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Contents

II *Non-legislative acts*

INTERNATIONAL AGREEMENTS

- ★ **Information concerning the signing and provisional application of a Protocol to the Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel, of the other part, to take account of the accession of the Republic of Croatia to the European Union** 1

REGULATIONS

- ★ **Commission Implementing Regulation (EU) 2019/423 of 13 March 2019 granting a Union authorisation for the biocidal product family 'Teat disinfectants biocidal product family of Novadan'** 2
- ★ **Commission Regulation (EU) 2019/424 of 15 March 2019 laying down ecodesign requirements for servers and data storage products pursuant to Directive 2009/125/EC of the European Parliament and of the Council and amending Commission Regulation (EU) No 617/2013⁽¹⁾** 46

DECISIONS

- ★ **Council Decision (EU) 2019/425 of 12 March 2019 on the position to be taken on behalf of the European Union within the Joint Committee established by the Agreement between the European Union and the Kingdom of Norway on administrative cooperation, combating fraud and recovery of claims in the field of value added tax** 67
- ★ **Council Decision (EU) 2019/426 of 12 March 2019 appointing a member and two alternate members, proposed by the Kingdom of Belgium, of the Committee of the Regions** 100
- ★ **Council Decision (EU) 2019/427 of 12 March 2019 appointing a member and an alternate member, proposed by the United Kingdom, of the Committee of the Regions** 101

⁽¹⁾ Text with EEA relevance.

EN

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

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

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

Information concerning the signing and provisional application of a Protocol to the Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the State of Israel, of the other part, to take account of the accession of the Republic of Croatia to the European Union

The above mentioned Protocol was signed in Brussels on 20 December 2018.

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2019/423

of 13 March 2019

granting a Union authorisation for the biocidal product family ‘Teat disinfectants biocidal product family of Novadan’

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) thereof,

Whereas:

- (1) On 27 August 2015, SCC GmbH, on behalf of Novadan ApS, submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named ‘Teat disinfectants biocidal product family of Novadan’ (‘the biocidal product family’) of product-type 3, as described in Annex V to that Regulation. The competent authority of Denmark agreed to evaluate the application as referred to in Article 43(1) of Regulation (EU) No 528/2012. The application was recorded under the case number BC-YV019394-00 in the Register for Biocidal Products.
- (2) The biocidal product family contains iodine, including polyvinylpyrrolidone iodine, as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012. Taking into account the intrinsic properties of the active substance, and the scientific criteria for the determination of endocrine-disrupting properties set out in Commission Delegated Regulation (EU) 2017/2100 ⁽²⁾, the Commission will consider the need to review the approval of iodine, including polyvinylpyrrolidone iodine, in accordance with Article 15 of Regulation (EU) No 528/2012. Depending on the outcome of that review, the Commission will then consider whether the Union authorisations for products containing the active substance have to be reviewed in accordance with Article 48 of Regulation (EU) No 528/2012.
- (3) On 11 April 2018, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, the assessment report and the conclusions of its evaluation to the European Chemicals Agency (‘the Agency’).
- (4) On 31 October 2018, the Agency submitted to the Commission an opinion ⁽³⁾, including the draft summary of the biocidal product characteristics (‘SPC’) of the biocidal product family and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012. The opinion concludes that the biocidal product family falls within the definition of ‘biocidal product family’ laid down in Article 3(1)(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, the biocidal product family meets the conditions laid down in Article 19(1) and (6) of that Regulation.
- (5) On 17 January 2019, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (6) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the biocidal product family.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1).

⁽³⁾ ECHA opinion of 6 July 2018 on the Union authorisation of ‘Teat disinfectants biocidal product family of Novadan’ (ECHA/BPC/215/2018).

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

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation is granted to Novadan ApS for the biocidal product family 'Teat disinfectants biocidal product family of Novadan' with authorisation number EU-0019757-0000.

The Union authorisation is valid from 7 April 2019 until 31 March 2029.

The Union authorisation is subject to compliance with the summary of the biocidal product characteristics set out in the Annex.

Article 2

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

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

Done at Brussels, 13 March 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Summary of product characteristics for a biocidal product family

Teat disinfectants biocidal product family of Novadan

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0019757-0000

R4BP asset number: EU-0019757-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	Teat disinfectants biocidal product family of Novadan
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1.2. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)
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1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	Novadan ApS
	Address	Platinvej 21, 6000 Kolding, Denmark
Authorisation number	EU-0019757-0000	
R4BP asset number	EU-0019757-0000	
Date of the authorisation	7 April 2019	
Expiry date of the authorisation	31 March 2029	

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

Name of manufacturer	Novadan ApS
Address of manufacturer	Platinvej 21, 6000 Kolding Denmark
Location of manufacturing sites	Platinvej 21, 6000 Kolding Denmark

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

Active substance	Polyvinylpyrrolidone iodine
Name of manufacturer	Marcus Research Laboratory, Inc.
Address of manufacturer	Delmar Blvd., 63103-1789 Saint Louis, Missouri United States
Location of manufacturing sites	Delmar Blvd., 63103-1789 Saint Louis, Missouri United States

Active substance	Iodine
Name of manufacturer	Cosayach Nitratos S.A.
Address of manufacturer	Hnos Amunátegui 178, 8320000 Santiago Chile
Location of manufacturing sites	S.C.M. Cosayach Cala Cala, 1180000 Pozo Almonte Chile
Active substance	Iodine
Name of manufacturer	ACF Minera S.A.
Address of manufacturer	San Martin No 499, 11 00000 Iquique Chile
Location of manufacturing sites	Lagunas mine, 1180000 Pozo Almonte Chile
Active substance	Iodine
Name of manufacturer	Sociedad Química y Minera (SQM) S.A.
Address of manufacturer	Los Militares 4290, Piso 4, Las Condes, 8320000 Santiago Chile
Location of manufacturing sites	Nueva Victoria plant, 5090000 Pedro de Valdivia plant Chile

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
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,714	3,57
Iodine		Active Substance	7553-56-2	231-442-4	0,15	0,75

2.2. Type(s) of formulation

Formulation(s)	SL — Soluble concentrate AL — Any other liquid EW — Emulsion, oil in water
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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
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1.2. **Suffix to the authorisation number**

Number	1-1
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1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)
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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
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		3,57	3,57
Iodine		Active Substance	7553-56-2	231-442-4	0,75	0,75

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

Formulation(s)	SL — Soluble concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	May be corrosive to metals. Harmful to aquatic life with long lasting effects. Safety data sheet available on request.
Precautionary statements	Keep out of reach of children. Keep only in original packaging. Avoid release to the environment. Absorb spillage to prevent material damage. Dispose of contents in accordance with local/regional/national/international regulation. Dispose of container in accordance with local/regional/national/international regulation.

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

4.1. **Use description****Table 1. Use # 1: Post-milking manual dipping (concentrate)**

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast

Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual dipping (concentrate) Fill the reservoir with the diluted concentrate and screw the dip cup on top. Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking. After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that the full length of the teat is immersed into the disinfectant. Top up with fresh disinfectant by squeezing the reservoir as needed. After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.
Application rate(s) and frequency	Dilution: 20 % Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2. Use description

Table 2. Use # 2 – Post-milking, manual spraying, trigger sprayer (concentrate)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual spraying, trigger sprayer (concentrate) Fill the reservoir with the diluted concentrate and screw the top of the trigger sprayer on it. Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking. After milking, spray the disinfectant on the teats using the trigger sprayer making sure that each teat is covered with the disinfectant. Top up the reservoir with fresh disinfectant as needed. After disinfection, empty the reservoir and clean reservoir and sprayer by rinsing with water.
Application rate(s) and frequency	Dilution: 20 % Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.2.1. Use-specific instructions for use

See general directions for use.

4.2.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) when applying the product by manual spraying.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.3. Use description

Table 3. Use # 3 – Post-milking manual spraying using an electronic sprayer (concentrate)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual spraying, electronic sprayer (concentrate) Open a can containing the diluted concentrate and insert the suction tube of the electronic sprayer. Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking. After milking, spray the disinfectant on the teats using the electronic sprayer making sure that each teat is covered with the disinfectant. Replace the empty can by a new can as needed. After disinfection, put the suction tube system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.
Application rate(s) and frequency	Dilution: 20 % Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.3.1. Use-specific instructions for use

See general directions for use.

4.3.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves (glove material to be specified by the authorisation holder within the product information) when applying the product by manual spraying.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.4. Use description

Table 4. Use # 4 – Post-milking automated dipping (concentrate)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Automated dipping (concentrate) Open a can containing the diluted concentrate and insert the suction tube of the automated dipping-system. Before milking clean teats carefully by automatic procedure or manually. After milking, the vacuum is shut off and the teat dip is injected into a manifold on the claw piece. The teats are coated with 2-4 ml of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air. In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air. Afterwards, the milking system is ready for the next milking event. The whole process is automated.
Application rate(s) and frequency	Dilution: 20 % Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.4.1. Use-specific instructions for use

See general directions for use.

4.4.2. Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.5. Use description

Table 5. Use # 5 – Post-milking automated spraying by robot (concentrate)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Automated spraying by robot (concentrate) Open a can containing the diluted concentrate and insert the suction tube of the robotic milking device. The teats are cleaned by robot with automatic brushes. After robotic milking, 2-4 ml of the disinfectant is sprayed automatically onto teats from a cluster arm. Rinsing of the sprayer is automatic.
Application rate(s) and frequency	Dilution: 20 % Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.5.1. Use-specific instructions for use

See general directions for use.

4.5.2. Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ⁽¹⁾ OF THE META SPC 1

5.1. **Instructions for use**

Dilute the concentrated product by decanting or pumping. Fill the reservoir with the diluted concentrate and screw the dip cup on top. The concentrate is to be diluted 1:4. The concentrated products in meta-SPC 1 contain 0,89 % total iodine and are diluted 1:4 to an in-use solution containing 0,178 % total iodine. This corresponds to a 20 % (w/w) dilution.

The use of a dosing pump for filling the product into the application equipment is recommended.

The products must be brought to temperatures above 20 °C before use.

To ensure sufficient contact time, care should be taken that the product is not removed after application. Leave the product on the teats and keep the animals standing for at least five minutes after treatment for post-milking disinfection.

5.2. **Risk mitigation measures**

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

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

Description of first aid measures

General: Remove affected person from source of contamination.

After inhalation: Remove person to fresh air and keep comfortable for breathing. Get medical attention if any discomfort continues.

After skin contact: Rinse with water. Remove contaminated clothing and shoes. Seek medical advice if any skin reaction/or discomfort occurs.

After eye contact: Immediately rinse with water (at least 15 minutes). Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if any discomfort continues.

After ingestion: Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities. Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.

If medical advice is needed, have product container or label at hand.

Environmental emergency measures

Prevent run-off from entering drains, sewers or waterways

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air)

Dike to collect larger liquid spills

Contain and/or absorb spill with inert material, then place in closed and suitable container for disposal according to regulations

Do not place spilled materials back into the original container

⁽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.

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

Method of disposal: Dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

Empty containers are rinsed with plenty of water and disposed to normal or commercial waste.

The paper towels used for the cleaning of teats are disposed in the normal rubbish.

Product classified as hazardous waste: No

Packaging classified as hazardous waste: No

EWC waste code: EWC: 0706 wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics

Other information: When handling waste, consideration should be made to the safety precautions applying to handling of the product. Waste code applies to product remnants in pure form.

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

Mentioned in the SDS: Keep in original container. Store the product away from direct sunlight in opaque containers. Keep separate from food, feedstuffs, fertilisers and other sensitive material. Store above freezing.

Storage temperature: 0 – 30 °C

Shelf-life: 24 months.

6. OTHER INFORMATION

pH range of meta-SPC 1: 4-5

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)	Nova Dip IO Dip Udder Des 1:4 Jod Ewodip Jodopax vet Fova Dip 1:4 Tehotippi				
Authorisation number	EU-0019757-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		3,57
Iodine		Active Substance	7553-56-2	231-442-4	0,75

META SPC 2**1. META SPC 2 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 2 identifier**

Identifier	meta-SPC 2
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1.2. **Suffix to the authorisation number**

Number	1-2
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1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)
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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
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,0	1,42
Iodine		Active Substance	7553-56-2	231-442-4	0,21	0,298

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

Formulation(s)	AL — Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	Harmful to aquatic life with long lasting effects. Safety data sheet available on request.
Precautionary statements	Keep out of reach of children. Avoid release to the environment. Dispose of contents in accordance with local/regional/national/international regulation. Dispose of container in accordance with local/regional/national/international regulation.

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

4.1. **Use description****Table 6. Use # 1 – Post-milking manual dipping (RTU)**

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.

Application method(s)	Manual dipping (RTU) Fill the reservoir with the RTU product and screw the dip cup on top. Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking. After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that the full length of the teat is immersed into the disinfectant. Top up with fresh disinfectant by squeezing the reservoir as needed. After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2. **Use description**

Table 7. Use # 2 – Post-milking automated dipping (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.

Application method(s)	Automated dipping (RTU) Open a can containing the RTU product and insert the suction tube of the automated dipping-system. Before milking clean teats carefully by automatic procedure or manually. After milking, the vacuum is shut off and the teat dip is injected into a manifold on the claw piece. The teats are coated with 2-4 ml of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air. In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air. Afterwards, the milking system is ready for the next milking event. The whole process is automated.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.2.1. *Use-specific instructions for use*

See general directions for use.

4.2.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

5.1. **Instructions for use**

The products must be brought to temperatures above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

To ensure sufficient contact time, care should be taken that the product is not removed after application. Leave the product on the teats and keep the animals standing for at least five minutes after treatment for post-milking disinfection.

⁽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.

5.2. Risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

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

General: Remove affected person from source of contamination.

After inhalation: Remove person to fresh air and keep comfortable for breathing. Get medical attention if any discomfort continues.

After skin contact: Rinse with water. Remove contaminated clothing and shoes. Seek medical advice if any skin reaction/or discomfort occurs.

After eye contact: Immediately rinse with water (at least 15 minutes). Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if any discomfort continues.

After ingestion: Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities. Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.

If medical advice is needed, have product container or label at hand.

