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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.

([1]) Text with EEA relevance.

II

*(Non-legislative acts)*

# REGULATIONS

## COMMISSION DELEGATED REGULATION (EU) 2020/1173

**of 4 June 2020**

**amending Regulation (EU) 2016/1036 on protection against dumped imports from countries not members of the European Union and Regulation (EU) 2016/1037 on protection against subsidised imports from countries not members of the European Union as regards the duration of the period of pre-disclosure**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 290(1) thereof,

Having regard to Regulation (EU) 2016/1036 of the European Parliament and of the Council of 8 June 2016 on protection against dumped imports from countries not members of the European Union ([1]), and in particular Articles 7(1) and 23a thereof,

Having regard to Regulation (EU) 2016/1037 of the European Parliament and of the Council of 8 June 2016 on protection against subsidised imports from countries not members of the European Union ([2]), and in particular Articles 12(1) and 32b thereof,

Whereas:

(1) On 7 June 2018, Regulation (EU) 2018/825 of the European Parliament and the Council ([3]) was published, amending Regulation (EU) 2016/1036 (hereafter 'the basic anti-dumping Regulation') and Regulation (EU) 2016/1037 (hereafter 'the basic anti-subsidy Regulation').

(2) In order to improve the transparency and predictability of anti-dumping and countervailing duty investigations, parties which will be affected by the imposition of provisional anti-dumping and countervailing measures, in particular importers, should be made aware of the impending imposition of such measures. In addition, in investigations where it is not appropriate to impose provisional measures, it is desirable that parties are aware sufficiently in advance of such non-imposition. Therefore, a pre-disclosure period of three weeks was introduced.

(3) According to Article 7(1) of the basic anti-dumping Regulation and Article 12(1) of the basic anti-subsidy Regulation, the Commission had to review by 9 June 2020, whether a substantial rise in imports occurred during the period of pre-disclosure and whether, if such rise did occur, that that rise caused additional injury to the Union industry, despite possible registration or adjustment to the injury margin.

(4) Based on this review, the Commission is required to amend the duration of the period of pre-disclosure to two weeks in the case of a substantial rise of imports which caused additional injury and to four weeks where that did not prove to be the case.

(5) As set out in Articles 7(1) and 23a(2) of the basic anti-dumping Regulation and Article 12(1) and 32b(2) of the basic anti-subsidy Regulation, this review is an obligation for the Commission that could only be exercised once.

([1]) OJ L 176, 30.6.2016, p. 21.
([2]) OJ L 176, 30.6.2016, p. 55.
([3]) Regulation (EU) 2018/825 of the European Parliament and of the Council of 30 May 2018 amending Regulation (EU) 2016/1036 on protection against dumped imports from countries not members of the European Union and Regulation (EU) 2016/1037 on protection against subsidised imports from countries not members of the European Union (OJ L 143, 7.6.2018, p. 1).

(6) Since the entry into force of Regulation (EU) 2018/825 on 8 June 2018, the Commission initiated 19 investigations ([4]) according to Article 5 of the basic anti-dumping Regulation and six investigations according to Article 10 of the basic anti-subsidy Regulation.

(7) For twelve of these investigations, they both passed the provisional stage and there are also import data available for the pre-disclosure period. They could therefore be analysed to review whether a substantial rise in imports occurred during the period of pre-disclosure ([5]).

(8) The number of cases at the Commission's disposal to base its assessment on whether a substantial rise in imports has occurred during the period of pre-disclosure, is therefore, and as expected at the time when Regulation (EU) 2018/825 was agreed, limited. However, a clear trend can be seen in those cases.

(9) In six of these twelve investigations, the Commission decided to impose provisional measures. In the other six, parties were informed three weeks before the deadline to impose provisional measures of the Commission's intention not to do so.

(10) On the basis of statistical data summarised in Table 1 below, the Commission found that the volume of imports from the countries concerned into the Union increased in only two investigations. In the other investigations, a substantial decrease occurred.

*Table 1*

**Import volumes per case**

| Case name and number | Decision to impose provisional measures | Imports originating from | Imports during IP (tonnes) | Imports during pre-disclosure (tonnes) | Rise in imports |
|---|---|---|---|---|---|
| Mixtures of urea and ammonium nitrate (AD649) | Yes | Russia | 35 297 | 8 497 | – 76 % |
| | | USA | 42 700 | 0 | – 100 % |
| | | Trinidad | 21 183 | 0 | – 100 % |
| | | **total** | **99 180** | **8 498** | **– 91 %** |
| Biodiesel (AS650) | Yes | Indonesia | 29 693 | 24 045 | – 19 % |
| Steel road wheels (AD652) | Yes | PRC | 13 763 | 914 | – 93 % |
| Glass fibre fabrics (AD653) | No | Egypt | 882 | 4 | – 100 % |
| | | PRC | 2 161 | 1 724 | – 20 % |
| | | **total** | **3 043** | **1 728** | **– 43 %** |
| Continuous filament glass fibre products (AD655) | No | Egypt | 8 295 | 3 076 | – 63 % |
| | | Bahrein | 1 350 | 327 | –76 % |
| | | **total** | **9 644** | **3 403** | **– 65 %** |
| Glass fibre fabrics (AS656) | No | Egypt | 882 | 37 | – 96 % |
| | | PRC | 2 161 | 2 500 | 16 % |
| | | **total** | **3 043** | **2 537** | **– 17 %** |
| Continuous filament glass fibre products (AS657) | Yes | Egypt | 8 295 | 11 574 | 38 % |

Source: Eurostat, verified data provided by the Union industry, and Surveillance II

([4]) The Commission follows the computation method used by the WTO. This means that if a case concerning the same product is directed against imports from more than one country, each country covered counts as one separate investigation.

([5]) Three cases (Hollow sections originating in the Republic of North Macedonia, Russia, and Turkey) have been terminated, the other 10 cases have just or not yet reached the end of the provisional stage and therefore no reliable statistical data is available for the period of pre-disclosure (date of writing 30 April 2020).

(11) No substantial rise occurred in the majority of reviewed cases. Moreover, in one of the two cases where a rise did occur, the imports were ultimately not the result of pre-disclosure but the result of the fact that the Commission did not impose provisional duties. Indeed, also under the previous system without pre-disclosure, imports could, in any event, enter the Union without attracting a duty once it was clear to all interested parties that no provisional duties would be imposed due to the expiry of the applicable deadline.

(12) This leaves one case where a further increase incurred in the period of pre-disclosure before the imposition of provisional measures.

(13) Consequently, the Commission concluded that overall no additional injury to the Union industry had been caused by the imports during the pre-disclosure period. Accordingly, the duration of the period of pre-disclosure should be amended to four weeks.

(14) In the absence of any other specific transitional rules regulating the matter, it is appropriate to clarify that all investigations initiated subject to a notice of initiation pursuant to Article 5(9) of Regulation (EU) 2016/1036 or Article 10(11) of Regulation (EU) 2016/1037 prior to the date of publication in the *Official Journal of the European Union* of this Regulation should be unaffected by the prolonged pre-disclosure period. That should ensure legal certainty, provide a reasonable opportunity for interested parties to adapt themselves to the expiry of the old rules and the entry into force of the new rules, and facilitate the efficient, orderly and equitable implementation of Regulations (EU) 2016/1036 and (EU) 2016/1037.

(15) Regulations (EU) 2016/1036 and (EU) 2016/1037 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

*Article 1*

Article 19a of Regulation (EU) 2016/1036 is replaced with:

'*Article 19a*

**Information at provisional stage**

1. Union producers, importers and exporters and their representative associations, and representatives of the exporting country, may request information on the planned imposition of provisional duties. Requests for such information shall be made in writing within the time limit prescribed in the notice of initiation. Such information shall be provided to those parties four weeks before the imposition of provisional duties. Such information shall include: a summary of the proposed duties for information purposes only, and details of the calculation of the dumping margin and the margin adequate to remove the injury to the Union industry, due account being taken of the need to respect the confidentiality obligations contained in Article 19. Parties shall have a period of three working days from the supply of such information to provide comments on the accuracy of the calculations.

2. In cases where it is intended not to impose provisional duties but to continue the investigation, interested parties shall be informed of the non-imposition of duties four weeks before the expiry of the deadline mentioned in Article 7(1) for the imposition of provisional duties.'.

*Article 2*

Article 29a of Regulation (EU) 2016/1037 is replaced with:

'*Article 29a*

**Information at provisional stage**

1. Union producers, importers and exporters and their representative associations, and the country of origin and/or export, may request information on the planned imposition of provisional duties. Requests for such information shall be made in writing within the time limit prescribed in the notice of initiation. Such information shall be provided to those parties four weeks before the imposition of provisional duties. Such information shall include: a summary of the proposed duties for information purposes only, and details of the calculation of the amount of the countervailable subsidy and the margin adequate to remove the injury to the Union industry, due account being taken of the need to respect the confidentiality obligations contained in Article 29. Parties shall have a period of three working days from the supply of such information to provide comments on the accuracy of the calculations.

2. In cases where it is intended not to impose provisional duties but to continue the investigation, interested parties shall be informed of the non-imposition of duties four weeks before the expiry of the deadline mentioned in Article 12(1) for the imposition of provisional duties.'.

*Article 3*

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

*Article 4*

This Regulation shall apply to all investigations for which the notice of initiation pursuant to Article 5(9) of Regulation (EU) 2016/1036 or Article 10(11) of Regulation (EU) 2016/1037 was published in the *Official Journal of the European Union* after the date of entry into force of this Regulation.

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

Done at Brussels, 4 June 2020.

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

# COMMISSION IMPLEMENTING REGULATION (EU) 2020/1174

## of 3 August 2020

## entering a name in the register of protected designations of origin and protected geographical indications ('Ελαιόλαδο Μάκρης' (Elaiolado Makris) (PDO))

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 Article 50(2)(a) of Regulation (EU) No 1151/2012, Greece's application to register the name 'Ελαιόλαδο Μάκρης' (Elaiolado Makris) was published in the *Official Journal of the European Union* ([2]).

(2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Ελαιόλαδο Μάκρης' (Elaiolado Makris) should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

*Article 1*

The name 'Ελαιόλαδο Μάκρης' (Elaiolado Makris) (PDO) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.5. – Oils and fats (butter, margarine, oil, etc.), as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 ([3]).

*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, 3 August 2020.

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

([1]) OJ L 343, 14.12.2012, p. 1.
([2]) OJ C 102, 30.3.2020, p. 13.
([3]) Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

# COMMISSION IMPLEMENTING REGULATION (EU) 2020/1175

## of 7 August 2020

## concerning the authorisation of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80180 *and Escherichia coli* KCCM 80181 as a feed additive for all animal species

**(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80180 and *Escherichia coli* KCCM 80181. This application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) This application concerns the authorisation of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80180 and *Escherichia coli* KCCM 80181 as a feed additive for all animal species. The applicant requested this additive to be classified in the additive category 'sensory additives'.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 10 January 2020 ([2]) that, under the proposed conditions of use in feed L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80180 and *Escherichia coli* KCCM 80181 does not have adverse effects on animal health, consumer safety or the environment. In its conclusions it also considered that the applicant proposes to label the additive with the hazard statement H335 (may cause respiratory irritation) under the Regulation (EC) No 1272/2008 ([3]). Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular, as regards the users of the additive. The Authority further concluded that since the substance is used in food and its function in feed is the same as that in food, no further demonstration of efficacy in feed is necessary.

(5) Restrictions and conditions should be provided for to allow for a better control. For L-cysteine hydrochloride monohydrate, recommended contents should be indicated on the label of the additive. Where such contents are exceeded, certain information should be indicated on the label of premixtures.

(6) The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(7) The assessment of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80180 and *Escherichia coli* KCCM 80181 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this substance should be authorised as specified in the Annex to this Regulation.

(8) The fact that L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80180 and *Escherichia coli* KCCM 80181 is not authorised for use as a flavouring in water for drinking, does not preclude its use in compound feed, which is administered via water.

([1]) OJ L 268, 18.10.2003, p. 29..
([2]) EFSA Journal 2020;18(2):6003.
([3]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

(9) 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*

The substances specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', are authorised as feed additives in animal nutrition subject to the conditions laid down in that Annex.

*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, 7 August 2020.

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

*ANNEX*

| Identification number of the additive | Name of the holder of authorisation | Additive | Composition, chemical formula, description, analytical method | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | End of period of authorisation |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | mg of active substance/kg of complete feedingstuff with a moisture content of 12 % | | | |
| **Category: Sensory additives. Functional group: Flavouring compounds** | | | | | | | | | |
| 2b920i | - | L-cysteine hydrochloride monohydrate | *Additive composition:*<br>L-cysteine hydrochloride monohydrate<br><br>*Characterisation of the active substance:*<br>L-cysteine hydrochloride monohydrate<br>Produced by fermentation with *Escherichia coli* KCCM 80180 and *Escherichia coli* KCCM 80181<br>Purity: min. 98,5 %<br>Chemical formula:<br>$C_3H_7NO_2S \cdot HClH_2O$.<br>CAS number 7048-04-6<br>FLAVIS 17.032<br><br>*Method of analysis* ([1]):<br>For the identification of L-cysteine hydrochloride monohydrate in the feed additive:<br>— ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Ph.Eur. 6.6-2.2.56-Method 1<br>For the quantification of L-cysteine hydrochloride monohydrate in the feed additive:<br>— ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FD)<br>For the quantification of L-cysteine hydrochloride<br>monohydrate in premixtures: | All animal species | - | - | - | 1. The additive shall be incorporated into the feed in the form of a premixture.<br>2. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated.<br>3. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg'.<br>4. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 25 mg/kg.<br>5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures | 30.9.2030 |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | — ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F) | | | | | and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection. | |

([1]) Details of the analytical methods are available at the following address of the Reference Laboratory: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports

# COMMISSION IMPLEMENTING REGULATION (EU) 2020/1176

## of 7 August 2020

## amending Implementing Regulation (EU) 2019/1387 as regards postponing dates of application of certain measures in the context of the COVID-19 pandemic

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 ([1]), and in particular Article 31 thereof,

Whereas:

(1) Measures introduced to contain the COVID-19 pandemic severely hamper the ability of Member States and the aviation industry to prepare for the application of a number of recently adopted Implementing Regulations in the field of aviation safety.

