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Legislation

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Contents

[1] Text with EEA relevance.

EN

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

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

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2023/402

of 22 February 2023

granting a Union authorisation for the biocidal product family 'CMIT/MIT SOLVENT BASED' 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 14 June 2017, Dow Europe GmbH ('the applicant') submitted an application to the European Chemicals Agency ('the Agency') in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a biocidal product family named 'CMIT/MIT SOLVENT BASED' of product-type 6, as described in Annex V to that Regulation, for preservation of aviation fuel, crude oil and middle distillate fuel, providing written confirmation that the competent authority of France had agreed to evaluate the application. The application was recorded under case number BC-NN032576-24 in the Register for Biocidal Products. On 16 April 2020, the applicant withdrew the application as regards use of 'CMIT/MIT SOLVENT BASED' in aviation fuels. On 31 October 2020, the application was transferred by the applicant to Nutrition & Biosciences Netherlands B.V.

(2) The biocidal product family 'CMIT/MIT SOLVENT BASED' comprises products for preservation of de-watered crude oil and refined products (middle and light distillate fuels) containing 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one ('C(M)IT/MIT') as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012.

(3) On 28 August 2019, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, the assessment report and the conclusions of its evaluation to the Agency.

(4) On 7 April 2020, the Agency submitted an opinion ([2]), the draft summary of the biocidal product characteristics ('SPC') of 'CMIT/MIT SOLVENT BASED' and the final assessment report on the biocidal product family to the Commission in accordance with Article 44(3) of Regulation (EU) No 528/2012.

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

([2]) ECHA opinion of 5 March 2020 on the Union authorisation of the biocidal product family 'CMIT-MIT Solvent Based' (ECHA/BPC/246/2020), https://echa.europa.eu/bpc-opinions-on-union-authorisation.

(5) The opinion concludes that 'CMIT/MIT SOLVENT BASED' is a biocidal product family within the meaning of Article 3(1), point (s), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation. The opinion included a minority position expressed by the member appointed by Germany, which concluded that the use of 'CMIT/MIT SOLVENT BASED' as a preservative in fuels conflicts with the national legislation of that Member State (10th Federal Emission Control Ordinance §2 (1) and (2)), which forbids that fuels for on-road motor vehicles contain additives with chlorine or bromine compounds and which forbids the placing on the market of additives that contain chlorine or bromine as these compounds cause formation of dioxins during the fuel combustion.

(6) On 15 January 2021, the Agency transmitted the draft SPC to the Commission in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(7) To address the concerns on dioxin formation expressed in the minority position to the opinion, on 24 July 2020, the Commission requested an opinion from the Agency under Article 75(1), point (g), of Regulation (EU) No 528/2012 to estimate the amount of formation of dioxins and the overall contribution to the emissions of dioxins due to the use of the biocidal product family 'CMIT/MIT SOLVENT BASED' in fuels used for road and water transport. The Commission also requested the Agency to clarify the level of the risks to the environment and human health due to the exposure to dioxins via the environment from the use of the biocidal product family 'CMIT/MIT SOLVENT BASED'.

(8) On 5 July 2021, the Agency submitted the requested opinion to the Commission ([3]) concluding that although the potential consequences of the use of C(M)IT/MIT as a preservative in oil and fuel cannot be neglected, it is not possible to draw any conclusions on the magnitude of the potential contribution of the use of C(M)IT/MIT in fuels with respect to dioxin exposure, nor on the potential consequences of chlorine additives such as C(M)IT/MIT in fuels on human health and on the environment.

(9) The objectives of the Stockholm Convention on Persistent Organic Pollutants ('Stockholm Convention') ([4]) and Regulation (EU) 2019/1021 of the European Parliament and of the Council ([5]) are to protect human health and the environment from persistent organic pollutants (POPs), which include dioxins. The Commission considers that refusing the Union authorisation for the biocidal product family 'CMIT/MIT SOLVENT BASED' would not lead to a significant decrease of dioxin emissions compared to granting it, as the same or similar chlorine-containing additives are currently allowed to be placed on the market under transitional measures of Regulation (EU) No 528/2012 by the Member States or could be authorised under national authorisations granted in accordance with Regulation (EU) No 528/2012. Furthermore, as a consequence of the ambitions of the European Green Deal ([6]) and Regulation (EU) 2021/1119 of the European Parliament and of the Council ([7]) (the European Climate Law ([8])) to achieve climate neutrality by 2050, the overall amount of fuel that may potentially be treated with the biocidal product family and combusted in motors or heating systems is expected to decline significantly in the coming decades. Consequently, the possible formation of dioxins associated with the use of the biocidal product family 'CMIT/MIT SOLVENT BASED' will decrease accordingly, thus contributing to achieve the objectives of the Stockholm Convention and Regulation (EU) 2019/1021.

([3]) Biocidal Products Committee (BPC) Opinion on a request according to Article 75(1)(g) of Regulation (EU) No 528/2012 on the evaluation of dioxins emissions from the use of the biocidal product family (BPF) 'CMIT/MIT SOLVENT BASED' in fuels used in road and ship transport (ECHA/BPC/283/2021).

([4]) Stockholm Convention on Persistent Organic Pollutants (OJ L 209, 31.7.2006, p. 3).

([5]) Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).

([6]) A European Green Deal | European Commission (europa.eu).

([7]) Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 (OJ L 243, 9.7.2021, p. 1).

([8]) European Climate Law (europa.eu).

(10) On 16 November 2021, in accordance with Article 44(5), second subparagraph, of Regulation (EU) No 528/2012, Denmark made a request to the Commission for the Union authorisation of the biocidal product family 'CMIT/MIT SOLVENT BASED' not to apply in its territory, based on the grounds provided in Article 37(1), points (a) and (c), of that Regulation, as the presence of halogenated organic compounds such as C(M)IT/MIT in fuel may result in the formation of dioxins during fuel combustion, alternatives for fuel preservation without halogenated compounds are available and preservatives for fuels are not used by refineries or at service stations in Denmark.

(11) On 12 December 2021, Germany requested that the Commission adjusts the conditions of the Union authorisation of the biocidal product family 'CMIT/MIT SOLVENT BASED' in its territory in accordance with Article 44(5), second subparagraph, of Regulation (EU) No 528/2012, based on the grounds referred to in Article 37(1) points (a) and (c), of that Regulation so as not to allow its use for the preservation of fuels for non-rail bound on-road motor vehicles, except for the purpose of research, development or analysis in line with national legislation as set out in the 10th Federal Emission Control Ordinance ([9]) in combination with the German Road Traffic Act (Straßenverkehrsgesetz) ([10]).