Environmental emergency measures

Prevent run-off from entering drains, sewers or waterways

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air)

Dike to collect larger liquid spills

Contain and/or absorb spill with inert material, then place in closed and suitable container for disposal according to regulations

Do not place spilled materials back into the original container

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

Method of disposal: Dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

Empty containers are rinsed with plenty of water and disposed to normal or commercial waste.

The paper towels used for the cleaning of teats are disposed in the normal rubbish.

Product classified as hazardous waste: No

Packaging classified as hazardous waste: No

EWC waste code: EWC: 0706 wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics

Other information: When handling waste, consideration should be made to the safety precautions applying to handling of the product. Waste code applies to product remnants in pure form.

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

Mentioned in the SDS: Keep in original container. Store the product away from direct sunlight in opaque containers. Keep separate from food, feedstuffs, fertilisers and other sensitive material. Store above freezing.

Storage temperature: 0 – 30 °C

Shelf-life: 24 months.

6. OTHER INFORMATION

pH range of meta-SPC 2: 4-5

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)	Jopo Film IO Super Dip Barrera Dip				
Authorisation number	EU-0019757-0002 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,42
Iodine		Active Substance	7553-56-2	231-442-4	0,298

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

Identifier	meta-SPC 3
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1.2. Suffix to the authorisation number

Number	1-3
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1.3. Product type(s)

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)
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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
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,82	0,99
Iodine		Active Substance	7553-56-2	231-442-4	0,172	0,208

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

Formulation(s)	AL — Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	Safety data sheet available on request.
Precautionary statements	Keep out of reach of children.

4. AUTHORISED USE(S) OF THE META SPC 3

4.1. Use description

Table 8. Use # 1 – Post-milking manual dipping (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual dipping (RTU) Fill the reservoir with the RTU product and screw the dip cup on top. Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking. After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that the full length of the teat is immersed into the disinfectant. Top up with fresh disinfectant by squeezing the reservoir as needed. After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment Post-milking application 1-3 times per day (apply after every milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.1.1. Use-specific instructions for use

See general directions for use

4.1.2. Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2. **Use description**

Table 9. Use # 2 – Post-milking automated dipping (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Automated dipping (RTU) Open a can containing the RTU product and insert the suction tube of the automated dipping-system. Before milking clean teats carefully by automatic procedure or manually. After milking, the vacuum is shut off and the teat dip is injected into a manifold on the claw piece. The teats are coated with 2-4 ml of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air. In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air. Afterwards, the milking system is ready for the next milking event. The whole process is automated.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment Post-milking application 1-3 times per day (apply after every milking)
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.2.1. *Use-specific instructions for use*

See general directions for use

4.2.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ⁽³⁾ OF THE META SPC 3

5.1. **Instructions for use**

Fill the reservoir with the RTU product and screw the dip cup on top.

The products must be brought to temperatures above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended

To ensure sufficient contact time, care should be taken that the product is not removed after application. Leave the product on the teats and keep the animals standing for at least five minutes after treatment for post-milking disinfection.

5.2. **Risk mitigation measures**

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

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

Description of first aid measures

General: Remove affected person from source of contamination.

After inhalation: Remove person to fresh air and keep comfortable for breathing. Get medical attention if any discomfort continues.

After skin contact: Rinse with water. Remove contaminated clothing and shoes. Seek medical advice if any skin reaction/or discomfort occurs.

After eye contact: Immediately rinse with water (at least 15 minutes). Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if any discomfort continues.

After ingestion: Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities. Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.

If medical advice is needed, have product container or label at hand.

Environmental emergency measures

Prevent run-off from entering drains, sewers or waterways

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air)

Dike to collect larger liquid spills

Contain and/or absorb spill with inert material, then place in closed and suitable container for disposal according to regulations

Do not place spilled materials back into the original container

⁽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.

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

Method of disposal: Dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

Empty containers are rinsed with plenty of water and disposed to normal or commercial waste.

The paper towels used for the cleaning of teats are disposed in the normal rubbish.

Product classified as hazardous waste: No

Packaging classified as hazardous waste: No

EWC waste code: EWC: 0706 wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics

Other information: When handling waste, consideration should be made to the safety precautions applying to handling of the product. Waste code applies to product remnants in pure form.

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

Mentioned in the SDS: Keep in original container. Store the product away from direct sunlight in opaque containers. Keep separate from food, feedstuffs, fertilisers and other sensitive material. Store above freezing.

Storage temperature: 0 – 30 °C

Shelf-life: 18 months.

6. OTHER INFORMATION

pH range of meta-SPC 3: 4-5

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)	Nova Dip Barriere IO Multi Dip				
Authorisation number	EU-0019757-0003 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,82
Iodine		Active Substance	7553-56-2	231-442-4	0,172

META SPC 4**1. META SPC 4 ADMINISTRATIVE INFORMATION****1.1. Meta SPC 4 identifier**

Identifier	meta-SPC 4
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1.2. Suffix to the authorisation number

Number	1-4
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1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)
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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
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,714	0,99
Iodine		Active Substance	7553-56-2	231-442-4	0,15	0,208

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

Formulation(s)	AL — Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Hazard statements	Safety data sheet available on request.
Precautionary statements	Keep out of reach of children.

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

4.1. **Use description****Table 10. Use # 1 – Post-milking manual dipping (RTU)**

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual dipping (RTU) Fill the reservoir with the RTU product and screw the dip cup on top. Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking. After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that the full length of the teat is immersed into the disinfectant. Top up with fresh disinfectant by squeezing the reservoir as needed. After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.

Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2. **Use description**

Table 11. Use # 2 – Post-milking, manual spraying, trigger sprayer (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual spraying, trigger sprayer (RTU) Fill the reservoir with the RTU product and screw the top of the trigger sprayer on it. Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking. After milking, spray the disinfectant on the teats using the trigger sprayer making sure that each teat is covered with the disinfectant. Top up the reservoir with fresh disinfectant as needed. After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.

Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.2.1. *Use-specific instructions for use*

See general directions for use.

4.2.2. *Use-specific risk mitigation measures*

Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information).

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.3. **Use description**

Table 12. Use # 3 – Post-milking manual spraying using an electronic sprayer (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual spraying, electronic sprayer (RTU) Open a can containing the RTU product and insert the suction tube of the electronic sprayer. Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking. After milking, spray the disinfectant on the teats using the electronic sprayer making sure that each teat is covered with the disinfectant. Replace the empty can by a new can as needed. After disinfection, put the suction tube system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.

Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0.5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.3.1. *Use-specific instructions for use*

See general directions for use.

4.3.2. *Use-specific risk mitigation measures*

Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information).

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.4. **Use description**

Table 13. Use # 4 – Post-milking automated dipping (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.

Application method(s)	Automated dipping (RTU) Open a can containing the RTU product and insert the suction tube of the automated dipping-system. Before milking clean teats carefully by automatic procedure or manually. After milking, the vacuum is shut off and the teat dip is injected into a manifold on the claw piece. The teats are coated with 2-4 ml of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air. In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air. Afterwards, the milking system is ready for the next milking event. The whole process is automated.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.4.1. Use-specific instructions for use

See general directions for use.

4.4.2. Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.5. Use description

Table 14. Use # 5 – Post-milking automated spraying by robot (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—

Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Automated spraying by robot (RTU) Open a can containing the RTU product and insert the suction tube of the robotic milking device. The teats are cleaned by robot with automatic brushes. After robotic milking, 2-4 ml of the disinfectant is sprayed automatically onto teats from a cluster arm. Rinsing of the sprayer is automatic.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.5.1. Use-specific instructions for use

See general directions for use.

4.5.2. Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

5. GENERAL DIRECTIONS FOR USE ⁽⁴⁾ OF THE META SPC 4

5.1. Instructions for use

Fill the reservoir with the RTU product and screw the dip cup on top.

The products must be brought to temperatures above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

To ensure sufficient contact time, care should be taken that the product is not removed after application. Leave the product on the teats and keep the animals standing for at least five minutes after treatment for post-milking disinfection.

⁽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.

5.2. Risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

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

General: Remove affected person from source of contamination.

After inhalation: Remove person to fresh air and keep comfortable for breathing. Get medical attention if any discomfort continues.

After skin contact: Rinse with water. Remove contaminated clothing and shoes. Seek medical advice if any skin reaction/or discomfort occurs.

After eye contact: Immediately rinse with water (at least 15 minutes). Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if any discomfort continues.

After ingestion: Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities. Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.

If medical advice is needed, have product container or label at hand.

Environmental emergency measures

Prevent run-off from entering drains, sewers or waterways

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air)

Dike to collect larger liquid spills

Contain and/or absorb spill with inert material, then place in closed and suitable container for disposal according to regulations

Do not place spilled materials back into the original container

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

Method of disposal: Dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

Empty containers are rinsed with plenty of water and disposed to normal or commercial waste.

The paper towels used for the cleaning of teats are disposed in the normal rubbish.

Product classified as hazardous waste: No

Packaging classified as hazardous waste: No

EWC waste code: EWC: 0706 wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics

Other information: When handling waste, consideration should be made to the safety precautions applying to handling of the product. Waste code applies to product remnants in pure form.

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

Mentioned in the SDS: Keep in original container. Store the product away from direct sunlight in opaque containers. Keep separate from food, feedstuffs, fertilisers and other sensitive material. Store above freezing.

Storage temperature: 0 – 30 °C

Shelf-life: 24 months.

6. OTHER INFORMATION

pH range of meta-SPC 4: 4-5

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)	Jopo Spray IO Spray Barrera Spray Agro Teat Spray Nova Dip Ready for Use				
Authorisation number	EU-0019757-0004 1-4				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		0,714
Iodine		Active Substance	7553-56-2	231-442-4	0,15

META SPC 5

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 5 identifier

Identifier	meta-SPC 5
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1.2. Suffix to the authorisation number

Number	1-5
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1.3. Product type(s)

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)
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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
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,0	1,46
Iodine		Active Substance	7553-56-2	231-442-4	0,21	0,307

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

Formulation(s)	AL — Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

Hazard statements	Harmful to aquatic life with long lasting effects. Safety data sheet available on request.
Precautionary statements	Keep out of reach of children. Avoid release to the environment. Dispose of contents in accordance with local/regional/national/international regulation. Dispose of container in accordance with local/regional/national/international regulation.

4. AUTHORISED USE(S) OF THE META SPC 5

4.1. **Use description****Table 15. Use # 1 – Post-milking manual dipping (RTU)**

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual dipping (RTU) Fill the reservoir with the RTU product and screw the dip cup on top. Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking. After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that the full length of the teat is immersed into the disinfectant. Top up with fresh disinfectant by squeezing the reservoir as needed.. After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2. **Use description**

Table 16. Use # 2 – Post-milking, manual spraying, trigger sprayer (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual spraying, trigger sprayer (RTU) Fill the reservoir with the RTU product and screw the top of the trigger sprayer on it. Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking. After milking, spray the disinfectant on the teats using the trigger sprayer making sure that each teat is covered with the disinfectant. Top up the reservoir with fresh disinfectant as needed. After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.2.1. *Use-specific instructions for use*

See general directions for use.

4.2.2. *Use-specific risk mitigation measures*

Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information).

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.3. **Use description**

Table 17. Use # 3 – Post-milking manual spraying using an electronic sprayer (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual spraying, electronic sprayer (RTU) Open a can containing the RTU product and insert the suction tube of the electronic sprayer. Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking. After milking, spray the disinfectant on the teats using the electronic sprayer making sure that each teat is covered with the disinfectant. Replace the empty can by a new can as needed. After disinfection, put the suction tube system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.3.1. *Use-specific instructions for use*

See general directions for use.

4.3.2. *Use-specific risk mitigation measures*

Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information).

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.4. **Use description**

Table 18. Use # 4 – Post-milking automated dipping (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Automated dipping (RTU) Open a can containing the RTU product and insert the suction tube of the automated dipping-system. Before milking clean teats carefully by automatic procedure or manually. After milking, the vacuum is shut off and the teat dip is injected into a manifold on the claw piece. The teats are coated with 2-4 ml of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air. In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air. Afterwards, the milking system is ready for the next milking event. The whole process is automated.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0.5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.4.1. *Use-specific instructions for use*

See general directions for use.

4.4.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.5. **Use description**

Table 19. Use # 5 – Post-milking automated spraying by robot (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Automated spraying by robot (RTU) Open a can containing the RTU product and insert the suction tube of the robotic milking device. The teats are cleaned by robot with automatic brushes. After robotic milking, 2-4 ml of the disinfectant is sprayed automatically onto teats from a cluster arm. Rinsing of the sprayer is automatic.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0.5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.5.1. *Use-specific instructions for use*

See general directions for use.

4.5.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

5.1. **Instructions for use**

Fill the reservoir with the RTU product and screw the dip cup on top.

The products must be brought to temperatures above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

To ensure sufficient contact time, care should be taken that the product is not removed after application. Leave the product on the teats and keep the animals standing for at least five minutes after treatment for post-milking disinfection.

5.2. **Risk mitigation measures**

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

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

Description of first aid measures

General: Remove affected person from source of contamination.

After inhalation: Remove person to fresh air and keep comfortable for breathing. Get medical attention if any discomfort continues.

After skin contact: Rinse with water. Remove contaminated clothing and shoes. Seek medical advice if any skin reaction/or discomfort occurs.

After eye contact: Immediately rinse with water (at least 15 minutes). Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if any discomfort continues.

After ingestion: Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities. Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.

If medical advice is needed, have product container or label at hand.

Environmental emergency measures

Prevent run-off from entering drains, sewers or waterways

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air)

⁽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 5.

Dike to collect larger liquid spills

Contain and/or absorb spill with inert material, then place in closed and suitable container for disposal according to regulations

Do not place spilled materials back into the original container

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

Method of disposal: Dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

Empty containers are rinsed with plenty of water and disposed to normal or commercial waste.

The paper towels used for the cleaning of teats are disposed in the normal rubbish.

Product classified as hazardous waste: No

Packaging classified as hazardous waste: No

EWC waste code: EWC: 0706 wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics

Other information: When handling waste, consideration should be made to the safety precautions applying to handling of the product. Waste code applies to product remnants in pure form.

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

Mentioned in the SDS: Keep in original container. Store the product away from direct sunlight in opaque containers. Keep separate from food, feedstuffs, fertilisers and other sensitive material. Store above freezing.