(2) Confinement and changes in the working conditions and availability of employees, combined with the additional workload required to manage the significant negative consequences of the COVID-19 pandemic for all stakeholders, are impairing preparations for the application of these Implementing Regulations.

(3) Commission Implementing Regulation (EU) 2019/1387 ([2]) lays down new standards on aircraft landing performance calculation, which are applicable from 5 November 2020. In order to avoid that the application of these standards impedes the seamless process of resumption of flights in the context of the recovery from the COVID-19 pandemic because of additional operational requirements, their applicability should thus be postponed in order to allow the competent authorities and stakeholders to prepare for their implementation.

(4) The European Union Aviation Safety Agency has confirmed to the Commission that postponing the application of the provisions referred to in recital 3 by a limited time is possible without having a detrimental effect on aviation safety, as those rules contain technical alleviations for industry that are best implemented in a normal operational environment.

(5) In order to provide an immediate relief for national authorities and all stakeholders during the COVID-19 pandemic and allow them to adapt their planning to prepare for the postponed application of the provisions concerned, this Regulation should enter into force on the day following that of its publication in the *Official Journal of the European Union*.

(6) The measures provided for in this Regulation are in accordance with the opinion of the committee established by Article 127 of Regulation (EU) 2018/1139,

HAS ADOPTED THIS REGULATION:

*Article 1*

In the third paragraph of Article 2 of Implementing Regulation (EU) 2019/1387, '5 November 2020' is replaced by '12 August 2021'.

([1]) OJ L 212, 22.8.2018, p. 1.

([2]) Commission Implementing Regulation (EU) 2019/1387 of 1 August 2019 amending Regulation (EU) No 965/2012 as regards requirements for aeroplane landing performance calculations and the standards for assessing the runway surface conditions, update on certain aircraft safety equipment and requirements and operations without holding an extended range operational approval (OJ L 229, 5.9.2019, p. 1).

*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, 7 August 2020.

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

# COMMISSION IMPLEMENTING REGULATION (EU) 2020/1177

## of 7 August 2020

## amending Implementing Regulation (EU) 2020/469 as regards postponing dates of application of certain measures in the context of the COVID-19 pandemic

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 ([1]), and in particular points (c) and (g) of Article 36(1), points (a) and (f) of Article 43(1) and Article 44(1) thereof,

Whereas:

(1) Measures introduced to contain the COVID-19 pandemic severely hamper the ability of Member States and the aviation industry to prepare for the application of a number of recently adopted Implementing Regulations in the field of aviation safety.

(2) Confinement and changes in the working conditions and availability of employees, combined with the additional workload required to manage the significant negative consequences of the COVID-19 pandemic for all stakeholders, are impairing preparations for the application of these Implementing Regulations.

(3) Commission Implementing Regulation (EU) 2020/469 ([2]) will be partly applicable as of 5 November 2020. The adaptation of the common reporting requirements and requirements concerning the SNOWTAM and METAR format, in line with International Civil Aviation Organization (ICAO) Standards and Recommended Practices, introduced by that Implementing Regulation is impaired by the lack of resources of competent authorities and operators concerned because of the COVID-19 outbreak and should thus be postponed in order to allow the competent authorities and stakeholders to prepare for their implementation.

(4) The European Union Aviation Safety Agency has confirmed to the Commission that postponing the application of the provisions referred to in recital 3 is possible without having a detrimental effect on aviation safety, since it will be for a very limited period and the new measures are aimed at updating already applicable provisions in accordance with current ICAO Standards and Recommended Practices.

(5) In order to provide an immediate relief for national authorities and all stakeholders during the COVID-19 pandemic and allow them to adapt their planning to prepare for the postponed application of the provisions concerned, this Regulation should enter into force on the day following that of its publication in the *Official Journal of the European Union*.

(6) The measures provided for in this Regulation are in accordance with the opinion of the committee established by Article 127 of Regulation (EU) 2018/1139,

([1]) OJ L 212, 22.8.2018, p. 1.

([2]) Commission Implementing Regulation (EU) 2020/469 of 14 February 2020 amending Regulation (EU) No 923/2012, Regulation (EU) No 139/2014 and Regulation (EU) 2017/373 as regards requirements for air traffic management/air navigation services, design of airspace structures and data quality, runway safety and repealing Regulation (EC) No 73/2010 (OJ L 104, 3.4.2020, p. 1).

HAS ADOPTED THIS REGULATION:

*Article 1*

Article 5 of Implementing Regulation (EU) 2020/469 is replaced by the following:

'*Article 5*

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 27 January 2022.

The following provisions shall apply from 12 August 2021:

(a) in Annex I, point 10(b);

(b) in Annex III, point 6: Appendix 3 "SNOWTAM FORMAT".

Point 5 of Annex III shall apply from 5 November 2020, with the exception of point 5(v): Appendix 1 Template for METAR, which shall apply from 12 August 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, 7 August 2020.

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

# DECISIONS

## COMMISSION DECISION (EU) 2020/1178

**of 27 July 2020**

**on the national provisions notified by the Kingdom of Denmark pursuant to Article 114(4) of the Treaty of the Functioning of the European Union concerning cadmium content in fertilisers**

*(notified under document C(2020) 4988)*

**(Only the Danish text is authentic)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty of the Functioning of the European Union, and in particular Article 114(6) thereof,

Whereas:

### 1. FACTS AND PROCEDURE

(1) On 27 January 2020, the Kingdom of Denmark notified the Commission, based on Article 114(4) of the Treaty on the Functioning of the European Union (TFEU), of its intention to maintain national provisions on cadmium content in fertilisers derogating from Regulation (EU) 2019/1009 of the European Parliament and of the Council ([1]).

#### 1.1. **Union legislation**

##### 1.1.1. *Article 114(4) and (6) TFEU*

(2) Article 114, paragraphs 4 and 6 TFEU provide:

> '4. If, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 36, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.
>
> […]
>
> 6. The Commission shall, within six months of the notifications referred to in paragraphs 4 […] approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.
>
> In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 […] shall be deemed to have been approved.'

([1]) Regulation (EU) 2019/1009 of the European Parliament and of the Council of 5 June 2019 laying down rules on the making available on the market of EU fertilising products and amending Regulations (EC) No 1069/2009 and (EC) No 1107/2009 and repealing Regulation (EC) No 2003/2003 (OJ L 170, 25.6.2019, p. 1).

## 1.2. **Harmonisation rules in the field of fertilising products**

### 1.2.1. *Regulation (EC) No 2003/2003*

(3) Regulation (EC) No 2003/2003 of the European Parliament and the Council ([2]) applies to products which are placed on the market as fertilisers designated 'EC fertilisers'. A fertiliser belonging to a type of fertilisers listed in Annex I to Regulation (EC) No 2003/2003 and complying with the conditions laid down in that Regulation may be designated 'EC fertiliser' and move freely in the internal market.

(4) Annex I to Regulation (EC) No 2003/2003 sets an exhaustive list of types of fertilisers covered by the harmonisation rules. For each type of fertiliser there are specific requirements concerning, for instance, nutrient content, nutrient solubility, or processing methods.

(5) Regulation (EC) No 2003/2003 applies mainly to inorganic fertilisers. Some of the types of fertilisers covered have a phosphorus content of 5 % phosphorus pentoxide ($P_2O_5$)-equivalent or more by mass.

(6) Article 5 of Regulation (EC) No 2003/2003 sets the principle of free circulation of EC fertilisers on the internal market, stating that Member States shall not, on grounds of composition, identification, labelling or packaging, and other provisions contained in that Regulation, prohibit, restrict or hinder the placing on the market of EC fertilisers which comply with that Regulation.

(7) Regulation (EC) No 2003/2003 sets no limit values for contaminants in EC fertilisers. Therefore, with a few exceptions based on the Commission Decisions in application of the respective TFEU provisions ([3]), EC fertilisers with a phosphorus content of at least 5 % $P_2O_5$ move freely in the internal market irrespective of their cadmium content.

(8) Nevertheless, the Commission's intention to address the issue of unintentional cadmium content in mineral fertilisers was already announced in recital 15 of Regulation (EC) No 2003/2003. According to it 'Fertilisers can be contaminated by substances that can potentially pose a risk to human and animal health and the environment. Further to the opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE), the Commission intends to address the issue of unintentional cadmium content in mineral fertilisers and will, where appropriate, draw up a proposal for a Regulation, which it intends to present to the European Parliament and the Council. Where appropriate, a similar review will be undertaken for other contaminants'.

### 1.2.2. *Regulation (EU) 2019/1009*

(9) Regulation (EU) 2019/1009 sets harmonisation rules for 'EU fertilising products'. It repeals Regulation (EC) No 2003/2003 as of 16 July 2022.

(10) EU fertilising products are fertilising products which are CE marked when made available on the internal market. An EU fertilising product must meet the requirements set out in Regulation (EU) 2019/1009 for the relevant product function category ('PFC') and component material category or categories, and be labelled in accordance with the labelling requirements laid down therein. There are seven PFCs for EU fertilising products, one of which covers fertilisers.

(11) Regulation (EU) 2019/1009 covers inorganic fertilisers in a more generic manner than Annex I to Regulation (EC) No 2003/2003, subject to some general requirements concerning their quality and safety. In addition, Regulation (EU) 2019/1009 applies to organic and organo-mineral fertilisers, which are outside the material scope of Regulation (EC) No 2003/2003.

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([2]) Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers (OJ L 304, 21.11.2003, p. 1).

([3]) See Commission Decisions of 3 January 2006: 2006/347/EC on the national provisions notified by the Kingdom of Sweden under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers, para. 41 (OJ L 129, 17.5.2006, p. 19), 2006/348/EC on the national provisions notified by the Republic of Finland under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers, para. 40 (OJ L 129, 17.5.2006, p. 25) and 2006/349/EC on the national provisions notified by the Republic of Austria under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers (OJ L 129, 17.5.2006, p. 31).

(12) Through points 3(a)(ii) in PFC 1(B) and 2(a)(ii) in PFC 1(C)(I) in Annex I to Regulation (EU) 2019/1009, that Regulation introduces at Union level the notion of 'phosphate fertilisers' for organo-mineral fertilisers or inorganic macronutrient fertilisers with a phosphorus content of at least 5 % $P_2O_5$-equivalent by mass.

(13) The Regulation sets, for the first time at Union level, limit values for contaminants in EU fertilising products. For phosphate fertilisers, the cadmium limit value is 60 mg/kg $P_2O_5$. For other fertilisers, other limit values apply, and are expressed not as mg/kg $P_2O_5$, but as mg/kg dry matter of the entire product with all its components.

(14) The principle of free movement is enshrined in Article 3(1) of Regulation (EU) 2019/1009, according to which Member States shall not impede, for reasons relating to composition, labelling or other aspects covered by that Regulation, the making available on the market of EU fertilising products which comply with that Regulation. However, in accordance with Article 3(2) of Regulation (EU) 2019/1009, a Member State which, on 14 July 2019, benefits from a derogation from Regulation (EC) No 2003/2003 in relation to cadmium content in fertilisers granted in accordance with Article 114(4) TFEU may continue to apply the national limit values for cadmium content in phosphate fertilisers until such time as harmonised limit values for cadmium content in phosphate fertilisers which are equal to or lower than the limit values applicable in the Member State concerned on 14 July 2019 are applicable at Union level.

(15) In addition, by 16 July 2026, the Commission has an obligation to review the limit values for cadmium content in phosphate fertilisers, with a view to assess the feasibility of reducing these limit values to a lower appropriate level. The Commission has to take into account environmental factors, in particular in the context of soil and climatic conditions, health factors, as well as socioeconomic factors, including considerations of security of supply.

1.2.3. *Optional regime*

(16) The EU market for fertilising products is only partly harmonised.

(17) Regulation (EC) No 2003/2003 aims to ensure the free circulation on the internal market of EC fertilisers. However, that Regulation does not affect so called 'national fertilisers' placed on the market of the Member States in accordance with national legislation. Producers can choose to market fertiliser as 'EC fertiliser' or as 'national fertiliser'.

(18) Regulation (EU) 2019/1009 maintains unchanged the optional regime. Thus, it ensures the free movement in the internal market of EU fertilising products and continues to allow the placing on the market of national fertilising products. The choice remains with the manufacturer.

(19) Based on both Regulations (EC) No 2003/2003 and (EU) No 2019/1009, Member States must not impede the making available on the market of compliant EC fertilisers and, respectively, EU fertilising products, for reasons relating to, inter alia, cadmium content.

(20) However, Member States may maintain or introduce any limit values deemed appropriate for contaminants in national fertilising products, which are outside the scope of Regulation (EU) 2019/1009. Every Member State is concerned to a greater or lesser extent by the threat that accumulation of cadmium poses to the long-term sustainability of crop production. The majority of Member States have already introduced rules limiting the cadmium content in national fertilising products with the objective of reducing emissions of cadmium in the environment and thereby the exposure of humans to cadmium. This Decision does not refer to this type of rules.

