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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

COUNCIL REGULATION (EU) 2023/1089

of 5 June 2023

amending Regulation (EU) No 269/2014 concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 215 thereof,

Having regard to Council Decision 2014/145/CFSP of 17 March 2014 concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine ([1]),

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

Whereas:

(1) Council Regulation (EU) No 269/2014 ([2]) gives effect to restrictive measures provided for in Decision 2014/145/CFSP.

(2) On 5 June 2023, the Council adopted Decision (CFSP) 2023/1094 ([3]), which amended one of the criteria for the listing of natural or legal persons, entities or bodies, to include leading businesspersons operating in Russia and their immediate family members, or other natural persons, benefitting from them, as well as businesspersons, legal persons, entities or bodies involved in economic sectors providing a substantial source of revenue to the Government of the Russian Federation.

(3) This amendment falls within the scope of the Treaty and therefore regulatory action at the level of the Union is necessary in order to implement it, in particular with a view to ensuring its uniform application in all Member States.

(4) Regulation (EU) No 269/2014 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Article 3(1), point (g), of Regulation (EU) No 269/2014, is replaced by the following:

([1]) OJ L 78, 17.3.2014, p. 16.

([2]) Council Regulation (EU) No 269/2014 of 17 March 2014 concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine (OJ L 78, 17.3.2014, p. 6).

([3]) See page 20 of this Official Journal.

‘(g) leading businesspersons operating in Russia and their immediate family members, or other natural persons, benefitting from them, or businesspersons, legal persons, entities or bodies involved in economic sectors providing a substantial source of revenue to the Government of the Russian Federation, which is responsible for the annexation of Crimea and the destabilisation of Ukraine; or’.

Article 2

This Regulation shall enter into force on the date 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, 5 June 2023.

For the Council
The President
J. ROSWALL

COMMISSION DELEGATED REGULATION (EU) 2023/1090

of 24 January 2023

amending Regulation (EU) 2019/833 of the European Parliament and of the Council, and Commission Delegated Regulation (EU) 2020/124 as regards certain provisions of the conservation and enforcement measures of the Northwest Atlantic Fisheries Organisation (NAFO)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/833 of the European Parliament and of the Council of 20 May 2019 laying down conservation and enforcement measures applicable in the Regulatory Area of the Northwest Atlantic Fisheries Organisation, amending Regulation (EU) 2016/1627 and repealing Council Regulations (EC) No 2115/2005 and (EC) No 1386/2007 ([1]), and in particular Article 50(1) and (2) thereof,

Whereas:

(1) The EU is party to the Convention on Future Multilateral Cooperation in the Northwest Atlantic Fisheries (the NAFO Convention), approved by Council Regulation (EEC) No 3179/78 ([2]).

(2) The European Parliament and the Council adopted Regulation (EU) 2019/833 in order to implement the NAFO conservation and enforcement measures ('CEM') into EU law.

(3) Commission Delegated Regulation (EU) 2020/124 ([3]) supplemented Regulation (EU) 2019/833 with a number of NAFO conservation and enforcement measures.

(4) Commission Delegated Regulation (EU) 2020/989 ([4]) amended Delegated Regulation (EU) 2020/124 with NAFO measures adopted at its 2019 annual meeting.

(5) Commission Delegated Regulation (EU) 2021/860 ([5]) amended Delegated Regulation (EU) 2020/124 with NAFO measures adopted at its 2020 annual meeting.

(6) Regulation (EU) 2021/1231 of the European Parliament and of the Council ([6]) amended Regulation (EU) 2019/833 with NAFO measures adopted at its 2019 and 2020 annual meetings.

(7) Commission Delegated Regulation (EU) 2022/1281 ([7]) amended Delegated Regulation (EU) 2020/124 with NAFO measures adopted at its 2021 annual meeting.

([1]) OJ L 141, 28.5.2019, p. 1.

([2]) Council Regulation (EEC) No 3179/78 of 28 December 1978 concerning the conclusion by the European Economic Community of the Convention on Future Multilateral Cooperation in the Northwest Atlantic Fisheries (OJ L 378, 30.12.1978, p. 1).

([3]) Commission Delegated Regulation (EU) 2020/124 of 15 October 2019 supplementing Regulation (EU) 2019/833 of the European Parliament and of the Council laying down conservation and enforcement measures applicable in the Regulatory Area of the Northwest Atlantic Fisheries Organisation (OJ L 34, 6.2.2020, p. 1).

([4]) Commission Delegated Regulation (EU) 2020/989 of 27 April 2020 amending Delegated Regulation (EU) 2020/124 as regards certain provisions of, and Annexes to, the conservation and enforcement measures of the Northwest Atlantic Fisheries Organisation (NAFO) (OJ L 221, 10.7.2020, p. 5).

([5]) Commission Delegated Regulation (EU) 2021/860 of 23 March 2021 amending Delegated Regulation (EU) 2020/124 as regards Annex to the conservation and enforcement measures of the Northwest Atlantic Fisheries Organisation (NAFO) (OJ L 190, 31.5.2021, p. 19).

([6]) Regulation (EU) 2021/1231 of the European Parliament and of the Council of 14 July 2021 amending Regulation (EU) 2019/833 laying down conservation and enforcement measures applicable in the Regulatory Area of the Northwest Atlantic Fisheries Organisation (OJ L 274, 30.7.2021, p. 32).

([7]) Commission Delegated Regulation (EU) 2022/1281 of 4 March 2022 amending Regulation (EU) 2019/833 of the European Parliament and of the Council, and Commission Delegated Regulation (EU) 2020/124 as regards certain provisions of, and Annexes to, the conservation and enforcement measures of the Northwest Atlantic Fisheries Organisation (NAFO) (OJ L 195, 22.7.2022, p. 21).

