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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.

I

(Legislative acts)

REGULATIONS

REGULATION (EU) 2022/1278 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 July 2022

amending Regulation (EU) No 508/2014 as regards specific measures to alleviate the consequences of Russia's war of aggression against Ukraine on fishing activities and to mitigate the effects of the market disruption caused by that war of aggression on the supply chain of fishery and aquaculture products

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 43(2) and 175 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee ([1]),

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ([2]),

Whereas:

(1) Russia's war of aggression against Ukraine since 24 February 2022 is having an impact on operators in the fishery and aquaculture sector in the Union. The disruption of trade flows of key commodities for the fishery and aquaculture sector from Russia and Ukraine abruptly intensified the increase in prices of key inputs such as energy and raw materials. Trade between Ukraine and the Union is also severely affected by the unavailability of transport, as Ukrainian airports have been rendered inoperable because of the Russian attacks and all commercial shipping operations in Ukrainian ports have been suspended. The current crisis is likely to have serious consequences for the supply of grain, vegetable oils and white fish from Russia and Ukraine to the Union, leading to shortages of key raw materials and to a substantial increase in fish feed prices. Part of the Union fleet has ceased fishing because of the impossibility of offsetting the increase in input costs such as soaring energy prices and the decrease in profitability of fishing. The combined impact of the raw material shortages and cost increases is also being felt by the seafood farming and processing sectors. There is therefore significant market disruption, caused by substantial cost increases, and trade disruptions, requiring effective and efficient action.

([1]) Opinion of 18 May 2022 (not yet published in the Official Journal).

([2]) Position of the European Parliament of 6 July 2022 (not yet published in the Official Journal) and decision of the Council of 18 July 2022.

(2) Therefore, it should be possible for the European Maritime and Fisheries Fund (EMFF) established by Regulation (EU) No 508/2014 of the European Parliament and of the Council ([3]) to support specific measures to mitigate the effects of the market disruption caused by Russia's war of aggression against Ukraine on the supply chain of fishery and aquaculture products. Those measures should comprise financial compensation to recognised producer organisations and associations of producer organisations which store fishery or aquaculture products in accordance with Articles 30 and 31 of Regulation (EU) No 1379/2013 of the European Parliament and of the Council ([4]), and financial compensation to operators of the fishery and aquaculture sector, including the processing sector, for their income foregone, and for additional costs they have incurred due to the market disruption caused by Russia's war of aggression against Ukraine and its effects on the supply chain of fishery and aquaculture products. Expenditure for operations supported under those measures should be eligible as from 24 February 2022, which is the date upon which Russia's war of aggression against Ukraine commenced.

(3) It should also be possible for the EMFF to support financial compensation for the temporary cessation of fishing activities where Russia's war of aggression against Ukraine jeopardises the security of fishing activities or where the impact of that war of aggression impedes the economic viability of fishing operations. Such temporary cessation of fishing activities should be eligible as from 24 February 2022.

(4) It should be possible to support both those measures with a maximum co-financing rate of 75 % of eligible public expenditure.

(5) Given the need for flexibility in the reallocation of financial resources, it should be possible to reallocate the fixed amounts established for control and enforcement measures and for measures on data collection to the measures alleviating the consequences of Russia's war of aggression against Ukraine on fishing activities and mitigating the effects of the market disruption caused by that war of aggression on the supply chain of fishery and aquaculture products. For the same reason, and without prejudice to the existing financial capping and limitation of duration for the other cases of temporary cessation of fishing activities, the provision of support for the temporary cessation of fishing activities caused by Russia's war of aggression against Ukraine should not be subject to financial capping or to a limitation on duration. The obligation to deduct support granted for temporary cessation of fishing activities from support granted for the permanent cessation of fishing activities to the same vessel should continue to apply. For the sake of legal clarity as regards the implementation of this new case of temporary cessation of fishing activities, it is necessary to refer to the eligibility period set out in Article 65(2) of Regulation (EU) No 1303/2013 of the European Parliament and of the Council ([5]).

(6) Given the urgency of providing the support needed, the scope of the simplified procedure for amending the operational programmes of Member States should be extended to include amendments related to the specific measures to alleviate the consequences of Russia's war of aggression against Ukraine on fishing activities and to mitigate the effects of the market disruption caused by that war of aggression on the supply chain of fishery and aquaculture products. That simplified procedure should cover all the amendments necessary for the full implementation of the measures concerned, including their introduction, the reallocation of financial resources from other measures, and the description of the methods for calculating support.

([3]) Regulation (EU) No 508/2014 of the European Parliament and of the Council of 15 May 2014 on the European Maritime and Fisheries Fund and repealing Council Regulations (EC) No 2328/2003, (EC) No 861/2006, (EC) No 1198/2006 and (EC) No 791/2007 and Regulation (EU) No 1255/2011 of the European Parliament and of the Council (OJ L 149, 20.5.2014, p. 1).

([4]) Regulation (EU) No 1379/2013 of the European Parliament and of the Council of 11 December 2013 on the common organisation of the markets in fishery and aquaculture products, amending Council Regulations (EC) No 1184/2006 and (EC) No 1224/2009 and repealing Council Regulation (EC) No 104/2000 (OJ L 354, 28.12.2013, p. 1).

([5]) Regulation (EU) No 1303/2013 of the European Parliament and of the Council of 17 December 2013 laying down common provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund, the European Agricultural Fund for Rural Development and the European Maritime and Fisheries Fund and laying down general provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund and the European Maritime and Fisheries Fund and repealing Council Regulation (EC) No 1083/2006 (OJ L 347, 20.12.2013, p. 320).

(7) Given the urgency of the support needed, this Regulation should enter into force on the day following that of its publication in the *Official Journal of the European Union*. Given the unexpected character of Russia's war of aggression against Ukraine and its serious impact on fishing activities and on the economic sectors and supply chains concerned, the provisions on eligibility of the costs should apply retroactively from 24 February 2022.

(8) Since the objective of this Regulation, namely to mitigate the impact of Russia's war of aggression against Ukraine on the fishery and aquaculture sector, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the proposed action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(9) Regulation (EU) No 508/2014 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EU) No 508/2014

Regulation (EU) No 508/2014 is amended as follows:

1. in Article 13, the following paragraph is added:

   '7. The budgetary resources referred to in paragraphs 2 and 3 of this Article may be reallocated to the support referred to in point (d) of Article 33(1), in Article 44(4a), in Article 67 and in Article 68(3) to alleviate the consequences of Russia's war of aggression against Ukraine on fishing activities and to mitigate the effects of the market disruption caused by that war of aggression on the supply chain of fishery and aquaculture products.';

2. in Article 22(2), point (e) is replaced by the following:

   '(e) amendments to operational programmes concerning the support referred to in point (d) of Article 33(1), Article 35, Article 44(4a), point (b) of Article 55(1), Articles 57, 66 and 67, Article 68(3) and Article 69(3), including the reallocation of financial resources thereto to address the consequences of the COVID-19 outbreak or to alleviate the consequences of Russia's war of aggression against Ukraine on fishing activities and to mitigate the effects of the market disruption caused by that war of aggression on the supply chain of fishery and aquaculture products.';

3. Article 33 is amended as follows:

   (a) paragraph 1 is amended as follows:

      (i) in the first subparagraph, point (d) is replaced by the following:

         '(d) where the temporary cessation of fishing activities occurs between 1 February and 31 December 2020 as a consequence of the COVID-19 outbreak, including for vessels operating under a sustainable fisheries partnership agreement, or occurs on or after 24 February 2022 as a consequence of Russia's war of aggression against Ukraine that jeopardises the security of fishing activities or impedes the economic viability of fishing operations.';

      (ii) the second subparagraph is replaced by the following:

         'In accordance with the second subparagraph of Article 65(9) of Regulation (EU) No 1303/2013 and by way of derogation from the first subparagraph thereof, expenditure for operations supported under point (d) of the first subparagraph of this paragraph shall be eligible as from 1 February 2020 if they are the consequence of the COVID-19 outbreak, or as from 24 February 2022 if they are the consequence of Russia's war of aggression against Ukraine that jeopardises the security of fishing activities or impedes the economic viability of fishing operations.';

(b) paragraph 2 is replaced by the following:

'2. The support referred to in points (a), (b) and (c) of the first subparagraph of paragraph 1 may be granted for a maximum duration of six months per vessel during the eligibility period referred to in Article 65(2) of Regulation (EU) No 1303/2013. That maximum duration shall not apply to the support referred to in point (d) of that subparagraph.';

4. in Article 44, paragraph 4a is replaced by the following:

'4a. The EMFF may support measures for temporary cessation of fishing activities caused by the COVID-19 outbreak or by Russia's war of aggression against Ukraine that jeopardises the security of fishing activities or impedes the economic viability of fishing operations, as provided for in point (d) of the first subparagraph of Article 33(1), under the conditions laid down in Article 33.';

5. in Article 67(1), first subparagraph, the introductory part is replaced by the following:

'1. Where needed to respond to the COVID-19 outbreak or to mitigate the effects of the market disruption caused by Russia's war of aggression against Ukraine on the supply chain of fishery and aquaculture products, the EMFF may support compensation to recognised producer organisations and associations of producer organisations which store fishery or aquaculture products listed in Annex II to Regulation (EU) No 1379/2013 or products falling within CN code 0302 as listed in point (a) of Annex I to that Regulation, provided that those products are stored in accordance with Articles 30 and 31 of that Regulation, and subject to the following conditions:';

6. in Article 67, paragraph 2 is replaced by the following:

'2. The support referred to in paragraph 1 shall end on 31 December 2020, except if it mitigates the effects of the market disruption caused by Russia's war of aggression against Ukraine on the supply chain of fishery and aquaculture products.

In accordance with the second subparagraph of Article 65(9) of Regulation (EU) No 1303/2013 and by way of derogation from the first subparagraph thereof, expenditure for operations supported under this Article shall be eligible as from 1 February 2020 to respond to the COVID-19 outbreak, and as from 24 February 2022 to mitigate the effects of the market disruption caused by Russia's war of aggression against Ukraine on the supply chain of fishery and aquaculture products.';

7. in Article 68, the following paragraph is added:

'3. The EMFF may support financial compensation to operators of the fishery and aquaculture sector for their income foregone, and for additional costs they incur due to the market disruption caused by Russia's war of aggression against Ukraine and its effects on the supply chain of fishery and aquaculture products.

In accordance with the second subparagraph of Article 65(9) of Regulation (EU) No 1303/2013, expenditure for operations supported under the first subparagraph of this paragraph shall be eligible as from 24 February 2022.

The compensation referred to in the first subparagraph of this paragraph shall be calculated in accordance with Article 96.';

8. in Article 95(2), point (e) is replaced by the following:

'(e) the operation is related to support under Article 33 or 34 or to compensation under Article 54, Article 55, Article 56, Article 68(3) or Article 69(3);'.

Article 2

Entry into force

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

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

Done at Brussels, 18 July 2022.

For the European Parliament	*For the Council*
The President	*The President*
R. METSOLA	Z. NEKULA

REGULATION (EU) 2022/1279 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 July 2022

on temporary trade-liberalisation measures supplementing trade concessions applicable to products from the Republic of Moldova under the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure ([1]),

Whereas:

(1) The Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part ([2]) (the 'Association Agreement'), constitutes the basis of the relationship between the Union and the Republic of Moldova. In accordance with Council Decision 2014/492/EU ([3]), Title V of the Association Agreement, which relates to trade and trade-related matters, has been applied provisionally since 1 September 2014, and entered into force on 1 July 2016 following ratification of the Association Agreement by all Member States.

(2) The Association Agreement expresses the desire of the Parties to the Association Agreement (the 'Parties') to strengthen and widen relations in an ambitious and innovative way, to facilitate and achieve gradual economic integration, and to do so in compliance with the rights and obligations arising out of the World Trade Organisation membership of the Parties.

(3) Article 143 of the Association Agreement provides for the progressive establishment of a free trade area between the Parties in accordance with Article XXIV of the General Agreement on Tariffs and Trade 1994 ('GATT 1994'). To that end, Article 147 of the Association Agreement provides for the progressive elimination of customs duties in accordance with the Schedules included in Annex XV to the Association Agreement and for the possibility of accelerating and broadening the scope of such elimination.

(4) Russia's unprovoked and unjustified war of aggression against Ukraine since 24 February 2022 has had a profoundly negative impact on the ability of the Republic of Moldova to trade with the rest of the world, in particular because exports of the Republic of Moldova relied for that trade on transit via Ukrainian territory and using Ukrainian infrastructure, which are now largely unavailable. Under such critical circumstances and to mitigate the negative

([1]) Position of the European Parliament of 5 July 2022 (not yet published in the Official Journal) and decision of the Council of 18 July 2022.

([2]) OJ L 260, 30.8.2014, p. 4.

([3]) Council Decision 2014/492/EU of 16 June 2014 on the signing, on behalf of the European Union, and provisional application of the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and the Republic of Moldova, of the other part (OJ L 260, 30.8.2014, p. 1).

effects on the Republic of Moldova's economy of Russia's war of aggression against Ukraine, it is necessary to accelerate the development of closer economic relations between the Union and the Republic of Moldova and to provide quick support to the Republic of Moldova's economy. It is therefore necessary and appropriate to stimulate the Republic of Moldova's trade flows in the form of temporary trade-liberalisation measures granting additional tariff-free quotas for seven agricultural products still subject to annual duty-free tariff-rate quotas (TRQs), in line with the acceleration of the elimination of customs duties on trade between the Union and the Republic of Moldova.

(5) In accordance with Article 21(3) of the Treaty on European Union (TEU), the Union is to ensure consistency between the different areas of its external action. Pursuant to Article 207(1) of the Treaty on the Functioning of the European Union (TFEU), the common commercial policy is to be conducted in the context of the principles and objectives of the Union's external action.

(6) The trade-liberalisation measures established by this Regulation should take the form of temporary additional duty-free quotas on some agricultural products still subject to TRQs. Through such measures, the Union will deepen the economic integration between the Union and the Republic of Moldova and temporarily provide appropriate economic support to the benefit of the Republic of Moldova and the economic operators that are affected by Russia's war of aggression against Ukraine. Under Annex XV-A to the Association Agreement, seven agricultural products from the Republic of Moldova are subject to TRQs. Those products are: tomatoes, garlic, table grapes, apples, cherries, plums and grape juice. Two of those products (plums and table grapes) were exported by the Republic of Moldova in large volumes to third markets, in particular to Russia, Belarus and Ukraine. For those products, it is appropriate to introduce additional duty-free quotas to temporarily support the redirection to the Union, if needed, of the sales volumes originally directed to those markets. For the remaining products (tomatoes, garlic, apples, cherries and grape juice), the newly introduced TRQ would consist of an additional duty-free volume of the same size as the one provided for in the Association Agreement.

(7) In order to prevent fraud, entitlement to the trade measures established by this Regulation should be conditional upon the Republic of Moldova having complied with all the relevant conditions for obtaining benefits under the Association Agreement, including the rules of origin of the products concerned and the procedures related thereto, as well as the Republic of Moldova's involvement in close administrative cooperation with the Union, as provided for by the Association Agreement.

(8) The Republic of Moldova should abstain from introducing new duties or charges having equivalent effect and new quantitative restrictions or measures having equivalent effect for imports originating in the Union, from increasing existing levels of duties or charges or from introducing any other restrictions, unless clearly justified in the war context. In the event that the Republic of Moldova fails to comply with any of those conditions, the Commission should be empowered to suspend temporarily all or part of the trade measures established by this Regulation.

(9) Article 2 of the Association Agreement provides that, among other things, respect for democratic principles, human rights and fundamental freedoms as well as the countering of the proliferation of weapons of mass destruction, related materials and their means of delivery constitute essential elements of the Association Agreement. Under the same Article, the Parties commit in particular to the following general principles: the respect for the principles of the rule of law and good governance, the fight against corruption, criminal activities, organised or otherwise, including those of transnational character, and terrorism, and the respect for the principles of sustainable development and effective multilateralism. It is appropriate to introduce the possibility of temporarily suspending the trade-liberalisation measures provided for in this Regulation if the Republic of Moldova fails to respect either those essential elements or those general principles.

(10) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to temporarily suspend the trade-liberalisation measures provided for in this Regulation in cases where Union producers of like or directly competing products are or might be seriously affected by imports under this Regulation. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ([4]).

(11) Subject to an investigation by the Commission, it is necessary to provide for the possibility to suspend temporarily the trade-liberalisation measures referred to in this Regulation with regard to one or more products falling under the scope of this Regulation which cause, or threaten to cause, serious difficulties to Union producers of like or directly competing products.

(12) The Commission's annual report on the implementation of the Deep and Comprehensive Free Trade Area, which is an integral part of the Association Agreement, should include a detailed assessment of the implementation of the trade-liberalisation measures established by this Regulation.

(13) In view of the urgency of the matter related to the situation caused by Russia's war of aggression against Ukraine, it is considered to be appropriate to invoke the exception to the eight-week period provided for in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the TEU, to the TFEU and to the Treaty establishing the European Atomic Energy Community.

(14) In light of the economic situation in the Republic of Moldova, this Regulation should, as a matter of urgency, enter into force on the day following that of its publication in the *Official Journal of the European Union*,

HAVE ADOPTED THIS REGULATION:

Article 1

Trade-liberalisation measures

In addition to the duty-free tariff-rate quotas ('TRQs') established by the Association Agreement in its Annex XV-A, the agricultural products listed in the Annex to this Regulation shall be admitted for import into the Union from the Republic of Moldova within the limits of Union duty-free TRQs as set out in that Annex. Those duty-free TRQs shall be administered by the Commission in accordance with Articles 49 to 54 of Commission Implementing Regulation (EU) 2015/2447 ([5]).