(21) Thus, Union harmonisation rules coexist with the national provisions applicable to fertilising products.

## 1.3. **National provisions notified**

(22) The national provisions notified by the Kingdom of Denmark ('the notified national provisions') are enshrined in Order No 223 of 5 April 1989 on the cadmium content of fertilisers containing phosphorus (hereinafter the 'Order'), according to which the current limit value applies as of 1998.

(23) The Order regulates the sale for use in Denmark. It sets a limit value for cadmium in artificial fertilisers, derived from mineral phosphate, with a total phosphorus (P) content of 1 % or more by weight. A phosphorus (P) content of 1 % by weight equals 2,3 % $P_2O_5$-equivalent by mass. The limit value for cadmium in those fertilisers is 110 mg Cd/kg phosphorus (P), which is equivalent to 48 mg Cd/kg $P_2O_5$. For fertilisers other than artificial fertilisers derived from mineral phosphate with a total phosphorus content of 2,3 % $P_2O_5$-equivalent by mass or more, the Order has no cadmium limit.

(24) The Kingdom of Denmark has been applying the limit value laid down in the Order to both national fertilisers and to fertilisers harmonised under Regulation (EC) No 2003/2003. The Order, which has applied in Denmark since 1989, has not been notified by the Kingdom of Denmark to the Commission pursuant to Article 114 TFEU or the predecessors of this Treaty provision ([4]) in respect of Regulation (EC) No 2003/2003. In the present notification in respect of Regulation (EU) 2019/1009, the Kingdom of Denmark has however pointed out that it notified the draft Order to the Commission on 19 January 1988 pursuant to Council Directive 83/189/EEC ([5]) and that it raised the envisaged national limit value before the Order was adopted to take into account objections raised by three other Member States following that notification.

(25) By the notification, the Kingdom of Denmark has requested the Commission's approval to apply the notified national provisions to artificial fertilisers derived from mineral phosphate with a total phosphorus content of 2,3 % $P_2O_5$-equivalent by mass or more by derogation from the cadmium limits laid down in Regulation (EU) 2019/1009. In other words, the Kingdom of Denmark intends to apply the national cadmium limit both to phosphate fertilisers and to certain other fertilisers regulated under that Regulation. The present notification does not contain a request to approve any derogation from Regulation (EC) No 2003/2003.

### 1.4. **Procedure**

(26) By letter of 27 January 2020, registered on 29 January 2020, the Kingdom of Denmark notified the Commission of its intention to maintain national provisions on cadmium content in artificial fertilisers derived from mineral phosphate with a total phosphorus content of 2,3 % $P_2O_5$-equivalent by mass or more, derogating from Regulation (EU) 2019/1009. According to Article 114(4) read in conjunction with Article 36 TFEU, the justification put forward by the Kingdom of Denmark is based on grounds of major needs relating to the protection of human health and the environment from exposure to cadmium in the environment.

(27) By letter of 30 January 2020, the Commission acknowledged receipt of the notification and informed the Kingdom of Denmark that the six-month period for its examination according to Article 114(6) TFEU ends on 30 July 2020.

(28) In support of its notification based on Article 114(4) TFEU, the Kingdom of Denmark submitted additional information to the Commission on 31 March 2020. That information provides some clarifications as regards the material scope of the national provisions that the Kingdom of Denmark seeks to maintain, as well as detailed data on the fertilisers market in Denmark.

(29) In the additional information, the Kingdom of Denmark clarified, inter alia, that the primary concern which the notified national provisions seek to address, and thus the primary focus of the scientific assessment in the Danish notification, is inorganic mineral fertilisers with high phosphorus content, as the highest cadmium load from fertilisers is associated with those fertilisers, and that a similar concern applies to organo-mineral fertilisers with a high content of inorganic mineral phosphorus. The Kingdom of Denmark also indicated that it would be willing to look into options for information or amending the legislation in relation to the product function categories and limit values of Regulation (EU) 2019/1009.

(30) Further, the Commission published a notice regarding the notification in the *Official Journal of the European Union* ([6]) in order to inform interested parties of the Kingdom of Denmark's national provisions, as well as of the grounds invoked to support the notification. No comments were received following the publication of the notice.

([4]) In particular Article 95 (ex. 100a) of the Treaty establishing the European Community (Consolidated version 2002) (OJ C 325, 24.12.2002, p. 33).

([5]) Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (OJ L 109, 26.4.1983, p. 8).

([6]) OJ C 124, 17.4.2020, p. 19.

(31) By letter of 6 April 2020, the Commission also informed the other Member States about the notification and gave them the opportunity to submit comments thereon within 30 days. The Commission received comments within the time-limit set from Belgium, the Slovak Republic, Hungary and Malta. The three first mentioned Member States mentioned that they did not have any comments as regards the notification. Malta noted that they have no objection to the Kingdom of Denmark maintaining its national limit values for cadmium content in fertilisers.

## 2. **ASSESSMENT**

(32) As a preliminary remark, the Commission notes that it flows clearly from the case-law of the Court of Justice of the European Union ('the Court'), that the procedure laid down in Article 114(4)-(6) TFEU is intended to ensure that no Member State may apply national rules derogating from the harmonised rules without obtaining confirmation from the Commission. A Member State is not authorised to apply the national provisions unilaterally without having notified them and without having obtained a decision from the Commission confirming them ([7]).

(33) The Commission also notes that Article 3(2) of Regulation (EU) 2019/1009 only applies to derogations from Article 5 of Regulation (EC) No 2003/2003 granted before 14 July 2019 on the basis of notifications made under Article 114(4) TFEU.

(34) The Commission considers that the abovementioned notification of the draft made by the Kingdom of Denmark under Directive 83/189/EEC on 19 January 1988 is not comparable to a procedure under Article 114(4) to (6) TFEU, as the purpose of that procedure is to prevent technical barriers to trade and not to aim at a derogation of existing national provisions from the Union harmonisation measure. In the present case, it is uncontested that the Kingdom of Denmark has not notified the Order pursuant to Article 114 TFEU before 14 July 2019 and the Commission has not approved it.

(35) Consequently, the Kingdom of Denmark does not benefit from a derogation from Article 5 of Regulation (EC) No 2003/2003. It can thus also not benefit from Article 3(2) of Regulation (EU) 2019/1009.

### 2.1. **Admissibility**

(36) Pursuant to Article 114(4) and (6) TFEU, a Member State may, after the adoption of a harmonisation measure, maintain its more stringent national provisions on grounds of major needs referred to in Article 36 TFEU, or relating to the protection of the environment or the working environment, provided that it notifies those national provisions to the Commission and the Commission approves those measures.

(37) To ascertain the admissibility of the notification, the Commission has to assess if the notified national provisions concerned are a pre-existing measure derogating from the newly introduced Union harmonisation rule and if they are more stringent.

(38) The Order has applied in Denmark since 1989. Therefore it already existed in substance at the time of adoption of Regulation (EU) 2019/1009.

#### 2.1.1. *On the pre-existence of the notified national provisions*

(39) There are two factors which need to be examined in order to establish whether the notified national provisions, introduced in 1989 and applying in their current form since 1998, are pre-existing for the purpose of Article 114 (4) TFEU.

(40) First, Regulation (EU) 2019/1009 will replace Regulation (EC) No 2003/2003, which in turn replaced the Directive that was generally applicable to fertilisers when the notified national provisions were introduced, i.e. Council Directive 76/116/EEC ([8]).

(41) This raises the question whether the notified national provisions can be considered as maintained in force and notifiable to the Commission in accordance with Article 114(4) TFEU with respect to Regulation (EU) 2019/1009, while having regard to the harmonisation established by Directive 76/116/EEC and Regulation (EC) No 2003/2003.

([7]) Case C-41/93, *French Republic vs Commission of the European Communities*, para. 23-30.

([8]) Council Directive 76/116/EEC of 18 December 1975 on the approximation of the laws of the Member States relating to fertilizers (OJ L 24, 30.1.1976, p. 21).

(42) On the one hand, Article 3(2) of Regulation (EU) 2019/1009 extends past derogations from Article 5 of Regulation (EC) No 2003/2003 to Article 3(1) of Regulation (EU) 2019/1009, thus allowing existing national measures lawfully applying, on the basis of notifications under Article 114(4) TFEU and Commission decisions under Article 114(6) TFEU, to fertilisers covered by the scope of harmonisation provided for by Regulation (EC) No 2003/2003 to also apply to EU fertilising products which will fall within the newly extended scope of harmonisation for the first time by virtue of Regulation (EU) 2019/1009. That confirms that Regulation (EU) 2019/1009 is a continuation of the harmonisation stemming from Regulation (EC) No 2003/2003.

(43) On the other hand, Recital 11 of Regulation (EU) 2019/1009 confirms that the legislator, by paraphrasing Article 114(4) TFEU, regarded that Regulation (EU) 2019/1009 should be considered for the purpose of assessments under Article 114(4) TFEU:

'Several Member States have in place national provisions limiting cadmium content in phosphate fertilisers on grounds relating to the protection of human health and of the environment. Should a Member State deem it necessary to maintain such national provisions after the adoption of harmonised limit values under this Regulation, and until those harmonised limit values are equal to or lower than the national limit values already in place, it should notify them to the Commission in accordance with Article 114(4) TFEU. Furthermore, in accordance with Article 114(5) TFEU, if a Member State deems it necessary to introduce new national provisions, such as provisions limiting cadmium content in phosphate fertilisers, based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of this Regulation, it should notify the Commission of the envisaged provisions as well as the grounds for introducing them. […]'.

(44) This interpretation is further supported by the difference in the regulatory regime and material scope of Regulation (EU) 2019/1009 compared with Directive 76/116/EEC and with Regulation (EC) No 2003/2003, as well as the fact that Regulation (EU) 2019/1009 imposes a harmonised limit value for cadmium for the first time.

(45) It can also be noted that in past cases where a new harmonisation measure had replaced an existing one, the Court, has referred only to the newly adopted harmonisation measure as the one that should be considered for the purpose of assessments under Article 114(4) TFEU ([9]).

(46) In conclusion, since Regulation (EU) 2019/1009 is the harmonisation measure that should be considered for the purpose of the notified national provisions under Article 114(4) TFEU, it is for the Commission to ascertain whether the notified national provisions were pre-existing to that Regulation, in accordance with the requirement of Article 114(4) TFEU.

(47) Second, the notified national provisions have never been notified to the Commission under Article 114 TFEU or its predecessor provisions before, neither as a derogation from Directive 76/116/EEC, nor as a derogation from Regulation (EC) No 2003/2003.

(48) This raises the question whether they can nevertheless be regarded as pre-existing to Regulation (EU) 2019/1009 for the purpose of Article 114(4) TFEU, rather than a new national provisions which should be notified pursuant to Article 114(5) TFEU. In order to determine this question, it is important to look to the purpose of the distinction between Article 114(4) and (5) TFEU.

(49) This distinction has been addressed by case-law of the Court. In the case C-3/00 Denmark v Commission, the Court concluded with respect to Article 95 TEC, which corresponds to Article 114 TFEU:

'The difference between the two situations envisaged in Article 95 is that, in the first, the national provisions predate the harmonisation measure. They are thus known to the Community legislature, but the legislature cannot or does not seek to be guided by them for the purpose of harmonisation. It is therefore considered acceptable for the Member State to request that its own rules remain in force. To that end, the EC Treaty requires that such national provisions must be justified on grounds of the major needs referred to in Article 30 EC or relating to the protection of the environment or the working environment. By contrast, in the second situation, the adoption of new national legislation is more likely to jeopardise harmonisation. The Community institutions could not, by definition, have

([9]) See C-360/14 P *Germany v European Commission*.

taken account of the national text when drawing up the harmonisation measure. In that case, the requirements referred to in Article 30 EC are not taken into account, and only grounds relating to protection of the environment or the working environment are accepted, on condition that the Member State provides new scientific evidence and that the need to introduce new national provisions results from a problem specific to the Member State concerned arising after the adoption of the harmonisation measure' ([10]).

(50) In the light of the cited case-law, it should be considered that the purpose of the distinction between Article 114(4) and (5) TFEU is to impose higher justification requirements in cases where harmonisation is more likely to be jeopardised since the national provision in question was not known to the legislator at the time of the adoption of the harmonised measure and was therefore not taken into account when the harmonisation measure was drawn up.

(51) As has already been established, the notified national provisions have been in force at their current state since 1998. Thus, they were in force at the time of drawing up Regulation (EU) 2019/1009 and therefore also predate that Regulation.

(52) Further, it is evident from the Impact Assessment Accompanying the Proposal for a Regulation of the European Parliament and of the Council laying down the rules on the making available on the market of CE marked fertilising products ([11]) that the notified national provisions were known to the Union legislature when drawing up Regulation (EU) 2019/1009.

(53) It can thus be concluded that the notified national provisions are a pre-existing measure derogating from the newly introduced harmonisation rule.

2.1.2. *On the stringency of the notified national provisions in relation to Regulation (EU) 2019/1009*

(54) Regarding the question whether the notified national provisions are also more stringent than the newly introduced harmonisation rule, the Commission notes that, although the Kingdom of Denmark intends to apply the national cadmium limit both to phosphate fertilisers as referred to in point 3(a)(ii) PFC 1(B) and point 2(a)(ii) PFC 1(C)(I) of Part II of Annex I to Regulation (EU) 2019/1009 and to certain other fertilisers regulated under that Regulation, the key concern which the notified national provisions seek to address is with the former category of fertilisers, which are inorganic and organo-mineral fertilisers with high phosphorus content.