(8) Regulation (EU) 2022/2037 of the European Parliament and of the Council ([8]) amended Regulation (EU) 2019/833 with NAFO measures adopted at its 2021 annual meeting.

(9) At its annual meeting in September 2022, the NAFO amended its CEM with updates of research vessel restrictions, control measures for landings or transhipments of cod catches from Division 3M, deleting provisions concerning observer programme reporting, and adding a cross reference in the fishing logbook.

(10) These changes should also be implemented into Union law. Therefore, Regulation (EU) 2019/833 and Delegated Regulation (EU) 2020/124 should be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EU) 2019/833 is hereby amended as follows:

(1) in Article 4(1), the following points (c) and (d) are inserted:

'(c) take cod from Division 3M in excess of 15 tonnes of Union catches in a calendar year. Should a research vessel's catch exceed this amount, the excess shall be counted against the allocation to the vessel's flag Member State. Furthermore, if the allocation to the Member State for cod from Division 3M is exhausted, that Member State shall not authorize its vessels to undertake further research activities. Any research activities underway shall be stopped by the flag Member State as soon as 15 tonnes have been caught by the Union; or

(d) take shrimp from Division 3M in excess of 10 tonnes of Union catches in a calendar year. The relevant Member State shall stop research activities on shrimp from Division 3M once 10 tonnes have been caught by the Union.';

(2) in Article 4, paragraph 1a is deleted;

(3) in Article 9a point (1)(c), the following sentence is added:

'Inspections of landings or transhipments shall be conducted at a rate of:

(i) at least 50 % when the total NAFO quota for cod in Division 3M in fishing opportunities is under 6 000 tonnes, and

(ii) at least 25 % when the total NAFO quota for cod in Division 3M in fishing opportunities is between 6 000 and 12 000 tonnes.';

(4) in Article 27(7), point (a) is deleted.

Article 2

The Annex to Delegated Regulation (EU) 2020/124 is amended in accordance with the Annex to this Regulation.

Article 3

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

([8]) Regulation (EU) 2022/2037 of the European Parliament and of the Council of 19 October 2022 amending Regulation (EU) 2019/833 laying down conservation and enforcement measures applicable in the Regulatory Area of the Northwest Atlantic Fisheries Organisation (OJ L 275, 25.10.2022, p. 11).

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

Done at Brussels, 24 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In the Annex, point 30, item (15) is replaced by the following:

‘(15) Was a trial tow conducted in accordance with Article 6.6(b)(iii) or Article 6.10 of the CEM? (Y/N)’

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1091

of 5 June 2023

granting a Union authorisation for the single biocidal product 'APESIN alcogel' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 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 44(5), first subparagraph, thereof,

Whereas:

(1) On 23 April 2019, Tana-Chemie GmbH submitted to the European Chemicals Agency ('the Agency') an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 and Article 4 of Commission Implementing Regulation (EU) No 414/2013 ([2]) for Union authorisation of the same single biocidal product, as referred to in Article 1 of Implementing Regulation (EU) No 414/2013, named 'APESIN alcogel', of product-type 1, as described in Annex V to Regulation (EU) No 528/2012. The application was recorded under case number BC-TV051115-15 in the Register for Biocidal Products ('the Register'). The application also indicated the application number of the related reference biocidal product family 'Knieler & Team Propanol Family', recorded in the Register under case number BC-AQ050985-22.

(2) The same single biocidal product 'APESIN alcogel' contains propan-1-ol and propan-2-ol as the active substances, which are included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 1.

(3) On 8 December 2021, the Agency submitted to the Commission an opinion ([3]) and the draft summary of the biocidal product characteristics ('SPC') of 'APESIN alcogel' in accordance with Article 6 of Implementing Regulation (EU) No 414/2013.

(4) The opinion concludes that the proposed differences between the same single biocidal product and the related reference biocidal product are limited to information which can be the subject of an administrative change in accordance with Commission Implementing Regulation (EU) No 354/2013 ([4]), and that based on the assessment of the related reference biocidal product family 'Knieler & Team Propanol Family' and subject to compliance with the draft SPC, the same single biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012.

(5) On 20 October 2022, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the same single biocidal product 'APESIN alcogel'.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 125, 7.5.2013, p. 4).

([3]) ECHA opinion on 'APESIN alcogel' of 8 December 2021, https://echa.europa.eu/opinions-on-union-authorisation.

([4]) Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 109, 19.4.2013, p. 4).

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0027672-0000 is granted to Tana-Chemie GmbH for the making available on the market and use of the same single biocidal product 'APESIN alcogel' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 26 June 2023 until 31 July 2032.

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, 5 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product

APESIN alcogel

Product type 1 - Human hygiene (Disinfectants)

Authorisation number: EU-0027672-0000

R4BP asset number: EU-0027672-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	E-HDG

1.2. Authorisation holder

Name and address of the authorisation holder	Name	tana-Chemie GmbH
	Address	Rheinallee 96, 55120 Mainz Germany
Authorisation number	EU-0027672-0000	
R4BP asset number	EU-0027672-0000	
Date of the authorisation	26 June 2023	
Expiry date of the authorisation	31 July 2032	

1.3. Manufacturer(s) of the product

Name of manufacturer	tana-Chemie GmbH
Address of manufacturer	Rheinallee 96, 55120 Mainz Germany
Location of manufacturing sites	Werner & Mertz GmbH & Co KG, Neualmerstr. 13, 5400 Hallein Austria Werner & Mertz GmbH, Rheinallee 96, 55120 Mainz Germany

