

Official Journal of the European Union

L 398



English edition

Legislation

Volume 63

27 November 2020

Contents

II *Non-legislative acts*

REGULATIONS

- ★ **Commission Implementing Regulation (EU) 2020/1767 of 20 November 2020 entering a name in the register of protected designations of origin and protected geographical indications ‘Rucola della Piana del Sele’ (PGI)** 1
- ★ **Commission Implementing Regulation (EU) 2020/1768 of 25 November 2020 amending Regulation (EC) No 1484/95 as regards fixing representative prices in the poultrymeat and egg sectors and for egg albumin** 2
- ★ **Commission Implementing Regulation (EU) 2020/1769 of 25 November 2020 on the reimbursement, in accordance with Article 26(5) of Regulation (EU) No 1306/2013 of the European Parliament and of the Council, of the appropriations carried over from financial year 2020** 4
- ★ **Commission Implementing Regulation (EU) 2020/1770 of 26 November 2020 on types and species of plants for planting not exempted from the traceability code requirement for plant passports under Regulation (EU) 2016/2031 of the European Parliament and of the Council and repealing Commission Directive 92/105/EEC** 6
- ★ **Commission Implementing Regulation (EU) 2020/1771 of 26 November 2020 approving reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA) as an existing active substance for use in biocidal products of product-types 2, 3 and 4 ⁽¹⁾** 9
- ★ **Commission Implementing Regulation (EU) 2020/1772 of 26 November 2020 amending Implementing Regulation (EU) 2017/2469 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods ⁽¹⁾** 13
- ★ **Commission Implementing Regulation (EU) 2020/1773 of 26 November 2020 amending Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives ⁽¹⁾** 19

⁽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.

DECISIONS

- ★ **Political and Security Committee Decision (CFSP) 2020/1774 of 24 November 2020 extending the mandate of the Head of Mission of the European Union CSDP Advisory Mission in the Central African Republic (EUAM RCA) (EUAM RCA/1/2020)** 22
- ★ **Commission Implementing Decision (EU) 2020/1775 of 25 November 2020 allowing the Netherlands to authorise biocidal products consisting of *in situ* generated nitrogen for the protection of cultural heritage (notified under document C(2020) 8052)** 23

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1767

of 20 November 2020

entering a name in the register of protected designations of origin and protected geographical indications ‘Rucola della Piana del Sele’ (PGI)

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Italy's application to register the name ‘Rucola della Piana del Sele’ 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 ‘Rucola della Piana del Sele’ should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name ‘Rucola della Piana del Sele’ (PGI) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.6. – Fruit, vegetables and cereals, fresh or processed, 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, 20 November 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 254, 3.8.2020, p. 17.

⁽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) 2020/1768**of 25 November 2020****amending Regulation (EC) No 1484/95 as regards fixing representative prices in the poultrymeat and egg sectors and for egg albumin**

THE EUROPEAN COMMISSION,

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

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

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

Whereas:

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 25 November 2020.

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

⁽¹⁾ OJ L 347, 20.12.2013, p. 671.

⁽²⁾ OJ L 150 20.5.2014, p. 1.

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

ANNEX

'ANNEX I

CN code	Description	Representative price (EUR/100 kg)	Security under Article 3 (EUR/100 kg)	Origin ⁽¹⁾
0207 14 10	Fowls of the species <i>Gallus domesticus</i> , boneless cuts, frozen	175,9	42	AR
		145,6	57	BR
		245	17	CL
		192,8	34	TH
1602 32 11	Preparations of fowls of the species <i>Gallus domesticus</i> , uncooked	167,3	41	BR'

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

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1769**of 25 November 2020****on the reimbursement, in accordance with Article 26(5) of Regulation (EU) No 1306/2013 of the European Parliament and of the Council, of the appropriations carried over from financial year 2020**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 ⁽¹⁾, and in particular Article 26(6) thereof,

After consulting the Committee on the Agricultural Funds,

Whereas:

- (1) In accordance with point (d) of the first subparagraph of Article 12(2) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council ⁽²⁾ non-committed appropriations relating to the actions financed by the European Agricultural Guarantee Fund (EAGF) as referred to in Article 4(1) of Regulation (EU) No 1306/2013 may be carried over to the following financial year. Such carryover is limited to 2 % of the initial appropriations voted by the European Parliament and by the Council and to the amount of the adjustment of direct payments as referred to in Article 8 of Regulation (EU) No 1307/2013 of the European Parliament and of the Council ⁽³⁾ which was applied during the preceding financial year.
- (2) In accordance with Article 26(5) of Regulation (EU) No 1306/2013, by way of derogation from the third subparagraph of Article 12(2) of Regulation (EU, Euratom) 2018/1046, Member States are to reimburse the carryover referred to in point (d) of the first subparagraph of Article 12(2) of Regulation (EU, Euratom) 2018/1046 to the final recipients who are subject to the adjustment rate in the financial year to which the appropriations are carried over. That reimbursement only applies to final beneficiaries in those Member States where financial discipline applied ⁽⁴⁾ in the preceding financial year.
- (3) When setting the amount of the carryover to be reimbursed, in accordance with Article 26(7) of Regulation (EU) No 1306/2013 the amounts of the reserve for crises in the agricultural sector referred to in Article 25 of that Regulation, not made available for crisis measures by the end of the financial year, are to be taken into account.
- (4) In accordance with Article 1(1) of Commission Implementing Regulation (EU) 2019/1928 ⁽⁵⁾, financial discipline is applied to direct payments in respect of calendar year 2019 to establish the crisis reserve. The crisis reserve has not been called on in financial year 2020.
- (5) In order to ensure that the reimbursement to the final recipients of unused appropriations as a result of the application of financial discipline remains proportionate to the amount of the financial discipline adjustment, it is appropriate that the Commission determines the amounts available to the Member States for the reimbursement.
- (6) To avoid compelling Member States to make an additional payment for that reimbursement, this Regulation needs to apply from 1 December 2020. Consequently, the amounts established by this Regulation are definitive and apply, without prejudice to the application of reductions in accordance with Article 41 of Regulation (EU) No 1306/2013, to any other corrections taken into account in the monthly payment decision concerning the expenditure effected by