Storage temperature: 0 – 30 °C

Shelf-life: 24 months.

6. OTHER INFORMATION

pH range of meta-SPC 5: 4-5

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)	Nova Dip Spray 3000 IO Spray Plus PV-Plus 3000 Tehotippi Soft Plus F 6 Robo V				
Authorisation number	EU-0019757-0005 1-5				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,46
Iodine		Active Substance	7553-56-2	231-442-4	0,307

META SPC 6

1. META SPC 6 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 6 identifier**

Identifier	meta-SPC 6
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1.2. **Suffix to the authorisation number**

Number	1-6
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1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)
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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
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,0	1,43
Iodine		Active Substance	7553-56-2	231-442-4	0,21	0,3

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

Formulation(s)	EW — Emulsion, oil in water
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

Hazard statements	Harmful to aquatic life with long lasting effects. Safety data sheet available on request.
Precautionary statements	Keep out of reach of children. Avoid release to the environment. Dispose of contents in accordance with local/regional/national/international regulation. Dispose of container in accordance with local/regional/national/international regulation.

4. AUTHORISED USE(S) OF THE META SPC 6

4.1. **Use description****Table 20. Use # 1 – Post-milking manual dipping (RTU)**

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—

Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual dipping (RTU) Fill the reservoir with the RTU product and screw the dip cup on top. Clean the teats carefully by wiping with a single service paper towel/cloth immediately before milking. After milking, squeeze the reservoir and put the dip cup over each teat from below making sure that the full length of the teat is immersed into the disinfectant. Top up with fresh disinfectant by squeezing the reservoir as needed. After disinfection, empty the reservoir and clean reservoir and dip cup by rinsing with water.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.2. **Use description**

Table 21. Use # 2 – Post-milking, manual spraying, trigger sprayer (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast

Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual spraying, trigger sprayer (RTU) Fill the reservoir with the RTU product and screw the top of the trigger sprayer on it. Clean carefully the teats by wiping with a single service paper towel/cloth before milking. After milking, spray the disinfectant on the teats using the trigger sprayer making sure that each teat is covered with the disinfectant. Top up the reservoir with fresh disinfectant as needed. After disinfection, empty the reservoir and clean reservoir and trigger sprayer by rinsing with water.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.2.1. Use-specific instructions for use

See general directions for use.

4.2.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information).

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.3. Use description

Table 22. Use # 3 – Post-milking manual spraying using an electronic sprayer (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast

Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Manual spraying, electronic sprayer (RTU) Open a can containing the RTU product and insert the suction tube of the electronic sprayer. Clean carefully the teats by wiping with a single service paper towel/cloth before milking. After milking, spray the disinfectant on the teats using the electronic sprayer making sure that each teat is covered with the disinfectant. Replace the empty can by a new can as needed. After disinfection, put the suction tube system into a bucket of water and rinse the sprayer by pumping the water through the sprayer.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.3.1. Use-specific instructions for use

See general directions for use.

4.3.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves when applying the product by manual spraying (glove material to be specified by the authorisation holder within the product information).

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.4. Use description

Table 23. Use # 4 – Post-milking automated dipping (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast

Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Automated dipping (RTU) Open a can containing the RTU product and insert the suction tube of the automated dipping-system. Before milking clean teats carefully by automatic procedure or manually. After milking, the vacuum is shut off and the teat dip is injected into a manifold on the claw piece. The teats are coated with 2-4 ml of dip when the teat cup is withdrawn by the Automatic Cluster Removal (ACR). After the removal of the ACR, every liner of the automated dipping-system is thoroughly rinsed with water and blown out with compressed air. In a final cleaning step after each milking session of the herd, the liners are disinfected (e.g. with a chlorine-based product) and blown out again with compressed air. Afterwards, the milking system is ready for the next milking event. The whole process is automated.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.4.1. Use-specific instructions for use

See general directions for use.

4.4.2. Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

4.5. Use description

Table 24. Use # 5 – Post-milking automated spraying by robot (RTU)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast
Field(s) of use	Indoor DISINFECTION FOR VETERINARY HYGIENE: Teat disinfection product for milkable animals (cows, buffaloes, sheep, goats) for use after milking.
Application method(s)	Automated spraying by robot (RTU) Open a can containing the RTU product and insert the suction tube of the robotic milking device. The teats are cleaned by robot with automatic brushes. After robotic milking, 2-4 ml of the disinfectant is sprayed automatically onto teats from a cluster arm. Rinsing of the sprayer is automatic.
Application rate(s) and frequency	Cows and buffaloes: 4 ml/animal per treatment; sheep: 2 ml/animal per treatment; goats: 3 ml/animal per treatment. Post-milking application 1-3 times per day (apply after every milking).
Category(ies) of users	Professional
Pack sizes and packaging material	Jerry can, HDPE: 0,5 L, 5 L, 10 L, 20 L, 60 L Plastic drum, HDPE: 200 L IBC, HDPE: 1 000 L Opaque containers.

4.5.1. Use-specific instructions for use

See general directions for use.

4.5.2. Use-specific risk mitigation measures

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

See general directions for use.

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

5.1. Instructions for use

Fill the reservoir with the RTU product and screw the dip cup on top.

⁽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.

The products must be brought to temperatures above 20 °C before use.

The use of a dosing pump for filling the product into the application equipment is recommended.

To ensure sufficient contact time, care should be taken that the product is not removed after application. Leave the product on the teats and keep the animals standing for at least five minutes after treatment for post-milking disinfection.

5.2. Risk mitigation measures

In case a combination of pre- and post-milking disinfection is necessary, using another product not containing iodine has to be considered for pre-milking disinfection.

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

Description of first aid measures

General: Remove affected person from source of contamination.

After inhalation: Remove person to fresh air and keep comfortable for breathing. Get medical attention if any discomfort continues.

After skin contact: Rinse with water. Remove contaminated clothing and shoes. Seek medical advice if any skin reaction/or discomfort occurs.

After eye contact: Immediately rinse with water (at least 15 minutes). Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if any discomfort continues.

After ingestion: Contact poison treatment specialist immediately if symptoms occur and/or in case of mouth contact with large quantities. Do not give fluids or induce vomiting in case of impaired consciousness; place in recovery position and seek medical advice immediately.

If medical advice is needed, have product container or label at hand.

Environmental emergency measures

Prevent run-off from entering drains, sewers or waterways

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air)

Dike to collect larger liquid spills

Contain and/or absorb spill with inert material, then place in closed and suitable container for disposal according to regulations

Do not place spilled materials back into the original container

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

Method of disposal: Dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to the municipal sewer or disposed to the manure deposit depending on local requirements. Avoid release to an individual waste water treatment plant.

Empty containers are rinsed with plenty of water and disposed to normal or commercial waste.

The paper towels used for the cleaning of teats are disposed in the normal rubbish.

Product classified as hazardous waste: No

Packaging classified as hazardous waste: No

EWC waste code: EWC: 0706 wastes from the MFSU of fats, grease, soaps, detergents, disinfectants and cosmetics

Other information: When handling waste, consideration should be made to the safety precautions applying to handling of the product. Waste code applies to product remnants in pure form.

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

Mentioned in the SDS: Keep in original container. Store the product away from direct sunlight in opaque containers. Keep separate from food, feedstuffs, fertilisers and other sensitive material. Store above freezing.

Storage temperature: 0 – 30 °C

Shelf-life: 24 months.

6. OTHER INFORMATION

pH range of meta-SPC 6: 4-5

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)	Jopo Winterspray IO Winterspray Jodopax RTU Barrera W				
Authorisation number	EU-0019757-0006 1-6				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Polyvinylpyrrolidone iodine		Active Substance	25655-41-8		1,43
Iodine		Active Substance	7553-56-2	231-442-4	0,3

COMMISSION REGULATION (EU) 2019/424**of 15 March 2019****laying down ecodesign requirements for servers and data storage products pursuant to Directive 2009/125/EC of the European Parliament and of the Council and amending Commission Regulation (EU) No 617/2013****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products ⁽¹⁾, and in particular Article 15(1) thereof,

After consulting the Consultation Forum referred to in Article 18 of Directive 2009/125/EC,

Whereas:

- (1) Directive 2009/125/EC requires the Commission to set ecodesign requirements for energy-related products that represent significant volumes of sales and trade, that have a significant environmental impact and that present significant potential for improvement in terms of their environmental impact without entailing excessive costs.
- (2) The Commission has carried out a preparatory study to analyse the technical, environmental and economic aspects of servers and data storage products typically used for commercial purposes. The study has been carried out with stakeholders and interested parties from the Union and third countries, and the results have been made publicly available.
- (3) Servers and data storage products are typically placed on the market for use in data centres, office and corporate environments.
- (4) The environmental aspects of servers and data storage products that have been identified as significant for the purposes of this Regulation are energy consumption in the use phase and resource efficiency, in particular on the aspects related to reparability, reusability, upgradeability and recyclability for security of supply.
- (5) Ecodesign requirements should harmonise energy consumption and resource efficiency requirements for servers and data storage products throughout the Union, for the internal market to operate better and in order to improve the environmental performance of those products.
- (6) The annual energy consumption related to servers directly is expected to be 48 TWh in 2030, which increases to 75 TWh when the annual energy consumption related to infrastructure (e.g. cooling systems and uninterruptible power supply systems) is also included. The annual energy consumption of data storage products is expected to be 30 TWh in 2030, 47 TWh when infrastructure is also included. The preparatory study shows that use-phase energy consumption by servers and data storage products can be significantly reduced.
- (7) The effect of the ecodesign requirements set out in this Regulation is estimated to result by 2030 in annual energy savings of approximately 9 TWh (approximately the yearly electricity consumption of Estonia in 2014). More in detail, the effect of the ecodesign requirements for servers set out in this Regulation is estimated to result by 2030 in direct annual energy savings of approximately 2,4 TWh and indirect (i.e. related to infrastructure) annual energy savings of 3,7 TWh, summing up to a total saving of 6,1 TWh, corresponding to a total of 2,1 Mt of CO₂ equivalent. The effect of the ecodesign requirements for data storage products set out in this Regulation is estimated to result by 2030 in direct annual energy savings of approximately 0,8 TWh and indirect (i.e. related to infrastructure) annual energy savings of 2 TWh, summing up to a total saving of 2,8 TWh, corresponding to 0,9 Mt of CO₂ equivalent.

⁽¹⁾ OJ L 285, 31.10.2009, p. 10.

- (8) In accordance with the Union action plan for the Circular Economy ⁽²⁾ the Commission should make sure that special emphasis is placed on aspects relevant to the circular economy, such as durability and reparability, when setting out or revising ecodesign criteria. Therefore requirements should be laid down on non-energy related aspects, including extraction of key-components and of critical raw materials (CRMs), availability of functionality for secure data deletion and provision of latest available version of firmware.
- (9) The requirement on the extraction of key-components is expected to foster the reparability and upgradability of servers and data storage products, in particular by third parties (such as spare parts repairers and maintenance).
- (10) The possibility to address CRMs in Ecodesign regulations (including for enterprise servers) has been mentioned in the recent Commission Staff Working Document 'Report on Critical Raw Materials and the Circular Economy' ⁽³⁾.
- (11) The requirement on a functionality for secure data deletion could be implemented by means of technical solutions such as, but not limited to, a functionality implemented in firmware, typically in the Basic Input/Output System (BIOS), in software included in a self-contained bootable environment provided in a bootable compact disc, digital versatile disc or universal serial bus memory storage device included with the product, or in software installable in the supported operating systems provided with the product.
- (12) The requirements on non-energy related aspects are expected to contribute prolonging the lifetime of servers by making it easier to refurbish and reuse them, while maintaining compliance with the principles of privacy and protection of personal data as set by Regulation (EU) 2016/679 of the European Parliament and of the Council ⁽⁴⁾.
- (13) The energy consumption of servers and data storage products could be reduced by applying existing non-proprietary technologies without an increase in the combined costs of purchasing and operating these products.
- (14) The ecodesign requirements should not affect the functionality or affordability of servers and data storage products from the end-user's perspective and should not negatively affect health, safety or the environment.
- (15) This Regulation should apply without prejudice to the requirements of Union legislation on safety and health, in particular the Directive 2014/35/EU of the European Parliament and of the Council ⁽⁵⁾, which covers all health and safety risks of electrical equipment operating with a voltage between 50 and 1000 V for alternating current and between 75 and 1500 V for direct current.
- (16) The introduction of ecodesign requirements should give manufacturers sufficient time to redesign their products subject to this Regulation. The timing should take into account the impact on manufacturers' costs, in particular for small and medium-sized enterprises, while ensuring timely achievement of the objectives of this Regulation.
- (17) Product parameters should be measured and calculated using reliable, accurate and reproducible methods which take into account recognised state-of-the-art measurement and calculation methods, including, where available, harmonised standards adopted by the European standardisation organisations following a request by the Commission, in accordance with the procedures laid down in Regulation (EU) No 1025/2012 of the European Parliament and of the Council ⁽⁶⁾.
- (18) In accordance with Article 8 of Directive 2009/125/EC, this Regulation specifies which conformity assessment procedures apply.

⁽²⁾ COM(2015) 614 final.

⁽³⁾ SWD(2018) 36 final.

⁽⁴⁾ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1).

⁽⁵⁾ Directive 2014/35/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits (OJ L 96, 29.3.2014, p. 357).