1.4. Manufacturer(s) of the active substance(s)

Active substance	Propan-1-ol
Name of manufacturer	OQ Chemicals GmbH (formerly Oxea GmbH)
Address of manufacturer	Rheinpromenade 4a, 40789 Monheim am Rhein Germany
Location of manufacturing sites	OQ Chemicals Corperation (formerly Oxea Coperation), 2001 FM 3057 TX, 77414 Bay City United States

Active substance	Propan-1-ol
Name of manufacturer	BASF SE
Address of manufacturer	Carl-Bosch-Str. 38, 67056 Ludwigshafen Germany
Location of manufacturing sites	BASF SE, Carl-Bosch-Str. 38, 67056 Ludwigshafen Germany

Active substance	Propan-1-ol
Name of manufacturer	SASOL Chemie GmbH & Co. KG
Address of manufacturer	Secunda Chemical Operations, Sasol Place, 50 Katherine Street, 2090 Sandton South Africa
Location of manufacturing sites	Secunda Chemical Operations, PDP Kruger Street, 2302 Secunda South Africa

Active substance	Propan-2-ol
Name of manufacturer	INEOS Solvent Germany GmbH
Address of manufacturer	Römerstrasse 733, 47443 Moers Germany
Location of manufacturing sites	INEOS Solvent Germany GmbH, Römerstrasse 733, 47443 Moers Germany INEOS Solvent Germany GmbH, Shamrockstrasse 88, 44623 Herne Germany

2. PRODUCT COMPOSITION AND FORMULATION

2.1. Qualitative and quantitative information on the composition of the product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	30,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	45,0

2.2. Type of formulation

AL - Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	Highly flammable liquid and vapour. Causes serious eye damage. May cause drowsiness or dizziness. Repeated exposure may cause skin dryness or cracking.

Precautionary statements	Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Keep container tightly closed. Avoid breathing vapours. Use only outdoors or in a well-ventilated area. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of container to an authorised waste collection point.

4. **AUTHORISED USE(S)**

4.1. **Use description**

Table 1. Use # 1 – hygienic handrub, gel

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Mycobacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: Enveloped viruses Development stage: no data
Field(s) of use	Indoor — hospitals and other health care institutions, ambulances, surgeries, nursing homes (including home-care of patients) — hospital canteens, large kitchens, pharmaceutical industries, production sites, laboratories: hygienic handrub onto visibly clean and dry hands. — For professional use only.
Application method(s)	Method: Manual application Detailed description: Rubbing
Application rate(s) and frequency	Application Rate: Dosage: At least 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 30 s Dilution (%): Ready-to-use product Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.

Category(ies) of users	Industrial Professional
Pack sizes and packaging material	100, 125, 500, 1 000 ml in transparent/white high-density polyethylene (HDPE) bottles with polypropylene (PP) flip top caps; 5 000 ml transparent/white HDPE canister with HDPE screwed cap. 500 and 1 000 ml in transparent HDPE lightweight bottle with integrated PP pump.

4.1.1. *Use-specific instructions for use*

The products can be applied directly or the products can be used in a dispenser or with a pump.

For hygienic handrub use 3 ml of product and keep hands wet for 30 seconds.

Do not refill.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use

4.2. **Use description**

Table 2. Use # 2 – surgical handrub, gel

Product type	PT01 - Human hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: no data Common name: Bacteria Development stage: no data Scientific name: no data Common name: Mycobacteria Development stage: no data Scientific name: no data Common name: Yeasts Development stage: no data Scientific name: no data Common name: enveloped viruses Development stage: no data
Field(s) of use	Indoor Hospitals and other health care institutions: surgical handrub onto visibly clean and dry hands and forearms. For professional use only.

Application method(s)	Method: Manual application Detailed description: Rubbing
Application rate(s) and frequency	Application Rate: Dosage: Rub sufficient amount in portions of 3 ml (use dispensers: for example set to 1,5 ml per stroke, 2 strokes per 3 ml). Contact time: 90 s Dilution (%): Ready-to-use product Number and timing of application: There is no restriction in the number and timing of applications. No safety intervals need to be considered between the application phases. The product may be used at any time and as often as required.
Category(ies) of users	Professional
Pack sizes and packaging material	100, 125, 500, 1 000 ml in transparent/white high-density polyethylene (HDPE) bottles with polypropylene (PP) flip top caps; 5 000 ml transparent/white HDPE canister with HDPE screwed cap. 500 and 1 000 ml in transparent HDPE lightweight bottle with integrated PP pump.

4.2.1. *Use-specific instructions for use*

The products can be applied directly or the products can be used in a dispenser or with a pump.

For surgical handrub use as many portions of 3 ml as necessary to keep hands wet for 90 seconds.

Do not refill.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

See general directions for use

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

See general directions for use

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

See general directions for use

5. **GENERAL DIRECTIONS FOR USE** [1]

5.1. Instructions for use

For professional use only.

5.2. Risk mitigation measures

Avoid contact with eyes.

Keep out of reach of children.

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

5.3. **Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment**

First-aid measures general: Move the affected person away from the contaminated area. Get medical advice/attention if you feel unwell. If possible, show this sheet.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

Information to Healthcare personnel/doctor:

The eyes should also be rinsed repeatedly on the way to the doctor if eye exposure to alkaline chemicals (pH > 11), amines and acids like acetic acid, formic acid or propionic acid.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

Accidental release measures: Stop leak if safe to do so. Remove ignition sources. Use special care to avoid static electric charges. No open flames. No smoking. Prevent entry to sewers and public waters. Wipe up with absorbent material (for example cloth). Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Take up mechanically (sweeping, shovelling). Dispose of in accordance with relevant local regulations.