⁽¹⁾ OJ L 347, 20.12.2013, p. 549.

⁽²⁾ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

⁽³⁾ Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009 (OJ L 347, 20.12.2013, p. 608).

⁽⁴⁾ Financial discipline does not apply in financial year 2020 in Croatia in accordance with Article 8(2) of Regulation (EU) No 1307/2013.

⁽⁵⁾ Commission Implementing Regulation (EU) 2019/1928 of 19 November 2019 adapting the adjustment rate for direct payments pursuant to Regulation (EU) No 1306/2013 of the European Parliament and of the Council in respect of the calendar year 2019 and repealing Commission Implementing Regulation (EU) 2019/916 (OJ L 299, 20.11.2019, p. 49).

the paying agencies of the Member States for October 2020, in accordance with Article 18(3) of Regulation (EU) No 1306/2013 and to any deductions and supplementary payments to be made in accordance with Article 18(4) of that Regulation or to any decisions which will be taken within the framework of the clearance of accounts procedure.

- (7) In accordance with the introductory phrase of Article 12(2) of Regulation (EU, Euratom) 2018/1046, the non-committed appropriations may be carried over to the following financial year only. It is therefore appropriate for the Commission to determine eligibility dates for the expenditure of the Member States in relation to the reimbursement in accordance with Article 26(5) of Regulation (EU) No 1306/2013, taking into account the agricultural financial year as defined in Article 39 of that Regulation.
- (8) As the amounts to be carried over and made available concern the 2021 budget, it follows from Article 135(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 that there is no need to set an amount in respect of the United Kingdom in this Regulation.
- (9) In order to take into account the short time span between the communication of the execution of 2020 EAGF appropriations under shared management for the period from 16 October 2019 to 15 October 2020 by the Member States and the need to apply this Regulation from 1 December 2020, this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The amounts of the appropriations that will be carried over from financial year 2020 in accordance with point (d) of the first subparagraph and the third subparagraph of Article 12(2) of Regulation (EU, Euratom) 2018/1046 and that in accordance with Article 26(5) of Regulation (EU) No 1306/2013 are made available to the Member States for the reimbursement to the final recipients who are subject to the adjustment rate in financial year 2021, are laid down in the Annex to this Regulation.

The amounts that will be carried over are subject to the carryover decision of the Commission in accordance with Article 12(3) of Regulation (EU, Euratom) 2018/1046.

Article 2

Member States' expenditure in relation to the reimbursement of the appropriations carried over shall only be eligible for Union financing if the relevant amounts have been paid to the beneficiaries before 16 October 2021.

Article 3

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

It shall apply from 1 December 2020.

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

Done at Brussels, 25 November 2020.

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

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1770**of 26 November 2020****on types and species of plants for planting not exempted from the traceability code requirement for plant passports under Regulation (EU) 2016/2031 of the European Parliament and of the Council and repealing Commission Directive 92/105/EEC**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC ⁽¹⁾, and in particular Article 83(3) thereof,

Whereas:

- (1) Regulation (EU) 2016/2031 lays down rules concerning the content and the format of the plant passport required for movement within the Union territory, and into and within protected zones, of certain plants, plant products and other objects.
- (2) The plant passport for movement within the Union territory includes a traceability code, except for certain plants for planting being ready for the sale to final users. That exception does not apply to types and species of plants for planting to be listed by the Commission.
- (3) Certain plants for planting are subject to Union measures adopted pursuant to Article 28 or Article 30 of Regulation (EU) 2016/2031 for specific pests. Some of these plants for planting, in particular those that are known to be more likely infested or infected with those specific pests or that have been intercepted on the internal market because of their infestation or infection with those specific pests, may contribute to spreading those pests within the Union, and thus increase a potential of those pests to cause a major and long-term negative impact on those plants for planting.
- (4) Certain plants for planting originating within the Union are subject to special requirements specified in respect of certain Union quarantine pests according to Article 41(2) of Regulation (EU) 2016/2031 and Article 8(2) of Commission Implementing Regulation (EU) 2019/2072 ⁽²⁾. Those plants for planting may contribute to spreading those pests within the Union, and thus increase a potential of those pests to cause a major and long-term negative impact on those plants for planting.
- (5) Certain of those plants for planting have been intercepted, while moving within the Union, for hosting Union quarantine pests.
- (6) It is therefore appropriate to require a traceability code for all cases of plant passports issued for those plants for planting, in order to enhance rapid traceability of those plants.
- (7) Regulation (EU) 2016/2031, Commission Implementing Regulation (EU) 2017/2313 ⁽³⁾ and this Regulation establish a set of new rules concerning the use and content of plant passports. For this reason, Commission Directive 92/105/EEC ⁽⁴⁾ becomes obsolete and should be repealed.