⁽⁶⁾ Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

- (19) In order to facilitate compliance checks, manufacturers should provide the information contained in the technical documentation referred to in Annexes IV and V to Directive 2009/125/EC insofar as that information relates to the requirements laid down in this Regulation.
- (20) In addition to the legally binding requirements laid down in this Regulation, indicative benchmarks for best available technologies should be determined to ensure that information on the life-cycle environmental performance of servers and data storage products is widely available and easily accessible.
- (21) Commission Regulation (EU) No 617/2013 ⁽⁷⁾ should be amended to exclude computer servers from its scope in order to prevent any overlap with the same products in the scope of this Regulation.
- (22) The definitions of this Regulation related to data storage products are consistent with the terminology developed by the Storage Networking Industry Association (SNIA) Green Storage Initiative as defined in the SNIA Emerald taxonomy.
- (23) In particular, the small data storage products definition corresponds to the online 1 equipment as set out in the SNIA Emerald taxonomy, and the large data storage products definition corresponds to the online 5 and 6 equipment as set out in the SNIA Emerald taxonomy.
- (24) The definitions of this Regulation related to server product types, server efficiency, server performance and maximum power, are consistent with the terminology adopted in EN 303 470:2018. The measurement and calculation methods for the server efficiency are consistent with the methods adopted in EN 303 470:2018.
- (25) The operating conditions classes, and their characteristics, are consistent with the classification set in the Thermal Guidelines for Data Processing Environments by the American Society of Heating, Refrigerating and Air-Conditioning Engineers. In particular, the boundary conditions of each operating condition class (such as temperature and humidity) are in accord with the allowable environmental ranges of the Thermal Guidelines for Data Processing Environments, where manufacturers test their equipment in order to verify that it will function within those boundaries.
- (26) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 19(1) of Directive 2009/125/EC,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation establishes ecodesign requirements for the placing on the market and putting into service of servers and online data storage products.
2. This Regulation shall not apply to the following products:
 - (a) servers intended for embedded applications;
 - (b) servers classified as small scale servers in terms of Regulation (EU) No 617/2013;
 - (c) servers with more than four processor sockets;
 - (d) server appliances;
 - (e) large servers;
 - (f) fully fault tolerant servers;
 - (g) network servers;
 - (h) small data storage products;
 - (i) large data storage products.

⁽⁷⁾ Commission Regulation (EU) No 617/2013 of 26 June 2013 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for computers and computer servers (OJ L 175, 27.6.2013, p. 13).

*Article 2***Definitions**

1. For the purpose of this Regulation, the following definitions shall apply:
 - (1) 'server' means a computing product that provides services and manages networked resources for client devices, such as desktop computers, notebook computers, desktop thin clients, internet protocol telephones, smartphones, tablets, tele-communication, automated systems or other servers, primarily accessed via network connections, and not through direct user input devices, such as a keyboard or a mouse and with the following characteristics:
 - (a) it is designed to support server operating systems (OS) and/or hypervisors, and targeted to run user-installed enterprise applications;
 - (b) it supports error-correcting code and/or buffered memory (including both buffered dual in-line memory modules and buffered on board configurations);
 - (c) all processors have access to shared system memory and are independently visible to a single OS or hypervisor;
 - (2) 'server with more than four processor sockets' means a server containing more than four interfaces designed for the installation of a processor. For multi-node servers, this term refers to a server having more than four processor sockets in each server node;
 - (3) 'embedded application' means a software application that permanently resides in an industrial or consumer device, typically stored in a non-volatile memory such as read-only memory or flash memory;
 - (4) 'server appliance' means a server that is not intended to execute user-supplied software, delivers services through one or more networks, is typically managed through a web or command line interface and is bundled with a pre-installed OS and application software that is used to perform a dedicated function or set of tightly coupled functions;
 - (5) 'resilient server' means a server designed with extensive reliability, availability, serviceability and scalability features integrated in the micro architecture of the system, central processing unit (CPU) and chipset;
 - (6) 'large server' means a resilient server which is shipped as a pre-integrated/pre-tested system housed in one or more full frame racks and that includes a high connectivity input/output subsystem with a minimum of 32 dedicated input/output slots;
 - (7) 'multi-node server' means a server that is designed with two or more independent server nodes that share a single enclosure and one or more power supply units. In a multi-node server, power is distributed to all nodes through shared power supply units. Server nodes in a multi-node server are not designed to be hot-swappable;
 - (8) 'fully fault tolerant server' means a server that is designed with complete hardware redundancy (to simultaneously and repetitively run a single workload for continuous availability in mission critical applications), in which every computing component is replicated between two nodes running identical and concurrent workloads (i.e., if one node fails or needs repair, the second node can run the workload alone to avoid downtime);
 - (9) 'network server' means a network product which contains the same components as a server in addition to more than 11 network ports with a total line rate throughput of 12 Gb/s or more, the capability to dynamically reconfigure ports and speed and support for a virtualized network environment through a software defined network;
 - (10) 'data storage product' means a fully-functional storage system that supplies data storage services to clients and devices attached directly or through a network. Components and subsystems that are an integral part of the data storage product architecture (e.g., to provide internal communications between controllers and disks) are considered to be part of the data storage product. In contrast, components that are normally associated with a storage environment at the data centre level (e.g. devices required for operation of an external storage area network) are not considered to be part of the data storage product. A data storage product may be composed of integrated storage controllers, data storage devices, embedded network elements, software, and other devices;
 - (11) 'Hard Disk Drive' (HDD) means a data storage device which reads and writes to one or more rotating magnetic disk platters;
 - (12) 'Solid State Drive' (SSD) means a data storage device that reads and writes to non-volatile solid state memory instead of rotating magnetic platters for data storage;

- (13) 'data storage device' means a device providing non-volatile data storage, with the exception of aggregating storage elements such as subsystems of redundant arrays of independent disks, robotic tape libraries, filers, and file servers and storage devices which are not directly accessible by end-user application programs, and are instead employed as a form of internal cache;
 - (14) 'online data storage product' means a data storage product designed for online, random-access of data, accessible in a random or sequential pattern, with a maximum time to first data of less than 80 milliseconds;
 - (15) 'small data storage product' means a data storage product containing a maximum of three data storage devices;
 - (16) 'large data storage product' means a high end or mainframe data storage product that supports more than 400 data storage devices in its maximum configuration and with the following required attributes: no single point of failure, non-disruptive serviceability and integrated storage controller.
2. For the purposes of Annexes II to V, additional definitions are set out in Annex I.

Article 3

Ecodesign requirements and timetable

- 1. The ecodesign requirements for servers and online data storage products are set out in Annex II.
- 2. From 1 March 2020 servers shall comply with the ecodesign requirements set out in Annex II points 1.1.1, 1.2.1, 1.2.2, 2.1, 2.2, 3.1, 3.3 and 3.4.
- 3. From 1 March 2020 online data storage products shall comply with the ecodesign requirements set out in Annex II points 1.1.1, 1.2.1, 1.2.2, 3.2, 3.3 and 3.4.
- (a) From 1 March 2021 servers and online data storage products shall comply with the ecodesign requirement set out in Annex II point 1.2.3.
- (b) From 1 January 2023 servers and online data storage products shall comply with the ecodesign requirements set out in Annex II point 1.1.2.
- (c) Compliance with ecodesign requirements shall be measured and calculated in accordance with the methods set out in Annex III.

Article 4

Conformity assessment

- 1. The conformity assessment procedure referred to in Article 8(2) of Directive 2009/125/EC shall be the internal design control set out in Annex IV to that Directive or the management system set out in Annex V to that Directive.
- 2. For the purposes of the conformity assessment pursuant to Article 8 of Directive 2009/125/EC, the technical documentation shall contain the information set out in point 3.4 of Annex II to this Regulation.

Article 5

Verification procedure for market surveillance purposes

Member States shall apply the verification procedure set out in Annex IV to this Regulation when performing the market surveillance checks referred to in Article 3(2) of Directive 2009/125/EC.

Article 6

Circumvention

The manufacturer or importer shall not place on the market products that have been designed to be able to detect they are being tested (e.g. by recognizing the test conditions or test cycle), and to react specifically by automatically altering their performance during the test with the objective of reaching a more favourable level for any of the parameters declared by the manufacturer or importer in the technical documentation or included in any of the documentation provided.

*Article 7***Indicative benchmarks**

The indicative benchmarks for best-performing servers and data storage products available on the market on 7 April 2019 are set out in Annex V.

*Article 8***Review**

The Commission shall assess this Regulation and shall present the results of this assessment, including, if appropriate, a draft revision proposal, to the Consultation Forum by March 2022. This assessment shall review the requirements in the light of the technological progress and shall address in particular the appropriateness:

- (a) to update the specific ecodesign requirements on server active state efficiency;
- (b) to update the specific ecodesign requirements for servers on idle state power;
- (c) to update the definitions or the scope of the Regulation;
- (d) to update the material efficiency requirements for servers and data storage products, including the information requirements on additional critical raw materials (tantalum, gallium, dysprosium and palladium), taking into account the needs of the recyclers;
- (e) to exempt server appliances, large servers, fully fault tolerant servers and network servers from the scope of the regulation;
- (f) to exclude resilient servers, High Performance Computing (HPC) servers and servers with integrated APA from the ecodesign requirements set out in Annex II point 2.1 and point 2.2;
- (g) to set specific ecodesign requirements on the Processor Power Management Function of servers;
- (h) to set specific ecodesign requirements on the operating condition class;
- (i) to set specific ecodesign requirements on the efficiency, performance and power demand of data storage products.

*Article 9***Amendment to Regulation (EU) No 617/2013**

Regulation (EU) No 617/2013 is amended as follows:

(1) Article 1 is amended as follows:

(a) paragraph 1 is replaced by the following:

‘1. This Regulation establishes ecodesign requirements for the placing on the market of computers.’;

(b) in paragraph 2, point (h) is deleted;

(c) in paragraph 3, points (a) to (d) are deleted;

(2) Article 2 is amended as follows:

(a) point 2 is deleted;

(b) point 4 is replaced by the following:

‘(4) “Internal power supply” means a component designed to convert AC voltage from the mains to DC voltage(s) for the purpose of powering the computer and has the following characteristics:

(a) is contained within the computer casing but is separate from the main computer board;

- (b) the power supply connects to the mains through a single cable with no intermediate circuitry between the power supply and the mains power; and
- (c) all power connections from the power supply to the computer components, with the exception of a DC connection to a display in an integrated desktop computer, are internal to the computer casing.

Internal DC-to-DC converters used to convert a single DC voltage from an external power supply into multiple voltages for use by a computer are not considered internal power supplies;;

(c) points 12 to 16 are deleted;

(d) point 22 is replaced by the following:

‘(22) “Product type” means desktop computer, integrated desktop computer, notebook computer, desktop thin client, workstation, mobile workstation, small-scale server, game console, docking station, internal power supply or external power supply;’;

(3) Article 3 is replaced by the following:

‘Article 3

Ecodesign requirements

The ecodesign requirements for computers are set out in Annex II.

Compliance of computers with the applicable ecodesign requirements shall be measured in accordance with the methods set out in Annex III.’;

(4) in Article 7, the second paragraph is replaced by the following:

‘Checking of computers for compliance with the applicable ecodesign requirements shall be carried out in accordance with the verification procedure set out in point 2 of Annex III to this Regulation.’;

(5) Annex II is amended as follows:

(a) point 5.2 is deleted;

(b) the title of point 7.3 is replaced by the following:

‘Workstation, mobile workstation, desktop thin client and small-scale server’.

Article 10

Entry into force

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

However, Article 9 shall apply from 1 March 2020.

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

Done at Brussels, 15 March 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

Definitions applicable to Annexes II to V

For the purposes of Annexes II to V the following definitions shall apply:

- (1) 'server with one or two processor sockets' means a server containing one or two interfaces designed for the installation of a processor. For multi-node servers, this term refers to a server having one or two processor sockets in each server node;
- (2) 'Input/Output (I/O) device' means a device, which provides data input and output capability between a server or a data storage product and other devices. An I/O device may be integral to the server motherboard or may be connected to the motherboard via expansion slots (such as Peripheral Component Interconnect, or Peripheral Component Interconnect Express);
- (3) 'motherboard' means the main circuit board of the server. For purposes of this regulation, the motherboard includes connectors for attaching additional boards and typically includes the following components: processor, memory, BIOS, and expansion slots;
- (4) 'processor' means the logic circuitry that responds to and processes the basic instructions that drive a server. For purposes of this regulation, the processor is the CPU of the server. A typical CPU is a physical package to be installed on the server motherboard via a socket or direct solder attachment. The CPU package may include one or more processor cores;
- (5) 'memory' means a part of a server external to the processor in which information is stored for immediate use by the processor, expressed in gigabyte (GB);
- (6) 'expansion card' means an internal component connected by an edge connection over a common/standard interface such as Peripheral Component Interconnect Express providing additional functionality;
- (7) 'graphics card' means an expansion card containing one or more graphics processing units with a local memory controller interface and local graphics-specific memory;
- (8) 'buffered double data rate (DDR) channel' means a channel or memory port connecting a memory controller to a defined number of memory devices in a server. A typical server may contain multiple memory controllers, which may in turn support one or more buffered DDR channels. As such, each buffered DDR channel serves only a fraction of the total addressable memory space in a server;
- (9) 'blade server' means a server that is designed for use in a blade chassis. A blade server is a high-density device that functions as an independent server and includes at least one processor and system memory, but is dependent upon shared blade chassis resources (e.g., power supply units, cooling) for operation. A processor or memory module will not be considered a blade server when the technical documentation for the product does not indicate that it scales up a standalone server;
- (10) 'blade chassis' means an enclosure that contains shared resources for the operation of blade servers, blade storage, and other blade form-factor devices. Shared resources provided by a blade chassis may include power supply units, data storage, and hardware for direct current power distribution, thermal management, system management, and network services;
- (11) 'High Performance Computing (HPC) server' means a server which is designed and optimized to execute highly parallel applications, for higher performance computing or deep learning artificial intelligence applications. HPC servers must meet all the following criteria:
 - (a) they consist of multiple computing nodes, clustered primarily to increase computational capability;
 - (b) they include high speed inter-processing interconnections between nodes;
- (12) 'server product family' means a high-level description referring to a group of servers sharing one chassis and motherboard combination that may contain more hardware and software configurations. All configurations within a server product family must share the following common attributes:
 - (a) be from the same model line or machine type;