5.4. **Instructions for safe disposal of the product and its packaging**

Disposal must be done according to official regulations. Do not empty into drains. Do not dispose of with domestic waste. Dispose of contents/container to an authorised waste collection point. Empty the packaging completely prior to disposal. When totally empty, containers are recyclable like any other packing.

5.5. **Conditions of storage and shelf-life of the product under normal conditions of storage**

Shelf-life: 24 months

Store in dry, cool, well-ventilated area. Keep container tightly closed. Keep out of direct sunlight.

Recommended storage temperature: 0-30°C

Do not store at temperatures below 0°C

Do not store near food, drink and animal feedingstuff. Keep away from combustible material.

6. **OTHER INFORMATION**

REGULATION (EU) 2023/1092 OF THE EUROPEAN CENTRAL BANK

of 25 May 2023

amending Regulation (EC) No 2157/1999 on the powers of the European Central Bank to impose sanctions *(ECB/1999/4)* (ECB/2023/13)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 132 thereof,

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular Articles 19.1 and 34.3 thereof,

Having regard to Council Regulation (EC) No 2532/98 of 23 November 1998 concerning the powers of the European Central Bank to impose sanctions ([1]), and in particular Article 6(2) thereof,

Whereas:

(1) Penalties imposed by the European Central Bank (ECB) for breaching obligations arising from ECB regulations or decisions should be effective, proportionate and dissuasive. In order to further enhance the effectiveness and the dissuasive effect of its powers to impose sanctions, and in the interests of consistency and legal certainty, the ECB should publish a decision to impose a sanction or information relating thereto as the default rule. This ensures that the exercise of the ECB's sanctioning power is more effective to act as a deterrent to the undertakings that are required to fulfil obligations arising from ECB regulations or decisions, enhancing the dissuasive effect of a pecuniary sanction.

(2) The publication of sanctions reinforces the transparency of decision-making and the accountability of the ECB when imposing them, including by allowing sanctions imposed on different undertakings to be compared. Hence, the publication of sanctions benefits the undertakings that are required to fulfil obligations arising from ECB regulations or decisions by promoting fair and equitable treatment. Publishing the amount, moreover, ensures that it can be verified that sanctions do not diverge without justification from one another, strenghtening the principle of non-discrimination and guaranteeing a level playing field.

(3) Publishing sanctions imposed by the ECB in the field of its central banking tasks is consistent with the regime applicable to sanctions imposed in the field of supervision, where all sanctions are published ([2]) unless specific exceptions apply. Considerations regarding the principle of consistency encourage the publication of sanctions in relation to all tasks of the ECB, because a similar rationale for publication applies. The publication of sanctions serves, on the one hand, as a signal to the market and, in certain cases, to potential counterparties of the sanctioned entity. On the other hand, the publicity enhances the dissuasive effect of the sanction.

(4) The publication of sanctions reinforces the visibility of efficient enforcement, fostering public confidence in the ECB, and Union institutions in general.

(5) In view of the specific features of financial markets, publication of the details of a sanction should be subject to carefully defined exceptions, to take into account justified market, security and business interests. In particular, if publication would jeopardise the stability of the financial markets or the financial system or an ongoing criminal investigation or cause disproportionate damage to the undertaking concerned, the publication of details of a sanction should either beanonymised or postponed where such circumstances are likely to cease within a reasonable period of time. This reflects the generally applicable principle of proportionality. Lastly, there should be

([1]) OJ L 318, 27.11.1998, p. 4.

([2]) Article 18(6) of Council Regulation (EU) No 1024/2013 of 15 October 2013 conferring specific tasks on the European Central Bank concerning policies relating to the prudential supervision of credit institutions (OJ L 287, 29.10.2013, p. 63), and Article 132 of Regulation (EU) No 468/2014 of the European Central Bank of 16 April 2014 establishing the framework for cooperation within the Single Supervisory Mechanism between the European Central Bank and national competent authorities and with national designated authorities (SSM Framework Regulation) (ECB/2014/17) (OJ L 141, 14.5.2014, p. 1).

an exception where publication would result in the publication of confidential information and the ECB considers that the risk to legitimate public interests in security may not be mitigated. This is of particular importance in the field of banknotes and the oversight of systemically important payment systems.

(6) In line with the general competence to decide whether a sanction is imposed, the Executive Board also decides whether an exception from publication applies. In this regard, the Executive Board takes note of the grounds brought forward by the investigating unit or the competent national central bank. If it decides that an exception applies, this should be indicated in its decision to impose the sanction, otherwise, the sanction will be published.

(7) In each case, in determining the appropriate sanction and whether an exception to publication of certain information should apply, the ECB is guided by the principle of proportionality.

(8) Therefore, Regulation (EC) No 2157/1999 of the European Central Bank (ECB/1999/4) ([3]) should be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments

Regulation (EC) No 2157/1999 (ECB/1999/4) is amended as follows:

(1) Article 7a is amended as follows:

(a) in paragraph 1, the following sentence is added:

'If the investigating unit or the competent national central bank considers that one or more of the exceptions set out in Article 9(1) applies, it shall specify this in its proposal.';

(b) the following paragraph 7a is inserted:

'7a. If the Executive Board, on the basis of a complete file, considers that a sanction shall be imposed, but that one or more of the exceptions set out in Article 9(1) applies, it shall decide whether and to what extent the sanction shall be published.';

(2) in Article 8(3), point (b) is replaced by the following:

'(b) amend the decision of the Executive Board by modifying any of the following:

(i) the amount of the sanction to be imposed;

(ii) the grounds giving rise to an infringement;

(iii) whether and to what extent the sanction is published;';

(3) in Article 9, paragraph 1 is replaced by the following:

'1. The ECB shall publish any decision imposing sanctions in case of a breach of an ECB regulation or decision on its official website without undue delay, once the decision has become final in accordance with Article 3(8) of Regulation (EC) No 2532/98.