(12) On 15 July 2022, in accordance with Article 44(5), second subparagraph, of Regulation (EU) No 528/2012, Belgium made a request to the Commission for the Union authorisation of the biocidal product family 'CMIT/MIT SOLVENT BASED' not to apply in its territory, based on the grounds provided in Article 37(1), points (a) and (c), of that Regulation, as it considers that the presence of halogenated organic compounds such as C(M)IT/MIT in fuel may result in the formation of dioxins during fuel combustion, that the formation of dioxins should be minimised and, where feasible, fully eliminated in Belgium, and that alternatives for fuel preservation without halogenated compounds are available.

(13) The Commission considers that the requests made by Germany to adjust the conditions and the requests made by Denmark and Belgium not to apply the Union authorisation of the biocidal product family 'CMIT/MIT SOLVENT BASED' in the respective territories of those Member States in accordance with Article 44(5), second subparagraph, of Regulation (EU) No 528/2012 can be considered justified on the grounds of the protection of the environment and the protection of health and life of humans pursuant to Article 37(1), points (a) and (c), of that Regulation as the presence of halogenated organic compounds, such as C(M)IT/MIT, in fuel may result in the formation of dioxins during fuel combustion.

(14) Therefore, the biocidal product family 'CMIT/MIT SOLVENT BASED' should not be authorised for use in Denmark and Belgium and should be not be used in Germany for the preservation of fuels for non-rail bound on-road motor vehicles, except for the purpose of research, development or analysis.

(15) Therefore, the Commission concurs with the opinion of the Agency and considers it appropriate to grant a Union authorisation for 'CMIT/MIT SOLVENT BASED' with the adjustments for Germany, Denmark and Belgium requested in accordance with Article 44(5), second subparagraph, of Regulation (EU) No 528/2012.

(16) 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-0023657-0000 is granted to Nutrition & Biosciences Netherlands B. V. for the making available on the market and use of the biocidal product family 'CMIT/MIT SOLVENT BASED' in accordance with the summary of the biocidal product characteristics set out in the Annex.

([9]) Zehnte Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes.
([10]) Straßenverkehrsgesetz.

However, the Union authorisation shall not apply in the territory of the Kingdom of Denmark and in the territory of the Kingdom of Belgium, nor shall it apply in the territory of the Federal Republic of Germany for the preservation of fuels for non-rail bound on-road motor vehicles, except for the purpose of research, development or analysis.

The Union authorisation is valid from 15 March 2023 until 28 February 2033.

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, 22 February 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

CMIT/MIT SOLVENT BASED

Product type 6 – Preservatives for products during storage (Preservatives)

Authorisation number: EU-0023657-0000

R4BP asset number: EU-0023657-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	CMIT/MIT SOLVENT BASED

1.2. **Product type(s)**

Product type(s)	PT06 – Preservatives for products during storage (Preservatives)

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	MC (Netherlands) 1 B.V.
	Address	Willem Einthovenstraat 4, 2342BH Oegstgeest Netherlands
Authorisation number	EU-0023657-0000	
R4BP asset number	EU-0023657-0000	
Date of the authorisation	15 March 2023	
Expiry date of the authorisation	28 February 2033	

1.4. **Manufacturer(s) of the biocidal products**

Name of manufacturer	Specialty Electronic Materials Switzerland GmbH
Address of manufacturer	Im Ochsensand, 9470 Buchs Switzerland
Location of manufacturing sites	Im Ochsensand, 9470 Buchs Switzerland

Name of manufacturer	AD Productions BV
Address of manufacturer	Markweg Zuid 27, 4794 SN Heijningen Netherlands
Location of manufacturing sites	Markweg Zuid 27, 4794 SN Heijningen Netherlands

1.5. **Manufacturer(s) of the active substance(s)**

Active substance	Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (Einecs 247-500-7) and 2-methyl-2H-isothiazol-3-one (Einecs 220-239-6) (Mixture of CMIT/MIT)
Name of manufacturer	Jiangsu FOPIA Chemicals Co., Ltd (Specialty Electronic Materials Switzerland GmbH)
Address of manufacturer	Touzeng Village, Binhuai Town, 224555 Binhai County, Yancheng City, Jiangsu China
Location of manufacturing sites	Touzeng Village, Binhuai Town, 224555 Binhai County, Yancheng City, Jiangsu China

2. PRODUCT FAMILY COMPOSITION AND FORMULATION

2.1. **Qualitative and quantitative information on the composition of the family**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (Einecs 247-500-7) and 2-methyl-2H-isothiazol-3-one (Einecs 220-239-6) (Mixture of CMIT/MIT)		Active Substance	55965-84-9		10,8	12,1
Butyl carbitol	2-(2-butoxyethoxy)ethanol	Non-active substance	112-34-5	203-961-6	0,0	89,2

2.2. **Type(s) of formulation**

Formulation(s)	AL – Any other liquid

PART II

SECOND INFORMATION LEVEL – META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 1 identifier**

Identifier	Meta SPC KATHON FP

1.2. **Suffix to the authorisation number**

Number	1-1

1.3. **Product type(s)**

Product type(s)	PT06 – Preservatives for products during storage (Preservatives)

2. META SPC 1 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 1**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (Einecs 247-500-7) and 2-methyl-2H-isothiazol-3-one (Einecs 220-239-6) (Mixture of CMIT/MIT)		Active Substance	55965-84-9		10,8	12,1

2.2. **Type(s) of formulation of the meta SPC 1**

Formulation(s)	AL – Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Causes severe skin burns and eye damage. May cause an allergic skin reaction. Very toxic to aquatic life with long lasting effects. Corrosive to the respiratory tract.
Precautionary statements	Do not breathe vapours. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection. Specific treatment (see supplemental first aid instructions on this label). IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN: Wash with plenty of water. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. 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. Take off contaminated clothing. And wash it before reuse. Collect spillage. If skin irritation or rash occurs: Get medical advice. Store locked up. Dispose of contents to an approved facility in accordance with local, regional, national and international regulations.

4. AUTHORISED USE(S) OF THE META SPC 1

4.1. **Use description**

Table 1. Use # 1 – Preservation of de-watered crude oil and refined products (middle and light distillate fuels) with a maximum water content of 2 %

Product type	PT06 – Preservatives for products during storage (Preservatives)
Where relevant, an exact description of the authorised use	Preservation of de-watered crude oil and refined products (middle and light distillate fuels) with a maximum water content of 2 %
Target organism(s) (including development stage)	Scientific name: Fungi/moulds Common name: mould Development stage: vegetative cells and spores Scientific name: Fungi/Yeast Common name: yeast Development stage: vegetative cells Scientific name: Bacteria Common name: bacteria Development stage: vegetative cells
Field(s) of use	Indoor The biocidal product family is recommended to control microorganisms in de-watered crude oil and refined products (middle and light distillate fuels) with a maximum water content of 2 %. The biocidal product family is not to be used for the preservation of aviation fuels, naphthas, alkenes/olefins and aromatics (simple and more complex structures).
Application method(s)	Method: Loading of biocidal product into the blend tank containing de-watered crude oils or refined products (middle and light distillate fuels) Detailed description: The biocidal product is added as a single dose at the time of manufacture, storage or shipment. Dose the biocidal product to the end use fluid at a point to ensure adequate mixing using automated metering or by manual pouring using a safe measuring dosing system. The biocidal product should not be dispensed as supplied into an empty fuel tank. Fuel tanks being treated with the biocidal product should be at least 10 % full in order to ensure good homogenisation of the biocidal product, which aids effectiveness of the treatment.