Article 2

Conditions for entitlement to the trade-liberalisation measures

The trade-liberalisation measures provided for in Article 1 shall be subject to the following conditions:

(a) compliance with the rules of origin of products and the procedures related thereto as provided for in the Association Agreement;

(b) the Republic of Moldova's abstention from introducing new duties or charges having equivalent effect and new quantitative restrictions or measures having equivalent effect for imports originating in the Union, from increasing existing levels of duties or charges or from introducing any other restrictions, including discriminatory internal administrative measures, unless clearly justified in the war context; and

([4]) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

([5]) 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).

(c) the Republic of Moldova's respect for democratic principles, human rights and fundamental freedoms as well as the countering of the proliferation of weapons of mass destruction, related materials and their means of delivery, respect for the principles of the rule of law and good governance, fight against corruption, criminal activities, organised or otherwise, including those of transnational character, and terrorism, and respect for the principles of sustainable development and effective multilateralism provided for in Articles 2, 9 and 16 of the Association Agreement.

Article 3

Temporary suspension of measures

1. Where the Commission finds that there is sufficient evidence of a failure by the Republic of Moldova to comply with the conditions set out in Article 2, it may, by means of an implementing act, suspend in whole or in part the trade-liberalisation measures provided for in this Regulation. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 5(2).

2. Where a Member State requests that the Commission suspend any of the trade-liberalisation measures provided for in this Regulation on the basis of a failure by the Republic of Moldova to comply with the conditions set out in Article 2, point (b), the Commission shall provide a reasoned opinion within four months of the request on whether the Member State's claim is substantiated. If the Commission concludes that the claim is substantiated, it shall initiate the procedure referred to in paragraph 1 of this Article.

Article 4

Safeguard clause

1. Where a product originating in the Republic of Moldova is imported on terms which cause, or threaten to cause, serious difficulties to Union producers of like or directly competing products, the trade-liberalisation measure provided for in Article 1 may be suspended at any time with respect to that product.

2. The Commission shall closely monitor the impact of this Regulation, including with regard to the prices on the Union market, taking into account the information on exports, imports and Union production of the products subject to the trade-liberalisation measures established by this Regulation.

3. The Commission shall take a decision to initiate an investigation within a reasonable period of time:

(a) at the request of a Member State;

(b) at the request of a legal person or an association that does not have legal personality, acting on behalf of all or a major proportion of Union producers of like or directly competing products; or

(c) on its own initiative if it is apparent to the Commission that there is sufficient *prima facie* evidence of serious difficulties to Union producers of like or directly competing products as referred to in paragraph 1.

For the purposes of this paragraph, 'major proportion of Union producers of like or directly competing products' means Union producers whose collective output constitutes more than 50 % of the total Union production of the like or directly competing products produced by that portion of the Union producers which have expressed either support for or opposition to the request and which represent no less than 25 % of total production of the like or directly competing products produced by the Union industry.

4. Where the Commission decides to initiate an investigation, it shall publish a notice in the *Official Journal of the European Union* announcing the initiation of the investigation. The notice shall provide a summary of the information received and state that any relevant information should be sent to the Commission. It shall specify the period within which interested parties may submit their views in writing. Such period shall not exceed four months from the date of publication of the notice.

5. The Commission shall seek all information it deems necessary and may verify the information received with the Republic of Moldova or any other relevant source. It may be assisted by officials of the Member State on whose territory verification might be sought, if that Member State requests that those officials assist.

6. In examining whether serious difficulties to Union producers of like or directly competing products as referred to in paragraph 1 exist, the Commission shall take account, among other things, of the following factors concerning Union producers, where relevant information is available:

— market share,

— production,

— stocks,

— production capacity,

— capacity utilisation,

— employment,

— imports,

— prices.

7. The investigation shall be completed within six months of the publication of the notice referred to in paragraph 4 of this Article. In exceptional circumstances, the Commission may extend that period by means of an implementing act adopted in accordance with the examination procedure referred to in Article 5(2).

8. Within three months of the completion of the investigation, the Commission shall decide whether to suspend the trade-liberalisation measure provided for in Article 1 with respect to the product subject to the investigation by way of an implementing act adopted in accordance with the examination procedure referred to in Article 5(2). That implementing act shall enter into force within one month of its publication. The suspension shall be maintained as long as necessary to counteract the deterioration in the economic or financial situation of Union producers, or for as long as the threat of such deterioration persists. Where the facts as finally established show that the conditions set out in paragraph 1 of this Article are not met, the Commission shall adopt an implementing act terminating the investigation and proceedings. That implementing act shall be adopted in accordance with the examination procedure referred to in Article 5(2).

9. Where exceptional circumstances requiring immediate action make an investigation impossible, the Commission may, after informing the Customs Code Committee referred to in Article 5(1), take any preventive measure which is necessary.

Article 5

Committee procedure

1. The Commission shall be assisted by the Customs Code Committee established by Article 285 of Regulation (EU) No 952/2013 of the European Parliament and of the Council ([6]). That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 6

Assessment of the implementation of the trade-liberalisation measures

The Commission's annual report on the implementation of the Deep and Comprehensive Free Trade Area shall include a detailed assessment of the implementation of the trade-liberalisation measures provided for in this Regulation and shall include, in so far as appropriate, an assessment of the social impact of those measures in the Union and in the Republic of Moldova. Information on the imports of products under Article 1 shall be made available via the website of the Commission.

([6]) Regulation (EU) No 952/2013 of the European Parliament and of the Council of 9 October 2013 laying down the Union Customs Code (OJ L 269, 10.10.2013, p. 1).

Article 7

Transitory provision

The trade-liberalisation measures provided for in this Regulation shall apply to products which, on 23 July 2022, are under customs control in the Union, subject to the making of a claim to that effect to the responsible customs authorities of the Union within six months of that date.

Article 8

Entry into force and application

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

2. This Regulation shall apply until 24 July 2023.

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

Done at Brussels, 18 July 2022.

For the European Parliament	*For the Council*
The President	*The President*
R. METSOLA	Z. NEKULA

ANNEX

ADDITIONAL DUTY-FREE TARIFF-RATE QUOTAS FOR THE AGRICULTURAL PRODUCTS REFERRED TO IN ARTICLE 1

Notwithstanding the rules for the interpretation of the Combined Nomenclature (CN), the wording of the description of the products is to be considered as having no more than an indicative value. For the purposes of this Annex, the scope of the preferential scheme is to be determined by CN codes as they exist on the date of adoption of this Regulation.

Order No.	CN code	Description of products	Annual quota volume (in tonnes)
09.6810	0702 00 00	Tomatoes, fresh or chilled	2 000
09.6811	0703 20 00	Garlic, fresh or chilled	220
09.6812	0806 10 10	Table grapes, fresh	38 000
09.6816	0808 10 80	Apples, fresh (excl. cider apples, in bulk, from 16 September to 15 December)	40 000
09.6813	0809 29 00	Cherries (excl. sour cherries), fresh	1 500
09.6814	0809 40 05	Plums, fresh	25 000
09.6815	2009 61 10	Grape juice, incl. grape must, unfermented, Brix value ≤ 30 at 20 °C, value of > EUR 18 per 100 kg, whether or not containing added sugar or other sweetening matter (excl. containing spirit)	500
	2009 69 19	Grape juice, incl. grape must, unfermented, Brix value > 67 at 20 °C, value of > EUR 22 per 100 kg, whether or not containing added sugar or other sweetening matter (excl. containing spirit)	
	2009 69 51	Concentrated grape juice, incl. grape must, unfermented, Brix value > 30 but ≤ 67 at 20 °C, value of > EUR 18 per 100 kg, whether or not containing added sugar or other sweetening matter (excl. containing spirit)	
	2009 69 59	Grape juice, incl. grape must, unfermented, Brix value > 30 but ≤ 67 at 20 °C, value of > EUR 18 per 100 kg, whether or not containing added sugar or other sweetening matter (excl. concentrated or containing spirit)	

REGULATION (EU) 2022/1280 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 18 July 2022

laying down specific and temporary measures, in view of Russia's invasion of Ukraine, concerning driver documents issued by Ukraine in accordance with its legislation

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 91 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

After consulting the European Economic and Social Committee,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure ([1]),

Whereas:

(1) On 24 February 2022, Russian armed forces initiated a large-scale invasion of Ukraine at multiple locations from the Russian Federation, from Belarus and from non-government-controlled areas of Ukraine. Consequently, substantial areas of Ukrainian territory now constitute areas of armed conflict from which millions of persons have fled or are fleeing.

(2) As a result of this unprovoked and unjustified military aggression against Ukraine, millions of persons have been displaced. In response, the Council has for the first time established the existence of a mass influx into the Union of displaced persons who have had to leave Ukraine as a consequence of an armed conflict in accordance with Council Directive 2001/55/EC ([2]) by adopting Council Implementing Decision (EU) 2022/382 ([3]), which sets out the categories of displaced persons entitled, in the Union, to temporary protection or adequate protection under national law.

(3) Driving licences enhance the mobility of their holders and facilitate their everyday lives by permitting them to drive power-driven vehicles. A certificate of professional competence is required for the holder to work as a professional driver transporting goods and passengers for an undertaking established in the Union. In the current context, both types of document promote the participation of persons enjoying temporary protection or adequate protection under national law in economic and social activities in their new environment.

([1]) Position of the European Parliament of 7 July 2022 (not yet published in the Official Journal) and decision of the Council of 18 July 2022.

([2]) Council Directive 2001/55/EC of 20 July 2001 on minimum standards for giving temporary protection in the event of a mass influx of displaced persons and on measures promoting a balance of efforts between Member States in receiving such persons and bearing the consequences thereof (OJ L 212, 7.8.2001, p. 12).

([3]) Council Implementing Decision (EU) 2022/382 of 4 March 2022 establishing the existence of a mass influx of displaced persons from Ukraine within the meaning of Article 5 of Directive 2001/55/EC, and having the effect of introducing temporary protection (OJ L 71, 4.3.2022, p. 1).

(4) In accordance with Annex XXXII 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 ([4]), Ukraine has approximated its laws to the provisions of Directive 2003/59/EC of the European Parliament and of the Council ([5]), in particular in order to allow the issuing of the corresponding certificates of professional competence to bus and truck drivers engaged in international operations.

(5) The Convention on Road Traffic concluded at Vienna on 8 November 1968 (the 'Vienna Convention on Road Traffic'), to which Ukraine is a party, provides for certain rules which allow for the recognition of driving permits under certain conditions. However, not all Member States are parties to that convention. In addition, there is currently no harmonised Union framework for the exchange of driving licences or certificates of professional competence issued by third countries, such as Ukraine. The requirements related to a possible exchange of driving licences are mostly laid down in the national legislation of Member States, or under existing bilateral agreements between those Member States and Ukraine. Diverging requirements between the different Member States, particularly as regards the recognition of driving licences and certificates of professional competence, may adversely affect the life and the freedoms of displaced persons fleeing Russia's military aggression against Ukraine, at a time when those persons are especially vulnerable.

(6) In this context, it is therefore appropriate to have a common Union framework applicable to the recognition of driving licences issued by Ukraine and held by persons enjoying temporary protection or adequate protection under national law. To reduce the burden on such persons and on the authorities of the Member States, driving licences duly issued by Ukraine to those persons should be recognised for as long as the period of their temporary protection lasts, without the need for their holders to exchange them.

(7) The Vienna Convention on Road Traffic requires the holders of driving permits to present international driving permits for their rights to drive to be recognised in certain cases. Such holders may also be required to present a certified translation of their driving permits. However, those requirements constitute a disproportionate burden on the people displaced from Ukraine and are unlikely to be complied with in many cases. Therefore, such persons enjoying temporary protection or adequate protection under national law should not be required to present such documents on the territory of the Union. That recognition should be without prejudice to the application of criminal and police rules, subject to the principle of territoriality.

(8) Despite the fact that Ukraine has already approximated its national law to Directive 2003/59/EC for drivers engaged in international transport operations, Ukrainian professional drivers seeking to work for road transport undertakings established in the Union still need to complete the appropriate qualification and training in a Member State. It should therefore be possible for Member States to issue a driver qualification card, as referred to in Directive 2003/59/EC, to the persons concerned, or to mark the special temporary Union code '95.01 (max 06.03.2025)' on the relevant driving licence, to persons enjoying temporary protection or adequate protection under national law and holding the driver qualification card issued by Ukraine in accordance with the Ukrainian national legislation for the purpose of giving to the persons concerned rights on a temporary basis similar to those of the persons qualified to carry out the activity of driving covered by Article 1 of Directive 2003/59/EC. To that end, Member States may adopt national rules laying down the scope and duration of complementary compulsory training and of a subsequent test, in order to ensure that the persons concerned meet the standards of Directive 2003/59/EC. In the case of a declaration of the loss or theft of a driver qualification card issued by Ukraine, Member States should be in a position to verify, including with the competent authorities of Ukraine, that the person concerned holds a valid certificate of professional competence issued by Ukraine. As a complementary measure, it should be possible for the special temporary Union code to be marked on the driver attestation issued for the driver.

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

([5]) Directive 2003/59/EC of the European Parliament and of the Council of 15 July 2003 on the initial qualification and periodic training of drivers of certain road vehicles for the carriage of goods or passengers, amending Council Regulation (EEC) No 3820/85 and Council Directive 91/439/EEC and repealing Council Directive 76/914/EEC (OJ L 226, 10.9.2003, p. 4).

(9) As driving licences and driver qualification cards usually have a limited period of validity, they need to be regularly renewed. The current context does not allow Ukraine to carry out its tasks in a normal fashion, which is why it may not be in a position to renew existing administrative documents. Member States should therefore take into account information that Ukraine may provide to them and to the Commission through official channels.

(10) The circumstances of fleeing war often entail the loss or theft of driving licences, or their being left behind in the war zone without an immediate possibility of recovering them. In such case, Member States should be allowed to issue temporary driving licences that replace the original ones for the duration of the temporary protection, provided that the competent authorities of the Member States are in a position to verify the information provided by the displaced persons, for example by accessing the national registers of Ukraine. Such temporary driving licences should be mutually recognised in the Union, and their administrative validity should not exceed the duration of the temporary protection.

(11) The issuance of temporary driving licences in the case of lost or stolen Ukrainian driving licences and the establishment of complementary compulsory training sessions for holders of the driver qualification card are optional measures that might require proportionate national implementing measures. Such national measures should be adopted in accordance with the relevant procedures set in each Member State.

(12) The fight against fraud and forgery is instrumental in maintaining road safety and law enforcement. In this respect, the implementation of this Regulation should be accompanied by administrative cooperation between Ukraine and the Union for the purpose of supporting the verification of the validity and authenticity of driver documents issued by Ukraine.

(13) Since the objective of this Regulation cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union (TEU). In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(14) To minimise the administrative burden on Member States and avoid multiple renewals, the expiry date recorded on driver documents issued in accordance with this Regulation should correspond to the current maximum possible duration of the temporary protection in respect of displaced persons from Ukraine, taking into account the possible extensions thereof pursuant to Article 4 of Directive 2001/55/EC. However, notwithstanding the expiry recorded on the documents, their validity should correspond to the duration of the temporary protection.

(15) In view of Russia's invasion of Ukraine and the urgency to lay down specific and temporary measures concerning driver documents issued by Ukraine in accordance with its legislation, it is considered to be appropriate to invoke the exception to the eight-week period provided for in Article 4 of Protocol No 1 on the role of national Parliaments in the European Union, annexed to the TEU, to the Treaty on the Functioning of the European Union and to the Treaty establishing the European Atomic Energy Community.

(16) In view of the need to lay down specific and temporary measures concerning driver documents issued by Ukraine in accordance with its legislation without delay, this Regulation should enter into force as a matter of urgency on the fifth day following that of its publication in the *Official Journal of the European Union*.

(17) In view of the exceptional circumstances that justify this Regulation and the specific objectives pursued, it is appropriate that its application be limited in time,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject-matter

This Regulation lays down specific and temporary measures applicable to driver documents issued by Ukraine in accordance with its legislation and held by persons enjoying temporary protection or adequate protection under national law in accordance with Directive 2001/55/EC and Implementing Decision (EU) 2022/382.

Article 2

Definition

For the purposes of this Regulation, 'driver documents issued by Ukraine' means:

(a) driving licences issued by Ukraine, proving that, and under what conditions, a driver is authorised to drive under the law of Ukraine; or

(b) driver qualification cards issued by Ukraine in accordance with its national legislation adopted to implement Directive 2003/59/EC, pursuant to Article 368(1) of, and Annex XXXII 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, to drivers of road vehicles engaged in the international carriage of goods or passengers by road falling under the scope of that Directive.

Article 3

Recognition of driving licences issued by Ukraine

1. Valid driving licences issued by Ukraine shall be recognised in the territory of the Union when their holders enjoy temporary protection or adequate protection under national law in accordance with Directive 2001/55/EC and Implementing Decision (EU) 2022/382 until the moment when that temporary protection ceases to apply. That recognition is without prejudice to the application of national provisions on the restriction, suspension, withdrawal or cancellation of the right to drive on the territory of that Member State, in accordance with the principle of territoriality of criminal and police laws.

2. Where a person enjoying temporary protection or adequate protection under national law in accordance with Directive 2001/55/EC and Implementing Decision (EU) 2022/382 is in possession of a valid driving licence issued by Ukraine, Member States shall not require the presentation of its certified translation or an international driving permit, as referred to in Article 41(2) of the Vienna Convention on Road Traffic. Member States may require the presentation of a passport, document of temporary residency or other adequate document in order to verify the identity of the holder of the driving licence.