- (b) either share the same form factor (i.e., rack-mounted, blade, pedestal) or share the same mechanical and electrical designs with only superficial mechanical differences to enable a design to support multiple form factors;
 - (c) either share processors from a single defined processor series or share processors that plug into a common socket type;
 - (d) share the power supply unit(s);
 - (e) have the same number of available processor sockets and number of available processor sockets populated;
- (13) 'power supply unit' (PSU) means a device that converts alternate current (AC) or direct current (DC) input power to one or more DC power outputs for the purpose of powering a server or a data storage product. A server or data storage product PSU must be self-contained and physically separable from the motherboard and must connect to the system via a removable or hard-wired electrical connection;
- (14) 'power factor' means the ratio of the real power consumed in Watts to the apparent power drawn in Volt Amperes;
- (15) 'single output PSU' means a PSU designed to deliver the majority of its rated output power to one primary DC output for the purpose of powering a server or a data storage product. Single output PSUs may offer one or more standby outputs that remain active whenever connected to an input power source. The total rated power output from any additional PSU outputs that are not primary and standby outputs shall be no greater than 20 Watts. PSUs that offer multiple outputs at the same voltage as the primary output are considered single-output PSUs unless those outputs:
- (a) are generated from separate converters or have separate output rectification stages, or
 - (b) have independent current limits;
- (16) 'multi output PSU' means a PSU designed to deliver the majority of its rated output power to more than one primary DC output for the purpose of powering a server or a data storage product. Multi output PSUs may offer one or more standby outputs that remain active whenever connected to an input power source. The total rated power output from any additional PSU outputs that are not primary and standby outputs shall be no greater than or equal to 20 Watts;
- (17) 'direct current server' means a server that is designed solely to operate on a DC power source;
- (18) 'direct current data storage product' means a data storage product that is designed solely to operate on a DC power source;
- (19) 'idle state' means the operational state in which the OS and other software have completed loading, the server is capable of completing workload transactions, but no active workload transactions are requested or pending by the system (i.e., the server is operational, but not performing any useful work). For servers where Advanced Configuration and Power Interface standards are applicable, idle state corresponds only to System Level S0;
- (20) 'idle state power' (P_{idle}) is the power demand, in Watts, in idle state;
- (21) 'low-end performance configuration' of a server product family means the combination of two data storage devices, processor with the lowest product of core count and frequency (in GHz) and memory capacity (in GB) that is at least equal to the product of the number of memory channels and the lowest capacity dual in-line memory module (DIMM) (in GB) offered on the server that represents the lowest performance product model within the server product family. All memory channels shall be populated with the same DIMM raw card design and capacity;
- (22) 'high-end performance configuration' of a server product family means the combination of two data storage devices, processor with the highest product of core count and frequency and memory capacity (in GB) equal to or greater than 3 times the product of the number of CPUs, cores and hardware threads that represents the highest performance product model within the product family. All memory channels shall be populated with the same DIMM raw card design and capacity;
- (23) 'hardware thread': means the hardware resources in a CPU core to execute a stream of software instructions. A CPU core may have the resources to execute more than one thread simultaneously;
- (24) 'active state efficiency' (Eff_{server}) means the numerical value for server efficiency as measured and calculated according to Annex III point 3;

- (25) 'active state' means the operational state in which the server is carrying out work in response to prior or concurrent external requests (e.g., instruction over the network). Active state includes both active processing and data seeking/retrieval from memory, cache, or internal/external storage while awaiting further input over the network;
 - (26) 'server performance' means the number of transactions per unit of time performed by the server under standardised testing of discrete system components (e.g. processors, memory and storage) and subsystems (e.g. RAM and CPU);
 - (27) 'maximum power' ($P_{\max}$) means the highest power, in Watts, recorded on the eleven worklet scores according to the standard;
 - (28) 'CPU performance (Perf_{CPU})' means the number of transactions per unit of time performed by the server under standardised testing of the CPU subsystem;
 - (29) 'Auxiliary Processing Accelerator' (APA) means a specialized processor and associated subsystem that provide an increase in computing capacity such as graphical processing units or field programmable gate arrays. An APA cannot operate in a server without a CPU. APAs can be installed in a server either on Graphics or Extension add-in cards installed in general-purpose add-in expansion slots or integrated into a server component such as the motherboard;
 - (30) 'Expansion APA' means an APA that is on an add-in card installed in an add-in expansion slot. An expansion APA add-in card may include one or more APAs and/or separate, dedicated removable switches;
 - (31) 'Integrated APA' means an APA that is integrated into the motherboard or CPU package;
 - (32) 'product type' means the design of the server or of the data storage product including the chassis (rack, tower or blade), the number of sockets and, for servers, whether it is a resilient server, a blade server, a multi node server, a HPC server, a server with integrated APA, a direct current server or none of the previous categories;
 - (33) 'disassembly' means a process whereby an item is taken apart in such a way that it can subsequently be reassembled and made operational;
 - (34) 'firmware' means system, hardware, component, or peripheral programming provided with the product to provide basic instructions for hardware to function inclusive of all applicable programming and hardware updates;
 - (35) 'secure data deletion' means the effective erasure of all traces of existing data from a data storage device, overwriting the data completely in such a way that access to the original data, or parts of them, becomes infeasible for a given level of effort.
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ANNEX II

Ecodesign requirements**1. SPECIFIC ECODESIGN REQUIREMENTS FOR SERVERS AND ONLINE DATA STORAGE PRODUCTS****1.1. PSU efficiency and power factor requirements**

- 1.1.1. From 1 March 2020, for servers and online data storage products, with the exception of direct current servers and of direct current data storage products, the PSU efficiency at 10 %, 20 %, 50 % and 100 % of the rated load level and the power factor at 50 % of the rated load level shall not be less than the values reported in Table 1.

Table 1

Minimum PSU efficiency and power factor requirements from 1 March 2020

% of rated load	Minimum PSU efficiency				Minimum power factor
	10 %	20 %	50 %	100 %	50 %
Multi output	—	88 %	92 %	88 %	0,90
Single output	—	90 %	94 %	91 %	0,95

- 1.1.2. From 1 January 2023, for servers and online data storage products, with the exception of direct current servers and of direct current data storage products, the PSU efficiency at 10 %, 20 %, 50 % and 100 % of the rated load level and the power factor at 50 % of the rated load level shall not be less than the values reported in Table 2.

Table 2

Minimum PSU efficiency and power factor requirements from 1 January 2023

% of rated load	Minimum PSU efficiency				Minimum power factor
	10 %	20 %	50 %	100 %	50 %
Multi output	—	90 %	94 %	91 %	0,95
Single output	90 %	94 %	96 %	91 %	0,95

1.2. Material efficiency requirements

- 1.2.1. From 1 March 2020, manufacturers shall ensure that joining, fastening or sealing techniques do not prevent the disassembly for repair or reuse purposes of the following components, when present:

- (a) data storage devices;
- (b) memory;
- (c) processor (CPU);
- (d) motherboard;
- (e) expansion card/graphic card;
- (f) PSU;
- (g) chassis;
- (h) batteries.

- 1.2.2. From 1 March 2020, a functionality for secure data deletion shall be made available for the deletion of data contained in all data storage devices of the product.
- 1.2.3. From 1 March 2021, the latest available version of the firmware shall be made available from two years after the placing on the market of the first product of a certain product model for a minimum period of eight years after the placing on the market of the last product of a certain product model, free of charge or at a fair, transparent and non-discriminatory cost. The latest available security update to the firmwares shall be made available from the time a product model is placed on the market until at least eight years after the placing on the market of the last product of a certain product model, free of charge.

2. SPECIFIC ECODSIGN REQUIREMENTS ONLY FOR SERVERS WITH ONE OR TWO PROCESSOR SOCKETS

2.1. Idle state power

From 1 March 2020, the idle state power (P_{idle}) of servers, with the exception of resilient servers, HPC servers and servers with integrated APA, shall not exceed the value calculated using the following equation:

$$P_{idle} = P_{base} + \Sigma P_{add_i}$$

where P_{base} is the basic idle state power allowance in Table 3, and ΣP_{add_i} is the sum of the idle state power allowances for applicable, additional components, as determined per Table 4. For blade servers, P_{idle} is calculated as the total measured power divided by the number of installed blade servers in the tested blade chassis. For multi-node servers, the number of sockets are counted per node while P_{idle} is calculated as the total measured power divided by the number of installed nodes in the tested enclosure.

Table 3

Base idle state power allowances

Product type	Base idle state power allowance, P_{base} (W)
1-socket servers (neither blade nor multi-node servers)	25
2-socket servers (neither blade nor multi-node servers)	38
Blade or multi-node servers	40

Table 4

Additional Idle Power Allowances for Extra Components

System characteristics	Applies to	Additional idle power allowance
CPU Performance	All servers	1 socket: $10 \times \text{Perf}_{\text{CPU}}$ W 2 socket: $7 \times \text{Perf}_{\text{CPU}}$ W
Additional PSU	PSU installed explicitly for power redundancy	10 W per PSU
HDD or SSD	Per installed HDD or SSD	5,0 W per HDD or SSD
Additional memory	Installed memory greater than 4 GB	0,18 W per GB
Additional buffered DDR channel	Installed buffered DDR channels greater than 8 channels	4,0 W per buffered DDR channel

System characteristics	Applies to	Additional idle power allowance
Additional I/O devices	Installed devices greater than two ports of ≥ 1 Gbit, on-board Ethernet	< 1 Gb/s: No Allowance
		= 1 Gb/s: 2,0 W/Active Port
		> 1 Gb/s and < 10 Gb/s: 4,0 W/Active Port
		≥ 10 Gb/s and < 25Gb/s: 15,0 W/Active Port
		≥ 25 Gb/s and < 50Gb/s: 20,0 W/Active Port
		≥ 50 Gb/s 26,0 W/Active Port

2.2. Active state efficiency

From 1 March 2020, the active state efficiency ($\text{Eff}_{\text{server}}$) of servers, with the exception of resilient servers, HPC servers and servers with integrated APA, shall not be lower than the values in Table 5.

Table 5

Active state efficiency requirements

Product type	Minimum active state efficiency
1-socket servers	9,0
2-socket servers	9,5
Blade or multi-node servers	8,0

3. INFORMATION TO BE PROVIDED BY MANUFACTURERS

- 3.1. From 1 March 2020, with the exception of custom made servers, made on a one-off basis, the following product information on servers shall be provided in the instruction manuals for installers and end-users (when present with the product), and on the free-access websites of manufacturers, their authorised representatives and importers from the time a product model is placed on the market until at least eight years after the placing on the market of the last product of a certain product model:

- product type;
- manufacturer's name, registered trade name and registered trade address at which they can be contacted;
- product model number, and if applicable the low-end performance configuration and the high-end performance configuration model numbers;
- year of manufacture;
- PSU efficiency at 10 % (if applicable), 20 %, 50 % and 100 % of rated output power, with the exception of direct current servers, expressed in % and rounded to the first decimal place;
- power factor at 50 % of the rated load level, with the exception of direct current servers, rounded to three decimal places;
- PSU rated power output (Watts), rounded to the nearest integer. If a product model is part of a server product family, all PSUs offered in a server product family shall be reported with the information specified in (e) and (f);
- idle state power, expressed in Watts and rounded to the first decimal place;
- list of all components for additional idle power allowances, if any (additional PSU, HDDs or SSDs, additional memory, additional buffered DDR channels, additional I/O devices);

- (j) maximum power, expressed in Watts and rounded to the first decimal place;
- (k) declared operating condition class, as detailed in Table 6;
- (l) idle state power (Watts) at the higher boundary temperature of the declared operating condition class;
- (m) the active state efficiency and the performance in active state of the server;
- (n) information on the secure data deletion functionality referred to in point 1.2.2 of this Annex, including instructions on how to use the functionality, the techniques used and the supported secure data deletion standard(s), if any;
- (o) for blade servers, a list of recommended combinations with compatible chassis;
- (p) if a product model is part of a server product family, a list of all model configurations that are represented by the model shall be supplied.

If a product model is part of a server product family, the product information required for items e) to m) under point 3.1 shall be reported for the low-end and high-end performance configurations of the server product family.

- 3.2. From 1 March 2020, with the exception of custom made data storage products, made on a one-off basis, the following product information on online data storage products shall be provided in the instruction manuals for installers and end-users (when present with the product), and on the free-access websites of manufacturers, their authorised representatives and importers from the time a product model is placed on the market until at least eight years after the placing on the market of the last product of a certain product model:

- (a) product type;
- (b) manufacturer's name, registered trade name and registered trade address at which they can be contacted;
- (c) product model number;
- (d) year of manufacture;
- (e) PSU efficiency at 10 % (if applicable), 20 %, 50 % and 100 % of rated output power, with the exception of direct current online data storage products, expressed in % and rounded to the first decimal place;
- (f) power factor at 50 % of the rated load level, with the exception of direct current online data storage products, rounded to three decimal places;
- (g) declared operating condition class, as detailed in Table 6; it shall also be indicated that 'This product has been tested in order to verify that it will function within the boundaries (such as temperature and humidity) of the declared operating condition class';
- (h) information on the data deletions tool(s) referred to in point 1.2.2 of this Annex, including instructions on how to use the functionality, the techniques used and the supported secure data deletion standard(s), if any.

- 3.3. From 1 March 2020, the following product information on servers and online data storage products shall be made available from the time a product model is placed on the market until at least eight years after the placing on the market of the last product of a certain product model free of charge by manufacturers, their authorised representatives and importers to third parties dealing with maintenance, repair, reuse, recycling and upgrading of servers (including brokers, spare parts repairers, spare parts providers, recyclers and third party maintenance) upon registration by the interested third party on a website provided:

- (a) indicative weight range (less than 5 g, between 5 g and 25 g, above 25 g) at component level, of the following critical raw materials:
 - (a) Cobalt in the batteries;
 - (b) Neodymium in the HDDs;
- (b) instructions on the disassembly operations referred to in point 1.2.1 of this Annex, including, for each necessary operation and component:
 - (a) the type of operation;
 - (b) the type and number of fastening technique(s) to be unlocked;
 - (c) the tool(s) required.

In the case of servers, if a product model is part of a server product family, the product information required for items a) and b) under point 3.3 shall be reported either for the product model or, alternatively, for the low-end and high-end configurations of the server product family.