	Fuel tanks and sumps should be drained of water regularly. Following treatment, drain off dead microorganisms and other debris from the treated fuel which have accumulated at the bottom of the tank. Filters should also be checked frequently and examined for the build-up of suspended solids. Whenever periodic maintenance is carried out, tanks should be checked for microbial growth.
Application rate(s) and frequency	Application Rate: Preservation for mid and long term storage and curative treatment 50-100 ppm v/v of biocidal product as supplied. Refined products (middle and light distillate fuels) and de-watered crude oils – Mid/long term preservation: 50 to 150 ppm v/v of biocidal product as supplied – Curative treatment: 200 to 400 ppm v/v of biocidal product as supplied Dilution (%): - Number and timing of application: **De-watered crude oils:** Mid/long-term preservation: — 50 to 150 ppm v/v of biocidal product as supplied (0,75 – 2,25 ppm v/v CMIT/MIT), contact time needs to be 1 to 4 weeks, depending on the dose used. Curative treatment:: — Bacteria: 200 to 400 ppm v/v of biocidal product as supplied (3 – 6 ppm v/v CMIT/MIT), contact time needs to be 1 to 3 days, depending on the dose used. — Fungi (Yeasts/Moulds): 400 ppm v/v of biocidal product as supplied (6 ppm v/v CMIT/MIT), contact time needs to be 1 to 3 days, depending on the dose used. Refined products (middle and light distillate fuels): Mid/long-term preservation: — 50 to 150 ppm v/v of biocidal product as supplied (0,75 – 2,25 ppm v/v CMIT/MIT), contact time needs to be 1 to 4 weeks, depending on the dose used. Curative treatment:: — Bacteria: 200 to 400 ppm v/v of biocidal product as supplied (3 – 6 ppm v/v CMIT/MIT), contact time needs to be 1 to 3 days, depending on the dose used. — Fungi (Yeasts/Moulds): 400 ppm v/v of biocidal product as supplied (6 ppm v/v CMIT/MIT), contact time needs to be 1 to 3 days, depending on the dose used. Repeat as necessary when contamination is detected.
Category(ies) of users	Professional
Pack sizes and packaging material	Flasks: 5 l nominal, material of construction is high density polyethylene (HDPE) Pails: 20 l nominal, material of construction is HDPE Pails: 25 l nominal, material of construction is HDPE Drums: 215 l nominal, material of construction is HDPE Drums: 220 l nominal, material of construction is HDPE Intermediate bulk container (IBC): 1000 l nominal, material of construction is HDPE

4.1.1. *Use-specific instructions for use*

See general directions for use.

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.

5. GENERAL DIRECTIONS FOR USE [1] OF THE META SPC 1

5.1. **Instructions for use**

— Always read the label or leaflet before use and follow all the instructions provided.

— Respect the conditions of use of the biocidal product (concentration, contact time, temperature, pH, etc.)

— For preservation during mid/long-term storage, contact time needs to be 1 to 4 weeks, depending on the dose used. For curative treatment, the biocidal effect is achieved after 1-3 days.

— Products are to be used only for mid or long-term storage or for curative treatment. Do not use in case of high turnover systems.

— Check regularly the residual concentration of the active substance (both in the fuel and aqueous phases) between fuel transfers in order to ensure lack of contamination between treatments. The choice of intervals between treatments is based on the check of the residual active substance concentrations.

— Microbiological tests to prove adequacy of preservation have to be undertaken (both in the fuel and aqueous phases) by the user of the product in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the manufacturer of the preservative product.

Not authorised for use in the Kingdom of Denmark and in the Kingdom of Belgium.

Applicable in the Federal Republic of Germany only: Do not use the products for the preservation of fuels for non rail bound on road motor vehicles, except for the purpose of research, development or analysis.

5.2. **Risk mitigation measures**

— For preservation up to the dose of 6 ppm, the maximum amount of treated de-watered crude oil or refined products emptied daily per site is 15 000 m^3.

— For preservation up to the dose of 3 ppm, the maximum amount of treated de-watered crude oil or refined products emptied daily per site is 35 000 m^3.

When handling the biocidal product:

— Wear protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) and a protective coverall (at least type 6 EN13034), during product handling phase.

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

— Wear chemical goggles meeting the requirements of the European Standard EN 166 during product handling phase.

— The following technical and organisational measures should be implemented:

  — regular cleaning of the equipment and work area;.

  — the use of a dosing pump for manual loading;

  — minimisation of manual phases;

  — adequate ventilation during application of product.

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

— IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER or doctor/physician if you feel unwell.

— IF ON SKIN: Rinse skin with water (or shower). Take off immediately all contaminated clothing and wash it before reuse.

— IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

— IF INHALED: Remove person to fresh air and keep comfortable for breathing.

— If skin irritation or rash occurs: Get medical advice/attention.

— Keep the container or label available.

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

— Release only to an industrial sewage treatment plant (STP).

— Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

— Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets) nor down the drain.

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

Shelf-life: 24 months

6. OTHER INFORMATION

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7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	KATHON FP 1.5 Biocide	Market area: EU
	BLUECIDE 832	Market area: EU
	BIOCIDA CARBURANTE DIESEL-BIODIESEL	Market area: EU
	T2642	Market area: EU
	XC85957	Market area: EU
	BIOSTOP 15 GL	Market area: EU
	C 412 GP 10	Market area: EU
	SPEC-AID 8Q700	Market area: EU
	Predator 9015	Market area: EU

	FuelClear M15	Market area: EU			
	MIRECIDE-KW/615	Market area: EU			
	BIOC41770A	Market area: EU			
	Bactron B1770	Market area: EU			
Authorisation number	EU-0023657-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (Einecs 247-500-7) and 2-methyl-2H-isothiazol-3-one (Einecs 220-239-6) (Mixture of CMIT/MIT)		Active Substance	55965-84-9		11,3

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 2 identifier**

Identifier	Meta SPC KATHON HP

1.2. **Suffix to the authorisation number**

Number	1-2

1.3. **Product type(s)**

Product type(s)	PT06 – Preservatives for products during storage (Preservatives)