Article 4

Driver qualification cards and driver attestations

1. At the request of a person who holds a driver qualification card issued by Ukraine as referred to in Article 2, point (b), of this Regulation, who enjoys temporary protection or adequate protection under national law in accordance with Directive 2001/55/EC and Implementing Decision (EU) 2022/382, the Member State where that person has been granted a temporary residence permit or the Member State where that person enjoys adequate protection under national law may:

(a) by way of derogation from point 12 of Annex I to Directive 2006/126/EC of the European Parliament and of the Council ([6]), mark a special temporary Union code '95.01 (max 06.03.2025)', which means 'Driver holding a CPC meeting the obligation of professional aptitude – special issuance only for the duration of temporary protection' in field 12 of side 2 of the driving licence of the person concerned, provided that that person also holds a Union model driving licence issued by that Member State; or

([6]) Directive 2006/126/EC of the European Parliament and of the Council of 20 December 2006 on driving licences (OJ L 403, 30.12.2006, p. 18).

(b) issue to that person a driver qualification card with a special temporary Union code '95.01 (max 06.03.2025)' in field 10 of side 2 thereof as referred to in Article 10(1) of Directive 2003/59/EC.

By way of derogation from Article 10(2) of Directive 2003/59/EC, a driver enjoying temporary protection or adequate protection under national law who holds a driver qualification card issued by Ukraine for the carriage of goods by road shall also be allowed to prove that he or she has the qualification and training referred to in paragraph 4 of this Article by means of the driver attestation provided for in Regulation (EC) No 1072/2009 of the European Parliament and of the Council ([7]), provided that it bears the Union code '95.01 (max 06.03.2025)'.

For the purposes of this Regulation, the issuing Member State shall indicate the Union code '95.01 (max 06.03.2025)' in the remarks section on the driver attestation, in accordance with Article 5 of Regulation (EC) No 1072/2009, if the holder concerned has fulfilled the training and test requirements and the minimum standards of physical and mental fitness provided for in this Article.

2. The driver qualifications cards and the mark on the driving licences referred to in paragraph 1 points (a) and (b) of this Article and driver attestations referred to in the second subparagraph of paragraph 1 of this Article shall be mutually recognised in the territory of the Union. The holders of such driver qualification cards, such driving licences marked with the special temporary Union code '95.01 (max 06.03.2025)' or such driver attestations marked with the special temporary Union code '95.01 (max 06.03.2025)' shall be deemed to have fulfilled the requirement of compulsory initial qualification necessary to carry out the activity of driving laid down by Article 3 of Directive 2003/59/EC.

3. Without prejudice to any future acts of the Union concerning the duration of the temporary protection, by way of derogation from points 4(b) and 11 of Annex I to Directive 2006/126/EC and point 4(b) of Annex II to Directive 2003/59/EC, the expiry date on such driver qualification cards or attached to the special temporary Union code marked on the driving licences shall be 6 March 2025.

However, notwithstanding that date marked on those documents, their administrative validity shall correspond to the duration of the temporary protection in respect of displaced persons from Ukraine, as referred to in Article 4 of Directive 2001/55/EC, of the adequate protection under national law of the holder, or of the period of validity of the driving licence, whichever ends the earliest. The holder shall be adequately informed of such a limitation.

4. Prior to issuing the driver qualification card or marking the special temporary Union code '95.01 (max 06.03.2025)' on the driving licence or on the driver attestation referred to in paragraph 1 of this Article, Member States shall require the holder of the driver qualification card issued by Ukraine referred to in Article 2, point (b), to undergo complementary compulsory training concluding with a test for the purpose of verifying that the driver has the level of knowledge required by Section 1 of Annex I to Directive 2003/59/EC.

The duration of the complementary compulsory training shall be at least 35 hours and shall not exceed 60 hours, including at least 2,5 hours of individual driving as specified in point 2.1 of Section 2 of Annex I to Directive 2003/59/EC. Such training may take place in the form of compulsory periodic training as specified in section 4 of Annex I to Directive 2003/59/EC. With regard to the specific training needs to be taken into account in this context, an emphasis should be placed on the driver acquiring knowledge of the rules in Regulation (EC) No 561/2006 of the European Parliament and of the Council ([8]).

At the end of that training, Member States' competent authorities or the entity designated by them shall test the driver in writing or orally or by means of a computer-based test in designated testing facilities.

([7]) Regulation (EC) No 1072/2009 of the European Parliament and of the Council of 21 October 2009 on common rules for access to the international road haulage market (OJ L 300, 14.11.2009, p. 72).

([8]) Regulation (EC) No 561/2006 of the European Parliament and of the Council of 15 March 2006 on the harmonisation of certain social legislation relating to road transport and amending Council Regulations (EEC) No 3821/85 and (EC) No 2135/98 and repealing Council Regulation (EEC) No 3820/85 (OJ L 102, 11.4.2006, p. 1).

Member States shall inform the Commission of national rules adopted in accordance with this paragraph prior to issuing the driver qualification card or to marking the driving licence referred to in paragraph 1.

5. In the event of loss or theft of a driver qualification card referred to in Article 2, point (b), of this Regulation, held by a person enjoying temporary protection or adequate protection under national law in accordance with Directive 2001/55/EC and Implementing Decision (EU) 2022/382, the Member State where that person has been granted a temporary residence permit or where that person enjoys adequate protection under national law may, at the request of that person, verify, including with the competent authorities of Ukraine, that that person is the holder of a valid certificate of professional competence issued by Ukraine in accordance with its national legislation and that that person is not in possession of a document marked or issued in accordance with paragraph 1 of this Article by another Member State.

After carrying out that verification, the Member State concerned may issue the driver qualification card or mark the special temporary Union code '95.01 (max 06.03.2025)' on the driving licence or on the driver attestation, in accordance with the procedures set out in paragraphs 1 to 4.

6. Where a person referred to in paragraph 1 of this Article does not hold a Union model driving licence issued by a Member State, Member States shall require an examination applying minimum standards of physical and mental fitness for driving in accordance with national law adopted to transpose Annex III to Directive 2006/126/EC prior to the issuance of a driver qualification card or to the marking of the special temporary Union code on the driver attestation in accordance with this Article.

7. When the period of application in respect of displaced persons from Ukraine, as referred to in Article 4 of Directive 2001/55/EC comes to an end, the driver qualification cards, driver attestations issued by the Member States and the special temporary Union code marked on the driving licence in accordance with this Article shall be null and void.

Article 5

Extension of the validity of expired driver documents issued by Ukraine

Without prejudice to Articles 3, 4 and 6, where Ukraine adopts decisions to extend the validity of driver documents issued by Ukraine having expired after 31 December 2021, Member States shall, for the purposes of Articles 3, 4 and 6, consider the holders of the relevant driver documents issued by Ukraine to be in possession of a valid document provided that Ukraine informs the Commission and the Member States of its decision to extend the validity of those driver documents. This information shall be communicated through appropriate official channels.

Article 6

Lost or stolen driving licences issued by Ukraine

1. Where a person enjoying temporary protection or adequate protection under national law in accordance with Directive 2001/55/EC and Implementing Decision (EU) 2022/382 declares the loss or theft of his or her driving licence, the Member State where that person has been granted a temporary residence permit or enjoys adequate protection under national law may, at the request of that person, verify, including with the competent authorities of Ukraine, the driving rights acquired by that person in conformity with the legislation applicable in Ukraine and that no other Member State has already issued a driving licence to that person in accordance with this Article, in particular in order to ascertain that the driving licence has not been restricted, suspended or withdrawn.

2. By way of derogation from Article 11(6) of Directive 2006/126/EC, after carrying out the verification referred to in paragraph 1 of this Article, a Member State may issue a driving licence of the same category or categories to the person concerned based on the Union model set out in Annex I to Directive 2006/126/EC. In such case, and by way of derogation from point 12 of Annex I of Directive 2006/126/EC, Member States shall introduce in the driving licence a special temporary Union code '99.01(max 06.03.2025)' in field 12, which means 'Special issuance valid only for the duration of temporary protection (lost or stolen UA licence)'.

Upon carrying out the verification referred to in paragraph 1 of this Article and prior to issuing a driving licence referred to in this paragraph for categories AM, A1, A2, A, B, B1 and BE, Member States may require an examination applying the minimum standards of physical and mental fitness for driving in accordance with national law adopted to transpose Annex III to Directive 2006/126/EC.

Upon carrying out the verification referred to in paragraph 1 of this Article prior to issuing a driving licence referred to in this paragraph for categories C, CE, C1, C1E, D, DE, D1 and D1E, Member States shall require an examination applying the minimum standards of physical and mental fitness for driving in accordance with national law adopted to transpose Annex III to Directive 2006/126/EC.

3. The driving licence referred to in paragraph 2 of this Article shall be mutually recognised in the Union. Without prejudice to any future acts of the Union concerning the duration of the temporary protection, by way of derogation from points 4(b) and 11 of Annex I to Directive 2006/126/EC, the expiry date on such driving licence shall be 6 March 2025. However, notwithstanding that date marked on such driving licence, its administrative validity shall correspond to the duration of the temporary protection in respect of displaced persons from Ukraine, as referred to in Article 4 of Directive 2001/55/EC, or the duration of the temporary protection or of the adequate protection under the national law of the holder, whichever ends the earliest. The holder shall be adequately informed of such a limitation.

4. Where the verification referred to in paragraph 1 is not possible, the Member State in question shall not issue the driving licence referred to in paragraph 2. In that case, the Member State may issue a driving licence valid exclusively on its territory to the person concerned, in accordance with its national law. Such a licence shall be different from the model laid down in Annex I to Directive 2006/126/EC.

5. When the period of application of temporary protection for displaced persons from Ukraine, as referred to in Article 4 of Directive 2001/55/EC, has come to an end, the driving licences issued by the Member States in accordance with this Article shall be null and void.

Article 7

Prevention of fraud and forgery

When applying this Regulation, Member States shall use all appropriate means to prevent and combat fraud in connection with driver documents issued by Ukraine, and their forgery.

Member States may, at any moment, verify the validity of the driver documents issued by Ukraine. Member States may refuse to recognise such a driver document in the event of a negative answer or absence of answer from the Ukrainian authorities consulted by them on the rights claimed by the holder of a driver document issued by Ukraine and when there are serious doubts as to the authenticity of the driver document which suggest that road safety could be endangered.

Member States shall not apply the provisions of this Regulation to driver documents issued by Ukraine in electronic format if they are not able to verify their authenticity, integrity and validity.

Article 8

Monitoring

The Commission shall inform the European Parliament and the Council of the implementation of this Regulation, once every six months after the entry into force of this Regulation, mainly on the basis of information provided by the Member States to the Commission.

Article 9

Entry into force and application

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

2. This Regulation shall cease to apply on the day following that on which the period of application of temporary protection in respect of displaced persons from Ukraine, as referred to in Article 4 of Directive 2001/55/EC, comes to an end, in accordance with Article 6 of that Directive.

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

Done at Brussels, 18 July 2022.

For the European Parliament	*For the Council*
The President	*The President*
R. METSOLA	Z. NEKULA

II

(Non-legislative acts)

REGULATIONS

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)

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 Union 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 Union 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 Commission Delegated Regulation (EU) 2020/124 with NAFO measures adopted at its 2019 annual meeting.

(5) Commission Delegated Regulation (EU) 2021/860 ([5]) amended Commission Delegated Regulation (EU) 2020/124 with NAFO measures adopted at its 2020 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 I, 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) The 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) At its annual meeting in September 2021, the NAFO amended its CEM with additional prohibited activities of research vessels, extended periods and areas of vulnerable marine ecosystem ('VME') closures and updated Annex II. M containing the observer report and Annex IV.A containing the surveillance report form.

(8) 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, the following paragraph (1a), is inserted:

'1a. In 2022, a research vessel shall not:

(a) take 3M cod in excess of 15 metric tonnes. Should a research vessel's catch exceed this amount, the excess shall be counted against the allocation to the vessel's flag State Contracting Party. If the allocation to the Member State for 3M cod is exhausted, the Member State shall not authorise its vessels to undertake further research activities. Any research activities under way must be stopped by the operator as soon as 15 tonnes have been caught.

(b) take 3M shrimp in excess of 10 metric tonnes. Given that no directed fishery is authorised on 3M shrimp in 2022, any research activities under way must be stopped by the operator as soon as 10 tonnes have been caught.'

(2) In Article 10(2), point (a) is replaced, by the following:

'(a) the master of the vessel shall notify the NAFO Executive Secretary and its flag FMC by email or fax, at the latest 72 hours prior to the vessel's entry into the Regulatory Area, of the amount of catch on board, the position by latitude and longitude where the master of the vessel intends to commence fishing, the estimated time of arrival at the position, and contact information for the fishing vessel (for example radio, satellite phone or email);'

(3) Article 18 is amended as follows:

— In paragraphs 1, 2 and 3, 'Until 31 December 2021' is replaced by 'Until 31 December 2026'.

— Paragraph 4 is added:

'4. Until 31 December 2023, no vessel shall engage in bottom fishing activities in the areas illustrated in Figure 5 and defined by connecting the coordinates specified in Table 7b in numerical order and back to coordinate 1 referred to in point 46 of the Annex to this Regulation.'

Article 2

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

[6] The 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).

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*.

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

Done at Brussels, 4 March 2022.

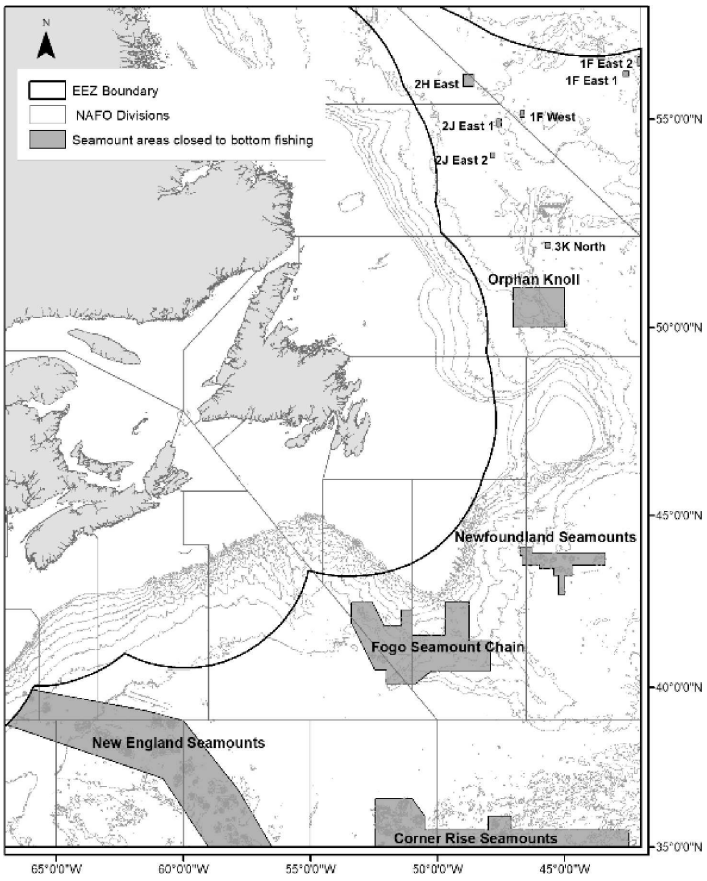
For the Commission
The President
Ursula VON DER LEYEN

ANNEX

The Annex of Commission Delegated Regulation (EU) 2020/124 is amended as follows:

1. Point (14) is replaced by the following:

'Figure 3 of the CEM referred to in Article 18(1) of Regulation (EU) 2019/833: Polygons delineating Seamount Closures



Legend:

— EEZ Boundary

— NAFO Divisions

— Seamount areas closed to bottom fishing

— East

— West

— North

— Orphan Knoll

— Newfoundland Seamounts

— Fogo Seamounts

— New England Seamounts

— Corner Rise Seamounts'

2. Point (15) is replaced by the following:

'Table 5 of the CEM referred to in Article 18(1) of Regulation (EU) 2019/833: Boundary points delineating the Seamount closures in the NAFO Regulatory Area

Table 5

Boundary Points Delineating the Seamount Closures in the NAFO Regulatory Area

Description	Coordinate No.	Latitude	Longitude
Fogo Seamount Chain	1	42° 31′ 33″ N	53° 23′ 17″ W
	2	42° 31′ 33″ N	52° 33′ 37″ W
	3	41° 51′ 00″ N	52° 07′ 00″ W
	4	41° 51′ 00″ N	51° 26′ 00″ W
	5	42° 18′ 00″ N	51° 26′ 00″ W
	6	42° 18′ 00″ N	51° 00′ 00″ W
	7	41° 33′ 00″ N	51° 00′ 00″ W
	8	41° 33′ 00″ N	49° 42′ 00″ W
	9	42° 32′ 00″ N	49° 42′ 00″ W
	10	42° 32′ 00″ N	48° 45′ 00″ W
	11	41° 24′ 00″ N	48° 45′ 00″ W
	12	41° 24′ 00″ N	47° 55′ 00″ W
	13	40° 30′ 00″ N	47° 55′ 00″ W
	14	40° 30′ 00″ N	50° 15′ 00″ W
	15	40° 05′ 00″ N	50° 55′ 00″ W
	16	40° 05′ 00″ N	52° 00′ 00″ W
	17	40° 31′ 37″ N	52° 00′ 00″ W
	18	40° 31′ 37″ N	52° 27′ 49″ W
	19	41° 55′ 48″ N	53° 23′ 17″ W
Orphan Knoll	1	50° 00′ 30″ N	45° 00′ 30″ W
	2	51° 00′ 30″ N	45° 00′ 30″ W
	3	51° 00′ 30″ N	47° 00′ 30″ W
	4	50° 00′ 30″ N	47° 00′ 30″ W
Corner Rise Seamounts	1	36° 33′ 00″ N	52° 27′ 00″ W
	2	36° 33′ 00″ N	51° 00′ 00″ W
	3	36° 00′ 00″ N	50° 30′ 00″ W
	4	35° 33′ 00″ N	50° 30′ 00″ W
	5	35° 33′ 00″ N	48° 00′ 00″ W