(55) The Commission also notes that it is only for phosphate fertilisers that the Danish cadmium limit value and the limit value laid down in Regulation (EU) 2019/1009 are expressed based on the same denominator, *i.e.* kg $P_2O_5$ rather than kg dry matter of the entire product with all its components.

(56) In other words, it is only for phosphate fertilisers that it is possible to compare the level of protection of human health and environment based on the Danish cadmium limit to that of the harmonised cadmium limit without knowing the exact composition of each product. Furthermore, phosphate fertilisers are by far the most pertinent products targeted by the notified national provisions. Therefore, for the purpose of assessing whether the notified national provisions are more stringent and protective than the newly introduced harmonisation rule, the Commission is only able to compare the two set of provisions with regard to phosphate fertilisers.

(57) The cadmium limit for phosphate fertilisers established by point 3(a)(ii) PFC 1(B) and point 2(a)(ii) PFC 1(C)(I) of Part II of Annex I to Regulation (EU) 2019/1009 is 60 mg/kg $P_2O_5$. On the other hand, the cadmium limit established by the notified national provisions is 48 mg/kg $P_2O_5$.

(58) The notified national provisions are therefore more stringent and more protective than the provisions of Regulation (EU) 2019/1009, at least insofar as they apply to phosphate fertilisers as referred to in that Regulation.

(59) In the light of the foregoing, the Commission considers that the notification submitted by the Kingdom of Denmark is admissible under Article 114(4) TFEU, at least insofar as it concerns phosphate fertilisers as referred to in Regulation (EU) 2019/1009.

([10]) C-3/00 *Denmark v Commission*, para. 58. Further confirmed in e.g. T-234/04 *Kingdom of the Netherlands v Commission*, para. 58, Joined Cases T 366/03 T-235/04 *Land Oberösterreich and Austria v Commission*, para. 62 and C-512/99 *Germany v Commission*, para. 41.

([11]) See the impact assessment accompanying the Commission's proposal which was specifically devoted to the cadmium limit, SWD (2016) 64 final, PART 2/2; https://ec.europa.eu/transparency/regdoc/rep/10102/2016/EN/SWD-2016-64-F1-EN-MAIN-PART-2.PDF; see in particular pages 5, 6, 25, 28, 29 and 32, and Annex I.

### 2.2. **Assessment of merits**

(60) In accordance with Article 114(4) and first subparagraph of Article 114(6) TFEU, the Commission must ascertain that all the conditions enabling a Member State to maintain its national provisions derogating from a Union harmonisation measure provided for in that Article are fulfilled.

(61) In particular, the Commission must assess whether or not the notified national provisions are justified by the major needs referred to in Article 36 TFEU or relating to the protection of the environment or the working environment and do not exceed what is necessary to attain the legitimate objective pursued. In addition, when the Commission considers that the national provisions fulfil the above conditions, it must verify, pursuant to Article 114(6) TFEU, whether or not the national provisions are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they constitute an obstacle to the functioning of the internal market.

(62) In the light of the timeframe established by Article 114(6) TFEU, the Commission, when examining whether the national provisions notified under Article 114(4) TFEU are justified, has to take as a basis the justifications put forward by the notifying Member State. The burden of proof lies with the notifying Member State that seeks to maintain its national provisions.

(63) However, where the Commission is in possession of information in the light of which the Union harmonisation measure from which the notified national provisions derogate may need to be reviewed, it can take such information into consideration in the assessment of the notified national provisions.

#### 2.2.1. *The position of the Kingdom of Denmark*

(64) Denmark's limit value for cadmium in artificial fertilisers derived from mineral phosphate with a total phosphorus content of 2,3 % $P_2O_5$-equivalent by mass or more is motivated by the protection of human health and of the environment from exposure to cadmium in the environment.

(65) In the notification submitted to the Commission, the Kingdom of Denmark states, that it has been applying the notified national provisions since 1989. The limit value currently in force has been applicable since 1998. The notified national provisions were introduced aiming at decreasing the contamination of agricultural land, which was identified in the national report conducted by the National Food Institute of the Technical University of Denmark ('DTU Fødevareinstituttet') on 'Cadmium contamination – a report on the use, occurrence and adverse effects of cadmium in Denmark' of 1980. Due to the conclusion that cadmium was continuously accumulating in Danish agricultural soil, the report recommended a reduction in the cadmium content in fertilisers, as such a reduction could lead to a significant decrease in contamination of agricultural land.

(66) Referring to the fact that exposure to and the input of cadmium into agricultural soils are generally lower in Denmark than the Union average, it is the view of the Kingdom of Denmark that the measures taken to ensure the aim sought by the notified national provisions have been successful. Therefore, to ensure protection of human health and the environment also in the future, the Kingdom of Denmark asserts a need to maintain a reduced exposure level in its territory under Regulation (EU) 2019/1009. Further, the Kingdom of Denmark has, in its notification to the Commission, analysed the expected national effects of the limit value of 60 mg/kg $P_2O_5$ set in Regulation (EU) 2019/1009. This limit value raised important concerns as regards the protection of human health and of the environment. The Kingdom of Denmark states that applying the limit values of Regulation (EU) 2019/1009 would lead to a reduced level of protection in Denmark.

(67) In support of that, the Kingdom of Denmark bases its assessment on the anticipation that applying the limit value of 60 mg/kg $P_2O_5$ set in Regulation (EU) 2019/1009 would result in an increase of cadmium input into Danish agricultural lands from fertilisers, due to the likelihood that fertilisers with a higher cadmium content will be marketed in Denmark.

(68) In particular, the Kingdom of Denmark presents justification related to the risks to human health associated with exposure to cadmium via food. The Kingdom of Denmark refers to the need to reduce cadmium content of food produced in Denmark and thereby protect some more vulnerable sections of the population, in particular children and vegetarians, who are consuming cadmium in their food at levels exceeding the health-based limit values.

(69) In support of that statement, the Kingdom of Denmark relies on a number of scientific studies. In particular, it refers to the European Food Safety Authority (EFSA) study ([12]) for the tolerable weekly intake (TWI) and compares it to a study performed by the Technical University of Denmark, with the conclusion that the dietary exposure to cadmium should be reduced. Further, the study performed by the Technical University of Denmark reveals that children are a high exposure group with the average exposure of small children exceeding the TWI. Vegetarians are also regarded as having a considerably higher cadmium intake than the average population. The greatest dietary exposure to cadmium comes from the consumption of cereals and vegetables. The consumed quantities by these groups lead to high exposure.

(70) Additionally, the Kingdom of Denmark has a high degree of self-sufficiency in its food production of, among other things, cereals, potatoes and carrots. The exposure of the Danish population to cadmium is thus closely linked to the amount of cadmium added to the Danish farmland.

(71) It should be noted that the soil conditions in Denmark vary from sandy soils in the west parts of the country, to clay soils in the east. As a result of the soil conditions, the accumulation of cadmium in the soils differ from higher levels in the clay soils on Zealand, Fyn and the most easterly parts of Jutland, while West Jutland has more sandy soils and generally lower cadmium levels. Further, the demographic information submitted by the Kingdom of Denmark shows that due to differences relating to agricultural efficiency factors deriving from the nature of soils, the agriculture cultivating plant crops are focused to areas where clay soils contain higher levels of cadmium.

(72) Another factor which varies from the east to the west of Denmark is the amount of livestock farming and thus the availability of manure as an alternative to artificial fertiliser. Livestock farming is generally concentrated in Jutland, while the cultivation of crops without farm animals is localised on Zealand. Consequently, geographical differences in soil conditions and livestock production in Denmark mean that the use of artificial fertilisers is relatively greater in the east of Denmark, where farms cultivating plant crops without keeping farm animals are more widespread and the clay soils contain higher background levels of cadmium. The Kingdom of Denmark notes that 91 % of artificial fertilisers in Europe in 2014 was estimated to fall within a limit of 60 mg Cd/kg $P_2O_5$, while 68 % was estimated to fall within a limit of 40 mg Cd/kg $P_2O_5$. A large proportion of the fertilisers on the European market therefore already meets the Danish limit. Over the last two decades, the average level of cadmium in artificial fertilisers has been 10-20 mg Cd/kg $P_2O_5$ in Denmark, while on the European market it is estimated to have been 32-36 mg Cd/kg $P_2O_5$.

(73) Moreover, the Danish share of the European market of artificial fertilisers is between 2-3 %. The Kingdom of Denmark maintains that it has not experienced any problems in the supply of fertilisers complying with the limit value for cadmium currently in place, as of 1998 when it entered into force.

(74) The notified national provisions are also of general application, applying both to Danish and to other firms selling fertilisers for use in Denmark. It should, in addition, be noted that Denmark does not have any natural deposits of phosphate rock, thus phosphate rock is not mined in Denmark.

(75) Further, the Kingdom of Denmark has provided statistics proving a gradual increase of fertilisers imported from other Member States in the period 1988-2018. The Kingdom of Denmark argues that according to this economic data, the cadmium limit set in the notified national provisions have not prevented increased imports from the other Member States. On the contrary, data shows distinct progress in trade across different Member States. Nor are the notified national provisions an obstacle to the ability to export artificial fertilisers to other Member States.

([12]) Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on cadmium in food. *EFSA Journal* 2009, 980, p. 1.

2.2.2. *Evaluation of the position of the Kingdom of Denmark*

2.2.2.1. Justification on grounds of major needs referred to in Article 36 TFEU or relating to the protection of the environment or the working environment

(76) The notified national provisions aim to achieve a higher level of protection of human health and the environment than that provided in Regulation (EU) 2019/1009 with regard to exposure to cadmium and thereby further avoid the accumulation of cadmium in the soil. The means for achieving this objective is by maintaining lower maximum limit values of cadmium in fertilisers covered by the notified national provisions.

(77) As regards the protection of human health, it should be noted that cadmium is a non-essential and toxic element for humans, and has no use for plants or animals. In particular, cadmium oxide has been classified as a carcinogen substance, category 2, under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([13]).

(78) The presence of cadmium in plants and cadmium intake from foodstuffs could eventually lead to adverse effects on human health in the longer term. Further, once absorbed by the human body, cadmium is efficiently retained and accumulates in the body throughout life ([14]).

(79) The general public is exposed to cadmium from multiple sources, including smoking and food intake. For the non-smoking population, food represents the most important source of cadmium intake. Cadmium is primarily toxic to the kidney, but can also cause bone demineralisation and has been statistically associated with increased risk of cancer in the lung, endometrium, bladder and breast ([15]).

(80) Cadmium can damage the kidneys, causing excess production of proteins in the urine. The duration and level of exposure to cadmium determines the severity of the effect. Skeletal damage is another critical effect of chronic cadmium exposure at levels somewhat higher than those where protein in the urine would be an early indicator. Mainly stored in the liver and kidneys, excretion of cadmium is slow, and it can remain in the human body for decades.

(81) Further, health risks cannot be excluded for adult smokers and people with depleted iron body stores and/or living near industrial sources ([16]).

(82) Moreover, in addition to human health impacts, the Kingdom of Denmark aim to achieve a higher level of protection of the environment. The Kingdom of Denmark maintains that further cadmium accumulation in soils could have negative effects on soil biodiversity and therefore on soil functions (e.g. decay of organic matter) and on groundwater quality via leaching in soils. Both toxicity and bioavailability of cadmium are influenced by soil characteristics.

(83) The differences in soil conditions and livestock production in Denmark result in a relatively greater use of artificial fertilisers in the east of Denmark, where farms cultivating plant crops without keeping farm animals are more widespread and the clay soils contain higher background levels of cadmium.

(84) Concerns regarding the risks posed by cadmium to human health and the environment were referred to by the Council already in its Resolution of 25 January 1988 ([17]). The Council emphasised the importance of reducing inputs of cadmium into soils from all sources including diffuse sources (e.g. atmospheric deposition, phosphate fertilisers, sewage sludge, etc.) by among others 'appropriate control measures for the cadmium content of phosphate fertilisers based on suitable technology not entailing excessive costs and taking into account environmental conditions in the different regions of the Community'.

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([13]) 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).

([14]) See the scientific report of the European Food Safety Authority on Cadmium dietary exposure in the European population of 2012, published at https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2012.2551, *EFSA Journal* 2012;10(1).

([15]) *EFSA Journal* 2012;10(1).

([16]) EU Risk assessment report on cadmium and cadmium oxide, as quoted in SWD(2016) 64 final, p. 11.

([17]) OJ C 30, 4.2.1988, p. 1.

(85) In 2002, the Scientific Committee on Health and Environmental Risks concluded that a limit for 40 mg/kg $P_2O_5$ or more would lead to cadmium accumulation in most Union soils. By contrast, a limit of 20 mg/kg $P_2O_5$ or less was not expected to result in long-term soil accumulation over 100 years if other cadmium inputs are not considered.

(86) In recital 15 of Regulation (EC) No 2003/2003, the Commission's intention to address the issue of unintentional cadmium content in mineral fertilisers was already announced.

(87) In its proposal for Regulation (EU) 2019/1009 ([18]), based on the scientific data available when assessing the impacts, the Commission has concluded that cadmium metal and cadmium oxide in general can pose serious risks to health and to the environment. The Commission proposed setting a limit value of 60 mg/kg $P_2O_5$ in phosphate fertilisers and reducing gradually this limit value to 20 mg/kg $P_2O_5$ in 12 years after the start of the application of the new Regulation.