2. META SPC 2 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 2**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (Einecs 247-500-7) and 2-methyl-2H-isothiazol-3-one (Einecs 220-239-6) (Mixture of CMIT/MIT)		Active Substance	55965-84-9		10,8	12,1

Butyl carbitol	2-(2-butoxye-thoxy)ethanol	Non-active substance	112-34-5	203-961-6	87,9	89,2

2.2. **Type(s) of formulation of the meta SPC 2**

Formulation(s)	AL – Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	Causes severe skin burns and eye damage. May cause an allergic skin reaction. Very toxic to aquatic life with long lasting effects. Corrosive to the respiratory tract.
Precautionary statements	Do not breathe vapours. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves meeting the requirements of the European Standard EN 374/protective clothing of at least type 6 EN13034/Wear chemical goggles meeting the requirements of the European Standard EN 166. Specific treatment (see supplemental first aid instructions on this label). IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN: Wash with plenty of water. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. 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. Take off contaminated clothing. And wash it before reuse. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical advice. Store locked up. Dispose of contents to an approved facility in accordance with local, regional, national and international regulations. Avoid release to the environment. Collect spillage.

4. AUTHORISED USE(S) OF THE META SPC 2

4.1. **Use description**

Table 2. Use # 1 – Preservation of de-watered crude oil and refined products (middle and light distillate fuels) with a maximum water content of 2 %

Product type	PT06 – Preservatives for products during storage (Preservatives)
Where relevant, an exact description of the authorised use	Preservation of de-watered crude oil and refined products (middle and light distillate fuels) with a maximum water content of 2 %

Target organism(s) (including development stage)	Scientific name: Bacteria Common name: bacteria Development stage: vegetative cells Scientific name: Fungi/Yeast Common name: yeast Development stage: vegetative cells Scientific name: Fungi/moulds Common name: mould Development stage: vegetative cells
Field(s) of use	Indoor The biocidal product family is recommended to control microorganisms in de-watered crude oil and refined products (middle and light distillate fuels) with a maximum water content of 2 %. The biocidal product family is not to be used for the preservation of aviation fuels, naphthas, alkenes/olefins and aromatics (simple and more complex structures).
Application method(s)	Method: Loading of biocidal product into the blend tank containing de-watered crude oils or refined products (middle and light distillate fuels) Detailed description: The biocidal product is added as a single dose at the time of manufacture, storage or shipment. Dose the biocidal product to the end use fluid at a point to ensure adequate mixing using automated metering or by manual pouring using a safe measuring dosing system. The biocidal product should not be dispensed as supplied into an empty fuel tank. Fuel tanks being treated with the biocidal product should be at least 10 % full in order to ensure good homogenisation of the biocidal product, which aids effectiveness of the treatment. Fuel tanks and sumps should be drained of water regularly. Following treatment, drain off dead microorganisms and other debris from the treated fuel which have accumulated at the bottom of the tank. Filters should also be checked frequently and examined for the build-up of suspended solids. Whenever periodic maintenance is carried out, tanks should be checked for microbial growth.
Application rate(s) and frequency	Application Rate: Refined products (middle and light distillate fuels) and de-watered crude oils – Mid/long term preservation: 50 to 150 ppm v/v of biocidal product as supplied – Curative treatment: 200 to 400 ppm v/v of biocidal product as supplied Dilution (%): Number and timing of application: **De-watered crude oils** Mid/long-term preservation: — Bacteria: 33 to 200 ppm v/v of biocidal product as supplied (0,5 – 3 ppm v/v CMIT/MIT), — Fungi (Yeasts/Moulds): 50 to 200 ppm v/v of biocidal product as supplied (0,75 – 3 ppm v/v CMIT/MIT), contact time needs to be 1-4 weeks, depending on the dose used.

	Curative treatment: — Bacteria: 200 to 400 ppm v/v of biocidal product as supplied (3 – 6 ppm v/v CMIT/MIT), contact time needs to be 1 to 3 days, depending on the dose used. — Fungi (Yeasts/Moulds): 400 ppm v/v of biocidal product as supplied (6 ppm v/v CMIT/MIT), contact time needs to be 1 to 3 days, depending on the dose used. **Refined products (middle and light distillate fuels)** Mid/long-term preservation: — Bacteria: 33 to 200 ppm v/v of biocidal product as supplied (0,5 – 3 ppm v/v CMIT/MIT), contact time needs to be 1-4 weeks, depending on the dose used. — Fungi (Yeasts/Moulds): 50 to 200 ppm v/v of biocidal product as supplied (0,75 – 3 ppm v/v CMIT/MIT), contact time needs to be 1-4 weeks, depending on the dose used. Curative treatment: — Bacteria: 200 to 400 ppm v/v of biocidal product as supplied (3 – 6 ppm v/v CMIT/MIT), contact time needs to be 1 to 3 days, depending on the dose used. — Fungi (Yeasts/Moulds): 400 ppm v/v of biocidal product as supplied (6 ppm v/v CMIT/MIT), contact time needs to be 1 to 3 days, depending on the dose used. Repeat as necessary when contamination is detected.
Category(ies) of users	Professional
Pack sizes and packaging material	Flasks: 5 l nominal, material of construction is high density polyethylene (HDPE) Pails: 20 l and 25 l nominal, material of construction is HDPE Drums: 215 l and 220 l nominal, material of construction is HDPE Intermediate bulk container (IBC): 1000 l nominal, material of construction is HDPE

4.1.1. Use-specific instructions for use

See general directions for use.

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.

5. GENERAL DIRECTIONS FOR USE [2] OF THE META SPC 2

5.1. **Instructions for use**

— Always read the label or leaflet before use and follow all the instructions provided.

— Respect the conditions of use of the biocidal product (concentration, contact time, temperature, pH, etc.)

— For preservation during mid/long-term storage, contact time needs to be 1 to 4 weeks, depending on the dose used. For curative treatment, the biocidal effect is achieved after 1-3 days.

— Products are to be used only for mid or long-term storage or for curative treatment. Do not use in case of high turnover systems.

— Check regularly the residual concentration of the active substance (both in the fuel and aqueous phases) between fuel transfers in order to ensure lack of contamination between treatments. The choice of intervals between treatments is based on the check of the residual active substance concentrations.

— Microbiological tests to prove adequacy of preservation have to be undertaken (both in the fuel and aqueous phases) by the user of the product in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the manufacturer of the preservative product.

Not authorised for use in the Kingdom of Denmark and in the Kingdom of Belgium.

Applicable in the Federal Republic of Germany only: Do not use the products for the preservation of fuels for non rail bound on road motor vehicles, except for the purpose of research, development or analysis.

5.2. **Risk mitigation measures**

— For preservation up to the dose of 6 ppm, the maximum amount of treated de-watered crude oil or refined products emptied daily per site is 15 000 m^3.