⁽¹⁾ OJ L 317, 23.11.2016, p. 4.

⁽²⁾ Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019 (OJ L 319, 10.12.2019, p. 1).

⁽³⁾ Commission Implementing Regulation (EU) 2017/2313 of 13 December 2017 setting out the format specifications of the plant passport for movement within the Union territory and the plant passport for introduction into, and movement within, a protected zone (OJ L 331, 14.12.2017, p. 44).

⁽⁴⁾ Commission Directive 92/105/EEC of 3 December 1992 establishing a degree of standardization for plant passports to be used for the movement of certain plants, plant products or other objects within the Community, and establishing the detailed procedures related to the issuing of such plant passports and the conditions and detailed procedures for their replacement (OJ L 4, 8.1.1993, p. 22).

- (8) In order for the professional operators and the competent authorities to have adequate time to adapt to those requirements, this Regulation should apply from 31 December 2021.
- (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

Types and species of plants for planting not exempted from the traceability code requirement for plant passports

The exemption from the traceability code requirement for plant passports for movement within the Union territory as provided for in the second subparagraph of Article 83(2) of Regulation (EU) 2016/2031 shall not apply to the types and species of plants for planting listed in the Annex to this Regulation.

Article 2

Repeal of Directive 92/105/EEC

Directive 92/105/EEC is repealed.

Article 3

Entry into force and date of application

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 31 December 2021.

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

Done at Brussels, 26 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Types and species of plants for planting not exempted from the traceability code requirement for plant passports

Plants for planting, other than seeds, of:

- *Citrus*,
 - *Coffea*,
 - *Lavandula dentata* L.,
 - *Nerium oleander* L.,
 - *Olea europea* L.,
 - *Polygala myrtifolia* L.,
 - *Prunus dulcis* (Mill.) D.A.Webb,
 - *Solanum tuberosum* L.
-

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1771**of 26 November 2020****approving reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA) as an existing active substance for use in biocidal products of product-types 2, 3 and 4****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014 ⁽²⁾ establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes peroxyoctanoic acid, to be renamed reaction mass of peracetic acid and peroxyoctanoic acid, as the result of its evaluation.
- (2) Reaction mass of peracetic acid and peroxyoctanoic acid has been evaluated for use in biocidal products of product-type 2, disinfectants and algacides not intended for direct application to humans or animals, product-type 3, veterinary hygiene, and product-type 4, food and feed area, as described in Annex V to Regulation (EU) No 528/2012.
- (3) France was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the European Chemicals Agency ('the Agency') on 2 January 2019.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinions of the Agency ⁽³⁾ on 4 March 2020, having regard to the conclusions of the evaluating competent authority.
- (5) According to those opinions, biocidal products of product-types 2, 3 and 4 containing reaction mass of peracetic acid and peroxyoctanoic acid may be expected to meet the criteria laid down in point (b) of Article 19(1) of Regulation (EU) No 528/2012, provided that certain specifications and conditions concerning their use are complied with.
- (6) Taking into account the opinions of the Agency, it is appropriate to approve reaction mass of peracetic acid and peroxyoctanoic acid for use in biocidal products of product-types 2, 3 and 4, subject to compliance with certain specifications and conditions.
- (7) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

⁽³⁾ Biocidal Products Committee Opinions on the application for approval of the active substance reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA); Product type: 2, 3 and 4; ECHA/BPC/242, 243 and 244, adopted on 4 March 2020.

HAS ADOPTED THIS REGULATION:

Article 1

Reaction mass of peracetic acid and peroxyoctanoic acid is approved as an active substance for use in biocidal products of product-types 2, 3 and 4 subject to the specifications and conditions set out in the 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, 26 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)		Date of approval	Expiry date of approval	Product type	Specific conditions	
Reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA)	IUPAC name: Reaction mass of peracetic acid (PAA) and peroxyoctanoic acid (POOA) EC No: 201-186-8 and 450-280-7 CAS No: 79-21-0 and 33734-57-5	The minimum purity of the active substance is not relevant as the active substance is a double equilibrium using hydrogen peroxide, acetic acid and octanoic acid as starting materials. The specifications correspond to a range of concentration.		1 April 2022	31 March 2032	2	The authorisations of biocidal products are subject to the following conditions: (a) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level assessment of the active substance. (b) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users.	
		Components					Specifications range content (%w/w)	
		Active substance	Peracetic acid				1,8–13,9	
		Active substance	Peroxyoctanoic acid				0,15–2,42	
		Relevant impurity	Hydrogn peroxyde				1,1–25,45	
		Relevant impurity	Acetic acid				5,74–51	
		Relevant impurity	Octanoic acid				1,63–9,03	
						3	The authorisations of biocidal products are subject to the following conditions: (a) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level assessment of the active substance. (b) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users.	
							4	The authorisations of biocidal products are subject to the following conditions: (a) The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an

						application for authorisation, but not addressed in the Union level assessment of the active substance. (b) Products containing reaction mass of peracetic acid and peroxyoctanoic acid shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council ⁽²⁾, unless the Commission has established specific limits on the migration of reaction mass of peracetic acid and peroxyoctanoic acid into food or it has established] in accordance with that Regulation that such limits are not necessary. (c) In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to professional users.
--	--	--	--	--	--	---