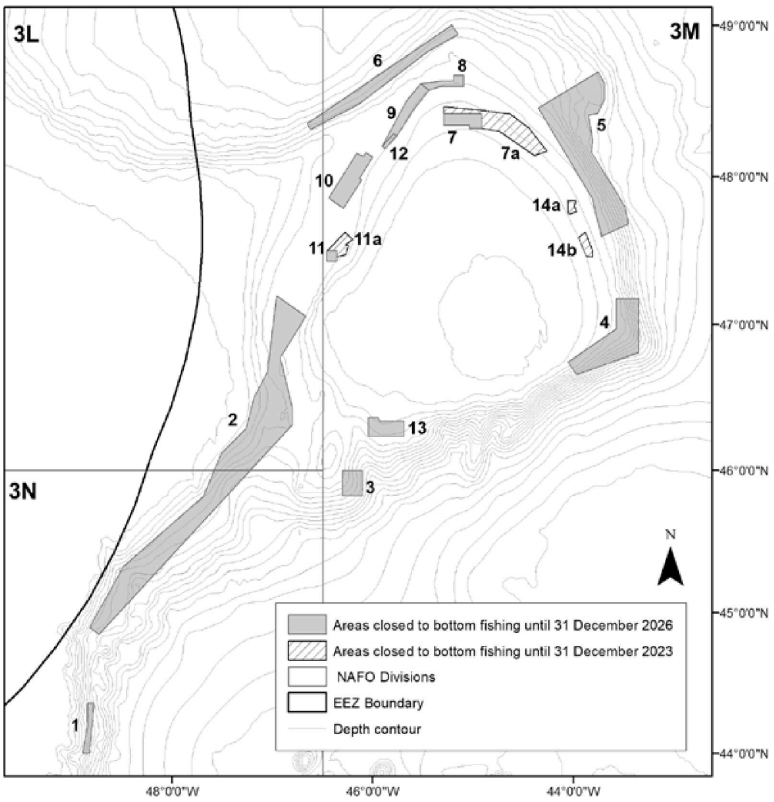
Description	Coordinate No.	Latitude	Longitude
	6	36° 00′ 00″ N	48° 00′ 00″ W
	7	36° 00′ 00″ N	47° 06′ 00″ W
	8	35° 33′ 00″ N	47° 06′ 00″ W
	9	35° 33′ 00″ N	42° 30′ 00″ W
	10	35° 00′ 00″ N	42° 30′ 00″ W
	11	35° 00′ 00″ N	52° 27′ 00″ W
Newfoundland Seamounts	1	44° 06′ 00″ N	46° 45′ 00″ W
	2	44° 06′ 00″ N	46° 18′ 00″ W
	3	43° 57′ 00″ N	46° 18′ 00″ W
	4	43° 57′ 00″ N	43° 24′ 00″ W
	5	43° 36′ 00″ N	43° 24′ 00″ W
	6	43° 36′ 00″ N	44° 42′ 00″ W
	7	43° 18′ 00″ N	44° 42′ 00″ W
	8	43° 18′ 00″ N	45° 00′ 00″ W
	9	42° 45′ 00″ N	45° 00′ 00″ W
	10	42° 45′ 00″ N	45° 15′ 00″ W
	11	43° 18′ 00″ N	45° 15′ 00″ W
	12	43° 18′ 00″ N	45° 25′ 00″ W
	13	43° 29′ 00″ N	45° 25′ 00″ W
	14	43° 29′ 00″ N	46° 00′ 00″ W
	15	43° 36′ 00″ N	46° 00′ 00″ W
	16	43° 36′ 00″ N	46° 40′ 00″ W
	17	43° 52′ 00″ N	46° 40′ 00″ W
	18	43° 52′ 00″ N	46° 45′ 00″ W
New England Seamounts (*)	1	38° 51′ 54″ N	66° 55′ 51.60″ W
	2	37° 12′ 00″ N	60° 48′ 00″ W
	3	35° 00′ 00″ N	59° 00′ 00″ W
	4	35° 00′ 00″ N	56° 30′ 00″ W
	5	36° 48′ 00″ N	57° 48′ 00″ W
	6	39° 00′ 00″ N	60° 00′ 00″ W
	7	39° 18′ 00″ N	61° 30′ 00″ W
	8	39° 56′ 20.40″ N	65° 56′ 34.80″ W

Description	Coordinate No.	Latitude	Longitude
2H East	1	56° 00′ 00″ N	49° 00′ 00″ W
	2	56° 00′ 00″ N	48° 35′ 00″ W
	3	55° 44′ 00″ N	48° 35′ 00″ W
	4	55° 44′ 00″ N	49° 00′ 00″ W
2J East 1	1	55° 00′ 00″ N	47° 42′ 00″ W
	2	55° 00′ 00″ N	47° 29′ 00″ W
	3	54° 50′ 00″ N	47° 29′ 00″ W
	4	54° 50′ 00″ N	47° 42′ 00″ W
2J East 2	1	54° 14′ 00″ N	47° 54′ 00″ W
	2	54° 14′ 00″ N	47° 45′ 00″ W
	3	54° 06′ 00″ N	47° 45′ 00″ W
	4	54° 06′ 00″ N	47° 54′ 00″ W
1F West	1	55° 12′ 00″ N	46° 45′ 00″ W
	2	55° 12′ 00″ N	46° 35′ 00″ W
	3	55° 02′ 00″ N	46° 35′ 00″ W
	4	55° 02′ 00″ N	46° 45′ 00″ W
3K North	1	52° 07′ 00″ N	45° 46′ 00″ W
	2	52° 07′ 00″ N	45° 33′ 00″ W
	3	51° 58′ 00″ N	45° 33′ 00″ W
	4	51° 58′ 00″ N	45° 46′ 00″ W
1F East 1	1	56° 04′ 00″ N	42° 42′ 00″ W
	2	56° 04′ 00″ N	42° 30′ 00″ W
	3	55° 57′ 00″ N	42° 30′ 00″ W
	4	55° 57′ 00″ N	42° 42′ 00″ W
1F East 2	1	56° 23′ 00″ N	42° 08′ 00″ W
	2	56° 23′ 00″ N	42° 00′ 00″ W
	3	56° 10′ 00″ N	42° 00′ 00″ W
	4	56° 10′ 00″ N	42° 08′ 00″ W

(*) From point 8 back to point 1, following the outer boundary of the US EEZ.'

3. Point (18) is replaced by the following:

'Figure 5 of CEM referred to in Article 18(3) and in Article 18(4) of Regulation (EU) 2019/833: Polygons delineating Vulnerable Marine Ecosystems Area Closures



Legend:

— Areas closed to bottom fishing until 31 December 2026

— Areas closed to bottom fishing until 31 December 2023

— NAFO Divisions

— EEZ boundary

— Depth contour'

4. Point (19) is replaced by the following:

'Table 7 of the CEM referred to in Article 18(3) of Regulation (EU) 2019/833: Boundary Points Delineating the Vulnerable Marine Ecosystem Area Closures in the NAFO Regulatory Area

	Description	Coordinate No.	Latitude	Longitude
1	Tail of the Bank	1.1	44° 02′ 53.88″ N	48° 49′ 09.48″ W
		1.2	44° 21′ 31.32″ N	48° 46′ 48.00″ W
		1.3	44° 21′ 34.56″ N	48° 50′ 32.64″ W
		1.4	44° 11′ 48.12″ N	48° 50′ 32.64″ W
		1.5	44° 02′ 54.60″ N	48° 52′ 52.32″ W
		1.6	44° 00′ 01.12″ N	48° 53′ 28.75″ W
		1.7	43° 59′ 57.52″ N	48° 49′ 26.47″ W

	Description	Coordinate No.	Latitude	Longitude
2	Flemish Pass/Eastern Canyon	2.1	44° 50′ 56.40″ N	48° 43′ 45.48″ W
		2.2	46° 18′ 54.72″ N	46° 47′ 51.72″ W
		2.3	46° 25′ 28.56″ N	46° 47′ 51.72″ W
		2.4	46° 46′ 32.16″ N	46° 55′ 14.52″ W
		2.5	47° 03′ 29.16″ N	46° 40′ 04.44″ W
		2.6	47° 11′ 47.04″ N	46° 57′ 38.16″ W
		2.7	46° 40′ 40.80″ N	47° 03′ 04.68″ W
		2.8	46° 30′ 22.20″ N	47° 11′ 02.93″ W
		2.9	46° 17′ 13.30″ N	47° 15′ 46.64″ W
		2.10	46° 07′ 01.56″ N	47° 30′ 36.36″ W
		2.11	45°49′06.24″ N	47° 41′ 17.88″ W
		2.12	45° 19′ 43.32″ N	48° 29′ 14.28″ W
		2.13	44° 53′ 47.40″ N	48° 49′ 32.52″ W
3	Beothuk Knoll	3.1	45° 49′ 10.20″ N	46° 06′ 02.52″ W
		3.2	45° 59′ 47.40″ N	46° 06′ 02.52″ W
		3.3	45° 59′ 47.40″ N	46° 18′ 08.28″ W
		3.4	45° 49′ 10.20″ N	46° 18′ 08.28″ W
4	Eastern Flemish Cap	4.1	46° 44′ 34.80″ N	44° 03′ 14.40″ W
		4.2	46° 58′ 19.20″ N	43° 34′ 16.32″ W
		4.3	47° 10′ 30.00″ N	43° 34′ 16.32″ W
		4.4	47° 10′ 30.00″ N	43° 20′ 51.72″ W
		4.5	46° 48′ 35.28″ N	43° 20′ 51.72″ W
		4.6	46° 39′ 36.00″ N	43° 58′ 08.40″ W
5	Northeast Flemish Cap	5.1	47° 47′ 46.00″ N	43° 29′ 07.00″ W
		5.2	47° 40′ 54.47″ N	43° 27′ 06.71″ W
		5.3	47° 35′ 57.48″ N	43° 43′ 09.12″ W
		5.4	47° 51′ 14.40″ N	43° 48′ 35.64″ W
		5.5	48° 27′ 19.44″ N	44° 21′ 07.92″ W

	Description	Coordinate No.	Latitude	Longitude
		5.6	48° 41′ 37.32″ N	43° 45′ 08.08″ W
		5.7	48° 37′ 13.00″ N	43° 41′ 24.00″ W
		5.8	48° 30′ 15.00″ N	43° 41′ 32.00″ W
		5.9	48° 25′ 08.00″ N	43° 45′ 20.00″ W
		5.10	48° 24′ 29.00″ N	43° 50′ 50.00″ W
		5.11	48° 14′ 20.00″ N	43° 48′ 19.00″ W
		5.12	48° 09′ 53.00″ N	43° 49′ 24.00″ W
6	Sackville Spur	6.1	48° 18′ 51.12″ N	46° 37′ 13.44″ W
		6.2	48° 28′ 51.24″ N	46° 08′ 33.72″ W
		6.3	48° 49′ 37.20″ N	45° 27′ 20.52″ W
		6.4	48° 56′ 30.12″ N	45° 08′ 59.99″ W
		6.5	49° 00′ 09.72″ N	45° 12′ 44.64″ W
		6.6	48° 21′ 12.24″ N	46° 39′ 11.16″ W
7	Northern Flemish Cap	7.1	48° 25′ 02.28″ N	45° 17′ 16.44″ W
		7.2	48° 25′ 02.28″ N	44° 54′ 38.16″ W
		7.3	48° 19′ 08.76″ N	44° 54′ 38.16″ W
		7.4	48° 19′ 08.76″ N	45° 01′ 58.56″ W
		7.5	48° 20′ 29.76″ N	45° 01′ 58.56″ W
		7.6	48° 20′ 29.76″N	45° 17′ 16.44″ W
8	Northern Flemish Cap	8.1	48° 38′ 07.95″ N	45° 19′ 31.92″ W
		8.2	48° 38′ 07.95″ N	45° 11′ 44.36″ W
		8.3	48° 40′ 09.84″ N	45° 11′ 44.88″ W
		8.4	48° 40′ 09.84″ N	45° 05′ 35.52″ W
		8.5	48° 35′ 56.40″ N	45° 05′ 35.52″ W
		8.6	48° 35′ 56.40″ N	45° 19′ 31.92″ W
		8.7	48° 34′ 23.52″ N	45° 26′ 18.96″ W
		8.8	48° 36′ 55.08″ N	45° 31′ 15.96″ W

	Description	Coordinate No.	Latitude	Longitude
9	Northern Flemish Cap	9.1	48° 34′ 23.52″ N	45° 26′ 18.96″ W
		9.2	48° 36′ 55.08″ N	45° 31′ 15.96″ W
		9.3	48° 30′ 18.36″ N	45° 39′ 42.48″ W
		9.4	48° 12′ 06.60″ N	45° 54′ 12.94″ W
		9.5	48° 17′ 11.82″ N	45° 47′ 25.36″ W
		9.6	48° 16′ 07.06″ N	45° 45′ 48.19″ W
		9.7	48° 27′ 30.60″ N	45° 34′ 40.44″ W
10	Northwest Flemish Cap	10.1	47° 49′ 41.51″ N	46° 22′ 48.18″ W
		10.2	47° 47′ 17.14″ N	46° 17′ 27.91″ W
		10.3	47° 58′ 42.28″ N	46° 06′ 43.74″ W
		10.4	47° 59′ 15.77″ N	46° 07′ 57.76″ W
		10.5	48° 07′ 48.97″ N	45° 59′ 58.46″ W
		10.6	48° 09′ 34.66″ N	46° 04′ 08.54″ W
		10.7	48° 07′ 59.70″ N	46° 05′ 38.22″ W
		10.8	48° 09′ 13.46″ N	46° 09′ 31.03″ W
		10.9	47° 51′ 30.13″ N	46° 26′ 15.61″ W
11	Northwest Flemish Cap	11.1	47° 25′ 48.00″ N	46° 21′ 23.76″ W
		11.2	47° 30′ 01.44″ N	46° 21′ 23.76″ W
		11.3	47° 30′ 01.44″ N	46° 27′ 33.12″ W
		11.4	47° 25′ 48.00″ N	46° 27′ 33.12″ W
12	Northwest Flemish Cap	12.1	48° 12′ 06.60″ N	45° 54′ 12.94″ W
		12.2	48° 17′ 11.82″ N	45° 47′ 25.36″ W
		12.3	48° 16′ 07.06″ N	45° 45′ 48.19″ W
		12.4	48° 11′ 03.32″ N	45° 52′ 40.63″ W
13	Beothuk Knoll	13.1	46° 13′ 58.80″ N	45° 41′ 13.20″ W
		13.2	46° 13′ 58.80″ N	46° 02′ 24.00″ W
		13.3	46° 21′ 50.40″ N	46° 02′ 24.00″ W
		13.4	46° 21′ 50.40″ N	45° 56′ 48.12″ W
		13.5	46° 20′ 14.32″ N	45° 55′ 43.93″ W
		13.6	46° 20′ 14.32″ N	45° 41′ 13.20″ W’

5. In point (35) Observer report in Annex II.M to the CEM as referred to in point (a) of Article 27(11) of Regulation (EU) 2019/833, Part 5 is replaced as follows:

'PART 5

Data for Each Greenland Shark Caught per Haul

Tow/Set Number	Total Number of Greenland Sharks in Tow/Set	Shark Number	Estimated Weight (kg live weight)	Total Length (cm, from tip of snout to tip of tail fin)	Length Measured (M) or Estimated (E)?	Sex (M if Male, F if Female, U if Unknown)	Catch Disposition (A if Alive, D if Dead, U if Unknown)	Comments (in English to the extent possible)'

6. In point (38) Surveillance Report Form in Annex IV.A to the CEM referred to in point (a) of Article 30(1) and point (a) of Article 45 of Regulation (EU) 2019/833, the following footnote is added under the table 3. VESSEL SIGHTED (*):

'(*) Reported as free text or using the codes outlined in Annex II.I Part B to the CEM'

7. Point (46) is added:

'(46) Table 7b of the CEM to referred to in Article 18(4) of Regulation (EU) 2019/833: Boundary Points Delineating the Vulnerable Marine Ecosystem Area Closures in the NAFO Regulatory Area

Area	Description	Coordinate No.	Latitude	Longitude
7a	Northern Flemish Cap	7a.1	48° 25′ 02.28″ N	45° 17′ 16.44″ W
		7a.2	48° 25′ 02.28″ N	44° 54′ 38.16″ W
		7a.3	48° 19′ 08.76″ N	44° 54′ 38.16″ W
		7a.4	48° 18′ 06.84″ N	44° 44′ 22.81″ W
		7a.5	48° 08′ 18.42″ N	44° 23′ 10.57″ W
		7a.6	48° 10′ 08.98″ N	44° 15′ 54.97″ W
		7a.7	48° 19′ 30.47″ N	44° 26′ 38.40″ W
		7a.8	48° 24′ 57.13″ N	44° 37′ 58.40″ W
		7a.9	48° 26′ 21.37″ N	44° 54′ 34.60″ W
		7a.10	48° 27′ 52.20″ N	45° 17′ 19.25″ W
11a	Northwest Flemish Cap	11a.1	47° 27′ 36.29″ N	46° 21′ 23.69″ W
		11a.2	47° 30′ 01.44″ N	46° 21′ 23.76″ W
		11a.3	47° 30′ 01.44″ N	46° 27′ 33.12″ W
		11a.4	47° 37′ 38.86″ N	46° 16′ 31.12″ W
		11a.5	47° 34′ 39.61″ N	46° 12′ 03.92″ W
		11a.6	47° 32′ 28.90″ N	46° 16′ 26.58″ W
		11a.7	47° 32′ 10.00″ N	46° 14′ 29.87″ W
		11a.8	47° 28′ 27.80″ N	46° 16′ 05.74″ W
14a	Eastern Flemish Cap	14a.1	47° 45′ 24.44″ N	44° 03′ 06.44″ W
		14a.2	47° 47′ 54.35″ N	44° 03′ 06.44″ W
		14a.3	47° 50′ 11.33″ N	44° 03′ 34.49″ W
		14a.4	47° 50′ 10.86″ N	43° 58′ 28.99″ W
		14a.5	47° 47′ 54.35″ N	43° 59′ 23.39″ W
		14a.6	47° 45′ 55.19″ N	43° 58′ 08.94″ W
		14a.7	47° 44′ 44.59″ N	44° 02′ 41.50″ W
14b	Eastern Flemish Cap	14b.1	47° 35′ 21.77″ N	43° 56′ 50.10″ W
		14b.2	47° 37′ 33.53″ N	43° 52′ 56.50″ W
		14b.3	47° 30′ 04.79″ N	43° 48′ 18.54″ W
		14b.4	47° 27′ 34.88″ N	43° 48′ 18.54″ W
		14b.5	47° 27′ 34.88″ N	43° 52′ 00.34″ W’

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1282

of 8 July 2022

granting a Union authorisation for the biocidal product family 'Knieler & Team Propanol Family'

(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 17 April 2019, Knieler & Team GmbH submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'Knieler & Team Propanol Family' of product-types 1, 2 and 4, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Switzerland had agreed to evaluate the application. The application was recorded under case number BC-AQ050985-22 in the Register for Biocidal Products.