— For preservation up to the dose of 3 ppm, the maximum amount of treated de-watered crude oil or refined products emptied daily per site is 35 000 m^3.

When handling the biocidal product:

— Wear protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) and a protective coverall (at least type 6 EN13034), during product handling phase.

— Wear chemical goggles meeting the requirements of the European Standard EN 166 during product handling phase.

— The following technical and organisational measures should be implemented:

  — regular cleaning of the equipment and work area;.

  — the use of a dosing pump for manual loading;

  — minimisation of manual phases;

  — adequate ventilation during application of product.

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

— IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER or doctor/physician if you feel unwell.

— IF ON SKIN: Rinse skin with water (or shower). Take off immediately all contaminated clothing and wash it before reuse.

— IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

— IF INHALED: Remove person to fresh air and keep comfortable for breathing.

[2] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.

— If skin irritation or rash occurs: Get medical advice/attention.

— Keep the container or label available.

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

— Release only to an industrial sewage treatment plant (STP).

— Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

— Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets) nor down the drain.

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

Shelf-life: 3 months

6. OTHER INFORMATION

—

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

7.1. **Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)	KATHON HP 120 Biocide			Market area: EU	
	BLUECIDE 833			Market area: EU	
	Predator 9000			Market area: EU	
	FuelClear M68 Pro			Market area: EU	
	MIRECIDE-KW/615.C			Market area: EU	
Authorisation number	EU-0023657-0002 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (Einecs 247-500-7) and 2-methyl-2H-isothiazol-3-one (Einecs 220-239-6) (Mixture of CMIT/MIT)		Active Substance	55965-84-9		11,3
Butyl carbitol	2-(2-butoxyethoxy)ethanol	Non-active substance	112-34-5	203-961-6	88,7

COMMISSION IMPLEMENTING REGULATION (EU) 2023/403

of 8 February 2023

amending Implementing Regulation (EU) 2015/2447 as regards the provision of information for entry summary declarations and risk analysis for security and safety purposes at entry of goods, and adding Ukraine to the list of countries in the guarantor's undertakings for transit

(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 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code ([1]), and in particular Article 17, first paragraph, Article 50(1), first subparagraph, Article 100(1), and Article 132, first paragraph, points (a) and (b), thereof,

Whereas:

(1) The practical implementation of Regulation (EU) No 952/2013 ('the Code') in combination with Commission Implementing Regulation (EU) 2015/2447 ([2]) has shown that some amendments to that Implementing Regulation are needed to better tailor it to the needs of economic operators and customs authorities and to take into account the developments regarding the forthcoming deployment of releases 2 and 3 of the Import Control System (ICS2).

(2) Article 36 of Implementing Regulation (EU) 2015/2447 provides for the use of the Customs Risk Management System for the exchange of risk-related information between Member States' customs authorities and the Commission, and between customs authorities, and for the storage of such information. Following the deployment of the security and safety analytics in ICS2, it is necessary to amend that Article in order to also allow the Member States and the Commission to exchange specific information needed for pre-arrival security and safety risk analysis purposes using the ICS2.

(3) Article 184 of Implementing Regulation (EU) 2015/2447 provides obligations for the submission of particulars of the entry summary declaration to customs authorities by persons other than the carrier. From the date set out in Part II of the Annex to Commission Implementing Decision (EU) 2019/2151 ([3]) for the deployment of release 2 of ICS2, the submission of entry summary declarations through the ICS2 system for goods entering the customs territory of the Union by air is to become obligatory. It should therefore be necessary to oblige the carrier to inform customs authorities when a third country postal operator does not provide him or her with the particulars required for the entry summary declaration.

(4) Furthermore, from the date set out in Part II of the Annex to Implementing Decision (EU) 2019/2151 for the deployment of release 3 of ICS2, the submission of entry summary declarations through the ICS2 system for goods entering the customs territory of the Union by rail is to become obligatory. It should therefore be necessary to oblige the carrier to inform the customs authorities if any person issuing a consignment note for goods entering the customs territory of the Union by rail does not provide him or her with the particulars required for the entry summary declaration, and to oblige the person issuing the consignment note to inform the other parties to the transport contract of that consignment note. Therefore, Article 184 of Implementing Regulation (EU) 2015/2447 should be amended.

([1]) OJ L 269, 10.10.2013, p. 1.

([2]) Commission Implementing Regulation (EU) 2015/2447 of 24 November 2015 laying down detailed rules for implementing certain provisions of Regulation (EU) No 952/2013 of the European Parliament and of the Council laying down the Union Customs Code (OJ L 343, 29.12.2015, p. 558).

([3]) Commission Implementing Decision (EU) 2019/2151 of 13 December 2019 establishing the work programme relating to the development and deployment of the electronic systems provided for in the Union Customs Code (OJ L 325, 16.12.2019, p. 168).

(5) It is necessary to align Annexes 32-01, 32-02 and 32-03 and Part II, Chapters VI and VII of Annex 72-04 to Implementing Regulation (EU) 2015/2447 with the Convention on a common transit procedure ([4]) to take into account the accession of Ukraine to that Convention, in accordance with Decision No 3/2022 of the EU-CTC Joint Committee ([5]). However, in order to use up the existing stock of the guarantor's undertaking forms, the specimen forms laid down in Annexes 32-01, 32-02 and 32-03 and which are valid on the day before the entry into force of this Regulation, should continue to apply until 1 April 2024, subject to the necessary geographical adaptations in point 1 of those Annexes and the mention of the name and address for service of the authorised agent in Ukraine in point 4 of those Annexes.

(6) Implementing Regulation (EU) 2015/2447 should therefore be amended accordingly.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Implementing Regulation (EU) 2015/2447 is amended as follows:

(1) in Article 36, the following paragraph 3 is added:

'3. By way of derogation from paragraphs 1 and 2 of this Article, the system referred to in Article 182(1) shall also be used for the exchange, processing and storage of specific risk information related to entry summary declarations.';

(2) Article 184 is amended as follows:

(a) paragraph 5 is replaced by the following:

'5. From the date set out in accordance with the Annex to Implementing Decision (EU) 2019/2151 for the deployment of release 2 of the electronic system referred to in Article 182(1) of this Regulation, in the cases referred to in Article 113a(2) and (3) of Delegated Regulation (EU) 2015/2446, the carrier shall provide, in the particulars of the entry summary declaration, the identity of the postal operator, third country postal operator or express carrier who does not make the particulars required for the entry summary declaration available to him or her.';

(b) the following paragraphs 6 and 7 are added:

'6. From the date set out in accordance with the Annex to Implementing Decision (EU) 2019/2151 for the deployment of release 3 of the electronic system referred to in Article 182(1) of this Regulation, in the cases referred to in Article 112a(1) of Delegated Regulation (EU) 2015/2446, the carrier and any of the persons issuing a consignment note shall provide in the particulars of the entry summary declaration, the identity of any person that has concluded a transport contract with them with the particulars required for the entry summary declaration.