(88) It is also generally agreed that cadmium in fertilisers is by far the most important source of cadmium input to soil and to the food chain ([19]).

(89) Regulation (EU) 2019/1009 sets a limit value of 60 mg/kg $P_2O_5$ applicable as of 16 July 2022. The vast majority of fertilisers available on the European market already comply with this limit value. While the introduction of this limit is a step in the right direction, based on available scientific data, it is not likely to significantly decrease the accumulation of cadmium in soils over long term.

(90) Recognising the need for more ambitious harmonised limit values for cadmium in phosphate fertilisers in the future, Regulation (EU) 2019/1009 sets an obligation upon the Commission to reassess these limits with the purpose of lowering them if feasible.

(91) Based on the above, it must be considered that the maximum limit value set out in the notified national provisions is justified by needs to protect human health and the environment.

2.2.2.2. Absence of any arbitrary discrimination, any disguised restriction on trade between Member States or any obstacle to the functioning of the internal market

(a) Absence of arbitrary discrimination

(92) Article 114(6) TFEU requires the Commission to verify that maintaining the notified national provisions are not a means of arbitrary discrimination. According to the case-law of the Court, in order for there to be no discrimination, similar situations must not be treated in different ways and different situations must not be treated in the same way unless objectively justified.

(93) The notified national provisions apply to both domestic products and products imported from other Member States. In the absence of any evidence to the contrary, it can be concluded that the national provisions are not a means of arbitrary discrimination.

(b) Absence of a disguised restriction on trade of phosphate fertilisers

(94) For assessing the condition pertaining to absence of a disguised restriction on trade, the Commission will first assess the notified national provisions insofar as they apply to those fertilisers for which the Commission has deemed the notification admissible, *i.e.* for phosphate fertilisers as referred to in Regulation (EU) 2019/1009.

([18]) COM/2016/0157 final – 2016/084 (COD).

([19]) See the study *'Revisiting and updating the effect of phosphate fertilizers to cadmium accumulation in European agricultural soils'* by Erik Smolders & Laetitia Six, commissioned by Fertilizers Europe in 2013, published at https://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_168_rd_en.pdf

(95) National provisions which set more stringent conditions for placing on the market of products than those laid down in Union law would normally constitute a barrier to trade. This is because some of the products that are lawfully placed on the market in the rest of the Union are not expected, as a result of the national provisions, to be placed on the market in the Member State concerned. The pre-conditions laid down in Article 114(6) TFEU are intended to prevent restrictions based on the criteria set out in paragraphs (4) and (5) of that Article from being applied for inappropriate reasons, and constituting in effect economic measures to impede the importation of products from other Member States, that is to say, a means of indirectly protecting national production ([20]).

(96) Given that the notified national provisions also impose stricter limit values as regards cadmium content in phosphate fertilisers to economic operators based in other Member States in an otherwise harmonised area, they are liable to constitute a disguised restriction on trade or an obstacle to the functioning of the internal market. It is recognised, however, that Article 114(6) TFEU must be read in the sense that only national measures constituting a disproportionate obstacle to the internal market may not be approved ([21]).

(97) In the absence of any evidence suggesting that the national provisions constitute in effect a measure intended to protect national production, it can be concluded that they are not a disguised restriction to trade between Member States. Therefore, it remains for the Commission to consider, whether the notified national provisions present an obstacle to the functioning of the internal market.

(c) Absence of obstacles to the functioning of the internal market for phosphate fertilisers

(98) For assessing the condition pertaining to absence of obstacles to the functioning of the internal market, the Commission must first assess the notified national provisions insofar as they apply to those fertilisers for which the Commission has deemed the notification admissible, i.e. phosphate fertilisers as referred to in Regulation (EU) 2019/1009.

(99) Article 114(6) TFEU obliges the Commission to verify whether or not maintaining the notified national provisions constitute obstacles to the functioning of the internal market. The condition cannot be interpreted in such a way that it precludes the approval of any national measure likely to affect the functioning of the internal market. Indeed, any national measure derogating from a harmonisation measure aimed at the establishment and operation of the internal market constitutes in substance a measure likely to affect the internal market. Consequently, in order to preserve the useful character of the procedure laid down in Article 114 TFEU, the concept of obstacle to the functioning of the internal market must, in the context of Article 114(6) TFEU, be understood as a disproportionate effect in relation to the pursued objective ([22]).

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([20]) Commission Decision of 8 May 2018 concerning national provisions notified by Denmark on the addition of nitrite to certain meat products, C/2018/2721, para. 54 (OJ L 118, 14.5.2018, p. 7), Commission Decision of 3 January 2006 on the national provisions notified by the Republic of Finland under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers, 2006/348/EC, para. 40 (OJ L 129, 17.5.2006, p. 25), Commission decision of 3 January 2006 on the national provisions notified by the Kingdom of Sweden under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers, 2006/347/EC, para. 41 (OJ L 129, 17.5.2006, p. 19), Commission Decision of 3 January 2006 on the national provisions notified by the Republic of Austria under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers, 2006/349/EC, para. 41 (OJ L 129, 17.5.2006, p. 31).

([21]) Commission Decision of 8 May 2018 concerning national provisions notified by Denmark on the addition of nitrite to certain meat products, C/2018/2721, para. 55, Commission Decision of 3 January 2006 on the national provisions notified by the Republic of Finland under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers, 2006/348/EC, para. 42, Commission decision of 3 January 2006 on the national provisions notified by the Kingdom of Sweden under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers, 2006/347/EC, para. 43, Commission Decision of 3 January 2006 on the national provisions notified by the Republic of Austria under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers, 2006/349/EC, para. 43.

([22]) Commission Decision of 8 May 2018 concerning national provisions notified by Denmark on the addition of nitrite to certain meat products, C/2018/2721, para. 55, Commission Decision of 3 January 2006 on the national provisions notified by the Republic of Finland under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers, 2006/348/EC, para. 42, Commission decision of 3 January 2006 on the national provisions notified by the Kingdom of Sweden under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers, 2006/347/EC, para. 43, Commission Decision of 3 January 2006 on the national provisions notified by the Republic of Austria under Article 95(4) of the EC Treaty concerning the maximum admissible content of cadmium in fertilisers, 2006/349/EC, para. 43.

(100) When assessing whether the notified national provisions are appropriate and necessary for achieving the objective they pursue, a number of factors need to be taken into account. The Commission has to evaluate whether the level of protection stemming from the limit value for cadmium set in the notified national provisions achieve their objective, which is to protect the human health on the one hand, and the environment on the other hand.

(101) The Commission notes, first, that the cadmium limit value in the notified national provisions is lower than the cadmium limit value for phosphate fertilisers laid down in Regulation (EU) 2019/1009. The notified national measures therefore provide a better level of protection for human health and the environment than the harmonisation measure does.

(102) Regarding the proportionality of the notified national provisions for phosphate fertilisers, the Commission makes the following observations:

(103) Firstly, the Kingdom of Denmark has not experienced any problems in the supply of fertilisers complying with the limit value for cadmium currently in place, which means that that limit does not pose major obstacles to the free movement on the internal market.

(104) Secondly, the Kingdom of Denmark refers to the need to reduce cadmium content of food produced in Denmark and thereby protect some sections of the population, in particular children and vegetarians, who are consuming cadmium in their food at levels exceeding the health-based limit values. The EFSA study referred to by the Kingdom of Denmark ([23]) reveals that children are a high exposure group with the average exposure of small children exceeding the TWI. Vegetarians are also assessed as having a considerably higher cadmium intake than the average population. ([24])

(105) In addition, the fact that exposure to and the input of cadmium into agricultural soils are generally lower in Denmark than the Union average is an indication that the measures taken in order to ensure the protection of the Danish soil and population has been successful.

(106) Concerning phosphate fertilisers, given the health and environmental benefits invoked by the Kingdom of Denmark in relation to the reduction of exposure to cadmium in the soil, and the fact that, on the basis of currently available information, trade hardly appears to be affected at all, the Commission considers that the notified national provisions may be maintained on grounds relating to the protection of health and the environment having regard to the fact that they are not disproportionate and, therefore, do not constitute an obstacle to the functioning of the internal market in the sense of Article 114(6) TFEU.

(d) Absence of a disguised restriction on trade and of obstacles to the functioning of the internal market for fertilisers other than phosphate fertilisers

(107) In addition to phosphate fertilisers as referred to in Regulation (EU) 2019/1009, the notified national provisions also cover other artificial fertilisers derived from mineral phosphate with a total phosphorus content of 2,3-5 % $P_2O_5$-equivalent by mass or more.

(108) For the purpose of assessing whether the notified national provisions constitute a disguised restriction on trade or obstacles to the functioning of the internal market for those fertilisers within the meaning of Article 114(6), and thus whether they have a disproportionate effect in relation to the pursued objective, the Commission notes that the Kingdom of Denmark has confirmed that the primary concern is phosphate fertilisers as referred to in Regulation (EU) 2019/1009, and that the primary focus of the scientific assessment in the Danish notification has been on a certain category of phosphate fertilisers, namely inorganic mineral fertilisers with high phosphorus content.

([23]) Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on cadmium in food. *EFSA Journal* 2009, 980, p. 1.

([24]) Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on cadmium in food. *EFSA Journal* 2009, 980, p. 1.

(109) Regarding the pursued objective of protecting health and the environment, the Commission notes, as indicated in recitals 55 and 56 above, that it is only for phosphate fertilisers that it is possible to compare the protective nature of the Danish cadmium limit with that of the harmonised cadmium limit without knowing the exact composition of each product, since it is only for phosphate fertilisers that the Danish limit value and the limit value laid down in Regulation (EU) 2019/1009 are expressed based on the same denominator. In other words, for fertilisers other than phosphate fertilisers, it is not possible to determine whether the notified national provisions are more stringent than the newly introduced harmonisation rule. It can therefore also not be established whether the notified national provisions provide a better level of protection for human health and the environment than the harmonisation measure does.

(110) Regarding the impact of the notified national provisions on the functioning of the internal market, the Commission notes that applying those provisions to CE marked fertilisers other than phosphate fertilisers as referred to in Regulation (EU) 2019/1009 would create serious administrative difficulties for economic operators wishing to place fertilisers on the market in Denmark. In order to ensure compliance with the notified national provisions, manufacturers would have to categorise their fertilisers not only according to Regulation (EU) 2019/1009 but also according to the notified national provisions. Furthermore, should a CE marked fertiliser constitute an artificial fertiliser derived from mineral phosphate with a total phosphorus content of 2,3 % $P_2O_5$-equivalent by mass or more under the notified national provisions, but *not* constitute a phosphate fertiliser under Regulation (EU) 2019/1009, the manufacturers would need to make two calculations of the cadmium content, one with kg $P_2O_5$ as denominator for the purpose of compliance with the notified national provisions, and one with kg dry matter as denominator for the purpose of compliance with Regulation (EU) 2019/1009.

(111) Considering the significant administrative barrier that applying the notified national provisions to fertilisers other than phosphate fertilisers would thus cause, together with the facts that it impossible to established whether they provide a higher level of protection than Regulation (EU) 2019/1009 and that cadmium pollution from them is not of any particular concern for the Kingdom of Denmark, the Commission considers that the notified national provisions, if applied to such fertilisers, would have a disproportionate effect on the functioning of the internal market in relation to the pursued objective.

(112) In conclusion, the Commission considers that maintaining the notified national provisions constitutes an obstacle to the functioning of the internal market within the meaning of Article 114(6) TFEU insofar as they apply to fertilisers other than phosphate fertilisers. Therefore, and without it being necessary to take a decision whether the notification is admissible in that part, the notified national provisions should be rejected insofar as they apply to fertilisers other than phosphate fertilisers as referred to in Regulation (EU) 2019/1009.

2.2.2.3. Limitation in time

(113) In order to ensure that the notified national provisions, and the potential obstacle to the functioning of the internal market, are limited to what is strictly necessary to achieve the objectives pursued by the Kingdom of Denmark, the national derogation should be limited in time. The derogation would cease to be necessary if, in the future, the harmonised limit value would be set at or below the level of the Danish limit value.

(114) The harmonised limit value could only be set at or below the level of the Danish limit value through a decision of the European Parliament and of the Council based on a proposal from the Commission, e.g. in the context of the review referred to in Article 49(b) of Regulation (EU) 2019/1009. The period for which the derogation is granted should therefore not be limited to a certain date, but be aligned with such a future decision by the co-legislators.

(115) This would be in line with Article 3(2) of Regulation (EU) 2019/1009, which provides that derogations from Regulation (EC) No 2003/2003 in accordance with Article 114(4) TFEU in relation to cadmium content may continue to apply until harmonised limit values for cadmium content in phosphate fertilisers which are equal or lower than the national ones are applicable at Union level.

(116) This Decision should apply until a revised harmonised limit value equal to or lower than the Danish limit value is applicable at Union level.

3. **CONCLUSIONS**

(117) In the light of the foregoing, it should be concluded that the request by the Kingdom of Denmark for maintaining national legislation derogating from Regulation (EU) 2019/1009 as submitted on 27 January 2020 is admissible insofar as it covers phosphate fertilisers as referred to in Regulation (EU) 2019/1009.

(118) Moreover, insofar as they apply to phosphate fertilisers as referred to in Regulation (EU) 2019/1009, the Commission finds that the notified national provisions:

— meet the needs on grounds of the protection of human health and the environment,

— are proportionate to the objectives pursued,

— are not a means of arbitrary discrimination,

— do not constitute a disguised restriction on trade between Member States.

(119) The Commission therefore considers that the notified national provisions can be approved insofar as they apply to such fertilisers.

