EC) No 1235/2008 laying down detailed rules for implementation of Council Regulation (EC) No 834/2007 as regards the arrangements for imports of organic products from third countries (OJ L 8, 14.1.2020, p. 18).

(6) In order to give the control authorities and control bodies concerned the opportunity to benefit fully from the time period left until 30 June 2021 after the relevant IT tool has been reactivated, this Regulation should enter into force as a matter of urgency on the day following that of its publication in the *Official Journal of the European Union*.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Committee on organic production,

HAS ADOPTED THIS REGULATION:

*Article 1*

In Article 11(1) of Regulation (EC) No 1235/2008, the date '30 June 2020' is replaced by '30 June 2021'.

*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, 16 March 2021.

*For the Commission*
*The President*
Ursula VON DER LEYEN

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