7. From the date set out in accordance with the Annex to Implementing Decision (EU) 2019/2151 for the deployment of release 3 of the electronic system referred to in Article 182(1) of this Regulation, in the cases referred to in Article 112a(1) of Delegated Regulation (EU) 2015/2446, the person issuing the consignment note shall inform the person that concluded a transport contract with him or her about the issuance of that consignment note.

In the case of a goods co-loading arrangement, the person issuing the consignment note shall inform the person with whom he or she entered into that arrangement of the issuance of that consignment note.';

([4]) Convention on a common transit procedure of 20 May 1987 (OJ L 226, 13.8.1987, p. 2).

([5]) Decision No 3/2022 of the EU-CTC Joint Committee of 29 September 2022 amending the Convention of 20 May 1987 on a common transit procedure [2022/1983] (OJ L 272, 20.10.2022, p. 36).

(3) in Part I (Undertaking by the guarantor) of Annex 32-01, point 1 is amended as follows:

(a) the word 'Ukraine,' is inserted after the text 'the Republic of Turkey';

(b) footnote (3), situated after the text 'the Republic of Turkey' is moved to after the text 'the United Kingdom of Great Britain and Northern Ireland';

(4) in Part I (Undertaking by the guarantor), point 1, of Annex 32-02, the word 'Ukraine,' is inserted after the text 'the Republic of Turkey';

(5) in Part I (Undertaking by the guarantor) of Annex 32-03, point 1 is amended as follows:

(a) the word 'Ukraine,' is inserted after the text 'the Republic of Turkey';

(b) footnote (3), situated after the text 'the Republic of Turkey' is moved to after the text 'the United Kingdom of Great Britain and Northern Ireland';

(6) in Part II, Chapter VI (Comprehensive guarantee certificate) (TC 31 Comprehensive guarantee certificate) (Front), point 7, of Annex 72-04, the word 'Ukraine', is inserted after the text 'Turkey';

(7) in Part II, Chapter VII (Guarantee waiver certificate) (TC33 Guarantee waiver certificate) (Front), point 6, of Annex 72-04, the word 'Ukraine', is inserted after the text 'Turkey'.

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*.

However, Article 1, points (3), (4) and (5), and the third paragraph of this Article shall apply from the date Ukraine accedes to the Convention on a common transit procedure.

The forms based on the specimen forms in Annex 32-01, Annex 32-02, Annex 32-03 and Part II, Chapter VI and Chapter VII of Annex 72-04 to Implementing Regulation (EU) 2015/2447, in the version applicable on the day before the entry into force of this Regulation, may continue to be used, subject to the necessary geographical adaptations and the mention of the address for service and the name of the authorised agent, until 1 April 2024.

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

Done at Brussels, 8 February 2023.

For the Commission
The President
Ursula VON DER LEYEN

DECISIONS

COUNCIL DECISION (EU) 2023/404

of 20 February 2023

on the position to be taken on behalf of the European Union within the Association Council established by the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part, as regards the amendment of Annex XLIV to that Agreement

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 83(2), in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) The Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part [1] ('the Agreement') entered into force on 1 September 2017.

(2) The Preamble to the Agreement recognises the Parties' desire to move the reform and approximation process forward in Ukraine, thus contributing to the gradual economic integration and deepening of political association, as well as to achieving economic integration through extensive regulatory approximation.

(3) Article 1(2), point (d), of the Agreement refers to the objective to support Ukrainian efforts to complete the transition into a functioning market economy by means of, inter alia, the progressive approximation of its legislation to that of the Union.

(4) Pursuant to Article 459(1) of the Agreement, the Parties are to implement assistance in accordance with the principles of sound financial management and cooperate in protecting of the financial interests of the EU and of Ukraine as set out in Annex XLIII to the Agreement. The Parties are to take effective measures to prevent and fight fraud, corruption and any other illegal activities, inter alia, by means of mutual administrative assistance and mutual legal assistance in the fields covered by the Agreement.

(5) Pursuant to Article 459(2) of the Agreement, Ukraine is to also gradually approximate its legislation in line with the provisions as set out in Annex XLIV to the Agreement.

(6) Article 474 of the Agreement provides for the general commitment of Ukraine to carry out gradual approximation of its legislation to EU law, based on commitments identified in, inter alia, Title VI of the Agreement. Commitments concerning gradual approximation of Ukrainian legislation to EU law identified in Title VI of the Agreement include protection of the financial interests of the EU and of Ukraine in the context of financial assistance provided through the relevant EU funding mechanisms and instruments in order to achieve the objectives of the Agreement, taking into account Ukraine's needs, sector capacities and progress with reforms.

(7) Pursuant to Article 463(1) and (3) of the Agreement, the Association Council has the power to take decisions for the purpose of attaining the objectives of the Agreement. In particular, it may update or amend the Annexes to the Agreement, taking into account the evolution of EU law and applicable standards set out in international instruments deemed relevant by the Parties.

[1] OJ L 161, 29.5.2014, p. 3.

(8) Since the conclusion of negotiations for the Agreement, EU law on protection of the financial interests of the European Union, provisions of which were incorporated in Annex XLIV to the Agreement, was replaced by Directive (EU) 2017/1371 of the European Parliament and of the Council ([2]), and thus Ukraine's commitments envisaged by the implementation of the Agreement have changed as well. Those amendments of EU law need to be reflected in Annex XLIV to the Agreement, which therefore needs to be amended.

(9) The Association Council is therefore to amend Annex XLIV to the Agreement and to adjust the deadline for implementation of the provisions referred to in that Annex in order to take into account the new amendments of EU law.

(10) It is appropriate to establish the position to be taken on the Union's behalf within the Association Council, as regards the amendment of Annex XLIV to the Agreement,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf within the Association Council established by the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part, as regards the amendment of Annex XLIV to that Agreement, shall be based on the draft Decision of the Association Council attached to this Decision.

Article 2

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

Done at Brussels, 20 February 2023.

For the Council
The President
J. BORRELL FONTELLES

([2]) Directive (EU) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union's financial interests by means of criminal law (OJ L 198, 28.7.2017, p. 29).

DRAFT

DECISION No …/2023 OF THE EU-UKRAINE ASSOCIATION COUNCIL

of …

as regards the amendment of Annex XLIV to the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part

THE EU-UKRAINE ASSOCIATION COUNCIL,

Having regard to the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part, and in particular Article 463 thereof,

Whereas:

(1) The Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Ukraine, of the other part ([1]) ('the Agreement') entered into force on 1 September 2017.