(120) However, insofar as the notified national provisions apply to fertilisers other than phosphate fertilisers as referred to in Regulation (EU) 2019/1009, the Commission finds that it would have a disproportionate effect on the functioning of the internal market in relation to the pursued objective. The Commission therefore considers that the measure must be rejected insofar as it applies to such fertilisers,

HAS ADOPTED THIS DECISION:

*Article 1*

The national provisions notified by the Kingdom of Denmark pursuant to Article 114(4) of the Treaty on the Functioning of the European Union, derogating from Regulation (EU) 2019/1009 as regards cadmium content in phosphate fertilisers, namely the prohibition of the placing on the Danish market of fertilisers with a cadmium content exceeding 48 mg/kg, $P_2O_5$, are approved insofar as they apply to phosphate fertilisers referred to in points 3(a)(ii) in PFC 1(B) and 2(a)(ii) in PFC 1(C)(I) in Annex I to Regulation (EU) 2019/1009, until a revised harmonised limit value equal to or lower than the Danish limit value is applicable at Union level.

*Article 2*

The national provisions notified by the Kingdom of Denmark are rejected insofar as they apply to fertilisers other than phosphate fertilisers referred to in points 3(a)(ii) in PFC 1(B) and 2(a)(ii) in PFC 1(C)(I) in Annex I to Regulation (EU) 2019/1009.

*Article 3*

This Decision is addressed to the Kingdom of Denmark.

Done at Brussels, 27 July 2020.

*For the Commission*
Thierry BRETON
*Member of the Commission*

# COMMISSION IMPLEMENTING DECISION (EU) 2020/1179

## of 6 August 2020

## amending Annex I to Decision 2009/177/EC as regards the status of the Province of Åland in Finland as regards a surveillance programme for viral haemorrhagic septicaemia (VHS), of Estonia as regards a surveillance and eradication programme for viral haemorrhagic septicaemia (VHS) and infectious haematopoetic necrosis (IHN), of Croatia for koi herpes virus (KHV) disease and of certain areas in the United Kingdom for infection with *Bonamia ostreae*

*(notified under document C(2020) 5303)*

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals ([1]), and in particular Articles 44(1)(2), and 53(3) thereof, in conjunction with Article 131 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 ([2]),

Whereas:

(1) Annex I to Commission Decision 2009/177/EC ([3]) sets out the list of Member States, zones and compartments which are subject to approved surveillance or eradication programmes for, or have been declared free of, certain diseases listed in Part II of Annex IV to Directive 2006/88/EC.

(2) The competent authority of Finland informed the Commission that it completed all the eradication measures under its ongoing programme for viral haemorrhagic septicaemia (VHS) in the Province of Åland and started the subsequent surveillance measures to be declared a disease-free area. Therefore, the Province of Åland should be deleted from Part B of Annex I to Decision 2009/177/EC and should instead be listed in Part A of that Annex as being subject to an approved surveillance programme.

(3) The competent authority of Estonia submitted a surveillance and eradication programme for VHS and infectious haematopoietic necrosis (IHN) to the Commission for approval and asked that the areas subject to that programme be listed in Annex I to Decision 2009/177/EC.

(4) The area in Estonia which is subject to surveillance measures for VHS and IHN should be listed in Part A of Annex I to Decision 2009/177/EC while a compartment infected with IHN and subject to the eradication measures against that disease should be listed in Part B of Annex I to Decision 2009/177/EC.

(5) Most of the territory of Croatia is listed in Part C of Annex I to Decision 2009/177/EC as being declared free from koi herpes virus (KHV) disease. The competent authority of Croatia informed the Commission about several outbreaks of KHV within the geographical area currently listed and indicated that such KHV disease-free status should be withdrawn. Therefore, Croatia should be deleted from that list.

(6) In accordance with Article 127(1) 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, Union law shall be applicable to and in the United Kingdom during the transition period provided for in that Agreement. That transition period will end on 31 December 2020.

([1]) OJ L 328, 24.11.2006, p. 14.
([2]) OJ L 29, 31.1.2020, p. 7.
([3]) Commission Decision 2009/177/EC of 31 October 2008 implementing Council Directive 2006/88/EC as regards surveillance and eradication programmes and disease-free status of Member States, zones and compartments (OJ L 63, 7.3.2009, p. 15).

(7) The competent authority of the United Kingdom informed the Commission about several outbreaks of *Bonamia ostreae* on its territory including in areas which are currently listed in Part C of Annex I to Decision 2009/177/EC as being declared free from that disease, and indicated that *Bonamia ostreae* disease-free status should be withdrawn for those areas. Therefore, those areas should be deleted from that list.

(8) Annex I to Decision 2009/177/EC should therefore be amended accordingly.

(9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

*Article 1*

In Part A of Annex I to Decision 2009/177/EC, in the table, the rows for viral haemorrhagic septicaemia (VHS) and infectious haematopoietic necrosis (IHN) are replaced by the following:

| Disease | Member State | ISO Code | Geographical demarcation of the area under a surveillance programme (Member State, zones or compartments) |
|---|---|---|---|
| 'Viral haemorrhagic septicaemia (VHS) | Estonia | EE | Whole territory |
| | Finland | FI | The Province of Åland |
| Infectious haematopoietic necrosis (IHN) | Estonia | EE | Whole territory except the compartment comprising the fish farm Neli Elementi OÜ (approval No 05/VV/KK01)' |

*Article 2*

Part B of Annex I to Decision 2009/177/EC is amended as follows:

(1) the entry for Finland is deleted from the row for viral haemorrhagic septicaemia (VHS);

(2) the row for infectious haematopoietic necrosis (IHN) is replaced by the following:

| Disease | Member State | ISO Code | Geographical demarcation of the area under an eradication programme (Member State, zones or compartments) |
|---|---|---|---|
| 'Infectious haematopoietic necrosis (IHN) | Estonia | EE | The compartment comprising the fish farm Neli Elementi OÜ (approval No 05/VV/KK01)' |

*Article 3*

In Part C of Annex I to Decision 2009/177/EC, the entry for Croatia is deleted from the row for koi herpes virus (KHV) disease.

*Article 4*

In Part C of Annex I to Decision 2009/177/EC, in the row 'Infection with *Bonamia ostreae*', the entry for the United Kingdom, in the column entitled 'Geographical demarcation of the disease-free area (Member State, zones or compartments)', is amended as follows:

(1) the following exception is added as point 7 for Great Britain: 'The Dornoch Firth, the area of tidal waters west of a line drawn from NH808873 to NH835857 (Ordnance Survey Landranger 1:50 000 series) to the mean high water mark;';

(2) the following exception is added as point 8 for Great Britain: 'Lynn of Lorn, Loch Creran and Loch Etive, the area of marine waters south-east of the island of Lismore, contained within a circle of radius 7 258 metres from point NM873391 (Ordnance Survey Landranger 1:50 000 series) and including the tidal waters of Loch Etive and Loch Creran to the mean high water mark.';

(3) the following text is deleted: 'The coastal area of the States of Jersey: the area consists of the intertidal and immediate coastal area between the mean high-water mark on the Island of Jersey and an imaginary line drawn three nautical miles from the mean low water mark of the Island of Jersey. The zone is situated in the Normano-Breton Gulf, on the south side of the English Channel.'.

*Article 5*

This Decision is addressed to the Member States.

Done at Brussels, 6 August 2020.

*For the Commission*
Stella KYRIAKIDES
*Member of the Commission*

# RULES OF PROCEDURE

## DECISION OF THE ADMINISTRATIVE COUNCIL OF THE COMMUNITY PLANT VARIETY OFFICE

## of 1 April 2020

## on internal rules concerning restrictions of certain rights of data subjects in relation to processing of personal data in the framework of the functioning of the CPVO

THE ADMINISTRATIVE COUNCIL OF THE COMMUNITY PLANT VARIETY OFFICE,

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

Having regard to 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 ([1]), and in particular Article 25 thereof,

Having regard to Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights ([2]), establishing the Community Plant Variety Office (CPVO), and in particular to Article 36 thereof,

Having regard to the consultation of the European Data Protection Supervisor (EDPS) of 18 December 2019,

After consulting the Staff Committee,

Whereas:

(1) The Community Plant Variety Office (the 'Office') carries out its activities in accordance with Regulation (EC) No 2100/94.

(2) In line with Article 25(1) of Regulation (EU) 2018/1725 restrictions of the application of Articles 14 to 22, 35 and 36, as well as Article 4 of that Regulation in so far as its provisions correspond to the rights and obligations provided for in Articles 14 to 22 should be based on internal rules to be adopted by the Office, where these are not based on legal acts adopted on the basis of the Treaties.

(3) These internal rules, including its provisions on the assessment of the necessity and proportionality of a restriction, should not apply where a legal act adopted on the basis of the Treaties provides for a restriction of rights of data subjects.

(4) Where the Office performs its duties with respect to data subject's rights under Regulation (EU) 2018/1725, it shall consider whether any of the exemptions laid down in that Regulation apply.

(5) Within the framework of its administrative functioning, the Office may be obliged to restrict rights of data subjects following Article 25 of Regulation (EU) 2018/1725.

(6) The Office, represented by its President, acts as the data controller irrespective of further delegations of the controller role within the Office to reflect operational responsibilities for specific personal data processing operations.

([1]) OJ L 295, 21.11.2018, p. 39.
([2]) OJ L 227, 1.9.1994, p. 1.

(7) The personal data are stored securely in an electronic environment or on paper preventing unlawful access or transfer of data to persons who do not have a need to know. The personal data processed are retained as specified in the data protection notices, privacy statements or records of the Office.

(8) These internal rules should apply to all processing operations carried out by the Office in the context of administrative inquiries, disciplinary proceedings, whistleblowing procedures, (formal and informal) procedures for dealing with harassment, processing complaints and medical data, conducting internal audits, investigations carried out by the Data Protection Officer in line with Article 45(2) of Regulation (EU) 2018/1725 and Information Technology (IT) security investigations handled internally or with external involvement (e.g. CERT-EU).

(9) In the cases where these internal rules apply the Office has to give justifications explaining why the restrictions are strictly necessary and proportionate in a democratic society and respect the essence of the fundamental rights and freedoms.

(10) Within this framework the Office is bound to respect, to the maximum extent possible, the fundamental rights of the data subjects during the above procedures, in particular, those relating to the right of provision of information, access and rectification, right to erasure, restriction of processing, right of communication of a personal data breach to the data subjects or confidentiality of communication as enshrined in Regulation (EU) 2018/1725.

(11) The Office should periodically monitor that the conditions that justify the restriction apply and lift the restriction as far as they do no longer apply.

(12) The Controller should inform the Data Protection Officer of each restriction applied to the data subject's rights, when the restriction has been lifted or when the restriction has been revised,

HAS ADOPTED THIS DECISION:

*Article 1*

**Subject matter and scope**

1. This Decision lays down rules relating to the conditions under which the Office in the framework of its processing operations set out in paragraph 2 may restrict the application of the rights enshrined in Articles 4, 14 to 21, 35 and 36 of Regulation (EU) 2018/1725, following Article 25 thereof.

2. Within the framework of the administrative functioning of the Office, this Decision applies to the processing of personal data by the Office for the purposes of: administrative inquiries, disciplinary proceedings, whistleblowing procedures, (formal and informal) procedures for dealing with harassment, processing complaints, processing medical data and/or files, conducting internal audits, investigations carried out by the Data Protection Officer in line with Article 45(2) of Regulation (EU) 2018/1725 and IT security investigations handled internally or with external involvement (e.g. CERT-EU).

This Decision applies to processing operations initiated and carried out by the Office, including prior to the opening of the procedures referred to above, during these procedures and during the monitoring of the follow-up to the outcome of these procedures. It also applies to assistance and cooperation provided by the Office, outside its own administrative procedures, to OLAF, competent authorities of Member States and/or other competent authorities.

3. The categories of data concerned are hard data ('objective' data such as identification data, contact data, professional data, administrative details, data received from specific sources, electronic communications and traffic data) and/or soft data ('subjective' data related to the case such as reasoning, behavioural data, appraisals, performance and conduct data and data related to or brought forward in connection with the subject matter of the procedure or activity).

4. Where the Office performs its duties with respect to the rights of data subjects under Regulation (EU) 2018/1725, it shall consider whether any of the exemptions laid down in that Regulation apply.

5. Subject to the conditions set out in this Decision, the restrictions may apply to the following rights: provision of information to data subjects, right of access, rectification, erasure, restriction of processing, communication of a personal data breach to the data subjects or confidentiality of electronic communications.

*Article 2*

**Specification of the controller and safeguards**

1. The Office shall put in place the following safeguards to prevent abuse or unlawful access or transfer:

(a) Paper documents shall be kept in secured cupboards and only accessible to authorised staff;

(b) All electronic data shall be stored in a secure IT application according to the Office's security standards, as well as in specific electronic folders accessible only to authorised staff. Appropriate levels of access shall be granted individually;

(c) IT systems and their databases must have mechanisms for verifying user's identity under a single sign-on system and connected automatically to the user's ID and password. End user accounts must be unique, personal and non-transferrable, sharing user accounts is strictly prohibited. E-records shall be held securely to safeguard the confidentiality and privacy of the data therein;

(d) All persons having access to the data are bound by the obligation of confidentiality.

2. The controller of the processing operations is the Office, represented by its President, who may delegate the function of the controller. Data subjects shall be informed of the delegated controller by way of the data protection notices or records published on the website and/or the intranet of the Office.