(2) 'Knieler & Team Propanol Family' 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-types 1, 2 and 4.

(3) On 29 March 2021, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency').

(4) On 4 November 2021, the Agency submitted to the Commission an opinion ([2]), including the draft summary of the biocidal product characteristics ('SPC') of 'Knieler & Team Propanol Family' and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012.

(5) The opinion concludes that 'Knieler & Team Propanol Family' 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.

(6) On 22 November 2021, 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.

(7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for 'Knieler & Team Propanol Family'.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on biocidal products,

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

([2]) ECHA opinion of 7 October 2021 on the Union authorisation of 'Knieler & Team Propanol Family' (ECHA/BPC/292/2021), https://echa.europa.eu/bpc-opinions-on-union-authorisation.

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0027467-0000 is granted to Knieler & team GmbH for the making available on the market and use of the biocidal product family 'Knieler & Team Propanol Family' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 11 August 2022 to 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, 8 July 2022.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

Knieler & Team Propanol Family

Product type 1 - Human hygiene (Disinfectants)

Product type 2 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Product type 4 - Food and feed area (Disinfectants)

Authorisation number: EU-0027467-0000

R4BP asset number: EU-0027467-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	Knieler & Team Propanol Family

1.2. **Product type(s)**

Product type(s)	PT01 - Human hygiene (Disinfectants) PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	Knieler & Team GmbH
	Address	Kattrepelsbrücke 1, 20095 Hamburg Germany
Authorisation number	EU-0027467-0000	
R4BP asset number	EU-0027467-0000	
Date of the authorisation	11 August 2022	
Expiry date of the authorisation	31 July 2032	

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

Name of manufacturer	Knieler & Team GmbH
Address of manufacturer	Kattrepelsbrücke 1, 20095 Hamburg Germany
Location of manufacturing sites	Knieler & Team GmbH, Kattrepelsbrücke 1, 20095 Hamburg Germany

	A.F.P. Antiseptica Forschungs- und Produktionsgesellschaft mbH, Otto-Brenner-Straße 16-18, 21337 Lüneburg Germany

1.5. **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	Stockmeier Chemie GmbH & Co. KG
Address of manufacturer	Am Stadtholz 37, 33609 Bielefeld Germany
Location of manufacturing sites	INEOS Solvent Germany GmbH, Römerstrasse 733, 47443 Moers Germany

Active substance	Propan-2-ol
Name of manufacturer	Brenntag GmbH
Address of manufacturer	Stinnes-Platz 1, 45472 Mülheim an der Ruhr Germany
Location of manufacturing sites	Shell Nederland Raffinaderij B.V., 3196 KK Rotterdam-Pernis Netherlands Exxon Mobil, LA 70805 Baton Rouge United States

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 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
Propan-1-ol		Active Substance	71-23-8	200-746-9	12,229	35,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	30,0	63,14

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 1

1.2. **Suffix to the authorisation number**

Number	1-1

1.3. **Product type(s)**

Product type(s)	PT01 - Human hygiene (Disinfectants)

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
Propan-1-ol		Active Substance	71-23-8	200-746-9	30,0	32,5
Propan-2-ol		Active Substance	67-63-0	200-661-7	45,0	45,0

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	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) OF THE META SPC 1

4.1. Use description

Table 1

Use # 1 – hygienic handrub, liquid

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: other Common name: Bacteria Development stage: Scientific name: other Common name: Mycobacteria Development stage: Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: Enveloped viruses Development stage:
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. In addition, exclusively for E-HDL (product 1.2): 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 of meta SPC 1

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 of meta SPC 1

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

See general directions for use of meta SPC 1

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 of meta SPC 1

4.2. **Use description**

Table 2

Use # 2 – surgical handrub, liquid

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: other Common name: Bacteria Development stage: Scientific name: other Common name: Mycobacteria Development stage: Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: enveloped viruses Development stage:
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. In addition, exclusively for E-HDL (product 1.2): 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 of meta SPC 1

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 of meta SPC 1

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

See general directions for use of meta SPC 1

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 of meta SPC 1

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

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.

[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.

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

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)	A-HDL		Market area: EU		
Authorisation number	EU-0027467-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	32,5
Propan-2-ol		Active Substance	67-63-0	200-661-7	45,0

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

Trade name(s)	E-HDL		Market area: EU		
Authorisation number	EU-0027467-0002 1-1				
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

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

Trade name(s)	H-HDL		Market area: EU		
Authorisation number	EU-0027467-0003 1-1				
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

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 2 identifier**

Identifier	meta SPC 2

1.2. **Suffix to the authorisation number**

Number	1-2

1.3. **Product type(s)**

Product type(s)	PT01 - Human hygiene (Disinfectants)

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
Propan-1-ol		Active Substance	71-23-8	200-746-9	20,0	20,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	60,0	60,0

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	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) OF THE META SPC 2

4.1. Use description

Table 3

Use # 1 – hygienic handrub, liquid

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: other Common name: Bacteria Development stage:

	Scientific name: other Common name: Tuberculosis bacilli Development stage: Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: Enveloped viruses Development stage:
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	150, 500, 1 000 ml in transparent/white high-density polyethylene (HDPE) bottles with polypropylene (PP) flip top caps; 5 000 ml HDPE canister with transparent/white HDPE screwed cap; 700 and 1 000 ml vacuum bag in white PE composite foil with integrated PP pump/valve and PE cap.

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 of meta SPC 2

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 of meta SPC 2

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

See general directions for use of meta SPC 2

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 of meta SPC 2.

4.2. **Use description**

Table 4

Use # 2 – surgical handrub, liquid

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: other Common name: Bacteria Development stage: Scientific name: other Common name: Tuberculosis bacilli Development stage: Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: enveloped viruses Development stage:
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	150, 500, 1 000 ml in transparent/white high-density polyethylene (HDPE) bottles with polypropylene (PP) flip top caps;

	5 000 ml HDPE canister with transparent/white HDPE screwed cap; 700 and 1 000 ml vacuum bag in white PE composite foil with integrated PP pump/valve and PE cap.

4.2.1. *Use-specific instructions for use*

The product can be applied directly or the product 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 of meta SPC 2

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 of meta 2

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

See general directions for use of meta 2

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 of meta 2

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

5.1. **Instructions for use**

For professional use only.

5.2. **Risk mitigation measures**

Avoid contact with eyes.

Keep out of reach of children.

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.

([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.

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 feeding stuff. Keep away from combustible material.

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)	C-HDL		Market area: EU		
Authorisation number	EU-0027467-0004 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	20,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	60,0

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 3 identifier**

Identifier	meta SPC 3

1.2. **Suffix to the authorisation number**

Number	1-3

1.3. **Product type(s)**

Product type(s)	PT01 - Human hygiene (Disinfectants)

2. META SPC 3 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 3**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-1-ol		Active Substance	71-23-8	200-746-9	12,229	14,3
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,751	63,14

2.2. **Type(s) of formulation of the meta SPC 3**

Formulation(s)	AL - Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

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) OF THE META SPC 3

4.1. **Use description**

Table 5

Use # 1 – hygienic handrub, liquid

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: other Common name: Bacteria Development stage: Scientific name: other Common name: Tuberculosis bacilli Development stage: Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: Enveloped viruses Development stage:
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, 150, 500, 1 000 ml in transparent/white high-density polyethylene (HDPE) bottles with polyethylene (PP) flip top caps; 5 000 ml transparent/white HDPE canister with HDPE screwed cap. In addition, exclusively for D-HDL (product 3.1): 100, 125, 150, 500, 1 000 ml in white HDPE bottles with PP flip top caps; 5 000 ml white HDPE canister with HDPE screwed cap. In addition, exclusively for B-HDL (product 3.3): 700 ml Pouch of transparent PE composite foil with integrated PP pump; 75 ml transparent/white HDPE bottle with PP flip top cap.

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 of meta SPC 3

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 of meta SPC 3

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

See general directions for use of meta SPC 3

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 of meta SPC 3

4.2. **Use description**

Table 6

Use # 2 – surgical handrub, liquid

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: other Common name: Bacteria Development stage: Scientific name: other Common name: Tuberculosis bacilli Development stage: Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: enveloped viruses Development stage:

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, 150, 500, 1 000 ml in transparent/white high-density polyethylene (HDPE) bottles with polyethylene (PP) flip top caps; 5 000 ml transparent/white HDPE canister with HDPE screwed cap. In addition, exclusively for D-HDL (product 3.1): 100, 125, 150, 500, 1 000 ml in white HDPE bottles with PP flip top caps; 5 000 ml white HDPE canister with HDPE screwed cap. In addition, exclusively for B-HDL (product 3.3): 700 ml Pouch of transparent PE composite foil with integrated PP pump; 75 ml transparent/white HDPE bottle with PP flip top cap.

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 of meta SPC 3

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 of meta SPC 3

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

See general directions for use of meta SPC 3

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 of meta SPC 3

5. GENERAL DIRECTIONS FOR USE [3] OF THE META SPC 3

5.1. **Instructions for use**

For professional use only.

5.2. **Risk mitigation measures**

Avoid contact with eyes.

Keep out of reach of children.

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.

[3] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 3.

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

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

Trade name(s)	D-HDL		Market area: EU		
Authorisation number	EU-0027467-0005 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	12,229
Propan-2-ol		Active Substance	67-63-0	200-661-7	62,751

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

Trade name(s)	G-HDL		Market area: EU		
Authorisation number	EU-0027467-0006 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,14

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

Trade name(s)	B-HDL		Market area: EU		
Authorisation number	EU-0027467-0007 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,14

META SPC 4

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 4 identifier**

Identifier	meta SPC 4

1.2. **Suffix to the authorisation number**

Number	1-4

1.3. **Product type(s)**

Product type(s)	PT01 - Human hygiene (Disinfectants)

2. META SPC 4 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 4**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-1-ol		Active Substance	71-23-8	200-746-9	30,0	32,5
Propan-2-ol		Active Substance	67-63-0	200-661-7	45,0	45,0

2.2. **Type(s) of formulation of the meta SPC 4**

Formulation(s)	AL - Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

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) OF THE META SPC 4

4.1. **Use description**

Table 7

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: other Common name: Bacteria Development stage: Scientific name: other Common name: Mycobacteria Development stage: Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: Enveloped viruses Development stage:
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. In addition, exclusively for E-HDG (product 4.2): 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 of meta SPC 4

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 of meta SPC 4

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

See general directions for use of meta SPC 4

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 of meta SPC 4

4.2. **Use description**

Table 8

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: other Common name: Bacteria Development stage: Scientific name: other Common name: Mycobacteria Development stage: Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: enveloped viruses Development stage:

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. In addition, exclusively for E-HDG (product 4.2): 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 of meta SPC 4

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 of meta SPC 4

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

See general directions for use of meta SPC 4

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 of meta SPC 4

5. GENERAL DIRECTIONS FOR USE [4] OF THE META SPC 4

5.1. **Instructions for use**

For professional use only.

5.2. **Risk mitigation measures**

Avoid contact with eyes.

Keep out of reach of children.

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

[4] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 4.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 4

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

Trade name(s)	A-HDG		Market area: EU		
Authorisation number	EU-0027467-0008 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	32,5
Propan-2-ol		Active Substance	67-63-0	200-661-7	45,0

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

Trade name(s)	E-HDG		Market area: EU		
Authorisation number	EU-0027467-0009 1-4				
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

META SPC 5

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 5 identifier**

Identifier	meta SPC 5

1.2. **Suffix to the authorisation number**

Number	1-5

1.3. **Product type(s)**

Product type(s)	PT01 - Human hygiene (Disinfectants)

2. META SPC 5 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3	15,5
Propan-2-ol		Active Substance	67-63-0	200-661-7	60,0	63,14

2.2. Type(s) of formulation of the meta SPC 5

Formulation(s)	AL - Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

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) OF THE META SPC 5

4.1. Use description

Table 9

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: other Common name: Bacteria Development stage:

	Scientific name: other Common name: Tuberculosis bacilli Development stage: Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: Enveloped viruses Development stage:
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	125, 150, 500, 1 000 ml in transparent/white high-density polypropylene (HDPE) bottles with polypropylene (PP) flip top caps; 5 000 ml transparent/white HDPE canister with HDPE screwed cap. In addition, exclusively for C-HDG (product 5.1): 700 and 1 000 ml vacuum bag in white PE composite foil with integrated PP pump/valve and PE cap. In addition, exclusively for B-HDG (product 5.2): 700 ml pouch of transparent PE composite foil with integrated PP pump; 75 ml transparent HDPE bottle with PP flip top cap.

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 of meta SPC 5

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 of meta SPC 5

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

See general directions for use of meta SPC 5

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 of meta SPC 5

4.2. **Use description**

Table 10

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: other Common name: Bacteria Development stage: Scientific name: other Common name: Tuberculosis bacilli Development stage: Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: enveloped viruses Development stage:
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	125, 150, 500, 1 000 ml in transparent/white high-density polypropylene (HDPE) bottles with polypropylene (PP) flip top caps; 5 000 ml transparent/white HDPE canister with HDPE screwed cap. In addition, exclusively for C-HDG (product 5.1): 700 and 1 000 ml vacuum bag in white PE composite foil with integrated PP pump/valve and PE cap. In addition, exclusively for B-HDG (product 5.2): 700 ml pouch of transparent PE composite foil with integrated PP pump; 75 ml transparent HDPE bottle with PP flip top cap.

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 of meta SPC 5

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 of meta SPC 5

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

See general directions for use of meta SPC 5

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 of meta SPC 5

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

5.1. **Instructions for use**

For professional use only.

5.2. **Risk mitigation measures**

Avoid contact with eyes.

Keep out of reach of children.

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.

([5]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 5.

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

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 5

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

Trade name(s)	C-HDG		Market area: EU		
Authorisation number	EU-0027467-0010 1-5				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	15,5
Propan-2-ol		Active Substance	67-63-0	200-661-7	60,0

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

Trade name(s)	B-HDG		Market area: EU		
Authorisation number	EU-0027467-0011 1-5				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,14

META SPC 6

1. META SPC 6 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 6 identifier**

Identifier	meta SPC 6

1.2. **Suffix to the authorisation number**

Number	1-6

1.3. **Product type(s)**

Product type(s)	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)

2. META SPC 6 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 6**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-1-ol		Active Substance	71-23-8	200-746-9	25,0	35,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	30,0	40,0

2.2. **Type(s) of formulation of the meta SPC 6**

Formulation(s)	AL - Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

Hazard statements	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. Wear eye protection.. 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) OF THE META SPC 6

4.1. **Use description**

Table 11

Use # 1 – hard non-porous small surface disinfection RTU liquid

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage: Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: viruses (limited spectrum virucidal activity) Development stage:
Field(s) of use	Indoor Health care facilities and pharmaceutical and cosmetic industry, for example patient-near surrounding, working areas/desks, general equipment (excluding food contact surfaces): disinfection of small hard/non-porous surfaces. For professional use only.

Application method(s)	Method: Manual application Detailed description: Ready-to-use surface disinfectant at room temperature (20±2 °C). The entire surface to be disinfected is wetted by pouring or spraying from a short distance and subsequently thoroughly wiped with a cloth. The amount of product should be sufficient (max. 50 ml/m^2 to keep the surface wet during the contact time.
Application rate(s) and frequency	Application Rate: Minimum exposure time: • for the control of bacteria, yeasts and enveloped viruses: 60 sec • for the control of viruses (limited spectrum virucidal activity): 5 min Dilution (%): Ready-to-use product Number and timing of application: A reasonable frequency of disinfection in a patient's room is 1-2 per day. Maximum number of applications is 6 per day. No safety intervals need to be considered between the application phases.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	100, 500, 750 and 1 000 ml transparent/white high-density polyethylene (HDPE) bottle with polypropylene (PP) flip top caps (accessory: PP screw closure with spray head); 5 000 ml transparent/white HDPE canister with HDPE screwed cap.