The publication shall include information on the type and nature of the breach and the identity of the undertaking concerned, as well as the amount and the nature of the sanction, unless the Executive Board determines that such publication would:

(a) jeopardise the stability of the financial markets or the financial system or an ongoing criminal investigation;

(b) cause, in so far as can be determined, disproportionate damage to the undertaking concerned; or

([3]) Regulation (EC) No 2157/1999 of the European Central Bank of 23 September 1999 on the powers of the European Central Bank to impose sanctions (ECB/1999/4) (OJ L 264, 12.10.1999, p. 21).

(c) result in the publication of confidential information, which would put at risk legitimate public interests in security, such as the security and protection of the integrity of euro banknotes or the secure management of cyber or operational risks to systemically important payment systems.

In the circumstances referred to in the second subparagraph, points (a) to (c), decisions regarding sanctions shall be published on an anonymised basis. Alternatively, where such circumstances are likely to cease within a reasonable period of time, publication under this paragraph may be postponed for such period of time.

For the purposes of second subparagraph, point (c), the ECB may choose not to publish a decision imposing a sanction where it considers that the risk to legitimate public interests in security may not be mitigated by publishing the relevant decisions on an anonymised basis or by postponing their publication, as referred to in the previous subparagraph.

Where a decision imposing a sanction is under appeal before the Court of Justice of the European Union, the ECB shall, without undue delay, also publish on its official website information on the status of the appeal in question and the outcome thereof.

The information published pursuant to this paragraph shall remain on the official website of the ECB for at least five years.';

(4) in Article 11, the following paragraph 7 is added:

'7. In the situations foreseen in paragraph 4, first indent, and in paragraph 5, the ECB shall publish the imposed sanction in accordance with Article 9(1). Where the Executive Board accepts a proposal submitted by the competent national central bank determining that one or more of the exceptions set out in Article 9(1), second subparagraph, applies, it may decide to publish that decision on an anonymised basis or postpone such publication. Where the exception in Article 9(1), second subparagraph, point (c), applies, the Executive Board may decide not to publish the imposed sanction.'.

Article 2

Final provisions

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 the Member States in accordance with the Treaties.

Done at Frankfurt am Main, 25 May 2023.

For the Governing Council of the ECB
The President of the ECB
Christine LAGARDE

DECISIONS

COUNCIL DECISION (EU) 2023/1093

of 15 May 2023

authorising the opening of negotiations with the Republic of Korea for an Agreement on the general principles for the participation of the Republic of Korea in Union programmes and on the association of the Republic of Korea to Horizon Europe – the Framework Programme for Research and Innovation (2021-2027)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 186 and 212, in conjunction with Article 218(3) and (4) thereof,

Having regard to the recommendation from the European Commission,

Whereas:

(1) The Republic of Korea ('Korea') fulfils the criteria in point (d) of Article 16(1) of Regulation (EU) 2021/695 of the European Parliament and of the Council [1].

(2) Negotiations should be opened with a view to concluding an agreement with Korea on the general principles for the participation of Korea in Union programmes and on the association of Korea to Horizon Europe – the Framework Programme for Research and Innovation (2021-2027),

HAS ADOPTED THIS DECISION:

Article 1

The Commission is hereby authorised to open negotiations with the Republic of Korea ('Korea'), on behalf of the Union, for an agreement on the general principles for the participation of Korea in Union programmes and on the association of Korea to Horizon Europe – the Framework Programme for Research and Innovation (2021-2027).

Article 2

The negotiating directives are set out in the addendum to this Decision.

Article 3

The negotiations shall be conducted in consultation with the Asia-Oceania Working Party, for matters related to the general conditions for the participation of Korea in any Union programmes, and with the Working Party on Research, for matters related to the specific conditions for the participation of Korea in the Horizon Europe Programme.

Article 4

This Decision is addressed to the Commission.

[1] Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ L 170, 12.5.2021, p. 1).

Done at Brussels, 15 May 2023.

For the Council
The President
J. FORSSMED

COUNCIL DECISION (CFSP) 2023/1094

of 5 June 2023

amending Decision 2014/145/CFSP concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 29 thereof,

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

Whereas:

(1) On 17 March 2014, the Council adopted Decision 2014/145/CFSP ([1]).

(2) The Union remains unwavering in its support for Ukraine's sovereignty and territorial integrity.

(3) In its conclusions of 9 February 2023, the European Council reiterated the Union's resolute condemnation of Russia's war of aggression against Ukraine, which constitutes a manifest violation of the United Nations Charter. The European Council also reiterated that the Union stands ready to continue to reinforce its restrictive measures against Russia.

(4) The Council has assessed that a relationship of mutual benefit and support exists between the Government of the Russian Federation and leading businesspersons operating in Russia. In particular, the Government of the Russian Federation has systematically allowed prominent Russian businesspersons to accumulate their wealth through the exploitation of natural and other public resources. The Council considers, in view of this relationship of interdependence between leading businesspersons and the Government of the Russian Federation, that the designation criteria should cover leading businesspersons operating in any economic sector of Russia. In addition, the Council considers that the designation criteria should be extended to allow for the listing as appropriate of other businesspersons who are involved in economic sectors providing a substantial source of revenue to the Government of the Russian Federation, in order to increase pressure on the Government of the Russian Federation to bring an end to its war of aggression against Ukraine.

(5) The Council has also assessed that leading Russian businesspersons have engaged in a systematic practice of distributing their funds and assets amongst their immediate family members and other persons, often in order to hide their assets, to circumvent the restrictive measures and to maintain control over the resources available to them. Therefore, the Council considers that immediate family members or other natural persons, who benefit in such a way from leading businesspersons operating in Russia, should also be designated as appropriate, in order to both increase pressure on the Government of the Russian Federation to bring an end to its war of aggression against Ukraine as well as to avoid the risk of circumvention of the restrictive measures.