3. The retention period of the personal data referred to in Article 1(3) shall be no longer than specified in the data protection notices, privacy statements or records referred to in Article 3(1). At the end of the retention period, the case related information, including personal data, is deleted, anonymised or transferred to the historical archives.

4. Where the Office considers applying a restriction, the risk to the rights and freedoms of the data subject shall be weighed, in particular, against the risk to the rights and freedoms of other data subjects and the risk of hindering the purpose of the processing operation. The risks to the rights and freedoms of the data subject concern primarily, but are not limited to, reputational risks and risks to the right of defence and the right to be heard.

*Article 3*

**Restrictions**

1. The Office shall publish on its website and/or on the intranet data protection notices, privacy statements and/or records in the sense of Article 31 of Regulation (EU) 2018/1725, informing all data subjects of its activities involving processing of their personal data and of their rights in the framework of a given procedure, including information relating to a potential restriction of these rights. The information shall cover which rights may be restricted, the reasons and the potential duration.

2. Without prejudice to the provisions of paragraph 3, where relevant, the Office shall ensure that the data subjects are informed individually in an appropriate format. The Office may also individually inform them about their rights concerning present or future restrictions.

3. Any restriction initiated by the Office shall only be applied to safeguard the purposes enumerated under Article 25(1) of Regulation (EU) 2018/1725:

(a) the national security, public security or defence of the Member States;

(b) the prevention, investigation, detection and prosecution of criminal offences or the execution of criminal penalties, including the safeguarding against and the prevention of threats to public security;

(c) other important objectives of general public interest of the Union or of a Member State, in particular the objectives of the common foreign and security policy of the Union or an important economic or financial interest of the Union or of a Member State, including monetary, budgetary and taxation matters, public health and social security;

(d) the internal security of Union institutions and bodies, including of their electronic communications networks;

(e) the protection of judicial independence and judicial proceedings;

(f) the prevention, investigation, detection and prosecution of breaches of ethics for regulated professions;

(g) a monitoring, inspection or regulatory function connected, even occasionally, to the exercise of official authority in the cases referred to in points (a) to (c);

(h) the protection of the data subject or the rights and freedoms of others;

(i) the enforcement of civil law claims.

4. In particular, when the Office restricts in the context of:

(a) administrative inquiries and disciplinary proceedings, restrictions may be based on Article 25(1)(c), (e), (g), (h) of Regulation (EU) 2018/1725;

(b) whistleblowing procedures, restrictions may be based on Article 25(1)(h) of Regulation (EU) 2018/1725;

(c) (formal and informal) procedures for dealing with harassment, restrictions may be based on Article 25(1)(h) of Regulation (EU) 2018/1725;

(d) processing complaints, restrictions may be based on Article 25(1)(c), (e), (g), (h) of Regulation (EU) 2018/1725;

(e) processing medical data, restrictions may be based on Article 25(1)(h) of Regulation (EU) 2018/1725;

(f) internal audits, restrictions may be based on Article 25(1)(c), (g), (h) of Regulation (EU) 2018/1725;

(g) investigations carried out by the Data Protection Officer in line with Article 45(2) of Regulation (EU) 2018/1725, restrictions may be based on Article 25(1)(c), (g), (h) of Regulation (EU) 2018/1725;

(h) IT security investigations handled internally or with external involvement (e.g. CERT-EU), restrictions may be based on Article 25(1)(c), (d), (g), (h) of Regulation (EU) 2018/1725.

5. Any restriction shall be necessary and proportionate taking into account in particular the risks to the rights and freedoms of data subjects and respect the essence of the fundamental rights and freedoms in a democratic society.

If the application of restriction is considered, a necessity and proportionality test shall be carried out based on the present rules. It shall be documented through an internal assessment note for accountability purposes on a case by case basis. The test will also be conducted in the context of reviewing the application of a restriction.

Restrictions shall be lifted as soon as the circumstances that justify them no longer apply. In particular, where it is considered that the exercise of the restricted right would no longer cancel the effect of the restriction imposed or adversely affect the rights or freedoms of other data subjects.

6. In addition, the Office may be requested to exchange personal data of data subjects with Commission services or other Union institutions, bodies, agencies and offices, competent authorities of Member States or other competent authorities from third countries or international organisations, including:

(a) where the Commission services or other Union institutions, bodies, agencies and offices restrict their obligations and the exercise of the rights of these data subjects on the basis of other acts provided for in Article 25 of Regulation (EU) 2018/1725 or in accordance with Chapter IX of that Regulation or with the founding acts of other Union institutions, bodies, agencies and offices;

(b) where the competent authorities of Member States restrict their obligations and the exercise of the rights of these data subjects on the basis of acts referred to in Article 23 of Regulation (EU) 2016/679 of the European Parliament and of the Council ([3]), or under national measures transposing Articles 13(3), 15(3) or 16(3) of Directive (EU) 2016/680 of the European Parliament and of the Council ([4]).

Wherever the exchange of personal data is initiated by another authority, no restriction is applied by the Office and the case related information, including personal data, shall be deleted or anonymised by the Office upon transmission of the requested data to that authority.

7. The records on the restrictions and, where applicable, the documents containing underlying factual and legal elements shall be made available to the European Data Protection Supervisor on request.

*Article 4*

**Review by the Data Protection Officer**

1. The Office shall, without undue delay, inform the Data Protection Officer of the Office ('the DPO') whenever the controller restricts the application of the rights of data subjects, lifts the restriction or revises the period of restriction, in accordance with this Decision. The controller shall provide the DPO access to the record containing the assessment of the necessity and proportionality of the restriction and document in the record the date of informing the DPO.

2. The DPO may request the controller in writing to review the application of the restrictions. The controller shall inform the DPO in writing about the outcome of the requested review.

3. The involvement of the DPO in the restrictions procedure, including information exchanges, shall be documented in an appropriate form.

*Article 5*

**Provision of information to data subject**

1. In duly justified cases and under the conditions stipulated in this Decision, the provision of information may be restricted by the controller, where necessary and proportionate, in the context of the processing operations foreseen under Article 1(2) of this Decision. In particular, the provision of information may be deferred, omitted or denied if it would cancel the effect of the processing operation.

2. Where the Office restricts, wholly or partly, the provision of information referred to in paragraph 1, it shall document in an internal assessment note the reasons for the restriction, including an assessment of the necessity, proportionality of the restriction and its duration.

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([3]) 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).

([4]) 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 (OJ L 119, 4.5.2016, p. 89).

3. The restriction referred to in paragraph 1 shall continue to apply as long as the reasons justifying it remain applicable.

Where the reasons for the restriction no longer apply, the Office shall provide information to the data subject on the principal reasons for the restriction. At the same time, the Office shall inform the data subject of the possibility of lodging a complaint with the European Data Protection Supervisor or of seeking a judicial remedy in the Court of Justice of the European Union.

4. The Office shall review the application of the restriction at least once a year and at the closure of the relevant procedure. Thereafter, the controller shall monitor the need to maintain any restriction on an annual basis.

*Article 6*

**Right of access, rectification, erasure and restriction of processing by data subject**

1. In duly justified cases and under the conditions stipulated in this Decision, the right to access, rectification, erasure and restriction of processing may be restricted by the controller, where necessary and proportionate, in the context of the processing operations foreseen under Article 1(2) of this Decision. The provisions contained in this present Article 6 do not apply to the right of access to medical data and/or files, for which specific rules are explicitly foreseen under Article 7 below.

2. Where data subjects request to exercise their right of access, rectification, erasure and restriction of processing concerning their personal data processed in the context of one or more specific cases or concerning a particular processing operation, the Office shall limit its assessment of the request to such personal data only.

3. Where the Office restricts, wholly or partly, the right of access, rectification, erasure and restriction of processing, it shall take the following steps:

(a) it shall inform the data subject concerned, in its reply to the request, of the restriction applied and of the principal reasons thereof, and of the possibility of lodging a complaint with the European Data Protection Supervisor or of seeking a judicial remedy in the Court of Justice of the European Union;

(b) it shall document in an internal assessment note the reasons for the restriction, including an assessment of the necessity, proportionality of the restriction and its duration.

In accordance with Article 25(8) of Regulation (EU) 2018/1725, the provision of information referred to in point (a) may be deferred, omitted or denied if it would cancel the effect of the restriction.

4. The Office shall review the application of the restriction of the rights of the data subjects at least once a year and at the closure of the relevant procedure. Thereafter, upon request of data subjects, the controller shall review the need to maintain the restriction.

*Article 7*

**Right of access to medical data and/or files**

1. Restriction of the right of access of data subjects to their medical data and/or files requires specific provisions which are stipulated under this Article.

2. Subject to the below paragraphs of this Article, the Office may restrict data subject's right to access directly personal medical data and/or files of a psychological or psychiatric nature concerning them which are processed by the Office, where access to such data is likely to represent a risk for the data subject's health. This restriction shall be proportionate to what is strictly necessary to protect the data subject.

3. Access to the information referred to in paragraph 2 shall be given to a doctor of the data subject's choice.

4. In such cases, the data subject shall, upon request, be reimbursed by the Medical Service of the part of the cost of the medical consultation with the doctor who received access to the medical data and/or files that has not been reimbursed by the Joint Sickness Insurance Scheme (JSIS). The reimbursement shall not exceed the difference between the ceiling laid down in the General Implementing Provisions for the reimbursement of medical expenses ([5]) and the amount reimbursed to the data subject by the JSIS pursuant to those rules.

5. Such reimbursement by the Medical Service shall be subject to the condition that access has not already been granted for the same data and/or files.

6. Subject to the below paragraphs of this Article, the Office may restrict, on a case-by-case basis data subject's right to access their personal medical data and/or files in its possession, in particular where the exercise of that right would adversely affect the rights and freedoms of the data subject or other data subjects.

7. Where data subjects request to exercise their right of access to their personal data processed in the context of one or more specific cases or to a particular processing operation, the Office shall limit its assessment of the request to such personal data only.

8. Where the Office restricts, wholly or partly, the right of access to personal medical data and/or files by data subjects, it shall take the following steps:

(a) it shall inform the data subject concerned, in its reply to the request, of the restriction applied and of the principal reasons thereof, and of the possibility of lodging a complaint with the European Data Protection Supervisor or of seeking a judicial remedy in the Court of Justice of the European Union;

(b) it shall document in an internal assessment note the reasons for the restriction, including an assessment of the necessity, proportionality of the restriction and its duration, notably by stating how the exercise of the right would present a risk for the data subject's health or would adversely affect the rights and freedoms of the data subjects or other data subjects.

In accordance with Article 25(8) of Regulation (EU) 2018/1725, the provision of information referred to in point (a) may be deferred, omitted or denied if it would cancel the effect of the restriction.

9. Restrictions referred to in the above paragraphs 2 and 6 shall continue to apply as long as the reasons justifying them remain applicable. Once the reasons for a restriction no longer apply, upon request of data subjects, the controller shall review the need to maintain the restriction.

*Article 8*

**Communication of a personal data breach to the data subject and confidentiality of electronic communications**

1. In duly justified cases and under the conditions stipulated in this Decision, the right to the communication of a personal data breach may be restricted by the controller, where necessary and appropriate in the context of the processing operations foreseen under Article 1(2) of this Decision. Such right shall however not be restricted in the context of the procedures for dealing with harassment.

2. In duly justified cases and under the conditions stipulated in this Decision, the right to confidentiality of electronic communications may be restricted by the controller, where necessary and appropriate in the context of the processing operations foreseen under Article 1(2) of this Decision.

3. Article 5(2)(3) and (4) of the present Decision applies where the Office restricts the communication of a personal data breach to the data subject or the confidentiality of electronic communications referred to in Articles 35 and 36 of Regulation (EU) 2018/1725.

([5]) Commission Decision C(2007) 3195 of 2 July 2007 laying down General Implementing Provisions for the reimbursement of medical expenses.

*Article 9*

**Entry into force**

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

Done at Angers, 1 April 2020.

*For the Community Plant Variety Office*
Bistra PAVLOVSKA
*Chair of the Administrative Council*

# ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

## DECISION No 1/2020 OF THE EU-MEXICO JOINT COUNCIL

**of 31 July 2020**

**amending Decision No 2/2000 [2020/1180]**

THE JOINT COUNCIL,

Having regard to the Economic Partnership, Political Coordination and Cooperation Agreement between the European Community and its Member States, of the one part, and the United Mexican States, of the other part [1] (the 'Global Agreement'), and in particular Articles 5 and 10 in conjunction with Article 47 thereof,

Whereas:

(1) Following the accession of the Republic of Croatia ('Croatia') to the European Union on 1 July 2013, the Third Additional Protocol to the Global Agreement was signed in Brussels on 27 November 2018 and is applicable since 1 March 2020.

(2) In view of that, it is necessary to adapt, with effect from the date on which Croatia acceded to the Global Agreement, certain provisions of Decision No 2/2000 [2], as amended by Decisions No 3/2004 [3] and No 2/2008 [4], concerning trade in goods, certification of origin and government procurement.

(3) Articles 5, 6, 7, 10 and 47 of the Global Agreement empower the Joint Council established under Article 45 of the Global Agreement to take decisions for the purpose of attaining the objectives of the Global Agreement, and in particular to decide on the appropriate arrangements and timetable related to trade in goods, trade in services and public procurement,

HAS ADOPTED THIS DECISION:

*Article 1*

1. Annex I to Decision 2/2000 is amended as set out in Annex I to this Decision.

2. This Article does not affect the content of the review clause set out in Article 10 of Decision No 2/2000.

*Article 2*

Articles 17(4) and 18(2) and Appendix IV to Annex III to Decision 2/2000 are amended as set out in Annex II to this Decision.