- 3.4. From 1 March 2020, the following product information on servers and online data storage products shall be provided in the technical documentation for the purposes of conformity assessment pursuant to Article 4:

(a) Information listed in points 3.1 and 3.3, in the case of servers

(b) Information listed in points 3.2 and 3.3, in the case of data storage products

Table 6

Operating condition classes

Operating condition class	Dry bulb temp °C		Humidity range, non-condensing		Max dew point (°C)	Maximum rate of change (°C/hr)
	Allowable range	Recommended range	Allowable range	Recommended range		
A1	15- 32	18-27	– 12 °C Dew Point (DP) and 8 % relative humidity (RH) to 17 °C DP and 80 % RH	– 9 °C DP to 15 °C DP and 60 % RH	17	5/20
A2	10-35	18-27	– 12 °C DP and 8 % RH to 21 °C DP and 80 % RH	Same as A1	21	5/20
A3	5-40	18-27	– 12 °C DP and 8 % RH to 24 °C DP and 85 % RH	Same as A1	24	5/20
A4	5-45	18-27	– 12 °C DP and 8 % RH to 24 °C DP and 90 % RH	Same as A1	24	5/20

ANNEX III

Measurements and calculations

1. For the purposes of compliance and verification of compliance with the applicable requirements of this Regulation, measurements and calculations shall be made using harmonised standards, the reference numbers of which have been published in the *Official Journal of the European Union*, or using other reliable, accurate and reproducible methods which take into account the generally recognised state of the art, and produce results deemed to be of low uncertainty.
2. Servers shall be tested either in their individual product model configuration or, for servers which are part of a server product family, in the low-end performance configuration and the high-end performance configuration as declared for Annex II, point 3.1.(p), which includes both hardware configuration and system settings, unless otherwise specified.

All configurations offered within a server product family shall contain the same number of populated processor sockets used during testing. A server product family can be defined for a server with only partially populated sockets (e.g. one processor populated in a two socket server) as long as the configuration(s) are tested as a separate server product family, as required, and meet the same requirements for the number of populated sockets within that separate server product family.

For servers with expansion APA, the unit under test shall be tested with the expansion APA removed, when measuring the idle state power, the active state efficiency) and the server performance in active state. Where an expansion APA relies on a separate Peripheral Component Interconnect Express switch for communication between the APA and CPU, the separate Peripheral Component Interconnect Express card(s) or riser(s) shall be removed for Active State and Idle State testing of all configurations.

For multi-node servers, the unit under test shall be tested for per node power consumption in the fully-populated chassis configuration. All multi-node servers in the multi-node chassis shall share the same configuration (homogeneous).

For blade servers, the unit under test shall be tested for blade server power consumption in the half-populated chassis configuration, and the chassis shall be populated as follows:

(1) Individual blade server configuration

- (a) All individual blade servers installed in the chassis shall be identical, sharing the same configuration

(2) Half chassis population

- (a) The number of blade servers required to populate half the number of single-wide blade server slots available in the blade chassis shall be calculated.
 - (b) For blade chassis having multiple power domains, the number of power domains that is closest to filling half of the chassis shall be chosen. If there are two choices that are equally close to filling half of the chassis, the test shall be performed with the domain or combination of domains which use a higher number of blade servers.
 - (c) All user manual or manufacturer recommendations for partially populating the chassis, which may include disconnecting some of the power supply units and cooling fans for the unpopulated power domains, shall be followed.
 - (d) If user manual recommendations are not available or are incomplete, then the following guidance shall be used:
 - (i) Completely populate the power domains;
 - (ii) If possible, disconnect the power supply units and cooling fans for unpopulated power domains;
 - (iii) Fill all empty bays with blanking panels or an equivalent airflow restriction for the duration of testing.
3. The data to calculate the active state efficiency ($\text{Eff}_{\text{server}}$) and the idle power (P_{idle}) shall be measured during the same test according to the relevant standard, where the idle power can be measured either before or after running part of the test for the active state efficiency.

The active state efficiency (Effserver) of servers shall be calculated as:

$$\text{Eff}_{\text{server}} = \exp [W_{\text{cpu}} \times \ln (\text{Eff}_{\text{cpu}}) + W_{\text{Memory}} \times \ln (\text{Eff}_{\text{Memory}}) + W_{\text{Storage}} \times \ln (\text{Eff}_{\text{Storage}})]$$

where: W_{CPU} , W_{Memory} and W_{Storage} are the weightings applied to the CPU, Memory and Storage worklets respectively, as follows:

- W_{CPU} is the weighting assigned to the CPU worklets = 0,65
- W_{Memory} is the weighting assigned to the Memory worklets = 0,30
- W_{Storage} is the weighting assigned to the Storage worklets = 0,05

and

$$\text{Eff}_{\text{CPU}} = \left(\prod_{i=1}^7 \text{Eff}_i \right)^{1/7}$$

where:

- $i = 1$ for workletCompress;
- $i = 2$ for workletLU;
- $i = 3$ for workletSOR;
- $i = 4$ for workletCrypto;
- $i = 5$ for workletSort;
- $i = 6$ for workletSHA256;
- $i = 7$ for workletHybrid SSJ;

$$\text{Eff}_{\text{Memory}} = \left(\prod_{i=1}^2 \text{Eff}_i \right)^{1/2}$$

where:

- $i = 1$ for workletFlood3;
- $i = 2$ for workletCapacity3;

$$\text{Eff}_{\text{Storage}} = \left(\prod_{i=1}^2 \text{Eff}_i \right)^{1/2}$$

where:

- $i = 1$ for workletSequential;
- $i = 2$ for workletRandom;

and

$$\text{Eff}_i = 1\,000 \frac{\text{Perf}_i}{\text{Pwr}_i}$$

where

- Perf_i : Geometric mean of the normalized interval performance measurements;
- Pwr_i : Geometric mean of the measured interval power values;

In order to create a single energy efficiency metric for a server the interval efficiency values for all the different worklets shall be combined using the following procedure:

- (a) combining the interval efficiency values for the individual worklets using the geometric mean to obtain individual worklet Efficiency values for the worklet;
 - (b) combining worklet efficiency scores using the geometric mean function by workload type (CPU, Memory, Storage) to obtain a workload type value;
 - (c) combining the three workload types using a weighted geometric mean function to obtain a single, total server efficiency value.
-

ANNEX IV

Verification procedure for market surveillance purposes

The verification tolerances defined in this Annex relate only to the verification of the measured parameters by Member State authorities and shall not be used by the manufacturer or importer as an allowed tolerance to establish the values in the technical documentation or in interpreting these values with a view to achieving compliance or to communicate better performance by any means.

Where a model has been designed to be able to detect it is being tested (e.g. by recognizing the test conditions or test cycle), and to react specifically by automatically altering its performance during the test with the objective of reaching a more favourable level for any of the parameters specified in this Regulation or included in the technical documentation or included in any of the documentation provided, the model shall be considered not compliant.

When verifying the compliance of a product model with the requirements laid down in this Regulation pursuant to Article 3(2) of Directive 2009/125/EC, for the requirements referred to in this Annex, the authorities of the Member States shall apply the following procedure:

1. The Member State authorities shall verify one single unit of the model or, in case the manufacturer reports on a server product family, of the model configuration. If the verification is done on the low-end performance configuration or the high-end performance configuration, the declared values shall be the values for the respective configuration. If the verification is performed on a randomly selected or ordered model configuration, the declared values shall be the values for the high-end performance configuration.
2. The model or model configuration shall be considered to comply with the applicable requirements if:
 - (a) the values given in the technical documentation pursuant to point 2 of Annex IV to Directive 2009/125/EC (declared values), and, where applicable, the values used to calculate these values, are not more favourable for the manufacturer or importer than the results of the corresponding measurements carried out pursuant to paragraph (g) thereof; and
 - (b) the declared values meet any requirements laid down in this Regulation, and any required product information published by the manufacturer or importer does not contain values that are more favourable for the manufacturer or importer than the declared values; and
 - (c) when the Member State authorities test the unit of the model or alternatively, in case the manufacturer declared the server to be represented by a server product family, of the low-end performance configuration or the high-end performance configuration of the server product family, the determined values (the values of the relevant parameters as measured in testing and the values calculated from these measurements) comply with the respective verification tolerances as given in Table 7.
3. If the results referred to in points 2(a) or 2(b) are not achieved, the model and all model configurations that are covered by the same product information (according to Annex II point 3.1(p)) shall be considered not to comply with this Regulation.
4. If the result referred to in point 2(c) is not achieved:
 - (a) for models or model configurations from a server product family that are produced in quantities of less than five per year, the model and all model configurations that are covered by the same product information (according to Annex II point 3.1(p)) shall be considered not to comply with this Regulation;
 - (b) for models that are produced in quantities of five or more per year, the Member State authorities shall select three additional unit of the same model or alternatively, in case the manufacturer declared the server to be represented by a server product family, a unit of both the low-end performance configuration and the high-end performance configuration for testing.
5. The model or model configuration shall be considered to comply with the applicable requirements if, for these three units, the arithmetical mean of the determined values complies with the respective verification tolerances given in Table 7.
6. If the result referred to in point 4(b) is not achieved, the model and all model configurations that are covered by the same product information (according to Annex II point 3.1(p)) shall be considered not to comply with this Regulation.

7. The Member State authorities shall provide all relevant information to the authorities of the other Member States and to the Commission without delay after a decision being taken on the non-compliance of the model according to points 3 and 6.

The Member State authorities shall use the measurement and calculation methods set out in Annex III.

The Member State authorities shall only apply the verification tolerances that are set out in Table 7 of this Annex and shall only use the procedure described in points 1 to 7 for the requirements referred to in this Annex. No other tolerances shall be applied.

Table 7

Verification tolerances

Parameters	Verification tolerances
PSU efficiency (%)	The determined value shall not be lower than the declared value by more than 2 %.
Power factor	The determined value shall not be lower than the declared value by more than 10 %.
Idle state power, P_{idle} and maximum power (W)	The determined value shall not exceed the declared value by more than 10 %.
Active state efficiency and performance in active state	The determined value shall not be lower than the declared value by more than 10 %.

ANNEX V

Indicative benchmarks referred to in Article 6

The following indicative benchmarks are identified for the purpose of Part 3, point 2 of Annex I to Directive 2009/125/EC.

They refer to the best available technology by 7 April 2019.

The indicative benchmarks for the best available technology on the market for servers and online data storage products are as follows.

Table 8

Benchmark for idle state power, server efficiency and operating condition

Product type	Idle power, W	Active state efficiency	Operating condition class
Tower server, 1 socket	21,3	17	A3
Rack server, 1 socket	18	17,7	A4
Rack server, 2 socket, low performance	49,9	18	A4
Rack server, 2 socket, high performance	67	26,1	A4
Rack server, 4 socket	65,1	34,8	A4
Blade server, 2 socket	75	47,3	A3
Blade server, 4 socket	63,3	21,9	A3
Resilient server, 2 socket	222	9,6	A3
Data storage products	Not applicable	Not applicable	A3

Table 9

Benchmark for PSU efficiency at 10 %, 20 %, 50 % and 100 % load level and power factor at 20 % or 50 % load level

PSU nameplate power	10 %	20 %	50 %	100 %
< 750W	91,17 %	93,76 %	94,72 % Power factor > 0,95	94,14 %
≥ 750W	95,02 %	95,99 % Power factor > 0,95	96,09 %	94,69 %

DECISIONS

COUNCIL DECISION (EU) 2019/425

of 12 March 2019

on the position to be taken on behalf of the European Union within the Joint Committee established by the Agreement between the European Union and the Kingdom of Norway on administrative cooperation, combating fraud and recovery of claims in the field of value added tax

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 113, in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

- (1) The Agreement between the European Union and the Kingdom of Norway on administrative cooperation, combating fraud and recovery of claims in the field of value added tax ⁽¹⁾ ('the Agreement') was concluded by the Union by means of Council Decision (EU) 2018/1089 ⁽²⁾ and entered into force on 1 September 2018.
- (2) The Agreement provides for a solid legal framework for cooperation with regard to the fight against fraud and the recovery of claims in the field of value added tax. Such cooperation will benefit from the same tools currently used by the Member States for administrative cooperation and the recovery of claims, such as electronic platforms and e-forms.
- (3) The Joint Committee set up by the Agreement is to make recommendations and adopt decisions, in order to ensure the proper functioning and implementation of the Agreement.
- (4) During its first meeting, the Joint Committee is to adopt its rules of procedure, the procedure for the conclusion of service level agreements and other decisions concerning the proper implementation and functioning of the Agreement.
- (5) It is appropriate to establish the position to be taken on the Union's behalf in the Joint Committee, as the service level agreements and other decisions will be binding on the Union.
- (6) In the Joint Committee, the Union is to be represented by the Commission in accordance with Article 17(1) of the Treaty on European Union,

HAS ADOPTED THIS DECISION:

Article 1

The position to be taken on the Union's behalf in the first meeting of the Joint Committee established by the Agreement between the European Union and the Kingdom of Norway on administrative cooperation, combating fraud and recovery of claims in the field of value added tax shall be based on the draft decisions of the Joint Committee attached to this Decision.

⁽¹⁾ OJ L 195, 1.8.2018, p. 3.

⁽²⁾ Council Decision (EU) 2018/1089 of 22 June 2018 on the conclusion, on behalf of the Union, of the Agreement between the European Union and the Kingdom of Norway on administrative cooperation, combating fraud and recovery of claims in the field of value added tax (OJ L 195, 1.8.2018, p. 1).

Article 2

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

Done at Brussels, 12 March 2019.

For the Council
The President
E.O. TEODOROVICI

DRAFT

**DECISION No 1/2019 OF THE JOINT COMMITTEE ESTABLISHED BY THE AGREEMENT
BETWEEN THE EUROPEAN UNION AND THE KINGDOM OF NORWAY ON ADMINISTRATIVE
COOPERATION, COMBATING FRAUD AND RECOVERY OF CLAIMS IN THE FIELD OF VALUE
ADDED TAX**

of ...

on the adoption of its Rules of Procedure

THE JOINT COMMITTEE,

Having regard to the Agreement between the European Union and the Kingdom of Norway on administrative cooperation, combating fraud and recovery of claims in the field of the value added tax ⁽¹⁾ ('the Agreement'), and in particular Article 41(1) thereof,

Whereas:

- (1) In accordance with Article 41(1) of the Agreement, a Joint Committee composed of representatives of the Parties has been established.
- (2) In accordance with Article 41(3) of the Agreement, the Joint Committee is to adopt its rules of procedure,

HAS ADOPTED THIS DECISION:

Article 1

The Rules of Procedure of the Joint Committee, as set out in the Annex to this Decision, are hereby adopted.