⁽¹⁾ The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

⁽²⁾ Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1772**of 26 November 2020****amending Implementing Regulation (EU) 2017/2469 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 13 and Article 35(3) thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 lays down rules for the placing on the market and use of novel foods in the Union.
- (2) Commission Implementing Regulation (EU) 2017/2469 ⁽²⁾ lays down administrative and scientific requirements for applications referred to in Article 10(1) of Regulation (EU) 2015/2283.
- (3) Regulation (EU) 2019/1381 of the European Parliament and the Council ⁽³⁾ amended Regulation (EC) No 178/2002 ⁽⁴⁾ and Regulation (EU) 2015/2283. Those amendments are aimed at strengthening the transparency and the sustainability of the EU risk assessment in all areas of the food chain where the European Food Safety Authority ('the Authority') delivers a scientific risk assessment, including in the area of novel foods.
- (4) As regards the placing on the market of novel foods, the amendments to Regulation (EC) No 178/2002 introduced new provisions concerning amongst other issues: general pre-submission advice by the staff of the Authority at the request of a potential applicant and the obligation to notify studies commissioned or carried out by business operators to support an application and the consequences of non-compliance with that obligation. It also introduced provisions on the public disclosure by the Authority of all scientific data, studies and other information supporting applications, with the exception of confidential information, early on in the risk assessment process, followed up by a consultation of third parties. The amendments also set out specific procedural requirements for the submission of confidentiality requests and the assessment thereof by the Authority in relation to the information submitted by an applicant, where the Commission requests the opinion of the Authority.
- (5) Regulation (EU) 2019/1381 also amended Regulation (EU) 2015/2283 to include provisions ensuring consistency with the adaptations of Regulation (EC) No 178/2002 and taking into account sectoral specificities with respect to confidential information.
- (6) Given the scope and application of all those amendments, Implementing Regulation (EU) 2017/2469 should be adjusted to accommodate the changes as regards the content, drafting and presentation of applications referred to in Article 10 of Regulation (EU) 2015/2283, the arrangements for verifying the validity of applications, and the information to be included in the opinion of the Authority. In particular, Implementing Regulation (EU) 2017/2469 should make reference to the standard data formats and require that applications provide information demonstrating compliance with the notification requirement laid down in Article 32b of Regulation (EC) No 178/2002. It should also clarify that the assessment of compliance with the notification requirement forms part of the verification of the validity of an application.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 64).

⁽³⁾ Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and the sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (OJ L 231, 6.9.2019, p. 1).

⁽⁴⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

- (7) Furthermore, taking into account the fact that the Authority is responsible for managing the database of studies in accordance with Article 32b of Regulation (EC) No 178/2002, it should also be made possible for the Commission to consult the Authority as part of the verification of the validity of applications to ascertain that the application fulfils the relevant requirements that are laid down in that Article.
- (8) Where public consultations are performed during the risk assessment in accordance with Article 32c(2) of Regulation (EC) No 178/2002, the opinion of the Authority should also include the results of those consultations, in line with the transparency requirements to which the Authority is subject.
- (9) This Regulation should apply from 27 March 2021 and to applications submitted as of that date, which is the date of application of Regulation (EU) 2019/1381.
- (10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Implementing Regulation (EU) 2017/2469

Implementing Regulation (EU) 2017/2469 is amended as follows:

- (1) Article 3 is amended as follows:

- (a) paragraph 1 is replaced by the following:

‘1. An application shall consist of the following:

- (a) a cover letter;
- (b) a technical dossier;
- (c) a summary of the dossier.

Prior to the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, the application shall be submitted through the electronic submission system provided by the Commission, in an electronic format allowing for the downloading, printing and searching of documents. After the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, the application shall be submitted through the electronic submission system provided by the Commission in accordance with those standard data formats.’;

- (b) paragraph 5 is replaced by the following:

‘5. In addition to the information referred to in points (a), (b) and (e) of Article 10(2) of Regulation (EU) 2015/2283, the summary of the dossier referred to in paragraph 1(c) of this Article shall set out the reasons why the use of the novel food complies with the conditions laid down in Article 7 of Regulation (EU) 2015/2283. The summary of the dossier shall not contain any information subject to a request for confidential treatment pursuant to Article 23 of Regulation (EU) 2015/2283 and Article 39a of Regulation (EC) No 178/2002.’;

- (2) Article 4 is replaced by the following:

‘Article 4

Administrative data requirements

In addition to the information set out in Article 10(2) of Regulation (EU) 2015/2283, the application shall include the following administrative data:

- (a) the name(s) of the manufacturer(s) of the novel food, if different than the applicant’s, address and contact details;
- (b) the name, address and contact details of the person responsible for the dossier authorised to communicate on behalf of the applicant with the Commission and the Authority;