(2) The Preamble to the Agreement recognises the Parties' desire to move the reform and approximation process forward in Ukraine, thus contributing to the gradual economic integration and deepening of political association, as well as to achieving economic integration through extensive regulatory approximation.

(3) Article 1(2), point (d), of the Agreement refers to the objective to support Ukrainian efforts to complete the transition into a functioning market economy by means of, inter alia, the progressive approximation of its legislation to that of the Union.

(4) Pursuant to Article 459(1) of the Agreement, the Parties are to implement assistance in accordance with the principles of sound financial management and cooperate in protecting of the financial interests of the EU and of Ukraine as set out in Annex XLIII to the Agreement. The Parties are to take effective measures to prevent and fight fraud, corruption and any other illegal activities, inter alia by means of mutual administrative assistance and mutual legal assistance in the fields covered by the Agreement.

(5) Pursuant to Article 459(2) of the Agreement, Ukraine is to also gradually approximate its legislation in line with the provisions as set out in Annex XLIV to the Agreement.

(6) Article 474 of the Agreement provides for the general commitment of Ukraine to carry out gradual approximation of its legislation to EU law, based on commitments identified in, inter alia, Title VI of the Agreement. Commitments concerning gradual approximation of Ukrainian legislation to EU law identified in Title VI of the Agreement include protection of the financial interests of the EU and of Ukraine in the context of financial assistance provided through the relevant EU funding mechanisms and instruments in order to achieve the objectives of the Agreement taking into account Ukraine's needs, sector capacities and progress with reforms.

(7) Pursuant to Article 463(1) and (3) of the Agreement, the Association Council has the power to take decisions for the purpose of attaining the objectives of the Agreement. In particular, it may update or amend the Annexes to the Agreement, taking into account the evolution of EU law and applicable standards set out in international instruments deemed relevant by the Parties.

(8) Since the conclusion of negotiations for the Agreement, EU law on protection of the financial interests of the European Union, provisions of which were incorporated in Annex XLIV to the Agreement, was replaced by Directive (EU) 2017/1371 of the European Parliament and of the Council ([2]), and thus Ukraine's commitments envisaged by the implementation of the Agreement have changed as well. Those amendments of EU law need to be reflected in Annex XLIV to the Agreement, which therefore needs to be amended.

([1]) OJ EU L 161, 29.5.2014, p. 3.

([2]) Directive (EU) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union's financial interests by means of criminal law (OJ EU L 198, 28.7.2017, p. 29).

(9) The Association Council is therefore to amend Annex XLIV to the Agreement and to adjust the deadline for implementation of the provisions referred to in that Annex in order to take into account the new amendments of EU law,

HAS ADOPTED THIS DECISION:

Article 1

Annex XLIV to the Agreement is replaced by the Annex to this Decision.

Article 2

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

Done at …,

For the Association Council
The Chair

ANNEX

'ANNEX XLIV TO TITLE VI

FINANCIAL COOPERATION, WITH ANTI-FRAUD PROVISIONS

Ukraine undertakes to gradually approximate its legislation to the following EU legislation within the stipulated timeframes:

Directive (EU) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union's financial interests by means of criminal law ([1]):

— Article 3 – Fraud affecting the Union's financial interests;

— Article 4 – Other criminal offences affecting the Union's financial interests;

— Article 6 – Liability of legal persons;

— Article 7 – Sanctions with regard to natural persons;

— Article 9 – Sanctions with regard to legal persons;

— Article 12 – Limitation periods for criminal offences affecting the Union's financial interests.

Timetable: these provisions shall be implemented by 31 December 2023.'.

([1]) OJ EU L 198, 28.7.2017, p. 29.

COUNCIL IMPLEMENTING DECISION (EU) 2023/405

of 20 February 2023

amending Implementing Decision 2014/170/EU, establishing a list of non-cooperating third countries in fighting illegal, unreported and unregulated fishing, as regards the Republic of Cameroon

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to Council Regulation (EC) No 1005/2008 of 29 September 2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing, amending Regulations (EEC) No 2847/93, (EC) No 1936/2001 and (EC) No 601/2004 and repealing Regulations (EC) No 1093/94 and (EC) No 1447/1999 ([1]), and in particular Article 33(1) thereof,

Having regard to the proposal from the European Commission,

Whereas:

1. INTRODUCTION AND PROCEDURE

(1) Regulation (EC) No 1005/2008 (the 'IUU Regulation') establishes a Union system to prevent, deter and eliminate illegal, unreported and unregulated (IUU) fishing.

(2) Chapter VI of the IUU Regulation lays down the procedure to identify non-cooperating third countries, the *démarches* in respect of such countries, the establishment of a list of such countries, their removal from that list, the publication of that list, and of any emergency measures.

(3) On 24 March 2014, the Council adopted Implementing Decision 2014/170/EU ([2]) establishing a list of non-cooperating third countries in fighting IUU fishing pursuant to Regulation (EC) No 1005/2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing.

(4) In accordance with Article 32 of the IUU Regulation, the Commission notified the Republic of Cameroon ('Cameroon'), by a decision of 17 February 2021 ([3]) (the 'Decision of 17 February 2021'), of the possibility of its identification as a country which the Commission considers as non-cooperating third country.

(5) In its decision of 17 February 2021, the Commission included information on the essential facts and considerations underlying such an identification.

(6) The decision of 17 February 2021 was notified to Cameroon together with a letter inviting Cameroon to implement, in close cooperation with the Commission, an action plan to rectify the identified shortcomings under the IUU Regulation.

(7) By its decision of 17 February 2021, the Commission opened a dialogue process with Cameroon.

(8) In particular, Commission invited Cameroon to take all necessary measures to implement the actions contained in the action plan suggested by the Commission, and to assess the implementation of those.

([1]) OJ L 286, 29.10.2008, p. 1.

([2]) Council Implementing Decision 2014/170/EU of 24 March 2014 establishing a list of non-cooperating third countries in fighting IUU fishing pursuant to Regulation (EC) No 1005/2008 establishing a Community system to prevent, deter and eliminate illegal, unreported and unregulated fishing (OJ L 91, 27.3.2014, p. 43).

([3]) Commission Decision of 17 February 2021 on notifying the Republic of Cameroon of the possibility of being identified as a non-cooperating third country in fighting illegal, unreported and unregulated fishing (OJ C 59 I, 19.2.2021, p. 1).

(9) Cameroon was given the opportunity to respond to the decision of 17 February 2021, as well as to other relevant information communicated by the Commission, and to submit evidence refuting or completing the facts stated in that decision. Cameroon was assured of its right to ask for, or to provide, additional information.