Article 2

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

Done at ..., ...

*For the Joint Committee
The Chair*

⁽¹⁾ OJ L 195, 1.8.2018, p. 3.

ANNEX

Rules of procedure of the Joint Committee established by the Agreement between the European Union and the Kingdom of Norway on administrative cooperation, combating fraud and recovery of claims in the field of value added tax

*Article 1***Composition and chairmanship**

1. The Joint Committee shall be composed of representatives of the European Union and of the Kingdom of Norway (hereinafter referred to collectively as 'the Parties').
2. The European Union ('the Union') shall be represented by the European Commission. The Kingdom of Norway shall be represented by [...].
3. The Joint Committee shall be chaired alternately by each of the Parties for two calendar years. The first period ends on 31 December of the year following the year of the entry into force of the Agreement. The first chair will be the Union.

*Article 2***Observers and experts**

1. Representatives of the Member States of the Union may participate as observers.
2. The Joint Committee may also admit other persons to its meetings as observers.
3. Observers may be permitted by the chair to take part in the discussions and provide expertise. However, they shall not have voting rights and shall not participate in the formulation of the decisions and recommendations of the Joint Committee.
4. Experts with special expertise may also be invited with regard to specific agenda items.

*Article 3***Convening a meeting**

1. Meetings of the Joint Committee shall be convened by the chair at least once every two years. Either Party may request that a meeting be convened.
2. The date and place of each meeting shall be determined and agreed between the Parties.
3. Meetings may also be held by means of teleconferencing/videoconferencing.
4. The chair shall communicate the invitation to the other Party, the observers referred to in Article 2(2) and the experts referred to in Article 2(4) at least 15 working days before the meeting. The European Commission shall invite the representatives of the Member States of the Union referred to in Article 2(1).
5. The meetings shall not be public unless otherwise agreed. The Joint Committee's deliberations shall be confidential.

*Article 4***Agenda**

1. The chair shall draw up the provisional agenda for each meeting and submit it to the Parties no later than six months before the meeting. The final agenda shall be agreed between the Parties no later than 15 working days before the meeting and circulated by the chair.
2. Reference papers and supporting documentation shall be sent to the Parties no later than by the date on which the provisional agenda is sent.
3. For agenda items referring to decisions of the Joint Committee, the request for inclusion in the agenda and any related documents shall be sent to the Joint Committee at least seven months in advance of the meeting.

*Article 5***Secretarial support**

1. The chair shall carry out the secretarial tasks of the Joint Committee. All correspondence to the Joint Committee, including requests for items to be included or removed from the agendas, shall be addressed to the chair.
2. Notwithstanding paragraph 1 of this Article, the Commission shall act as secretary for the communication of statistical data provided under Articles 20 and 39 of the Agreement.

*Article 6***Minutes of the meeting**

1. The chair shall draft the minutes of each meeting. The chair shall circulate the minutes without delay and no later than one month after the meeting. The minutes shall be subject to mutual agreement between the Parties.
2. The chair shall send the adopted minutes to the other Party.

*Article 7***Adoption of decisions and recommendations**

1. Any decisions and recommendations of the Joint Committee shall be subject to prior discussion between the Parties.
2. Decisions and recommendations of the Joint Committee shall be adopted during its meetings by unanimity.
3. Decisions or recommendations may be adopted by written procedure provided that both Parties agree.

Under the written procedure, the chair shall send draft decisions and recommendations to the Parties and shall lay down a time limit for them to express their position. If neither Party opposes a draft decision or recommendation before the expiry of that time limit, the adoption of that decision or recommendation shall be regarded as having been tacitly agreed to.

The chair shall inform the Parties of the outcome of the written procedure without delay, and no later than 14 calendar days after the expiry of the time limit referred to in the second subparagraph.

*Article 8***Expenses**

Each Party, and when applicable each observer and expert, shall bear the expenses it incurs in taking part in the meetings of the Joint Committee.

DRAFT

**DECISION No 2/2019 OF THE JOINT COMMITTEE ESTABLISHED BY THE AGREEMENT
BETWEEN THE EUROPEAN UNION AND THE KINGDOM OF NORWAY ON ADMINISTRATIVE
COOPERATION, COMBATING FRAUD AND RECOVERY OF CLAIMS IN THE FIELD OF VALUE
ADDED TAX**

of ...

**on standard forms for the communication of information, the transmission of information via the
CCN/CSI network and the practical arrangements for the organisation of contacts between central
liaison offices and liaison departments**

THE JOINT COMMITTEE,

Having regard to the Agreement between the European Union and the Kingdom of Norway on administrative cooperation, combating fraud and recovery of claims in the field of the value added tax ⁽¹⁾ ('the Agreement'), and in particular Article 41(1) thereof,

Whereas:

- (1) Administrative cooperation under the Agreement involves mutual exchange of information.
- (2) Tools for the communication of information, such as standard forms and electronic communication systems, are already implemented within the framework of Council Regulation (EU) No 904/2010 ⁽²⁾ and Council Directive 2010/24/EU ⁽³⁾ and are fully compatible with the administrative cooperation framework of the Agreement.
- (3) It is necessary to adopt practical arrangements for the implementation of points (d), (e), (g) and (h) of Article 41(2) of the Agreement,

HAS ADOPTED THIS DECISION:

Article 1

Standard forms for the communication of information

Pursuant to Articles 21(1) and 40(1) of the Agreement, for the communication of information under Titles II and III of the Agreement, the competent authorities shall make use of the standard forms adopted for the implementation of Regulation (EU) No 904/2010 and Directive 2010/24/EU.

The structure and layout of the standard forms may be adapted to any new requirements and capabilities of the communication and information exchange systems, provided that the data and information contained therein are not substantially altered.

Article 2

Transmission of information via the CCN/CSI network

All information communicated pursuant to Titles II and III of the Agreement shall be transmitted only by electronic means via the Common Communication Network / Common System Interface (CCN/CSI) network, unless this is impracticable for technical reasons.

⁽¹⁾ OJ L 195, 1.8.2018, p. 3.

⁽²⁾ Council Regulation (EU) No 904/2010 of 7 October 2010 on administrative cooperation and combating fraud in the field of value added tax (OJ L 268, 12.10.2010, p. 1).

⁽³⁾ Council Directive 2010/24/EU of 16 March 2010 concerning mutual assistance for the recovery of claims relating to taxes, duties and other measures (OJ L 84, 31.3.2010, p. 1).

*Article 3***Organisation of contacts between central liaison offices and liaison departments**

1. In order to organise contacts between the central liaison offices and liaison departments referred to in point (b) of Article 4(2) and point (b) of Article 4(3) of the Agreement, the competent authorities shall make use of the rules adopted for the implementation of Directive 2010/24/EU.
2. The central liaison offices designated pursuant to Article 4(2) of the Agreement shall keep the list of liaison departments and competent officials designated pursuant to Article 4(3) and (4) up-to-date and make it available to the other central liaison offices via electronic means.

Article 4

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

Done at ..., ...

For the Joint Committee
The Chair

DRAFT

**DECISION No 3/2019 OF THE JOINT COMMITTEE ESTABLISHED BY THE AGREEMENT
BETWEEN THE EUROPEAN UNION AND THE KINGDOM OF NORWAY ON ADMINISTRATIVE
COOPERATION, COMBATING FRAUD AND RECOVERY OF CLAIMS IN THE FIELD OF VALUE
ADDED TAX**

of ...

on the procedure for the conclusion of service level agreements

THE JOINT COMMITTEE,

Having regard to the Agreement between the European Union and the Kingdom of Norway on administrative cooperation, combating fraud and recovery of claims in the field of the value added tax ⁽¹⁾ ('the Agreement'), and in particular Article 41(1) thereof,

Whereas:

- (1) Pursuant to Article 5 of the Agreement, a service level agreement ensuring the technical quality and quantity of the services for the functioning of the communication and information exchange systems is to be concluded according to the procedure established by the Joint Committee. However, for practical reasons, it is appropriate to conclude two separate service level agreements, each of which covers different aspects of the communication and information exchange systems.
- (2) It is necessary to adopt practical arrangements for the implementation of Article 5 of the Agreement,

HAS ADOPTED THIS DECISION:

Article 1

1. The service level agreements set out in Annexes I and II to this Decision shall be concluded between the European Commission, representing the European Union, and the Kingdom of Norway and shall be binding on the Parties to the Agreement from the day following their approval by the Joint Committee.
2. Either Party to the Agreement may request a revision of the service level agreements by sending a request to the chair of the Joint Committee. Until the Joint Committee decides on the proposed changes, the provisions of the last concluded version of the relevant service level agreement will remain in force.

Article 2

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

Done at ..., ...

*For the Joint Committee
The Chair*

⁽¹⁾ OJ L 195, 1.8.2018, p. 3.

ANNEX I

Service Level Agreement for the systems and the applications for administrative cooperation and recovery of claims in the area of VAT

1. APPLICABLE ACTS AND REFERENCE DOCUMENTS

1.1. APPLICABLE ACTS

This Service Level Agreement ('SLA') takes into account the list of agreements and applicable decisions listed below.

Table 1

Applicable acts

[AD.1.]	Agreement between the European Union and the Kingdom of Norway on administrative co-operation, combating fraud and recovery of claims in the field of value added tax ('the Agreement') (OJ L 195, 1.8.2018, p. 3)
[AD.2.]	Decision No 2/2019 of the Joint Committee established by the Agreement between the European Union and the Kingdom of Norway on administrative cooperation, combating fraud and recovery of claims in the field of the value added tax of ... [date] on standard forms for the communication of information, the transmission of information via the CCN/CSI network and the practical arrangements for the organisation of contacts between central liaison offices and liaison departments

1.2. REFERENCE DOCUMENTS

This SLA takes into account the information provided in the following reference documents. Applicable versions of the documents are published on CIRCABC or ITSM Web Portal.

Table 2

Reference Documents

[RD.1.]	CCN Mail III User Guide for NAs (<i>ITSM Web Portal</i>)
[RD.2.]	CCN Intranet – Local Network Administrator Guide (<i>ITSM Web Portal</i>)
[RD.3.]	Statistics – Guidelines and instructions (ANNEX rev1) to SCAC No 560
[RD.4.]	VAT e-Forms – Functional Specifications
[RD.5.]	VAT e-Forms – Technical Specifications
[RD.6.]	Recovery e-Forms – Functional Specifications
[RD.7.]	Recovery e-Forms – Technical Specifications
[RD.8.]	CCN/CSI General Security Policy (<i>ITSM Web Portal</i>)
[RD.9.]	CCN Gateway Management Procedures (<i>ITSM Web Portal</i>)
[RD.10.]	CCN/CSI Baseline Security Checklist (<i>ITSM Web Portal</i>)

2. TERMINOLOGY

2.1. ACRONYMS

Table 3

Acronyms

ACRONYM	DEFINITION
CCN/CSI	Common Communication Network / Common System Interface
CET	Central European Time
CIRCABC	Communication and Information Resource Centre Administrator
DG	Directorate General
EoF	Exchange of Forms
ITIL ⁽¹⁾	Information Technology Infrastructure Library
ITSM	Information Technology Service Management
Party	Within the scope of this SLA, 'Party' shall mean either Norway or the Commission.
VAT	Value Added Tax

⁽¹⁾ ITIL: <http://www.itil-officialsite.com>
http://www.best-management-practice.com/gempdf/itSMF_An_Introductory_Overview_of_ITIL_V3.pdf

2.2. DEFINITIONS

Table 4

Definitions

EXPRESSION	DEFINITION
CET	Central European Time, GMT+1 and during summer time GMT+2 hours
Working days and hours (ITSM service desk)	7:00 to 20:00 (CET), 5 days a week (Monday to Friday including holidays)

3. INTRODUCTION

This document consists of a SLA between the Kingdom of Norway ('Norway') and the European Commission ('the Commission'), collectively referred as 'the Parties to the SLA'.

3.1. SCOPE OF THE SLA

Article 5 of the Agreement specifies that 'A service level agreement ensuring the technical quality and quantity of the services for the functioning of the communication and information exchange systems shall be concluded'.

This SLA sets out the relationship between Norway and the Commission concerning the use of the systems and applications for administrative cooperation and recovery of claims in the area of VAT, and between Norway and the Member States concerning the exchange of forms.

The following systems are operational and are subject to the terms of the SLA:

- Exchange of Forms (EoF);
- Monitoring, statistics and testing.

The Commission steers the process to achieve agreement for the administrative cooperation by means of information technology. This involves standards, procedures, tools, technology and infrastructure. Assistance to Norway is provided to ensure data exchange systems are available and are properly implemented. The monitoring, supervision and evaluation of the overall system is also provided by the Commission. Furthermore the Commission provides Norway with guidelines to be respected in relation to this exchange of information.

All targets referred to in the SLA will be applicable under normal working conditions only.

In case of events of *force majeure*, the applicability of the SLA for Norway will be suspended for the duration of these *force majeure* conditions.

Force majeure represents an unpredictable event or occurrence outside the control of Norway or the Commission, and which is not attributable to any act or failure to take preventive action by the responsible Party. Such events shall refer to government actions, war, fire, explosion, flood, import or export regulations or embargoes and labour disputes.

The Party invoking the *force majeure* shall inform the other Party without delay about the impossibility to provide services or to accomplish the SLA targets due to *force majeure* incidents, setting out the affected services and targets. When the incidence of *force majeure* has ceased the affected Party shall likewise inform the other Party without delay.

3.2. AGREEMENT PERIOD

The SLA is binding on the Parties from the day following its approval by the Joint Committee established by Article 41 of the Agreement ('the Joint Committee').

4. RESPONSIBILITIES

The purpose of this SLA is to ensure the quality and quantity of the services to be delivered by the Commission and by Norway in order to make the specified systems and applications for administrative cooperation and recovery of claims in the area of VAT available to Norway and to the Commission.

4.1. SERVICES PROVIDED BY THE COMMISSION TO NORWAY

The Commission shall make the following services available:

- Operational services as follows:
 - Helpdesk and operations:
 - (a) Helpdesk Support;
 - (b) Incident Handling;
 - (c) Monitoring and Notification;
 - (d) Training;
 - (e) Security Management;
 - (f) Reporting and statistics;
 - (g) Consulting.
 - Reference centre:
 - (a) Information management;
 - (b) Documentation centre (CIRCABC).