- (c) the date of submission of the dossier;
 - (d) a table of contents of the dossier;
 - (e) a detailed list of documents annexed to the dossier, including references to titles, volumes and pages;
 - (f) where the applicant submits, in accordance with Article 23 of Regulation (EU) 2015/2283, a request to treat as confidential certain parts of the information of the dossier, including supplementary information, a list of the parts to be treated as confidential accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree;
 - (g) where the production process contains confidential data, a non-confidential summary of the production process;
 - (h) separately included information and explanations substantiating the existence of the applicant's right of reference to the proprietary scientific evidence or scientific data in accordance with Article 26 of Regulation (EU) 2015/2283;
 - (i) a list of the studies submitted to support the application, including information demonstrating compliance with Article 32b of Regulation (EC) No 178/2002.;
- (3) Article 6 is replaced by the following:

'Article 6

Verification of the validity of an application

1. On receipt of an application, the Commission shall, without delay verify whether the application falls within the scope of Regulation (EU) 2015/2283 and whether the application fulfils the requirements set out in Article 10(2) of that Regulation, Articles 3 to 5 of this Regulation and in Article 32b of Regulation (EC) No 178/2002.
 2. The Commission may consult the Authority on whether the application fulfils the relevant requirements referred to in paragraph 1. The Authority shall provide the Commission with its views within a period of 30 working days.
 3. The Commission may request additional information from the applicant as regards the validity of the application and inform the applicant of the period within which that information has to be provided.
 4. By way of derogation from paragraph 1 of this Article, and without prejudice to Article 10(2) of Regulation (EU) 2015/2283 and to Article 32b(4) and (5) of Regulation (EC) No 178/2002, an application may be considered valid even if it does not contain all the elements required under Articles 3 to 5 of this Regulation, provided that the applicant has submitted appropriate justification for each missing element.
 5. The Commission shall inform the applicant, the Member States and the Authority whether the application is considered valid or not. Where the application is not considered valid, the Commission shall indicate the reasons for that finding.;
- (4) in Article 7(1), the following point (n) is added:
- (n) the results of consultations performed during the risk assessment process in accordance with Article 32c(2) of Regulation (EC) No 178/2002.;
- (5) Annex I is replaced in accordance with the Annex to this Regulation;
- (6) Annex II is deleted.

Article 2

Entry into force and application

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

It shall apply from 27 March 2021 and to applications submitted to the Commission from that date.

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

Done at Brussels, 26 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

‘ANNEX

Template cover letter accompanying an application for novel food

EUROPEAN COMMISSION

Directorate-General

Directorate

Unit

Date:

Subject: **Application for authorisation of a novel food in accordance with Regulation (EU) 2015/2283***(Please indicate clearly by ticking one of the boxes)*

- ☐ Application for an authorisation of a new novel food.
- ☐ Application for adding, removing or changing the conditions of use of an already authorised novel food. Please provide a reference to that authorisation.
- ☐ Application for adding, removing or changing the specifications of an already authorised novel food. Please provide a reference to that authorisation.
- ☐ Application for adding, removing or changing additional specific labelling requirements of an already authorised novel food. Please provide a reference to that authorisation.
- ☐ Application for adding, removing or changing post market monitoring requirements of an already authorised novel food. Please provide a reference to that authorisation.

The Applicant(s) or their Representative(s) in the Union

(name(s), address(es)...)

.....

submit(s) this application in order to update the Union list on novel foods.

Identity of the novel food (Please provide information on the identity of the novel food depending on the category(ies) under which the novel food falls):

.....

Confidentiality. Where appropriate, state whether the application includes confidential data in accordance with Article 23 of Regulation (EU) 2015/2283:

- ☐ Yes
- ☐ No

Data Protection (*). Where appropriate, state whether the application includes a request for the protection of proprietary data according to Article 26 of Regulation (EU) 2015/2283:

- ☐ Yes
- ☐ No

Food categories, conditions of use and labelling requirements

Food category	Specific conditions of use	Additional specific labelling requirement

Yours sincerely,

Signature

Enclosures:

- ☐ Complete dossier
- ☐ Summary of the dossier (non-confidential)
- ☐ List of the parts of the dossier requested to be treated as confidential, accompanied by verifiable justification demonstrating how the disclosure of such information would potentially harm the interests of the applicant to a significant degree
- ☐ Information supporting the protection of proprietary data relating to the novel food application
- ☐ Copy of administrative data of applicant(s)
- ☐ List of studies and all information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002*

(*) Applicant should specify the part(s) of the application which include(s) proprietary data for which protection is requested, clearly stating section(s) and page number(s). Applicant should provide verifiable justification/declaration for the proprietary claim.