4.1.1. *Use-specific instructions for use*

Surfaces should always be visibly clean prior to disinfection. Maximum number of applications is 6 per day.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 6

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 of meta SPC 6

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

See general directions for use of meta SPC 6

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 of meta SPC 6

4.2. **Use description**

Table 12

Use # 2 – hard non-porous small surface disinfection RTU liquid

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage: Scientific name: other Common name: Yeasts Development stage:
Field(s) of use	Indoor Health care facilities and in food industry, for example food preparation and handling in kitchens/restaurants: disinfection of small hard/non-porous surfaces. For professional use only.
Application method(s)	Method: Manual application Detailed description: Ready-to-use surface disinfectant at room temperature (20±2 °C). The entire surface to be disinfected is wetted by pouring or spraying from a short distance and subsequently thoroughly wiped with a cloth. The amount of product should be sufficient (max. 50 ml/m^2) to keep the surface wet during the contact time.
Application rate(s) and frequency	Application Rate: Minimum exposure time: for the control of bacteria and yeasts at 20°C: 60 sec Dilution (%): Ready-to-use product Number and timing of application: The products can be used as often as necessary. A reasonable frequency in kitchens is 1-2 per day. No safety intervals need to be considered between the application phases.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	100, 500, 750 and 1 000 ml transparent/white high-density polyethylene (HDPE) bottle with polypropylene (PP) flip top caps (accessory: PP screw closure with spray head); 5 000 ml transparent/white HDPE canister with HDPE screwed cap.

4.2.1. *Use-specific instructions for use*

Surfaces should always be visibly clean prior to disinfection.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 6

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 of meta SPC 6

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

See general directions for use of meta SPC 6

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 of meta SPC 6

5. GENERAL DIRECTIONS FOR USE ([6]) OF THE META SPC 6

5.1. **Instructions for use**

For professional use only.

5.2. **Risk mitigation measures**

The use of eye protection during handling of the product is mandatory.

Keep out of reach of children

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.

([6]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 6.

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

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 6

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

Trade name(s)	F-FDL		Market area: EU		
Authorisation number	EU-0027467-0012 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	25,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	30,0

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

Trade name(s)	A-FDL		Market area: EU		
Authorisation number	EU-0027467-0013 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	35,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	35,0

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

Trade name(s)	C-FDL		Market area: EU		
Authorisation number	EU-0027467-0014 1-6				
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	40,0

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

Trade name(s)	E-FDL		Market area: EU		
Authorisation number	EU-0027467-0015 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	25,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	40,0

META SPC 7

1. META SPC 7 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 7 identifier**

Identifier	meta SPC 7

1.2. **Suffix to the authorisation number**

Number	1-7

1.3. **Product type(s)**

Product type(s)	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)

2. META SPC 7 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 7**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3	14,925
Propan-2-ol		Active Substance	67-63-0	200-661-7	44,73	63,14

2.2. **Type(s) of formulation of the meta SPC 7**

Formulation(s)	AL - Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7

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. Wear eye protection. Immediately call a POISON CENTER/doctor. 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. Store in a well-ventilated place.Keep cool. Store locked up. Dispose of container to an authorised waste collection point.

4. AUTHORISED USE(S) OF THE META SPC 7

4.1. **Use description**

Table 13

Use # 1 – hard non-porous small surface disinfection RTU liquid

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage: Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: Enveloped viruses Development stage:
Field(s) of use	Indoor Health care facilities and pharmaceutical and cosmetic industry, for example in patient-near surrounding, working areas/desks, general equipment (excluding food contact surfaces): disinfection of small hard/non-porous surfaces. For professional use only.
Application method(s)	Method: Manual application Detailed description: Ready-to-use surface disinfectant at room temperature (20±2 °C).

	The entire surface to be disinfected is wetted by pouring or spraying from short distance and subsequently thoroughly wiped with a cloth. The amount of product should be sufficient (max. 50 ml/m²) to keep the surface wet during the contact time.
Application rate(s) and frequency	Application Rate: Minimum exposure time: • for the control of bacteria, yeasts and enveloped viruses: 60 sec Dilution (%): Ready-to-use product Number and timing of application: A reasonable frequency of disinfection in a patient's room is 1-2 per day. Maximum number of applications is 6 per day. No safety intervals need to be considered between the application phases.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	125, 150, 500, 1 000 ml transparent/white high-density polyethylene (HDPE) bottle with polypropylene (PP) flip top caps (accessory: PP screw closure with spray head); 5 000 ml transparent/white HDPE canister with HDPE screwed cap.

4.1.1. *Use-specific instructions for use*

Surfaces should always be visibly clean prior to disinfection. Maximum number of applications is 6 per day.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 7

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 of meta SPC 7

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

See general directions for use of meta SPC 7

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 of meta SPC 7

4.2. **Use description**

Table 14

Use # 2 – hard non-porous small surface disinfection RTU liquid

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage:

	Scientific name: other Common name: Yeasts Development stage:
Field(s) of use	Indoor Health care facilities and in food industry, for example food preparation and handling in kitchens/restaurants): disinfection of small hard/non-porous surfaces. For professional use only.
Application method(s)	Method: Manual application Detailed description: Ready-to-use surface disinfectant at room temperature (20±2 °C). The entire surface to be disinfected is wetted by pouring or spraying from short distance and subsequently thoroughly wiped with a cloth. The amount of product should be sufficient (max. 50 ml/m^2) to keep the surface wet during the contact time.
Application rate(s) and frequency	Application Rate: Minimum exposure time: for the control of bacteria and yeasts at 20°C: 60 sec Dilution (%): Ready-to-use product Number and timing of application: The products can be used as often as necessary. A reasonable frequency in kitchens is 1-2 per day. No safety intervals need to be considered between the application phases.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	125, 150, 500, 1 000 ml transparent/white high-density polyethylene (HDPE) bottle with polypropylene (PP) flip top caps (accessory: PP screw closure with spray head); 5 000 ml transparent/white HDPE canister with HDPE screwed cap.

4.2.1. *Use-specific instructions for use*

Surfaces should always be visibly clean prior to disinfection.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 7

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 of meta SPC 7

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

See general directions for use of meta SPC 7

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 of meta SPC 7

5. GENERAL DIRECTIONS FOR USE ([7]) OF THE META SPC 7

5.1. **Instructions for use**

For professional use only.

5.2. **Risk mitigation measures**

The use of eye protection during handling of the product is mandatory.

Keep out of reach of children.

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

([7]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 7.

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

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

Trade name(s)	D-FDL		Market area: EU		
Authorisation number	EU-0027467-0016 1-7				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,925
Propan-2-ol		Active Substance	67-63-0	200-661-7	44,73

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

Trade name(s)	B-FDL		Market area: EU		
Authorisation number	EU-0027467-0017 1-7				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,14

META SPC 8

1. META SPC 8 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 8 identifier**

Identifier	meta SPC 8

1.2. **Suffix to the authorisation number**

Number	1-8

1.3. **Product type(s)**

Product type(s)	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)

2. META SPC 8 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 8

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-1-ol		Active Substance	71-23-8	200-746-9	25,0	30,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	30,0	40,0

2.2. Type(s) of formulation of the meta SPC 8

Formulation(s)	AL - Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 8

Hazard statements	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 or doctor/physician. Store in a well-ventilated place. Keep cool. Store locked up. Dispose of container to an authorised waste collection point.

4. AUTHORISED USE(S) OF THE META SPC 8

4.1. Use description

Table 15

Use # 1 – hard non-porous small surface disinfection RTU wipes

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage:

	Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: viruses (limited spectrum virucidal activity) Development stage:
Field(s) of use	Indoor Health care facilities and pharmaceutical and cosmetic industry, for example patient-near surrounding, working areas/desks, general equipment (excluding food contact surfaces): disinfection of small hard/non-porous surfaces. For professional use only.
Application method(s)	Method: Manual application Detailed description: Ready-to-use disinfectant wipes at room temperature (20±2 °C). The surface to be disinfected is wiped and wetted with a sufficient amount of the product, ensuring complete coverage.
Application rate(s) and frequency	Application Rate: Minimum exposure time: • for the control of bacteria, yeasts and enveloped viruses: 60 sec • for the control of viruses (limited spectrum virucidal activity): 5 min; Make the surface completely wet. Dilution (%): Ready-to-use product Number and timing of application: A reasonable frequency of disinfection in a patient's room is 1-2 per day. Maximum number of applications is 6 per day. No safety intervals need to be considered between the application phases.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Flow-pack of white polyethylene (PE)-composite foil with polypropylene (PP) Flap cover, containing 40 30% Viscose and 70% Polyethylene Terephtalate (VIS/PET) wipes. Exclusively for C-FDT (product 8.2): Transparent high-density polyethylene (HDPE) Canister with PP screwed cap, containing 30 PET wipes; Dispenser bag of white PE composite foil, containing 30 or 90 PET wipes used with dispenser box.

4.1.1. *Use-specific instructions for use*

Surfaces should always be visibly clean prior to disinfection. Maximum number of applications is 6 per day.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 8.

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 of meta SPC 8.

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

See general directions for use of meta SPC 8

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 of meta SPC 8

4.2. **Use description**

Table 16

Use # 2 – hard non-porous small surface disinfection RTU wipes

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage: Scientific name: other Common name: Yeasts Development stage:
Field(s) of use	Indoor Health care facilities and food industry, for example food preparation and handling in kitchens/restaurants): disinfection of small hard/non-porous surfaces. For professional use only.
Application method(s)	Method: Manual application Detailed description: Ready-to-use disinfectant wipes at room temperature (20±2 °C). The surface to be disinfected is wiped and wetted with a sufficient amount of the product by wiping, ensuring complete coverage.
Application rate(s) and frequency	Application Rate: Minimum exposure time: • for the control of bacteria and yeasts at 20°C: 60 sec; Make the surface completely wet Dilution (%): Ready-to-use product Number and timing of application: The product can be used as often as necessary. A reasonable frequency of disinfection in kitchens is 1-2 per day. No safety intervals need to be considered between the application phases.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Flow-pack of white polyethylene (PE)-composite foil with polypropylene (PP) Flap cover, containing 40 30% viscose and 70% polyethylene terephtalate (VIS/PET) wipes. Exclusively for C-FDT (product 8.2): Transparent high-density polyethylene (HDPE) Canister with PP screwed cap, containing 30 PET wipes; Dispenser bag of white PE composite foil, containing 30 or 90 PET wipes used with dispenser box.

4.2.1. Use-specific instructions for use

Surfaces should always be visibly clean prior to disinfection.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 8

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 of meta SPC 8

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

See general directions for use of meta SPC 8

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 of meta SPC 8

5. GENERAL DIRECTIONS FOR USE ([8]) OF THE META SPC 8

5.1. **Instructions for use**

For professional use only.

For wipes reseal the package after opening.

5.2. **Risk mitigation measures**

Avoid contact with eyes.

Keep out of reach of children.

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.

([8]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 8.

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

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 8

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

Trade name(s)	F-FDT		Market area: EU		
Authorisation number	EU-0027467-0018 1-8				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	25,0
Propan-2-ol		Active Substance	67-63-0	200-661-7	30,0

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

Trade name(s)	C-FDT		Market area: EU		
Authorisation number	EU-0027467-0019 1-8				
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	40,0

META SPC 9

1. META SPC 9 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 9 identifier**

Identifier	meta SPC 9

1.2. **Suffix to the authorisation number**

Number	1-9

1.3. **Product type(s)**

Product type(s)	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants) PT04 - Food and feed area (Disinfectants)

2. META SPC 9 COMPOSITION

2.1. **Qualitative and quantitative information on the composition of the meta SPC 9**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3	14,925
Propan-2-ol		Active Substance	67-63-0	200-661-7	44,73	63,14

2.2. **Type(s) of formulation of the meta SPC 9**

Formulation(s)	AL - Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 9

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 contents to an authorised waste collection point.

4. AUTHORISED USE(S) OF THE META SPC 9

4.1. **Use description**

Table 17

Use # 1 – hard non-porous small surface disinfection RTU wipes

Product type	PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage: Scientific name: other Common name: Yeasts Development stage: Scientific name: other Common name: Enveloped viruses Development stage:
Field(s) of use	Indoor Health care facilities and pharmaceutical and cosmetic industry, for example patient-near surrounding, working areas/desks, general equipment (excluding food contact surfaces): disinfection of small hard/non-porous surfaces For professional use only.
Application method(s)	Method: Manual application Detailed description: Ready-to-use disinfectant wipes at room temperature (20±2 °C). The surface to be disinfected is wiped and wetted with a sufficient amount of the product, ensuring complete Coverage.
Application rate(s) and frequency	Application Rate: Minimum exposure time: for the control of bacteria, yeasts and enveloped viruses: 60 sec; Make the surface completely wet. Dilution (%): Ready-to-use product Number and timing of application: A reasonable frequency of disinfection in a patient's room is 1-2 per day. Maximum number of applications is 6 per day. No safety intervals need to be considered between the application phases.

Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Flow-pack of polyethylene (PE) composite foil with high-density polyethylene (HDPE) Flap cover, containing 80 Cellulose wipes; Dispenser bag of PE composite foil, containing 70 Cellulose wipes used with dispenser box Exclusively for B-FDT (product 9.2): Dispenser of PE composite foil with screwed-in PE cap, containing 100 PP/PE wipes.

4.1.1. *Use-specific instructions for use*

Surfaces should always be visibly clean prior to disinfection. Maximum number of applications is 6 per day.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 9

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 of meta SPC 9

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

See general directions for use of meta SPC 9

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 of meta SPC 9

4.2. **Use description**

Table 18

Use # 2 – hard non-porous small surface disinfection RTU wipes

Product type	PT04 - Food and feed area (Disinfectants)
Where relevant, an exact description of the authorised use	Not relevant
Target organism(s) (including development stage)	Scientific name: other Common name: Bacteria Development stage: Scientific name: other Common name: Yeasts Development stage:
Field(s) of use	Indoor Health care facilities and food industry, for example patient-near surrounding, food preparation and handling in kitchens/restaurants): disinfection of small hard/non-porous surfaces. For professional use only.

Application method(s)	Method: Manual application Detailed description: Ready-to-use disinfectant wipes at room temperature (20±2 °C). The surface to be disinfected is wetted with a sufficient amount of the product by wiping, ensuring complete coverage.
Application rate(s) and frequency	Application Rate: Minimum exposure time: for the control of bacteria and yeasts at 20°C: 60 sec; Make the surface completely wet. Dilution (%): Ready-to-use product Number and timing of application: The product can be used as often as necessary. A reasonable frequency of disinfection in kitchens is 1-2 per day. No safety intervals need to be considered between the application phases.
Category(ies) of users	Industrial Professional
Pack sizes and packaging material	Flow-pack of polyethylene (PE) composite foil with high-density polyethylene (HDPE) Flap cover, containing 80 Cellulose wipes; Dispenser bag of PE composite foil, containing 70 Cellulose wipes used with dispenser box Exclusively for B-FDT (product 9.2): Dispenser of PE composite foil with screwed-in PE cap, containing 100 PP/PE wipes.

4.2.1. *Use-specific instructions for use*

Surfaces should always be visibly clean prior to disinfection.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use of meta SPC 9

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 of meta SPC 9

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

See general directions for use of meta SPC 9

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

ee general directions for use of meta SPC 9

5. GENERAL DIRECTIONS FOR USE ([9]) OF THE META SPC 9

5.1. **Instructions for use**

For professional use only.

For wipes reseal the package after opening.

([9]) Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 9.

5.2. **Risk mitigation measures**

Avoid contact with eyes.

Keep out of reach of children

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 feeding stuff. Keep away from combustible material.

6. OTHER INFORMATION

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 9

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

Trade name(s)	D-FDT		Market area: EU		
Authorisation number	EU-0027467-0020 1-9				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,925
Propan-2-ol		Active Substance	67-63-0	200-661-7	44,73

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

Trade name(s)	B-FDT		Market area: EU		
Authorisation number	EU-0027467-0021 1-9				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Propan-1-ol		Active Substance	71-23-8	200-746-9	14,3
Propan-2-ol		Active Substance	67-63-0	200-661-7	63,14

COMMISSION IMPLEMENTING REGULATION (EU) 2022/1283

of 15 July 2022

entering a name in the register of protected designations of origin and protected geographical indications

'Μακαρόνια της Σμίλας/Makaronia tis Smilas/Μακαρόνια του Σκλινιτζιού/Makaronia tou Sklinitziou' (PGI)

THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Cyprus's application to register the name 'Μακαρόνια της Σμίλας/Makaronia tis Smilas/Μακαρόνια του Σκλινιτζιού/Makaronia tou Sklinitziou' was published in the *Official Journal of the European Union* ([2]).

(2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Μακαρόνια της Σμίλας/Makaronia tis Smilas/Μακαρόνια του Σκλινιτζιού/Makaronia tou Sklinitziou' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Μακαρόνια της Σμίλας/Makaronia tis Smilas/Μακαρόνια του Σκλινιτζιού/Makaronia tou Sklinitziou' (PGI) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 2.5. – pasta, as listed in Annex XI to Commission Implementing Regulation (EU) No 668/2014 ([3]).

Article 2

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

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

Done at Brussels, 15 July 2022.

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

([1]) OJ L 343, 14.12.2012, p. 1.
([2]) OJ C 131, 24.3.2022, p. 12.
([3]) Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

DECISIONS

COUNCIL DECISION (CFSP) 2022/1284

of 21 July 2022

amending Decision (CFSP) 2022/339 on an assistance measure under the European Peace Facility to support the Ukrainian Armed Forces

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 28(1) and 41(2) thereof,

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

Whereas:

(1) On 28 February 2022, the Council adopted Decision (CFSP) 2022/339 ([1]), which established an assistance measure with a financial reference amount of EUR 50 000 000 intended to cover the financing of the provision of equipment and supplies not designed to deliver lethal force, such as personal protective equipment, first aid kits and fuel, to the Ukrainian Armed Forces.

(2) On 23 March 2022, the Council adopted Decision (CFSP) 2022/472 ([2]) amending Decision (CFSP) 2022/339, which increased the financial reference amount to EUR 100 000 000.

(3) On 13 April 2022, the Council adopted Decision (CFSP) 2022/637 ([3]) amending Decision (CFSP) 2022/339, which increased the financial reference amount to EUR 150 000 000.

(4) On 23 May 2022, the Council adopted Decision (CFSP) 2022/810 ([4]) amending Decision (CFSP) 2022/339, which increased the financial reference amount to EUR 160 000 000.