(10) The Commission has continued to seek and verify all relevant information. The oral and written comments submitted by Cameroon following the decision of 17 February 2021 were considered and taken into account and a virtual meeting was held between Cameroon and the Commission to discuss relevant points. Cameroon was kept informed, either orally or in writing, of the Commission's considerations.

(11) On the basis of the information gathered, the Commission took the view that the areas of concern and shortcomings set out in the decision of 17 February 2021 had not been addressed sufficiently by Cameroon. Moreover, the Commission concluded that the measures proposed in the plan of action had not been fully implemented.

(12) As a consequence, the Commission adopted Implementing Decision of 5 January 2023 identifying Cameroon as a non-cooperating third country in fighting IUU fishing ('the Implementing Decision of 5 January 2023').

(13) Based on the investigation and dialogue process carried out by the Commission, including the correspondence exchanged and the meetings held, and the reasons underlying the decision of 17 February 2021 and the Implementing Decision of 5 January 2023, it is appropriate to place Cameroon on the list of non-cooperating third countries in fighting IUU fishing.

2. IDENTIFICATION OF CAMEROON AS A NON-COOPERATING THIRD COUNTRY

(14) In the decision of 17 February 2021, the Commission analysed the duties of Cameroon and evaluated its compliance with its international obligations as flag, port, coastal or market State. For the purpose of that review, the Commission took into account the criteria listed in Article 31(4) to (7) of the IUU Regulation.

(15) The Commission reviewed the compliance of Cameroon in line with the findings of the decision of 17 February 2021 and with regard to relevant information provided thereon by Cameroon, the suggested plan of action, and the measures taken to rectify the situation.

(16) The main shortcomings identified by the Commission were related to several failures to implement obligations under international law, in particular the failure to adopt an adequate and updated legal framework, the lack of clear and transparent registration and licensing procedures, and the lack of efficient and adequate monitoring of fishing vessels. The identified shortcomings were related, more generally, to the conditions established for the registration of fishing vessels and their control under international law. A lack of alignment with recommendations and resolutions from relevant bodies, such as the FAO International Plan of Action against Illegal, Unreported and Unregulated Fishing of the United Nations (IPOA-IUU) and FAO Voluntary Guidelines on Flag State Performance, was also identified. However, the lack of consistency of Cameroonian procedures with non-binding recommendations and resolutions was considered only as supporting evidence and not as a basis for the identification.

(17) In the Implementing Decision of 5 January 2023, the Commission therefore identified Cameroon as a non-cooperating third country pursuant to the IUU Regulation.

(18) Having regard to the possible constraints upon Cameroon as a developing country, it is noted that the development status and overall performance of Cameroon with respect to fisheries are not impaired by its general level of development.

(19) Having regard to the decision of 17 February 2021, to the Implementing Decision of 5 January 2023, and to the dialogue process with Cameroon held with the Commission and its outcome, it is concluded that the actions undertaken by Cameroon in light of its duties as flag State are insufficient to comply with Articles 91, 92, 94, 117 and 118 of the United Nations Convention on the Law of the Sea.

(20) Therefore, Cameroon has failed to discharge its duties under international law as flag State to take action to prevent, deter and eliminate IUU fishing.

3. ESTABLISHMENT OF A LIST OF NON-COOPERATING THIRD COUNTRIES

(21) In view of the conclusions reached with regard to Cameroon, that country should be added, in accordance with Article 33 of the IUU Regulation, to the list of non-cooperating third countries established by the Implementing Decision 2014/170/EU. That Decision should therefore be amended accordingly.

(22) The inclusion of Cameroon in the list of non-cooperating countries in the fight against IUU fishing entails the application of the measures laid down in Article 38 of the IUU Regulation. Article 38(1) of the IUU Regulation provides for the prohibition of importation of fisheries products caught by vessels flying the flag of non-cooperating third countries. In the case of Cameroon, that prohibition should cover all stocks and species defined in Article 2, point 8, of the IUU Regulation, as the lack of appropriate measures adopted in relation to IUU fishing which has led to the identification of Cameroon as a non-cooperating third country is not limited to a given stock or species.

(23) It is noted that IUU fishing, inter alia, depletes fish stocks, destroys marine habitats, undermines the conservation and sustainable use of marine resources, distorts competition, endangers food security, puts compliant fishermen at an unfair disadvantage and weakens coastal communities. In view of the magnitude of the problems related to IUU fishing, it is considered necessary for the Union to expeditiously implement the actions in respect of Cameroon as a non-cooperating third country. Therefore, this Decision should enter into force on the day following that of its publication in the *Official Journal of the European Union*.

(24) If Cameroon demonstrates that the situation that warranted its listing has been rectified, the Council, acting by qualified majority on a proposal from the Commission, is to remove Cameroon from the list of non-cooperating third countries in line with Article 34(1) of the IUU Regulation. Any such removal decision should also take into consideration whether Cameroon has adopted concrete measures capable of achieving a lasting improvement of the situation,

HAS ADOPTED THIS DECISION:

Article 1

The Republic of Cameroon is hereby added to the Annex to Implementing Decision 2014/170/EU.

Article 2

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

Done at Brussels, 20 February 2023.

For the Council
The President
J. BORRELL FONTELLES

CORRIGENDA

Corrigendum to Council Regulation (EU) 2022/2583 of 19 December 2022 amending Regulation (EU) 2021/2278 suspending the Common Customs Tariff duties referred to in Article 56(2), point (c), of Regulation (EU) No 952/2013 on certain agricultural and industrial products

(Official Journal of the European Union L 340 of 30 December 2022)

1. On page 15, in the Annex replacing the Annex to Regulation (EU) 2021/2278, in the table, in the entry relating to serial number 0.3227, under the column 'CN code':

for: '2846 90 30

2846 90 40

2846 90 50

2846 90 60

2846 90 90',

read: '2846 90 30

2846 90 40

2846 90 50

2846 90 60

2846 90 70

2846 90 90'.

2. On page 201, in the Annex replacing the Annex to Regulation (EU) 2021/2278, in the table, in the entry relating to serial number 0.7029, under the column 'CN code':

for: 'ex 8505 11 00',

read: 'ex 8505 11 10'.

Corrigendum to Council Decision (EU) 2022/2571 of 24 November 2022 on the position to be adopted, on behalf of the European Union, within the EEA Joint Committee concerning the amendment to Annex XI (Electronic communication, audiovisual services and information society) and Protocol 37 (containing the list provided for in Article 101) to the EEA Agreement (Audiovisual Media Services Directive)

(Official Journal of the European Union L 331 of 27 December 2022)

1. The title on the contents page and the title on page 1:

for: '… of 24 November 2022 …',

read: '… of 24 October 2022 …'.

2. On page 2, where the place and date of adoption are cited:

for: 'Done at Luxembourg, 24 November 2022.',

read: 'Done at Luxembourg, 24 October 2022.'.

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