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1773**of 26 November 2020****amending Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives****(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 7(4) thereof,

After consulting the European Food Safety Authority,

Whereas:

- (1) Commission Regulation (EC) No 429/2008 ⁽²⁾ sets out detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the preparation and the presentation of applications for the authorisation of feed additives and the assessment of such applications.
- (2) Regulation (EU) 2019/1381 of the European Parliament and of the Council ⁽³⁾ aims at increasing the transparency and the sustainability of Union risk assessment in the food chain. For that purpose, it amends Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽⁴⁾ and Regulation (EC) No 1831/2003 with a view to strengthening transparency in procedures concerning the authorisation of feed additives.
- (3) To take into account sectoral specificities, Regulation (EU) 2019/1381 amends the provisions relating to transparency and confidentiality laid down in Regulation (EC) No 1831/2003.
- (4) As regards the authorisation of feed additives, the amendments brought to Regulation (EC) No 178/2002 by Regulation (EU) 2019/1381 have also a direct impact on the requirements laid down in Regulation (EC) No 429/2008 as far as the preparation and the presentation of application dossiers are concerned, requiring the adaptation of those requirements for reasons of consistency and legal certainty. Regulation (EC) No 429/2008 should be amended to lay down the necessary additional provisions regarding the preparation and the presentation of application dossiers.
- (5) In particular, the provisions of Regulation (EC) No 429/2008 should be adapted as regards confidentiality requests, the format of the information and data supporting applications, which should be electronic and will need to comply with standard data formats, the concept of summary of the dossier due to the transparency principle laid down by Regulation (EU) 2019/1381 and the reference to studies notified in accordance with Article 32b of Regulation (EC) No 178/2002.
- (6) This Regulation should apply from 27 March 2021 and to applications and dossiers submitted as of that date, which is the date of application of Regulation (EU) 2019/1381.
- (7) Regulation (EC) No 429/2008 should therefore be amended accordingly.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1).

⁽³⁾ Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (OJ L 231, 6.9.2019, p. 1).

⁽⁴⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 429/2008

Regulation (EC) No 429/2008 is amended as follows:

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

‘2. Prior to the adoption of standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002 of the European Parliament and of the Council (*), the application and the dossier shall be submitted through the electronic submission system provided by the Commission, in an electronic format allowing for the downloading, printing and searching of documents. After the adoption of the standard data formats pursuant to Article 39f of Regulation (EC) No 178/2002, the application and the dossier shall be submitted through the electronic submission system provided by the Commission in accordance with those standard data formats.

(*) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002. p. 1).’;

(2) Annexes I and II are amended in accordance with the Annex to this Regulation.

Article 2

Entry into force and application

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

It shall apply from 27 March 2021 and to applications and dossiers submitted from that date.

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

Done at Brussels, 26 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Annexes I and II to Regulation (EC) No 429/2008 are amended as follows:

(1) in Annex I, point 1.5 is replaced by the following:

1.5. Enclosures

- ☐ complete dossier;
- ☐ summary of the dossier in accordance with Article 7(3)(h) of Regulation (EC) No 1831/2003;
- ☐ scientific summary of the dossier;
- ☐ all information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002;
- ☐ confidentiality request in accordance with Article 18 of Regulation (EC) No 1831/2003;
- ☐ copy of the administrative data of the applicant(s);
- ☐ three samples of the feed additive to the CRL in accordance with Article 7(3)(f) of Regulation (EC) No 1831/2003;
- ☐ to the CRL: material safety data sheet;
- ☐ to the CRL: certificate of identification and analysis; and
- ☐ confirmation that the fee to the CRL has been paid (Article 4 of Commission Regulation (EC) No 378/2005 (*)).

(*) Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).;

(2) Annex II is amended as follows:

(a) in the part 'General aspects', the penultimate paragraph before the heading 'Safety assessment' is replaced by the following:

'Each dossier shall contain a summary and a scientific summary in order to enable the additive concerned to be identified and characterised.';

(b) in point 1.1 under Section I, the title is replaced by the following:

'1.1. Summary in accordance with Article 7(3)(h) of Regulation (EC) No 1831/2003';

(c) point 1.1.1(d) is replaced by the following:

'(d) studies on safety and efficacy of the additive, along with all information concerning the notification of the studies in accordance with Article 32b of Regulation (EC) No 178/2002;'.

DECISIONS

POLITICAL AND SECURITY COMMITTEE DECISION (CFSP) 2020/1774

of 24 November 2020

extending the mandate of the Head of Mission of the European Union CSDP Advisory Mission in the Central African Republic (EUAM RCA) (EUAM RCA/1/2020)

THE POLITICAL AND SECURITY COMMITTEE,

Having regard to the Treaty on European Union, and in particular the third paragraph of Article 38 thereof,

Having regard to Council Decision (CFSP) 2019/2110 of 9 December 2019 on the European Union CSDP Advisory Mission in the Central African Republic (EUAM RCA) ⁽¹⁾, and in particular Article 8(1) thereof,

Having regard to the proposal from the High Representative of the Union for Foreign Affairs and Security Policy,

Whereas:

- (1) Pursuant to Article 8(1) of Decision (CFSP) 2019/2110, the Political and Security Committee (PSC) is authorised, in accordance with Article 38 of the Treaty on European Union, to take the relevant decisions for the purpose of exercising political control and strategic direction of the European Union CSDP Advisory Mission in the Central African Republic (EUAM RCA), including the decision to appoint a Head of Mission.
- (2) On 17 December 2019, the PSC adopted Decision (CFSP) 2019/2189 ⁽²⁾, appointing Mr Paulo SOARES as Head of Mission of EUAM RCA from 9 December 2019 to 8 December 2020.
- (3) On 30 July 2020, the Council adopted Decision (CFSP) 2020/1131 ⁽³⁾, which launched EUAM RCA on 9 August 2020.
- (4) The High Representative of the Union for Foreign Affairs and Security Policy has proposed to extend the mandate of Mr Paulo SOARES as Head of Mission of EUAM RCA from 9 December 2020 to 8 December 2021,

HAS ADOPTED THIS DECISION:

Article 1

The mandate of Mr Paulo SOARES as Head of Mission of the European Union CSDP Advisory Mission in the Central African Republic (EUAM RCA) is hereby extended until 8 December 2021.