(5) In light of the ongoing armed aggression by the Russian Federation against Ukraine, the financial reference amount should be increased by an additional EUR 10 000 000, intended to cover the financing of the provision of equipment and supplies not designed to deliver lethal force, such as personal protective equipment, first aid kits and fuel, to the Ukrainian Armed Forces.

(6) Decision (CFSP) 2022/339 should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Decision (CFSP) 2022/339 is amended as follows:

([1]) Council Decision (CFSP) 2022/339 of 28 February 2022 on an assistance measure under the European Peace Facility to support the Ukrainian Armed Forces (OJ L 61, 28.2.2022, p. 1).
([2]) Council Decision (CFSP) 2022/472 of 23 March 2022 amending Decision (CFSP) 2022/339 on an assistance measure under the European Peace Facility to support the Ukrainian Armed Forces (OJ L 96, 24.3.2022, p. 45).
([3]) Council Decision (CFSP) 2022/637 of 13 April 2022 amending Decision (CFSP) 2022/339 on an assistance measure under the European Peace Facility to support the Ukrainian Armed Forces (OJ L 117, 19.4.2022, p. 36).
([4]) Council Decision (CFSP) 2022/810 of 23 May 2022 amending Decision (CFSP) 2022/339 on an assistance measure under the European Peace Facility to support the Ukrainian Armed Forces (OJ L 145, 24.5.2022, p. 42).

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

'4. The duration of the Assistance Measure shall be 70 months from the adoption of this Decision.';

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

'1. The financial reference amount intended to cover the expenditure related to the Assistance Measure shall be EUR 170 000 000.';

(3) in Article 2, paragraph 3 is replaced by the following:

'3. In accordance with Article 29(5) of Decision (CFSP) 2021/509, the administrator for assistance measures may call for contributions following the adoption of this Decision, up to EUR 170 000 000. The funds called by the administrator for assistance measures shall only be used to pay expenditure within the limits approved by the Committee established by Decision (CFSP) 2021/509 in the 2022 amending budget and in the budgets for subsequent years corresponding to the Assistance Measure.';

(4) in Article 2, paragraph 4 is replaced by the following:

'4. Expenditure related to the implementation of the Assistance Measure shall be eligible as from 1 January 2022 and until a date to be determined by the Council. The maximum eligible expenditure incurred before 11 March 2022 shall be EUR 50 000 000. The amount of EUR 10 000 000 shall be eligible from 21 July 2022.'.

Article 2

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

Done at Brussels, 21 July 2022.

For the Council
The President
M. BEK

COUNCIL DECISION (CFSP) 2022/1285

of 21 July 2022

amending Decision (CFSP) 2022/338 on an assistance measure under the European Peace Facility for the supply to the Ukrainian Armed Forces of military equipment, and platforms, designed to deliver lethal force

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 28(1) and 41(2) thereof,

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

Whereas:

(1) On 28 February 2022, the Council adopted Decision (CFSP) 2022/338 ([1]), which established an assistance measure with a financial reference amount of EUR 450 000 000 intended to cover the supply to the Ukrainian Armed Forces of military equipment, and platforms, designed to deliver lethal force.

(2) On 23 March 2022, the Council adopted Decision (CFSP) 2022/471 ([2]) amending Decision (CFSP) 2022/338, which increased the financial reference amount to EUR 900 000 000.

(3) On 13 April 2022, the Council adopted Decision (CFSP) 2022/636 ([3]) amending Decision (CFSP) 2022/338, which increased the financial reference amount to EUR 1 350 000 000.

(4) On 23 May 2022, the Council adopted Decision (CFSP) 2022/809 ([4]) amending Decision (CFSP) 2022/338, which increased the financial reference amount to EUR 1 840 000 000.

(5) In light of the ongoing armed aggression by the Russian Federation against Ukraine, the financial reference amount should be increased by an additional EUR 490 000 000.

(6) Decision (CFSP) 2022/338 should therefore be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Decision (CFSP) 2022/338 is amended as follows:

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

'4. The duration of the Assistance Measure shall be 70 months from the adoption of this Decision.';

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

'1. The financial reference amount intended to cover the expenditure related to the Assistance Measure shall be EUR 2 330 000 000.';

([1]) Council Decision (CFSP) 2022/338 of 28 February 2022 on an assistance measure under the European Peace Facility for the supply to the Ukrainian Armed Forces of military equipment, and platforms, designed to deliver lethal force (OJ L 60, 28.2.2022, p. 1).

([2]) Council Decision (CFSP) 2022/471 of 23 March 2022 amending Decision (CFSP) 2022/338 on an assistance measure under the European Peace Facility for the supply to the Ukrainian Armed Forces of military equipment, and platforms, designed to deliver lethal force (OJ L 96, 24.3.2022, p. 43).

([3]) Council Decision (CFSP) 2022/636 of 13 April 2022 amending Decision (CFSP) 2022/338 on an assistance measure under the European Peace Facility for the supply to the Ukrainian Armed Forces of military equipment, and platforms, designed to deliver lethal force (OJ L 117, 19.4.2022, p. 34).

([4]) Council Decision (CFSP) 2022/809 of 23 May 2022 amending Decision (CFSP) 2022/338 on an assistance measure under the European Peace Facility for the supply to the Ukrainian Armed Forces of military equipment, and platforms, designed to deliver lethal force (OJ L 145, 24.5.2022, p. 40).

(3) in Article 2, paragraph 3 is replaced by the following:

'3. In accordance with Article 29(5) of Decision (CFSP) 2021/509, the administrator for assistance measures may call for contributions following the adoption of this Decision, up to EUR 2 330 000 000. The funds called by the administrator for assistance measures shall only be used to pay expenditure within the limits approved by the Committee established by Decision (CFSP) 2021/509 in the 2022 amending budget and in the budgets for subsequent years corresponding to the Assistance Measure.';

(4) in Article 2, paragraph 4 is replaced by the following:

'4. Expenditure related to the implementation of the Assistance Measure shall be eligible as from 1 January 2022 and until a date to be determined by the Council. The maximum eligible expenditure incurred before 11 March 2022 shall be EUR 450 000 000. The amount of EUR 490 000 000 shall be eligible from 21 July 2022.'.

Article 2

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

Done at Brussels, 21 July 2022.

For the Council
The President
M. BEK

COMMISSION IMPLEMENTING DECISION (EU) 2022/1286

of 15 July 2022

on the applicability of Article 34 of Directive 2014/25/EU of the European Parliament and of the Council to the award of contracts to pursue the retail supply of electricity and gas to small customers in the Netherlands

(notified under document C(2022) 4872)

(Only the Dutch text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC ([1]), and in particular Article 35(3) thereof,

After consulting the Advisory Committee for Public Contracts,

Whereas:

1. **FACTS**

(1) The measures provided for in this Decision are in accordance with the opinion of the Advisory Committee for Public Contracts.

(2) On 30 January 2017, Eneco B.V. ('Eneco') and N.V. Nuon Energy ('Nuon') submitted to the Commission a request pursuant to Article 35(1) of Directive 2014/25/EU ('the request'). The request complies with the formal requirements set out in Article 1(1) of Commission Implementing Decision (EU) 2016/1804 ([2]) and in Annex I to that Implementing Decision.

(3) The shares in Nuon are fully held by Vattenfall AB, a non-listed company owned by the Swedish State. As a result, Nuon is considered as a contracting entity within the meaning of Article 4(2) of Directive 2014/25/EU. Following a change in ownership in March 2020 (the company, previously owned by local governments in the Netherlands, was sold to a joint venture composed by Mitsubishi Corporation and Chubu Electric Power), Eneco is no longer considered as a contracting entity.

(4) The request concerns the activities of retail supply of electricity to small customers (households as well as small industrial and commercial users connected to the low-voltage grid with a connection with a maximum connection capacity of no more than 3 * 80A) and retail supply of gas to small customers (households and small businesses connected to the gas network with a maximum connection capacity of no more than 40 m^3).

([1]) OJ L 94, 28.3.2014, p. 243.

([2]) Commission Implementing Decision (EU) 2016/1804 of 10 October 2016 on the detailed rules for the application of Articles 34 and 35 of Directive 2014/25/EU of the European Parliament and of the Council on procurement by entities operating in the water, energy, transport and postal services sectors (OJ L 275, 12.10.2016, p. 39).

(5) In accordance with point 1(a) of Annex IV to Directive 2014/25/EU, considering that free access to the market can be presumed on the basis of Article 34(3), first subparagraph, of that Directive, the Commission is to adopt an Implementing Decision on the request within 90 working days. As the request has not been accompanied by a reasoned and substantiated position adopted by an independent national authority within the meaning of Article 35(2) of Directive 2014/25/EU, the Commission informed the Dutch authorities about the request and required additional information on 24 March 2017. The reply to this request for information was transmitted by the Dutch authorities by email, on 19 June 2017. The response was deemed to be incomplete and led the Commission to ask further clarifications on 27 July 2017, which the Dutch authorities provided on 25 September 2017.

(6) As the available information was still insufficient for the Commission to form its view on the exposure of the activities to competition, further requests for information were sent to the Dutch authorities on 21 December 2017 and 2 March 2018. The Dutch authorities sent a reply on 11 October 2021.

(7) Nuon submitted a substantially modified request on 24 January 2022. The Commission and the applicant agreed that the Commission should adopt an Implementing Decision by 15 July 2022.

2. **LEGAL FRAMEWORK**

(8) Directive 2014/25/EU applies to the award of contracts intended to enable activities related to the retail supply of electricity and gas [as referred to in Article 9(1), point(a), of that Directive], unless those activities are exempted pursuant to Article 34 of that Directive.

(9) Article 34 of Directive 2014/25/EU provides that contracts intended to enable the performance of an activity to which that Directive applies are not to be subject to that Directive if, in the Member State in which it is carried out, the activity is directly exposed to competition on markets to which access is not restricted. Direct exposure to competition is to be assessed on the basis of objective criteria, taking account of the specific characteristics of the sector concerned.

3. **ASSESSMENT**

3.1. **Free access to the market**

(10) Access to a market is deemed to be unrestricted if the Member State has implemented and applied the relevant Union legal acts opening a given sector or a part of it. Those legal acts are listed in Annex III to Directive 2014/25/EU. Directive 2019/944/EU of the European Parliament and of the Council ([3]), that repeals Directive 2009/72/EC of the European Parliament and of the Council ([4]), is applicable to the electricity sector, while Directive 2009/73/EC of the European Parliament and of the Council ([5]) is applicable to the gas sector.

(11) The Netherlands has transposed Directives 2019/944/EU and 2009/73/EC into national law through the Dutch Electricity Act ([6]) (Elektriciteitswet) and Dutch Gas Act ([7]) (Gaswet). Consequently, and in accordance with Article 34(3), first subparagraph, of Directive 2014/25/EU, access to the market is deemed not to be restricted on the entire territory of the Netherlands.

([3]) Directive (EU) 2019/944 of the European Parliament and of the Council of 5 June 2019 on common rules for the internal market for electricity and amending Directive 2012/27/EU (OJ L 158, 14.6.2019, p. 125).
([4]) Directive 2009/72/EC of the European Parliament and of the Council of 13 July 2009 concerning common rules for the internal market in electricity and repealing Directive 2003/54/EC (OJ L 211, 14.8.2009, p. 55).
([5]) Directive 2009/73/EC of the European Parliament and of the Council of 13 July 2009 concerning common rules for the internal market in natural gas and repealing Directive 2003/55/EC (OJ L 211, 14.8.2009, p. 94).
([6]) Wet van 12-7-2012, Stb. 2012, 334 en Inwerkingtredingsbesluit van 12-7-2012, Stb. 2012, 336.
([7]) Wet van 12-7-2012, Stb. 2012, 334 en Inwerkingtredingsbesluit van 12-7-2012, Stb. 2012, 336.

3.2. **Direct exposure to competition**

(12) Direct exposure to competition is to be evaluated on the basis of various indicators, none of which are, per se, decisive. In respect of the markets concerned by this decision, the market share of the main players on a given market constitutes one criterion which should be taken into account. Given the characteristics of the markets concerned, further criteria, such as the number of market players, the liquidity of wholesale markets, the switching rates of customers or the existence of price regulation should also be taken into account.

(13) This Decision is without prejudice to the application of the Union rules on competition and of the provisions in other fields of Union law. In particular, while the criteria and the methodology used to assess direct exposure to competition under Article 34 of Directive 2014/25/EU are to be in conformity with the provisions on competition of the Treaty, they do not necessarily need to be identical to those used to perform an assessment under Article 101 or Article 102 of the Treaty or under Council Regulation (EC) No 139/2004 ([8]), as confirmed by the General Court ([9]).

(14) The aim of this Decision is to establish whether the activities concerned by the request are, in markets to which access is not restricted within the meaning of Article 34 of Directive 2014/25/EU, exposed to a level of competition which ensures that, also in the absence of the procurement discipline brought about by the detailed procurement rules laid down in Directive 2014/25/EU, procurement for the pursuit of the activities concerned will be carried out in a transparent and non-discriminatory manner based on criteria allowing purchasers to identify the solution which overall is the economically most advantageous one.

(15) In this context, it is important to keep in mind that, in the markets concerned, not all market players are subject to the public procurement rules. In the present case, only Nuon is considered as a contracting entity within the meaning of Article 4 of Directive 2014/25/EU and is hence subject to public procurement rules.

3.2.1. *Relevant product markets*

(16) According to Commission precedents ([10]), the following relevant product markets can be distinguished in the electricity sector: (i) generation and wholesale supply; (ii) transmission; (iii) distribution and (iv) retail supply to final customers ([11]). In the gas sector, the following product markets can be distinguished: (i) upstream market (exploration for crude oil and natural gas); (ii) (upstream and downstream) wholesale markets; (iii) retail market, which can be defined as the sales, marketing and distribution of gas to final customers ([12]).

(17) There are eight regional distribution companies or Distribution System Operators ('DSOs') in the electricity and gas sector in the Netherlands: Cogas Infra & Beheer, Enduris, Enexis, Liander, Endinet, RENDO Netbeheer, Stedin Netbeheer and Westland Infra Netbeheer. The areas in which the DSOs transport electricity may differ from the areas in which they transport gas. Since the liberalisation of the energy markets, the independent operation of the DSOs was ensured by a series of rules in accordance with the Union sectoral legislation. The Dutch legislator mandated full ownership unbundling at the DSO level. The Dutch authorities confirmed ([13]) that, currently, all DSOs are legally and ownership unbundled from generators and suppliers.

([8]) Council Regulation (EC) No 139/2004 of 20 January 2004 on the control of concentrations between undertakings (the EC Merger Regulation) (OJ L 24, 29.1.2004, p. 1).

([9]) Judgment of 27 April 2016, Österreichische Post AG v. Commission, T-463/14, ECLI:EU:T:2016:243, paragraph 28.

([10]) Case COMP M. 4110 E.ON – ENDESA, 25.4.2006, paragraphs 10 and 11; Commission Implementing Decision (EU) 2016/1674 of 15 September 2016 exempting retail supply of electricity and gas in Germany from the application of Directive 2014/25/EU of the European Parliament and of the Council (OJ L 253, 17.9.2016, p. 6).

([11]) M.3440 – *EDP/ENI/GDP*, 9.12.2004, paragraph 56.

([12]) M. 4180 *Gaz de France/Suez*, 14.11.2006, paragraph 63; M.3868 – *DONG/Elsam/Energi E2*, 14.3.2006, paragraph 193 et seq.; M. 3440 – *EDP/ENI/GDP*, 09.12.2004, paragraph 215 et seq.; M.5740 – *Gazprom/A2A/JOF*, 16.6.2010, paragraph 17 et seq.

([13]) Letter of the Dutch authorities to the Commission of 25 September 2017.

Retail supply of electricity

(18) As regards the supply of electricity to end customers, in its previous decisions the Commission distinguished between supply to small customers (households and small businesses) connected to low-voltage distribution grids and supply to large industrial customers typically connected to the high and medium voltage grid (large industrial and commercial consumers) ([14]). That distinction is related to the different requirements and profiles on the demand side and the different services and technologies on the supply side ([15]).

(19) In the past decisions, the Dutch Authority for Consumers and Markets (Autoriteit Consument & Markt – 'ACM') also made a distinction between supply to small-scale customers ([16]) and supply to large-scale customers ([17]). ACM observed that differences in sale and marketing, pricing and delivery terms, different switching patterns, differences on the demand side and separate licence needed for each type of customers justified such distinction.

(20) The present request concerns small customers, i.e. households as well as small industrial and commercial users connected to the low-voltage grid with a maximum connection capacity of no more than 3 * 80A.

Retail supply of gas

(21) In its previous Decisions, the Commission distinguished between the following markets: supply of natural gas to: (i) gas-fired power plants ([18]); (ii) large industrial customers ([19]) and (iii) small customers ([20]). The last category, based on a case-by-case analysis, could be further divided into the supply of natural gas to: (i) households and (ii) commercial customers ([21]).

(22) In its past decisions, ACM made a distinction between supply of natural gas to small customers and supply to large customers and power stations ([22]). ACM held that competitive conditions were different in both markets as regards purchase profile, prices and switching. As in the case of retail supply of electricity, a specific licence was needed for each type of customers.

(23) ACM also indicated that a possible further subdivision of the market for the supply of natural gas could be made on the basis of the quality of gas ([23]), between low calorific gas ('L-gas') used typically by small customers and high calorific gas ('H-gas') used by both large and small customers.

(24) The present request concerns small customers, i.e. households and small businesses with a maximum connection capacity of no more than 40 m^3.

Conclusion

(25) In view of the factors examined under recitals 15 to 23, for the purposes of assessing whether the conditions laid down in Article 34 of Directive 2014/25/EU are fulfilled, and without prejudice to the application of other Union law, the Commission considers that the relevant product markets are the markets for the retail supply of electricity to small customers and the retail supply of gas to small customers.