(6) Further action by the Union is needed in order to implement certain measures.

(7) Decision 2014/145/CFSP should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Decision 2014/145/CFSP is amended as follows:

([1]) Council Decision 2014/145/CFSP of 17 March 2014 concerning restrictive measures in respect of actions undermining or threatening the territorial integrity, sovereignty and independence of Ukraine (OJ L 78, 17.3.2014, p. 16).

(1) in Article 1(1), point (e) is replaced by the following:

'(e) leading businesspersons operating in Russia and their immediate family members, or other natural persons, benefitting from them, or businesspersons involved in economic sectors providing a substantial source of revenue to the Government of the Russian Federation, which is responsible for the annexation of Crimea and the destabilisation of Ukraine; or';

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

'(g) leading businesspersons operating in Russia and their immediate family members, or other natural persons, benefitting from them, or businesspersons, legal persons, entities or bodies involved in economic sectors providing a substantial source of revenue to the Government of the Russian Federation, which is responsible for the annexation of Crimea and the destabilisation of Ukraine; or'.

Article 2

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

Done at Brussels, 5 June 2023.

For the Council
The President
J. ROSWALL

COUNCIL DECISION (CFSP) 2023/1095

of 5 June 2023

amending Joint Action 2008/124/CFSP on the European Union Rule of Law Mission in Kosovo *, EULEX KOSOVO

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 42(4) and Article 43(2) thereof,

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

Whereas:

(1) On 4 February 2008, the Council adopted Joint Action 2008/124/CFSP ([1]).

(2) On 3 June 2021, the Council adopted Decision (CFSP) 2021/904 ([2]), amending Joint Action 2008/124/CFSP and extending the European Union Rule of Law Mission in Kosovo (EULEX KOSOVO) until 14 June 2023.

(3) In the context of the strategic review of EULEX KOSOVO, the Political and Security Committee (PSC) agreed that EULEX KOSOVO should be extended until 14 June 2025. The PSC also agreed that, in addition to continuing to implement its tasks, EULEX KOSOVO should assist the law enforcement authorities of Kosovo in developing their capacities to exchange information with regional and international counterparts in the field of legal assistance and cooperation in criminal matters.

(4) Nothing in this Decision should be understood as prejudicing the independence and the autonomy of the judges and prosecutors active in judicial proceedings in the context of EULEX KOSOVO.

(5) Due to the special character of the activities of EULEX KOSOVO in support of relocated judicial proceedings within a Member State, it is appropriate to identify the amount envisaged to cover the support for such relocated judicial proceedings and to provide for the implementation of that part of the budget through a grant.

(6) Joint Action 2008/124/CFSP should be amended accordingly.

(7) EULEX KOSOVO will be conducted in the context of a situation which may deteriorate and could impede the achievement of the objectives of the Union's external action as set out in Article 21 of the Treaty,

HAS ADOPTED THIS DECISION:

Article 1

Joint Action 2008/124/CFSP is amended as follows:

(1) in Article 3, first paragraph, point (f) is replaced by the following:

'(f) cooperate with relevant EU agencies, judicial and law enforcement authorities of Member States and third States in the execution of its mandate and assist the law enforcement authorities of Kosovo in developing their capacities to exchange information with regional and international counterparts in the field of legal assistance and cooperation in criminal matters.';

* This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

([1]) Council Joint Action 2008/124/CFSP of 4 February 2008 on the European Union Rule of Law Mission in Kosovo, EULEX KOSOVO (OJ L 42, 16.2.2008, p. 92).

([2]) Council Decision (CFSP) 2021/904 of 3 June 2021 amending Joint Action 2008/124/CFSP on the European Union Rule of Law Mission in Kosovo (EULEX KOSOVO) (OJ L 197, 4.6.2021, p. 114).

(2) in Article 16(1), the last subparagraph is replaced by the following:

'The financial reference amount intended to cover the expenditure of EULEX KOSOVO from 15 June 2023 until 14 June 2025 shall be EUR 165 310 000. Out of that amount, the amount intended to cover the expenditure of EULEX KOSOVO for the implementation of its mandate in Kosovo shall be EUR 58 500 000 and the amount intended to cover the support to the relocated judicial proceedings within a Member State shall be EUR 106 810 000.

The Commission shall sign a grant agreement with a registrar acting on behalf of a registry in charge of the administration of the relocated judicial proceedings for the amount of EUR 106 810 000. The rules on grants provided for in Regulation (EU, Euratom) 2018/1046 shall apply to the grant agreement.

The financial reference amount for the subsequent period for EULEX KOSOVO shall be decided by the Council.';

(3) in Article 20, second paragraph, the first sentence is replaced by the following:

'It shall expire on 14 June 2025.'.

Article 2

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

Done at Brussels, 5 June 2023.

For the Council
The President
J. ROSWALL

COMMISSION IMPLEMENTING DECISION (EU) 2023/1096

of 2 June 2023

laying down rules for the application of Directive 2013/29/EU of the European Parliament and of the Council as regards the regular collection and updating of data on accidents related to the use of pyrotechnic articles

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2013/29/EU of the European Parliament and of the Council of 12 June 2013 on the harmonisation of the laws of the Member States relating to the making available on the market of pyrotechnic articles ([1]), and in particular Article 43(b) thereof,

Whereas:

(1) Pursuant to Article 43(b) of Directive 2013/29/EU, the Commission is to determine the practical arrangements for the regular collection and updating of data on accidents related to pyrotechnic articles, so as to enable, as far as possible, an overview of the accident situation in the Union, based on common reporting principles. The regular and reliable collecting, updating and exchanging of such data is therefore an important tool to define a clear picture on the degree of effective implementation of the Directive as regards the lawful and safe use of pyrotechnic articles and thus to evaluate on whether additional harmonization measures would be required.