Article 2

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

It shall apply from 9 December 2020.

Done at Brussels, 24 November 2020.

For the Political and Security Committee

The Chairperson

S. FROM-EMMESBERGER

⁽¹⁾ OJ L 318, 10.12.2019, p. 141.

⁽²⁾ Political and Security Committee Decision (CFSP) 2019/2189 of 17 December 2019 on the appointment of the Head of Mission of the European Union CSDP Advisory Mission in the Central African Republic (EUAM RCA) (EUAM RCA/1/2019) (OJ L 330, 20.12.2019, p. 51).

⁽³⁾ Council Decision (CFSP) 2020/1131 of 30 July 2020 launching the European Union CSDP Advisory Mission in the Central African Republic (EUAM RCA) (OJ L 247, 31.7.2020, p. 16).

COMMISSION IMPLEMENTING DECISION (EU) 2020/1775**of 25 November 2020****allowing the Netherlands to authorise biocidal products consisting of *in situ* generated nitrogen for the protection of cultural heritage***(notified under document C(2020) 8052)***(Only the Dutch text is authentic)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 55(3) thereof,

After consulting the Standing Committee for Biocidal Products,

Whereas:

- (1) Annex I to Regulation (EU) No 528/2012 contains active substances which have a more favourable environmental or human or animal health profile. Products containing these active substances may therefore be authorised under a simplified procedure. Nitrogen is included in Annex I to Regulation (EU) No 528/2012, subject to the restriction that it is used in limited quantities in ready-for-use canisters.
- (2) Pursuant to Article 86 of Regulation (EU) No 528/2012, nitrogen is approved as active substance for use in biocidal products of product-type 18, insecticides ⁽²⁾. Biocidal products consisting of nitrogen as approved are authorised in several Member States and are supplied in gas cylinders ⁽³⁾.
- (3) Nitrogen can also be generated *in situ* from ambient air. *In situ* generated nitrogen is currently not approved for use in the Union and it is neither listed in Annex I to Regulation (EU) No 528/2012, nor inserted in the list of active substances included in the review programme of existing active substances in biocidal products in Annex II to Commission Delegated Regulation (EU) No 1062/2014 ⁽⁴⁾.
- (4) Pursuant to Article 55(3) of Regulation (EU) No 528/2012, on 9 July 2020 the Netherlands submitted to the Commission an application for derogation from Article 19(1)(a) of that Regulation asking to allow it to authorise biocidal products consisting of nitrogen generated *in situ* from ambient air for the protection of cultural heritage ('the application').
- (5) Cultural heritage can be damaged by a wide range of harmful organisms, from insects to microorganisms. The presence of those organisms not only can lead to the loss of the cultural good itself, but also poses the risk of those harmful organisms being spread to other objects nearby. Without an appropriate treatment, objects could be irretrievably damaged, putting the cultural heritage at serious risk.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Directive 2009/89/EC of 30 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include nitrogen as an active substance in Annex I thereto (OJ L 199, 31.7.2009, p. 19).

⁽³⁾ List of authorised products available at <https://echa.europa.eu/fr/information-on-chemicals/biocidal-products>