([14]) M.3440 – *EDP/ENI/GDP* of 9.12.2004, paragraph 73; M.2947 – *Verbund/EnergieAllianz*,of 11.6.2003, paragraph 35.
([15]) M.5496 – *VATTENFALL/NUON ENERGY*, 22.6.2009, paragraph 12.
([16]) Small-scale customers include both households and small commercial customers.
([17]) ACM Decision Case 6017 Nuon/Essent of 21 May 2007, paragraph 53. In this (negative) decision, the ACM concluded that there would be a concentration on various markets, including supply to retail consumers.
([18]) Case COMP/M.4180 *GDF/Suez*, 14.11.2006, paragraphs 362-367.
([19]) Case COMP/M.4180 *GDF/Suez*, 14.11.2006, paragraphs 78-81.
([20]) Case COMP/M.3440 EDP/GDP/ENI, 9.12.2004.
([21]) Case COMP/M.4180 *GDF/Suez*, 14.11.2006, paragraphs 78-81, and case COMP/M.3696 *E.ON/MOL* 21.12.2005, paragraphs 122-124.
([22]) ACM Decision Case 5975 Essent/Westland 13.3.2007, paragraph 18 and ACM Decision Case 6017 Nuon/Essent, 21.5.2007, paragraph 56.
([23]) ACM decision, Case 5724/Electrabel – Rendo, paras 25 en 26 and ACM decision, Case 5975/Essent – Westland, 13.3.2007, paragraph 19. See also ACM decision, Nuon/Essent, 21.5.2007, paragraph 61.

3.2.2. *Relevant geographic markets*

Retail supply of electricity

(26) The Commission previously found ([24]) that the markets for retail supply of electricity in the Netherlands were national in scope.

(27) From the geographical perspective, in its previous practice ([25]), ACM has defined the relevant product markets in the sector of retail supply of electricity as national in scope.

(28) According to the information received from the Dutch authorities ([26]), there are around 55 active electricity suppliers in the Netherlands and they are all active at national level.

(29) For the purposes of assessing whether the conditions laid down in Article 34 of Directive 2014/25/EU are fulfilled, and without prejudice to the application of other Union law, the Commission considers that the relevant geographic market for retail supply of electricity to small customers is national in scope.

Retail supply of gas

(30) The Commission has generally defined the markets for retail supply of gas, including possible further subdivisions, as national in scope, provided that these are fully liberalised ([27]).

(31) From the geographical perspective, in its previous practice ([28]), ACM has defined the relevant product markets in the sector of retail supply of gas as national in scope.

(32) According to the information received from the Dutch authorities ([29]), there are 55 active gas suppliers in the Netherlands and all are active at national level.

(33) For the purposes of assessing whether the conditions laid down in Article 34 of Directive 2014/25/EU are fulfilled, and without prejudice to the application of other Union law, the Commission considers that that the relevant geographic market for the retail supply of gas to small customers is national in scope.

3.2.3. *Market analysis*

(34) The Commission has already adopted several decisions ([30]) exempting retail supply of electricity and gas in a number of Member States from the application of public procurement rules. The Commission will base its assessment in particular on the following criteria: number of market participants, combined market share of the largest undertakings, switching rate of final consumers, liquidity of the wholesale markets and price regulation.

3.2.3.1. Number of market players and market shares of the largest undertakings

(35) According to the Dutch authorities ([31]), there are 55 active suppliers at national level on both the electricity retail market and the gas retail market.

([24]) M. 5467 – RWE/Essent, 23.6.2009, paragraph 61.
([25]) ACM decision Case Nuon/Essent, 21.5.2007, paragraph 107.
([26]) Letter of the Dutch authorities to the Commission of 19 June 2017.
([27]) M.5224 – EDF/British Energy, 22.12.2008; COMP/M.4180 – Gaz de France/Suez, 14.11.2006 and COMP/M.3696 – E.ON/MOL, 21.12.2005.
([28]) ACM decision Case 5975 Essent/Westland, of 13.03.2007, para 26.
([29]) Letter of the Dutch authorities of 19 June 2017.
([30]) Commission Implementing Decision (EU) 2016/1674 of 15 September 2016 exempting retail supply of electricity and gas in Germany from the application of Directive 2014/25/EU of the European Parliament and of the Council (OJ L 253, 17.9.2016, p. 6); Commission Decision 2010/403/EC of 14 July 2010 exempting the production and wholesale of electricity in Italy's Macro-zone North and the retail of electricity to end customers connected to the medium, high and very high voltage grid in Italy, from the application of Directive 2004/17/EC of the European Parliament and of the Council coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 186, 20.7.2010, p. 44).
([31]) Letter of the Dutch Authorities of 19 June 2017.

(36) According to the present request ([32]), the total cost of entry into the market for retail supply of electricity and gas is low and does not constitute a barrier to entry.

(37) In previous decisions ([33]), the Commission considered that, concerning the retail supply market, the total market share of the largest three undertakings was relevant. Other measures of concentration could also be considered relevant. A particular feature was that only one market player was subject to the public procurement rules.

Retail supply of electricity to small customers

(38) Nuon is subject to the public procurement rules, while its two biggest competitors, Essent and Eneco are not. According to the information provided by the Dutch authorities ([34]), the market shares of the main suppliers remained fairly stable over the 2017-2020 period: Nuon's market share decreased from 27 % to 25 %, Eneco's market share decreased from 25 % to 22 % and Essent's market share decreased from 27 % to 26 %.

(39) Overall, the consolidated market share of the three largest retailers on the Dutch market for electricity retail supply shrank from 79 % in 2017 to 73 % in 2020.

Retail supply of gas to small customers

(40) According to the information provided by the Dutch authorities ([35]), the market shares of the main suppliers remained fairly stable over the 2017-2020 period: Nuon's market share decreased from 27 % to 25 %, Eneco's market share decreased from 25 % to 22 % and Essent's market share remained unchanged at 27 %.

(41) Overall, the consolidated market share of the three largest retailers on the Dutch market for gas retail supply shrank from 79 % in 2017 to 74 % in 2020.

3.2.3.2. Switching rates of final consumers

(42) The number of customers switching to another supplier (external switching) or to another tariff or contract within the same supplier (internal switching) is considered a relevant indicator of effectiveness of competition. In previous decisions ([36]), the Commission analysed mainly the external switching.

(43) Most small customers in the Netherlands are supplied through dual-fuel contracts which implies that they receive both gas and electricity from one supplier.

(44) The external switching rate for the retail supply of electricity and gas in the Netherlands was increasingly high, from 17 % in 2017 to 21 % in 2020 ([37]).

(45) According to available public information ([38]), the internal switching rates for small customers' accounts for 8 % for electricity and for gas in 2020.

(46) Those switching rates indicate that small customers are willing to switch and that there are valid alternatives to meet their needs related to the electricity and gas supply.

([32]) Section 5.3.3 of the request.
([33]) Letter of the Dutch Authorities of 19 June 2017.
([34]) Letter of the Dutch authorities to the Commission of 11 October 2021.
([35]) ACER Report on the functioning of the gas wholesale market 2020 https://documents.acer.europa.eu/en/Electricity/Market%20monitoring/Documents/MMR%202020%20 Summary%20-%20Final.pdf
([36]) ACER Report on the functioning of the gas wholesale market 2020 https://documents.acer.europa.eu/en/Electricity/Market%20monitoring/Documents/MMR%202020%20 Summary%20-%20Final.pdf
([37]) ACER Annual Report on the Results of Monitoring the Internal Electricity and Gas Markets in 2020- Energy retail markets and consumer protection volume, p. 44.
([38]) ACER Annual Report on the Results of Monitoring the Internal Electricity and Gas Markets in 2020- Energy retail markets and consumer protection volume, p. 45.

3.2.3.3. Liquidity of the wholesale electricity and gas markets

(47) Electricity and gas can be traded on different types of wholesale markets: on power exchanges or multilateral trading platforms and/or in bilateral over-the-counter (OTC) trading. Power exchanges are platforms used by market players to negotiate purchases and sales of electricity. Gas is also traded in liquid gas hubs. These arrangements provide an open market, organise competition and establish a transparent reference price for market participants.

(48) The wholesale market is a market that is directly upstream to the retail market. While some retailers belong to vertically integrated groups, many electricity retailers do not have their own generation assets. These retailers source electricity in the wholesale market with a view to reselling it in the retail market in competition with the vertically integrated retailers. Liquid and well-functioning competitive wholesale markets, where retailers without generation assets can easily source electricity at competitive prices, is therefore a key condition for competitive retail markets where vertically and non-vertically integrated retailers compete on an equal footing. Liquid gas hubs underpin the functioning of the market in many ways and ensure that new entrants can secure access to gas at wholesale level.

(49) The ACM has concluded in its liquidity report ([39]) that the liquidity of the Dutch wholesale electricity market (e.g. higher traded volumes, lower price volatility and smaller bid-ask spread) has increased over the period 2009-2013. Higher volumes and improved liquidity help the wholesale markets function better, and enable market participants to make efficient decisions when buying or selling electricity. In in 2020, the Dutch electricity wholesale market was about 3 times larger than national consumption, compared to 1.5 times in 2015 ([40]).

(50) The Commission considers that the liquidity of the Dutch wholesale electricity market has reached a level that is sufficient so as not to constitute an obstacle to retail supply of electricity to household customers being subject to direct exposure to competition.

(51) The level of competition in the Dutch wholesale gas market is shown in particular by the functioning of the Title Transfer Facility (TTF), the wholesale gas trading hub of the Netherlands. The latest annual ACER report on the functioning of the gas wholesale market ([41]) ('the ACER report') shows that TTF has a high liquidity and that liquidity has increased in recent years ([42]). The report also shows the efficient and transparent pricing setting process at TTF, leading to low bid-ask spreads ([43]).

(52) The ACER Report singles out the Dutch gas wholesale market as a good example ([44]), in the following terms: 'TTF in the Netherlands and NBP in the UK continue to be the two most liquid and competitive trading hubs, accounting for the bulk of forward gas trading activity in the EU.'

(53) Given the above characteristics, the Commission considers that the liquidity of the Dutch wholesale gas market is sufficient to allow new suppliers to enter the market and does not constitute an obstacle to retail supply of gas to small customers being subject to direct exposure to competition.

([39]) ACM, 2014 Liquidity Report, wholesale markets for natural gas and electricity, https://www.acm.nl/en/publications/publication/13483/2014-Liquidity-Report-wholesale-markets-for-natural-gas-and-electricity

([40]) Total volume traded in the Netherlands in 2015 amounted to 175 TWh. This was the sum of 44 TWh (spot) + 61 TWh (futures via the exchange) + 70 TWh (other OTC deals). Total consumption of electricity was 113 TWh. The ratio between total volume traded and total consumption was therefore approximately 1,5 (175TWh/113 TWh). The 2020 data comes from the European Commission's quarterly report on European electricity markets, 4th quarter 2020, p. 20 https://ec.europa.eu/energy/sites/default/files/quarterly_report_on_european_electricity_markets_q4_2020.pdf

([41]) ACER Report on the functioning of the gas wholesale market 2020 https://documents.acer.europa.eu/en/Electricity/Market%20monitoring/Documents/MMR%202020%20Summary%20-%20Final.pdf

([42]) ACER Report on the functioning of the gas wholesale market 2016, p. 24, paragraph 83.

([43]) ACER Report on the functioning of the gas wholesale market 2016, p. 30, paragraph 94.

([44]) ACER Report on the functioning of the gas wholesale market 2016, p. 5, paragraph 5.

3.2.3.4. Price regulation

Retail supply of electricity and gas to small customers

(54) The price of electricity and gas supply to final customers is composed of 1) energy tax, 2) network cost, 3) meter rental, 4) VAT and 5) supply cost ([45]). While the first four elements are regulated, the supply cost is not regulated.

3.2.3.5. Other elements

(55) Nuon is vertically integrated in the electricity sector and is active in the Dutch market for production and wholesale of electricity (16,8 % market share) and in the Dutch market for retail supply of electricity and gas.

(56) Among the operators that are not subject to the public procurement rules, Eneco and Essent are also vertically integrated, with 4,6 % and 13 % market shares in terms of installed capacity in the market for production and wholesale ([46]).

(57) Despite vertical integration in the electricity sector, the market position of Nuon at both the production and wholesale levels do not constitute an obstacle for retail supply of electricity to small customers to be directly exposed to competition. Similarly, given the liquid gas wholesale markets, there are no significant obstacles for the retail supply of gas to household small customers to be directly exposed to competition.

4. **CONCLUSIONS**

(58) As regards the retail supply of electricity to small customers in the Netherlands, the situation can be summarised as follows: the market share of the three largest market players is decreasing; the switching rate is high and increasing; there is no end-user price control and the functioning of the wholesale market does not constitute an obstacle for the retail market for small customers to be exposed to competition.

(59) As regards the retail supply of gas to small customers in the Netherlands, the situation can thus be summarised as follows: the market share of the three largest market players is decreasing; the switching rate is high; there is no end-user price control and the wholesale market liquidity is high.

(60) In view of the factors examined in recitals 34 to 57, the condition of direct exposure to competition laid down in Article 34(1) of Directive 2014/25/EU should be considered to be met in respect of retail supply of electricity and gas to small customers in the Netherlands.

(61) This Decision is based on the legal and factual situation as of January 2017 to October 2021 as it appears from the information submitted by Nuon and by the Dutch authorities. It may be reviewed as a result of significant changes in the legal or factual situation, the conditions for the applicability of Article 34(1) of Directive 2014/25/EU are no longer met.

(62) Since some activities related to retail supply of electricity and gas continue to be subject to Directive 2014/25/EU, it is recalled that procurement contracts covering several activities should be treated in accordance with Article 6 of that Directive. This means that, where a contracting entity is engaged in a 'mixed' procurement, that is procurement used to support the performance of both activities exempted from the application of Directive 2014/25/EU and activities not exempted therefrom, regard must be had to the activities for which the contract is principally intended. In the event of such mixed procurement, where the purpose is principally to support activities which are not exempted, the provisions of Directive 2014/25/EU are to be applied. Where it is objectively impossible to determine for which activity the contract is principally intended, the contract is to be awarded in accordance with the rules referred to in Article 6(3) of Directive 2014/25/EU.

([45]) ACM Reports on market operation and consumer confidence trends in the energy market for second half of 2015, p. 22.

([46]) This market was analysed for the purposes of the exemption request for production and wholesale of electricity in the Netherlands referred in footnote 2.

(63) It is recalled that Article 16 of Directive 2014/23/EU of the European Parliament and of the Council ([47]) on the award of concession contracts provides for an exemption from the application of that Directive for concessions awarded by contracting entities where, for the Member State in which the concessions are to be performed, it has been established pursuant to Article 35 of Directive 2014/25/EU that the activity is directly exposed to competition in accordance with Article 34 of Directive 2014/25/EU. Since it was concluded that the activities of retail supply of electricity and gas to small customers are directly exposed to competition, concession contracts intended to enable the performance of those activities in the Netherlands will be excluded from the scope of application of Directive 2014/23/EU,

HAS ADOPTED THIS DECISION:

Article 1

Directive 2014/25/EU shall not apply to contracts awarded by contracting entities and intended to enable the retail supply of electricity and gas to small customers in the Netherlands.

Article 2

This Decision is addressed to the Kingdom of Netherlands.

Done at Brussels, 15 July 2022.

For the Commission
Thierry BRETON
Member of the Commission

([47]) Directive 2014/23/EU of the European Parliament and of the Council of 26 February 2014 on the award of concession contracts (OJ L 94, 28.3.2014, p. 1).

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

DECISION No 1/2022 OF THE EU-GEORGIA ASSOCIATION COUNCIL

of 8 June 2022

on the granting of reciprocal market access for supplies for central government authorities in accordance with Annex XVI-B to the Association Agreement between the European Union and the European Atomic Energy Community and their Member States, of the one part, and Georgia, of the other part [2022/1287]

THE 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 Georgia, of the other part, and in particular Articles 146 and 406 and Article 419(5) 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 Georgia, of the other part (the 'Agreement') was signed on 27 June 2014 and entered into force on 1 July 2016.

(2) The Preamble to the Agreement recognises the commitment of Georgia to progressively approximating its legislation in the relevant sectors with that of the Union, in accordance with the Agreement and to implementing it effectively, thus contributing to providing the benefits of closer political association and economic integration of Georgia with the Union to all citizens of Georgia including the communities divided by conflict.

(3) In accordance with Article 147 of the Agreement, the Parties to the Agreement agree that the effective and reciprocal opening of their respective markets is to be attained gradually and simultaneously.

(4) Pursuant to Article 146 of the Agreement, Georgia is to ensure that its legislation on public procurement is gradually approximated to the Union's public procurement *acquis*, and that approximation to the Union *acquis* is carried out in consecutive phases as set out in the schedule in Annex XVI-B to the Agreement. In accordance with Decision No 2/2021 of the Association Committee in Trade configuration of 8 October 2021, the Association Committee in Trade configuration has given a positive assessment regarding the completion by Georgia of Phase 1 as set out in Annex XVI-B to the Agreement

(5) In accordance with Article 419(5) of the Agreement, the Association Council, pursuant to the powers conferred to it by Articles 406 and 408 of the Agreement, should decide on further market opening where provided for in Title IV (Trade and Trade-related Matters) of the Agreement,

HAS ADOPTED THIS DECISION:

Article 1

Reciprocal market access is hereby granted for public procurement of supplies by central government authorities in the European Union to Georgia and for public procurement of supplies by Georgian central government authorities to the European Union in the territories specified in Article 429 of the Agreement.

Article 2

This decision has been established in the Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish, Swedish and Georgian languages, each text being equally authentic.

Article 3

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

Done at Brussels, 8 June 2022.

For the Association Council
The President
I. GARIBASHVILI

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