(2) All Member States have already agreed that it is, in principle, useful and feasible to collect the data on accidents related to the use of pyrotechnic articles. However, the collection of data relating to pyrotechnic articles of categories other than F1 to F4 would create an unjustified administrative burden. In addition, pyrotechnic articles of category P1 for vehicles, including airbag and seat belt pre-tensioner systems, do not generally present a risk of misuse or accident as they are part of safety devices in vehicles. Considering that Member States have already regularly reported data on accidents related to the use of fireworks to the Commission on a voluntary basis, the existing voluntary system should be used as basis when determining the practical arrangements for the regular collection and updating by all Member States of data on accidents related to the use of fireworks.

(3) In order to ensure relevance and comparability of the data, the minimum mandatory data should include information on the overall number of accidents with injuries or the overall number of injuries related to the use of pyrotechnic articles as well as the number of injuries resulting from the accidents by age group and the type of injury. In order to better understand the causality and, subsequently, inform national or Union policy decisions, additional data should be provided if available. In order to reduce administrative burden for Member States, where collecting the minimum required data is not possible, reporting of extrapolated data gathered from representative samples should be allowed.

(4) The measures provided for in this Decision are in accordance with the opinion of the Committee on Pyrotechnic Articles,

([1]) OJ L 178, 28.6.2013, p. 27.

HAS ADOPTED THIS DECISION:

Article 1

Minimum mandatory data

1. From 1 January 2024, Member States shall collect for each calendar year at least the following data on accidents occurred within their territory, which were related to the use of pyrotechnic articles of categories F1 to F4:

(a) the overall number of accidents with injuries or the overall number of injuries related to the use of pyrotechnic articles;

(b) number of injuries divided by the following age groups of the victims:

  (i) from 0 to 12 years;

  (ii) from 13 to 18 years;

  (iii) older than 18 years;

(c) number of injuries by type in the following categories:

  (i) hand or arm;

  (ii) face or head;

  (iii) eyes;

  (iv) hearing;

  (v) other;

(d) number of injuries by degree of seriousness in the following categories:

  (i) injuries requiring hospitalisation;

  (ii) deaths;

  (iii) other.

2. Where collecting any of the data referred to in paragraph 1 is not possible, Member States may collect data from representative samples and extrapolate it.

3. Where collection of data, as referred to in paragraphs 1 and 2, is not possible in a given year, Member States shall collect all other data on accidents related to the use of pyrotechnic articles of categories F1 to F4 available to them.

Article 2

Additional data

Member States shall, in addition to the data referred to in Article 1, collect the following data where available:

(a) type of pyrotechnic article causing the accident;

(b) information on whether the accident was caused by incorrect use, misuse or malfunctioning of the article;

(c) information on whether the article was made available on the market illegally;

(d) any other information which the Member State considers important for accident data analysis.

Article 3

Transmission of information

1. Member States shall transmit the data referred to in Articles 1 and 2 for each calendar year to the Commission by 1 October of the subsequent calendar year.

2. Where Member States transmit data in accordance with Article 1(2), they shall indicate which data has been extrapolated.

3. Where Member States transmit data in accordance with Article 1(3), they shall submit a justification explaining why neither collection nor extrapolation of data was possible that year.

4. Member States shall provide the Commission with the data referred to in Articles 1(1), 1(2) and 2 using the electronic format to be provided by the Commission.

Article 4

Addressees

This Decision is addressed to the Member States.

Done at Brussels, 2 June 2023.

For the Commission
Thierry BRETON
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2023/1097

of 5 June 2023

not approving cyanamide as an existing active substance for use in biocidal products of product-types 3 and 18 in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 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 89(1), third subparagraph, 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 cyanamide (EC No: 206-992-3; CAS No: 420-04-2).

(2) Cyanamide has been evaluated for use in biocidal products of product-type 3, veterinary hygiene biocidal products, and product-type 18, insecticides, acaricides and products to control other arthropods, as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ([3]), which correspond respectively to product-types 3 and 18 as described in Annex V to Regulation (EU) No 528/2012.

(3) Germany was designated as the rapporteur Member State and its evaluating competent authority submitted the assessment report together with its conclusions to the Commission on 30 July 2013. After the submission of the assessment report, discussions took place in technical meetings organised by the European Chemicals Agency ('the Agency').

(4) It follows from Article 90(2) of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 should be evaluated in accordance with the provisions of Directive 98/8/EC.

(5) In accordance with Article 75(1), point (a), of Regulation (EU) No 528/2012, the Biocidal Products Committee is responsible for preparing the opinion of the Agency regarding applications for approval of active substances. In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinions of the Agency on 16 June 2016 ("the opinions of 16 June 2016") ([4]), having regard to the conclusions of the evaluating competent authority.

(6) According to the opinions of 16 June 2016, cyanamide met the criteria to be classified as carcinogen category 2 and toxic for reproduction category 2 in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([5]), and was therefore considered as also having endocrine-disrupting properties in accordance with Article 5(3) of Regulation (EU) No 528/2012, pending the adoption of delegated acts specifying the scientific

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

([4]) Biocidal Products Committee Opinion on the application for approval of the active substance: Cyanamide, Product type: 3, ECHA/BPC/116/2016, adopted on 16 June 2016; Biocidal Products Committee Opinion on the application for approval of the active substance: Cyanamide, Product type: 18, ECHA/BPC/117/2016, adopted on 16 June 2016.