⁽⁴⁾ Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

- (6) *In situ* generated nitrogen is used to create a controlled atmosphere with a very low concentration of oxygen (anoxia) in permanent or temporary sealed treatment tents or chambers for the control of harmful organisms on cultural heritage objects. Nitrogen is separated from the ambient air and is pumped into the treatment tent or chamber, where the nitrogen content of the atmosphere is increased to 99 % approximately and consequently oxygen is almost completely depleted. The humidity of the nitrogen pumped into the treatment area is set according to the demands of the object to be treated. Harmful organisms cannot survive under the conditions created in the treatment tent or chamber.
- (7) According to the information submitted by the Netherlands, the use of *in situ* generated nitrogen appears to be the only effective technique for the control of harmful organisms that can be used for all types of materials and combinations of materials present in cultural institutions without damaging them and is effective against all developmental stages of pests in cultural heritage.
- (8) As stated in the application, for more than 25 years heritage institutions in the Netherlands have implemented Integrated Pest Management strategies, turning to low-toxic approaches and moving away from the use of highly toxic substances used previously.
- (9) The method of anoxia or modified or controlled atmosphere is listed in the standard EN 16790:2016 'Conservation of cultural heritage – Integrated pest management (IPM) for protection of cultural heritage' and nitrogen is described in this standard as 'most used' for creating anoxia.
- (10) Other techniques for the control of harmful organisms are available, such as thermal shock techniques (high or low temperatures), gamma radiation. In addition, biocidal products containing other active substances can be used for that purpose. However, according to the Netherlands, each of those techniques has limitations in terms of damage that could occur to certain materials during treatment.
- (11) According to the information in the application, thermal shock processes (freezing or heat treatments) have undesired effects on several materials. Low temperature treatments are not suitable for objects with a layered structure or made of anisotropic materials, due to the difference in expansion coefficients between materials or in different directions leading to stress and delamination (for example, paintings, furniture with veneer or inlays, musical instruments), and for objects containing oil, grease or wax, that may crystalize and form a white bloom on the surface of the objects.
- (12) High temperature treatments can cause migration of resins and colour change in wood, softening of varnishes and changes in moisture distribution in materials. Such treatments are not suitable for objects with a layered structure or made of anisotropic materials (for example, paintings, furniture with veneer or inlays, musical instruments), leather, materials that soften, deform or melt at increased temperatures (for example, paints, varnishes, composite objects containing plastics, waxes, resins, certain glues), natural history specimens, and objects that have been treated in the past with biocidal products containing certain active substances such as dichlorodiphenyltrichloroethane (DDT) or lindane, as the heat causes the residues to evaporate.
- (13) As stated in the application, other active substances are seldom used in cultural institutions due to their hazard profile. After treatment with those substances, the residues on the treated objects can be progressively released to the environment, which poses a risk to human health. Moreover, those substances may react with the materials of the heritage objects causing unacceptable changes such as discoloration and staining.
- (14) According to the application, the use of gamma radiation could cause unwanted reactions and increased degradation of cellulosic materials such as paper, proteinaceous materials like leather, and synthetic polymers like plastics. In addition, it requires transportation of objects and collections to specific facilities for treatment.
- (15) According to the information in the application, the use of nitrogen in cylinders is not an appropriate alternative for cultural institutions, as it presents practical disadvantages. The limited quantities in cylinders require frequent transport and a separate storage facility. The treatment with nitrogen in cylinders would also generate high costs for the cultural institutions.
- (16) As stated in the application, during the last decades several cultural institutions invested in the construction of treatment chambers and the purchase of nitrogen generators. Due to its versatility and suitability for the treatment of all materials, *in situ* generated nitrogen anoxia is very widely used in the conservation of cultural heritage.

- (17) Requesting cultural institutions to use several techniques to control harmful organisms – each of them suitable for specific materials and objects – instead of using one technique already used and suitable to all materials, would involve additional costs for cultural institutions and make it more complicated for them to reach the objective of moving away from the use of more hazardous active substances in their IPM. In addition, the abandonment of facilities and equipment acquired for *in situ* generated nitrogen anoxia would represent a loss of previous investments.
- (18) Discussions related to a possible derogation pursuant to Article 55(3) of Regulation (EU) No 528/2012 for *in situ* generated nitrogen took place in several meetings ^(*) of the Commission expert group of Competent Authorities for Biocidal Products in 2019.
- (19) In addition, at the request of the Commission, following the first, similar application for derogation for products consisting of *in situ* generated nitrogen from Austria, the European Chemicals Agency conducted a public consultation on that application, allowing all interested parties to provide their views. The vast majority of the 1487 comments received were in favour of the derogation. Many contributors outlined the disadvantages of the alternative techniques available: thermal treatments may damage certain materials; the use of other active substances leaves toxic residues on artefacts that are progressively released to the environment; the use of nitrogen in cylinders does not allow the control of the relative humidity in the treatment area, which is needed for the treatment of some materials.
- (20) Two international organisations representing museums and cultural heritage sites – International Council of Museums and International Council on Monuments and Sites – have expressed their intention to submit an application for inclusion of *in situ* generated nitrogen in Annex I to Regulation (EU) No 528/2012, which would allow Member States to authorise products consisting of *in situ* generated nitrogen without the need for a derogation in accordance with Article 55(3) of that Regulation. However, performing the evaluation of such an application, including the substance into Annex I to Regulation (EU) No 528/2012 and obtaining product authorisations require time.
- (21) The application shows that no appropriate alternatives are available in the Netherlands, since all the alternative techniques currently available present disadvantages either due to non-suitability for the treatment of all materials or practical disadvantages.
- (22) Based on all those arguments it is appropriate to conclude that *in situ* generated nitrogen is essential for the protection of cultural heritage in the Netherlands and that no appropriate alternatives are available. The Netherlands should therefore be allowed to authorise the making available on the market and use of biocidal products consisting of *in situ* generated nitrogen for the protection of cultural heritage.
- (23) The possible inclusion of *in situ* generated nitrogen into Annex I to Regulation (EU) No 528/2012 and the subsequent authorisation by Member States of products consisting of *in situ* generated nitrogen requires time. It is therefore appropriate to allow a derogation for a period that would allow the completion of the underlying procedures,

HAS ADOPTED THIS DECISION:

Article 1

The Netherlands may authorise the making available on the market and use of biocidal products consisting of *in situ* generated nitrogen for the protection of cultural heritage until 31 December 2024.

Article 2

This Decision is addressed to the Kingdom of the Netherlands.

^(*) 83rd, 84th, 85th and 86th meeting of the Commission Expert Group of representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012, held in May 2019, July 2019, September 2019 and November 2019, respectively. The minutes of the meetings are available at https://ec.europa.eu/health/biocides/events_en#anchor0

Done at Brussels, 25 November 2020.

For the Commission
Stella KYRIAKIDES
Member of the Commission

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



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

EN