*Article 3*

1. The entities of Croatia listed in Annex III to this Decision are added to the relevant sections of Part B of Annex VI to Decision 2/2000.

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[1] OJL 276, 28.10.2000, p. 45.
[2] Decision No 2/2000 of the EC-Mexico Joint Council of 23 March 2000 (OJ L 157, 30.6.2000, p. 10).
[3] Decision No 3/2004 of the EC-Mexico Joint Council of 29 July 2004 amending Joint Council Decision No 2/2000 of 23 March 2000 (OJ L 293, 16.9.2004, p. 15).
[4] Decision No 2/2008 of the EU-Mexico Joint Council of 25 July 2008 amending Joint Council Decision No 2/2000, as amended by Joint Council Decision No 3/2004 (OJ L 198, 26.7.2008, p. 55).

2. The publications of Croatia listed in Annex IV to this Decision are added to Part B of Annex XIII to Decision 2/2000.

*Article 4*

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

It shall apply from the date on which Croatia acceded to the Global Agreement.

Done at Brussels, 31 July 2020.

*For the Joint Council*
*The President*
J. BORRELL FONTELLES

*ANNEX I*

**TARIFF ELIMINATION SCHEDULE OF THE COMMUNITY**

The following is inserted in Annex I to Decision No 2/2000:

| 'CN code | Description | Quantity of the annual tariff quota | Tariff quota duty rate |
|---|---|---|---|
| 0803 00 19 | Bananas, fresh (excluding plantains) | 2 010 tonnes (*) | 70 EUR/tonne |

(*) This annual tariff quota shall be open from 1 January to 31 December of each calendar year. However, it shall be applied for the first time from the third day after the publication of this Decision in the *Official Journal of the European Union*.'

*ANNEX II*

**NEW LANGUAGE VERSIONS OF ADMINISTRATIVE REMARKS AND 'INVOICE DECLARATION' CONTAINED IN ANNEX III TO DECISION No 2/2000**

Annex III to Decision No 2/2000 is amended as follows:

(1) in Article 17, paragraph 4 is replaced by the following:

'4. Movement certificates EUR.1 issued retrospectively must be endorsed with one of the following phrases:

BG "ИЗДАДЕН ВПОСЛЕДСТВИЕ"

ES "EXPEDIDO A POSTERIORI"

CS "VYSTAVENO DODATEČNE"

DA "UDSTEDT EFTERFØLGENDE"

DE "NACHTRÄGLICH AUSGESTELLT"

ET "TAGANTJÄRELE VÄLJA ANTUD"

EL "ΕΚΔΟΘΕΝ ΕΚ ΤΩΝ ΥΣΤΕΡΩΝ"

EN "ISSUED RETROSPECTIVELY"

FR "DÉLIVRÉ A POSTERIORI"

HR "NAKNADNO IZDANO"

IT "RILASCIATO A POSTERIORI"

LV "IZSNIEGTS RETROSPEKTĪVI"

LT "RETROSPEKTYVUSIS IŠDAVIMAS"

HU "KIADVA VISSZAMENŐLEGES HATÁLLYAL"

MT "MAHRUG RETROSPETTIVAMENT"

NL "AFGEGEVEN A POSTERIORI"

PL "WYSTAWIONE RETROSPEKTYWNIE"

PT "EMITIDO A POSTERIORI"

RO "EMIS A POSTERIORI"

SK "VYDANÉ DODATOČNE"

SL "IZDANO NAKNADNO"

FI "ANNETTU JÄLKIKÄTEEN"

SV "UTFÄRDAT I EFTERHAND"';

(2) in Article 18, paragraph 2 is replaced by the following:

'2. The duplicate issued pursuant to paragraph 1 must be endorsed with one of the following words:

BG "ДУБЛИКАТ"

ES "DUPLICADO"

CS "DUPLIKÁT"

DA "DUPLIKAT"

DE "DUPLIKAT"

ET "DUPLIKAAT"

EL "ΑΝΤΙΓΡΑΦΟ"

EN "DUPLICATE"

FR "DUPLICATA"

HR "DUPLIKAT"

IT "DUPLICATO"

LV "DUBLIKĀTS"

LT “DUBLIKATAS”

HU “MÁSODLAT”

MT “DUPLIKAT”

NL “DUPLICAAT”

PL “DUPLIKAT”

PT “SEGUNDA VIA”

RO “DUPLICAT”

SK “DUPLIKÁT”

SL “DVOJNIK”

FI “KAKSOISKAPPALE”

SV “DUPLIKAT”’;

(3) the following is added to Appendix IV after the French version:

‘Croatian version

Izvoznik proizvoda obuhvaćenih ovom ispravom (carinsko ovlaštenje br.... ([1])) izjavljuje da su, osim ako je drukčije izričito navedeno, ovi proizvodi... ([2]) preferencijalnog podrijetla.

_____

([1]) When the invoice declaration is made out by an approved exporter within the meaning of Article 21 of this Annex, the authorisation number of the approved exporter must be entered in this space. When the invoice declaration is not made out by an approved exporter, the words in brackets shall be omitted or the space left blank.

([2]) Origin of products to be indicated. When the invoice declaration relates in whole or in part, to products originating in Ceuta and Melilla within the meaning of Article 37 of this Annex, the exporter must clearly indicate them in the document on which the declaration is made out by means of the symbol “CM“.’.

*ANNEX III*

**CENTRAL GOVERNMENTAL ENTITIES**

1. The following central governmental entities are added to Section 1 of Part B of Annex VI to Decision No 2/2000:

'AC – Croatia

| | | |
|---|---|---|
| 1 | Croatian Parliament | *Hrvatski Sabor* |
| 2 | President of the Republic of Croatia | *Predsjednik Republike Hrvatske* |
| 3 | Office of the President of the Republic of Croatia | *Ured predsjednika Republike Hrvatske* |
| 4 | Office of the President of the Republic of Croatia after the expiry of the term of office | *Ured predsjednika Republike Hrvatske po prestanku obnašanja dužnosti* |
| 5 | Government of the of the Republic of Croatia | *Vlada Republike Hrvatske* |
| 6 | Offices of the Government of the Republic of Croatia | *uredi Vlade Republike Hrvatske* |
| 7 | Ministry of Economy | *Ministarstvo gospodarstva* |
| 8 | Ministry of Regional Development and EU Funds | *Ministarstvo regionalnoga razvoja i fondova Europske unije* |
| 9 | Ministry of Finance | *Ministarstvo financija* |
| 10 | Ministry of Defence | *Ministarstvo obrane* |
| 11 | Ministry of Foreign and European Affairs | *Ministarstvo vanjskih i europskih poslova* |
| 12 | Ministry of the Interior | *Ministarstvo unutarnjih poslova* |
| 13 | Ministry of Justice | *Ministarstvo pravosuđa* |
| 14 | Ministry of Public Administration | *Ministarstvo uprave* |
| 15 | Ministry of Entrepreneurship and Crafts | *Ministarstvo poduzetništva i obrta* |
| 16 | Ministry of Labour and Pension System | *Ministarstvo rada i mirovinskoga sustava* |
| 17 | Ministry of Maritime Affairs, Transport and Infrastructure | *Ministarstvo pomorstva, prometa i infrastrukture* |
| 18 | Ministry of Agriculture | *Ministarstvo poljoprivrede* |
| 19 | Ministry of Tourism | *Ministarstvo turizma* |
| 20 | Ministry of Environmental and Nature Protection | *Ministarstvo zaštite okoliša i prirode* |
| 21 | Ministry of Construction and Physical Planning | *Ministarstvo graditeljstva i prostornoga uređenja* |
| 22 | Ministry of Veterans' Affairs | *Ministarstvo branitelja* |
| 23 | Ministry of Social Policy and Youth | *Ministarstvo socijalne politike i mladih* |
| 24 | Ministry of Health | *Ministarstvo zdravlja* |
| 25 | Ministry of Science, Education and Sports | *Ministarstvo znanosti, obrazovanja i sporta* |
| 26 | Ministry of Culture | *Ministarstvo kulture* |
| 27 | State administrative organisations | *državne upravne organizacije* |
| 28 | County state administration offices | *uredi državne uprave u županijama* |

| | | |
|---|---|---|
| 29 | Constitutional Court of the Republic of Croatia | *Ustavni sud Republike Hrvatske* |
| 30 | Supreme Court of the Republic of Croatia | *Vrhovni sud Republike Hrvatske* |
| 31 | Courts | *sudovi* |
| 32 | State Judiciary Council | *Državno sudbeno vijeće* |
| 33 | State attorney's offices | *državna odvjetništva* |
| 34 | State Prosecutor's Council | *Državno odvjetničko vijeće* |
| 35 | Ombudsman's offices | *pravobraniteljstva* |
| 36 | State Commission for the Supervision of Public Procurement Procedures | *Državna komisija za kontrolu postupaka javne nabave* |
| 37 | Croatian National Bank | *Hrvatska narodna banka* |
| 38 | State agencies and offices | *državne agencije i uredi* |
| 39 | State Audit Office | *Državni ured za reviziju*' |

2. The following bodies and categories of bodies are added to the Attachment to Section 2 of Part B of Annex VI to Decision No 2/2000:

'a

*Annex I*

**'PRODUCTION, TRANSPORT OR DISTRIBUTION OF DRINKING WATER':**

'CROATIA

Public undertakings which are contracting entities referred to in Article 6 of the Zakon o javnoj nabavi (Narodne novine broj 90/11, 83/13, 143/13 i 13/14) (Public Procurement Act, Official Gazette No 90/11, 83/13, 143/13 and 13/14) which, in accordance with special regulations, engage in the activity of construction (providing) of fixed networks or managing fixed networks for public service delivery in relation to the production, transmission and distribution of drinking water and supplying fixed networks with drinking water, such as the entities established by the local self-government units acting as the public supplier of water supply services or drainage services in accordance with the Waters Act (Official Gazette 153/09, 63/11, 130/11, 53/13 and 14/14).';

b

*Annex II*

**'PRODUCTION, TRANSPORT OR DISTRIBUTION OF ELECTRICITY':**

'CROATIA

Public undertakings which are contracting entities referred to in Article 6 of the Zakon o javnoj nabavi (Narodne novine broj 90/11, 83/13, 143/13 i 13/14) (Public Procurement Act, Official Gazette No 90/11, 83/13, 143/13 and 13/14) which, in accordance with special regulations, engage in the activity of construction (providing) of fixed networks or managing fixed networks for public service delivery in relation to the production, transmission and distribution of electric energy and supplying fixed networks with electric energy, such as the entities engaging in the said activities based on the licence for carrying out energy activities in accordance with the Energy Act (Official Gazette 120/12 and 14/14).';

c

*Annex VII*

**‘CONTRACTING ENTITIES IN THE FIELD OF URBAN RAILWAY, TRAMWAY, TROLLEYBUS OR BUS SERVICES’:**

‘CROATIA

Public undertakings which are contracting entities referred to in Article 6 of the Zakon o javnoj nabavi (Narodne novine broj 90/11, 83/13, 143/13 i 13/14) (Public Procurement Act, Official Gazette No 90/11, 83/13, 143/13 and 13/14) which, in accordance with special regulations, engage in the activity of making available the networks or managing the networks for public services of urban railway, automated systems, tramway, bus, trolleybus and cable car (cableway) transport, such as the entities engaging in the said activities as a public service in accordance with the Utilities Act (Official Gazette 36/95, 70/97, 128/99, 57/00, 129/00, 59/01, 26/03, 82/04, 110/04, 178/04, 38/09, 79/09, 153/09, 49/11, 84/11, 90/11, 144/12, 94/13, 153/13 and 147/14).’;

d

*Annex VIII*

**‘CONTRACTING ENTITIES IN THE FIELD OF AIRPORT FACILITIES’:**

‘CROATIA

Public undertakings which are contracting entities referred to in Article 6 of the Zakon o javnoj nabavi (Narodne novine broj 90/11, 83/13, 143/13 i 13/14) (Public Procurement Act, Official Gazette No 90/11, 83/13, 143/13 and 13/14) which, in accordance with special regulations, engage in the activity relating to the exploiting of a geographical area with the aim of making available airports and other terminal equipment to air transport operators, such as the entities engaging in the said activities based on the awarded concession in accordance with the Airports Act (Official Gazette 19/98 and 14/11).’;

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*Annex IX*

**‘CONTRACTING ENTITIES IN THE FIELD OF MARITIME OR INLAND PORT OR OTHER TERMINAL FACILITIES’:**

‘CROATIA

Public undertakings which are contracting entities referred to in Article 6 of the Zakon o javnoj nabavi (Narodne novine broj 90/11, 83/13, 143/13 i 13/14) (Public Procurement Act, Official Gazette No 90/11, 83/13, 143/13 and 13/14) which, in accordance with special regulations, engage in the activity relating to the exploiting of a geographical area with the aim of making available sea ports, river ports and other transport terminals to operators in sea or river transport, such as the entities engaging in the said activities based on the awarded concession in accordance with the Maritime Domain and Seaports Act (Official Gazette 158/03, 100/04, 141/06 and 38/09)’.’

*ANNEX IV*

**PUBLICATIONS**

The following is added to Part B of Annex XIII to Decision 2/2000:

'Croatia

Notices:

— *Official Journal of the European Union*

— Narodne Novine

— Electronic Public Procurement Classifieds of the Republic of Croatia (https://eojn.nn.hr/Oglasnik/clanak/electronic-public-procurement-of-the-republic-of-croatia/0/81/)'.

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