([5]) 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).

criteria for the determination of endocrine-disrupting properties. The opinions of 16 June 2016 also considered that the risks to human health and the environment of using the representative biocidal products presented in the application for approval of cyanamide for product-types 3 and 18 were acceptable subject to appropriate risk mitigation measures. However, the risk assessment presented in those opinions did not take into account the risks resulting from the endocrine-disrupting properties of cyanamide.

(7) Commission Delegated Regulation (EU) 2017/2100 ([6]) setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 entered into force on 7 December 2017 and came into effect on 7 June 2018.

(8) In anticipation of the application of the new scientific criteria set out in Delegated Regulation (EU) 2017/2100, and to provide clarity as regards the hazard properties and the risks resulting from the use of cyanamide, on 26 April 2018, pursuant to Article 75(1), point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency ([7]) to revise its opinions of 16 June 2016 and to clarify whether cyanamide has also endocrine-disrupting properties on the basis of the scientific criteria laid down in that Delegated Regulation. The Agency was requested to update only that part of the opinions relating to the assessment of the endocrine-disrupting properties, unless the conclusion of that assessment affected the results of the risk assessment already performed or the recommendations for approval. In the latter case, such assessment and recommendations were also to be updated. For the preparation of the revised opinions of the Agency, the evaluating competent authority of Germany invited the applicant to submit additional information as regards the assessment of the endocrine-disrupting properties of cyanamide in accordance with the criteria laid down in Delegated Regulation (EU) 2017/2100.

(9) The Biocidal Products Committee adopted the revised opinions of the Agency on 10 December 2019 ("the opinions of 10 December 2019") ([8]), having regard to the conclusions of the evaluating competent authority.

(10) According to the opinions of 10 December 2019, cyanamide has endocrine-disrupting properties that may cause adverse effects in humans and the environment (non-target organisms) on the basis of the criteria laid down in Delegated Regulation (EU) 2017/2100. The opinions remarked that there is no agreed methodology for undertaking a risk assessment of endocrine-disrupting properties and that, given the exposure to cyanamide of humans and the environment, a risk related to endocrine-disrupting properties cannot be excluded.

(11) The opinions of 10 December 2019 did not contain any information as to whether a safe threshold can be derived in relation to endocrine-disrupting properties of cyanamide, and, if so, whether the risks of using the representative biocidal products presented in the application for approval of cyanamide for product-types 3 and 18 could be considered acceptable or not, in relation to the endocrine-disrupting properties of cyanamide.

(12) On 2 September 2020, pursuant to Article 75(1), point (g), of Regulation (EU) No 528/2012, the Commission requested the Agency ([9]) to revise its opinions of 10 December 2019 and to clarify whether a safe threshold may be derived in relation to the endocrine-disrupting properties of cyanamide, and to conclude whether the risks for human health and for the environment could be considered acceptable or not.

([6]) Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

([7]) Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR – 'Evaluation of the Endocrine disrupting properties of certain biocidal actives substances according to the new scientific criteria'

([8]) Biocidal Products Committee Opinion on the application for approval of the active substance: Cyanamide, Product type: 3, ECHA/BPC/230/2019, adopted on 10 December 2019; Biocidal Products Committee Opinion on the application for approval of the active substance: Cyanamide, Product type: 18, ECHA/BPC/231/2019, adopted on 10 December 2019.

([9]) Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR – 'Evaluation of the level of the risks for human health and for the environment of cyanamide used in biocidal products of product types 3 and 18'.

(13) The Biocidal Products Committee adopted the new revised opinions of the Agency on 30 November 2021 ('the opinions of 30 November 2021') ([10]), having regard to the conclusions of the evaluating competent authority. According to those opinions, since it was not possible to derive a safe threshold with respect to the endocrine-disrupting properties of cyanamide, it is not possible to conclude whether risks for both human health for the general public and the environment for the representative biocidal product used for product-type 3 (for the disinfection by professional users against *Brachyspira hyodysenteriae* of the liquid manure stored underneath the slatted floor in pig stables in order to protect fattening pigs against the pig disease dysenteria) and product-type 18 (for the control by professional users of *Musca domestica* in liquid manure in pig stables) are acceptable or not. Therefore, no conclusion could be drawn whether cyanamide fulfils the approval conditions.

(14) Therefore, given that the opinions of 30 November 2021 of the Agency do not provide either a positive or a negative conclusion on whether cyanamide fulfils the approval conditions, the Commission considers that it has ultimately not been demonstrated based on the data available in the application submitted for the approval that the representative biocidal product containing cyanamide for product-types 3 and 18 may be expected to not have unacceptable effects itself, or as a result of its residues, on human health and on the environment.

(15) Taking into account the opinions of 30 November 2021, it has not been demonstrated that biocidal products of product-types 3 and 18 containing cyanamide meet the criteria laid down in Article 5(1), points (b) (iii) and (iv), read in conjunction with Article 10(1) of Directive 98/8/EC. It is therefore appropriate not to approve cyanamide for use in biocidal products of product-types 3 and 18.

(16) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

Cyanamide (EC No: 206-992-3; CAS No: 420-04-2) is not approved as an active substance for use in biocidal products of product-types 3 and 18.

Article 2

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

Done at Brussels, 5 June 2023.

For the Commission
The President
Ursula VON DER LEYEN

([10]) Biocidal Products Committee Opinion on the application for approval of the active substance: Cyanamide, Product type: 3, ECHA/BPC/301/2021, adopted on 30 November 2021; Biocidal Products Committee Opinion on the application for approval of the active substance: Cyanamide, Product type: 18, ECHA/BPC/302/2021, adopted on 30 November 2021.

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