In order to provide these services, the Commission shall maintain the following applications:

- Statistical applications;
- CIRCABC;
- Service desk tool.

4.2. SERVICES PROVIDED BY NORWAY TO COMMISSION

Norway shall do the following:

- communicate to the Commission any available information relevant to their application of the Agreement;
- communicate to the Commission any exceptional conditions;
- provide annually the statistics regarding the communication of information set out in Article 20 of the Agreement.

5. SERVICE LEVEL REVIEW

This chapter provides a detailed description of the quantitative and qualitative aspects of the services to be provided by the Commission and by Norway as described above.

5.1. COMMISSION SERVICE LEVELS

5.1.1. Service desk

5.1.1.1. Agreement

The Commission shall make available a Service Desk in order to respond to any questions and to report any problems which Norway experiences with the systems and applications for administrative cooperation and recovery of claims in the area of VAT or any component that could affect them. This Service Desk will be operated by ITSM and its operating hours shall be the same as the ITSM working hours.

The availability of the ITSM Service Desk shall be ensured in at least 95 % of the operating hours. All questions or problems can be communicated to the service desk during the ITSM working hours by telephone, fax or e-mail and outside those working hours by e-mail or fax message. Where these questions or problems are sent outside the working hours of the ITSM they shall be automatically deemed to have arrived at 8:00 CET on the next working day.

The Service Desk shall register and classify the service calls in a Service Management Tool and shall inform the reporting Party of any change in status regarding their service calls.

The ITSM shall deliver a first line support to the users and shall dispatch any service call, which is the responsibility of another party (e.g. developer's team, ITSM contractors) within the specified time. ITSM shall ensure compliance with the registration deadlines in at least 95 % of the cases occurring over a reporting month.

The ITSM shall monitor the resolution procedure for all service calls and shall start an escalation procedure by informing the Commission where the resolution period exceeds a predefined threshold, which will depend on the type of problem.

The priority level shall determine both the response and the resolution times. This is set by ITSM, but Member States or the Commission may require a specific priority level.

The registration time is the maximum time interval that is allowed to pass between the time of the receipt of the email and the sending of the acknowledgment email.

The resolution time is the time interval between the registration of the incident and the resolution information being sent to the issuer. This also includes the time involved in closing the incident.

These shall not be absolute deadlines as they take into account only the time when ITSM acts on the service call. When a service call is dispatched to Norway, the Commission or another party (e.g. developer's team, ITSM contractors) then this time does not form part of the resolution time of ITSM.

ITSM shall ensure the compliance with the registration and resolution deadlines in at least 95 % of the cases occurring over a reporting month.

Table 5

Registration times and resolution times (working hours / days)

PRIORITY	REGISTRATION TIME	RESOLUTION TIME
P1: Critical	0,5 h	4 h
P2: High	0,5 h	13 h (1 day)
P3: Medium	0,5 h	39 h (3 days)
P4: Low	0,5 h	65 h (5 days)

5.1.1.2. Reporting

The Commission shall report on all service calls related to the systems and applications for administrative cooperation and recovery of claims in the area of VAT as follows:

- all the service calls closed during the month for Norway;
- all the service calls created during the month for Norway;
- all the service calls pending at the reporting date and time for Norway.

5.1.2. Statistical Service

5.1.2.1. Agreement

The Commission shall generate statistics about the number of exchanged forms in the VAT and recovery domain using CCN/Mail, which are available on the ITSM Web portal.

5.1.2.2. Reporting

The Commission shall produce a report on the conformance test reports, where applicable, and shall make them available to Norway.

5.1.3. Exchange of Forms

5.1.3.1. Agreement

The following table illustrates the maximum transmission deadline or answer time for the exchange of forms as defined in the legislation.

Table 6

Performance EoF

CCN/Mail mailbox	Form	Deadline
VIESCLO	Exchange of Information under Articles 7, 10, 12 and 18 of the Agreement General exchanges	The time limit for providing information is as quickly as possible, and no later than 3 months following the date of the request (Article 8 of the Agreement). However when the requested authority is already in possession of the information the time limit shall be reduced to a maximum period of one month (Article 8 of the Agreement).
VIESCLO	Exchange of Information under Articles 7, 10, 12 and 18 of the Agreement Request for notification	Request for notification with immediate answer (Article 12 of the Agreement).

CCN/Mail mailbox	Form	Deadline
TAXFRAUD	Exchange of Information under Articles 7, 10, 12 and 18 of the Agreement Anti-fraud exchanges	Missing trader information shall be sent as soon as the information becomes available.
TAXAUTO	Automatic exchanges	The categories of information subject to automatic exchange, in accordance with Article 11 of the Agreement, are to be determined by the Joint Committee.
REC-A-CUST; REC-B-VAT; REC-C-EXCISE; REC-D-INCOME-CAP; REC-E-INSUR; REC-F-INHERIT-GIFT; REC-G-NAT-IMMOV; REC-H-NAT-TRANSP; REC-I-NAT-OTHER; REC-J-REGIONAL; REC-K-LOCAL; REC-L-OTHER; REC-M-AGRI	Request for information under Art. 22 of the Agreement Request for notification under Art. 25 of the Agreement Request for recovery under Art. 27 of the Agreement Request for precautionary measures under Art. 33 of the Agreement	Request for information: — acknowledgment of receipt within 7 calendar days; — update at the end of 6 months from the date of acknowledgment. Request for notification: — acknowledgment of receipt within 7 calendar days. Request for recovery and request for precautionary measures: — acknowledgment of receipt within 7 calendar days; — update at the end of every 6 months from the date of acknowledgment.

5.1.3.2. Reporting

Norway shall also provide on an annual basis to the Commission statistical data via e-mail regarding to the communication of information as set out in Articles 20 and 39 of the Agreement [RD.3.].

5.1.4. Problem Management

5.1.4.1. Agreement

Norway shall maintain an adequate problem registration ⁽¹⁾ and follow-up mechanism for any problems affecting their application host, system software, data and applications software.

Problems with any part of the CCN network (Gateways and/or Exchange Mail servers) shall be reported to ITSM immediately.

5.1.4.2. Reporting

Norway shall inform the ITSM where they have an internal problem with the technical infrastructure related to their own systems and applications for administrative cooperation and recovery of claims in the area of VAT.

Where Norway considers that a problem reported to ITSM is not being addressed or resolved or was not addressed or resolved in a satisfactory way, it shall report this to the Commission as soon as possible.

5.1.5. Security Management

5.1.5.1. Agreement ⁽²⁾

Norway shall protect its systems and applications for administrative cooperation and recovery of claims in the area of VAT against security violations and shall keep track of any security violations and of any security improvements made.

⁽¹⁾ Linked to Problem and Change management processes of ITIL.

⁽²⁾ These are the documents versions available at the time of writing this SLA. The reader is invited to check any subsequent updates on the CCN/CSI Portal (<http://portal.ccncs.int:8080/portal/DesktopDefault.aspx?tabid=1>).

Norway shall apply the security recommendations and/or requirements specified in the following documents:

Table 7

Security recommendations

Name	Version	Date
https security recommendations of CCN /Mail III Webmail access – Ref. CCN /Mail III User Guide for NAs	3.0	15.6.2012
Security recommendations of CCN /Mail III Webmail access – Ref. CCN Intranet – Local Network Administrator Guide	4.0	11.9.2008

5.1.5.2. Reporting

Norway shall on an ad-hoc basis report to the Commission on any security violations and on any measures taken.

5.2. NORWAY'S SERVICE LEVELS

5.2.1. All Service Level Management Areas

5.2.1.1. Agreement

Norway shall register any unavailability problems or changes ⁽³⁾ regarding to the technical, functional and organisational aspects of Norway's systems and applications for administrative cooperation and recovery of claims in the area of VAT.

5.2.1.2. Reporting

Norway shall inform the ITSM where necessary in relation to any unavailability problems or changes regarding the technical, functional or organisational aspects of their system. ITSM shall always be informed for any changes regarding the operating personnel (operators, system administrators).

5.2.2. Service desk

5.2.2.1. Agreement

Norway shall make available a service desk for responding to incidents assigned to Norway, for giving assistance and to carry out testing. The working hours of the service desk should be the same as the working hours of the ITSM Service Desk during ITSM working days. Norway's service desk shall operate at a minimum between 10:00-16:00 CET during working days, except on its national holiday. It is recommended that Norway's service desk follows the ITIL service support guidelines in handling the questions and incidents.

5.2.2.2. Reporting

Norway shall inform the ITSM where necessary in relation to any availability problem related to its service desk.

6. QUALITY MEASUREMENT

6.1. AGREEMENT

The Commission shall evaluate the reports (activity reports generated by ITSM, notifications, statistics, other information) received from the ITSM and Norway, shall determine the levels of adherence to this SLA and in case of problems shall contact Norway in order to solve the problem and to ensure that the quality of the service is in line with this agreement.

6.2. REPORTING

The Commission shall report on a monthly basis to Norway the level of the service as defined in Section 5.1.2.

⁽³⁾ Use of principles described in the incident management in ITIL is recommended.

7. APPROVAL OF THE SLA

The Service Level Agreement has to be approved by the Joint Committee in order to be applicable.

8. CHANGES TO THE SLA

The Service Level Agreement will be reviewed following a written request from the Commission or Norway to the Joint Committee.

Until the Joint Committee decides on the proposed changes, the provisions of the current SLA remain in force. The Joint Committee acts as the decision making body for the present agreement.

9. CONTACT POINT

For any questions or remarks regarding this document, feel free to contact:

SERVICE PROVIDER - SERVICE DESK

support@itsmtaxud.europa.eu

ANNEX II

Service Level Agreement for the Common Communication Network / Common System Interface services
(‘CCN/CSI SLA’)

1. APPLICABLE ACTS AND REFERENCE DOCUMENTS

1.1. APPLICABLE ACTS

This CCN/CSI SLA takes into account the list of agreements and applicable decisions provided below.

Table 1

Applicable acts

[AD.1.]	Agreement between the European Union and the Kingdom of Norway on administrative co-operation, combating fraud and recovery of claims in the field of value added tax (‘the Agreement’) (OJ L 195, 1.8.2018, p. 3)
[AD.2.]	Decision No 2/2019 of the Joint Committee established by the Agreement between the European Union and the Kingdom of Norway on administrative cooperation, combating fraud and recovery of claims in the field of the value added tax of ... [date] on standard forms for the communication of information, the transmission of information via the CCN/CSI network and the practical arrangements for the organisation of contacts between central liaison offices and liaison departments

1.2. REFERENCE DOCUMENTS

This CCN/CSI SLA takes into account the information provided in the following reference documents. Applicable versions of the documents are those available at the time of signing this agreement.

Table 2

Reference Documents

ID	REFERENCE	TITLE	VERSION
RD1	CCN-COVW-GEN	CCN/CSI & SPEED2 Systems Overview	EN18.01
RD2	CCN-CMPR-GW	CCN Gateways Management Procedures	EN19.20
RD3	CCN-CSEC-POL	CCN/CSI General Security Policy	EN05.00
RD4	CCN-CSEC-BSCK	CCN/CSI Baseline Security Checklist	EN03.00
RD5	CCN-CLST-ROL	Description of CCN/CSI roles	EN02.10
RD6	CCN-CNEX-031	External note 031 – Procedure for the Move of a CCN/CSI Site	EN06.20
RD7	CCN-CNEX-060	External Note 060 – Install new CCN Site	EN02.20
RD8	CCN/CSI-PRG-AP/C-01-MARB	CCN/CSI-PRG-AP/C-01-MARB-Application Programming Guide (C Language)	EN11.00

2. TERMINOLOGY

2.1. ACRONYMS

Table 3

Acronyms

ACRONYMS	DEFINITION
ACT	Application Configuration Tool
AIX	IBM Unix OS
CCN	Common Communication Network
CCN/CSI	Common Communication Network / Common System Interface
CCN/WAN	Framework service for the provision of network services to CCN
CI	Configuration Item
CIRCABC	Communication and Information Resource Centre for Administrations, Businesses and Citizens
COTS	Common Off The Shelf
CPR	Customer Premises Router
CSA	CCN Security Administrator
CSI	Common System Interface
DG	Directorate General
DMZ	De-Militarised Zone
EC	European Commission
HPUX	Hewlett Packard Unix Operating System
HTTP	Hyper Text Transport Protocol
HTTPS	Hyper Text Transport Protocol – Secure
HVAC	Heating, Ventilating, and Air-Conditioning
HW	Hardware
ICT	Information and Communication Technology
IMAP	Internet Message Access Protocol
IP	Internet Protocol
ITCAM	IBM Tivoli Composite Application Manager
ITSM	Information Technology Service Management
LAN	Local Area Network
LSA	Local System Administrator
MQ	IBM MQ Series SW
MVS	Multiple Virtual Storage
NA	National Administration

ACRONYMS	DEFINITION
OBS	Orange Business Services
OS	Operating System
OSP	Obligation of the Service Provider
OSR	Obligation of the Service Requester
PoP	Point of Presence
QA	Quality Assurance
RAP	Remote API Proxy
RD	Reference Document
SMTP	Simple Mail Transport Protocol
SQI	Service Quality Indicator
SSG	Secure Services Gateways (Juniper Encryption box)
SW	Software
TAXUD	Taxation and Customs Union
TCP	Transmission Control Protocol
UPS	Uninterruptible Power Supply
WAN	Wide Area Network

2.2. DEFINITIONS OF TERMS FOR THE PURPOSE OF THE CCN/CSI SLA

Table 4

Definitions

TERM	DESCRIPTION
Reporting period	The elapsed time covered is one month.
Working day	The working days are the working days of the Service Provider Service Desk. These are 7 days a week including public holidays.
Working hour	The working hours are the working hours of the Service Provider SD. These are 24/24 during the working days.
Duty Period	The Service Provider's 'Duty Period' is the hours of coverage of the Service Desk function. The duty is ensured by Service Provider SD from 24/24, 7 days a week including public holidays. Depending of the CI's Service Window, there is an immediate action (24/7) or the intervention is scheduled for the next day. Letter, fax, e-mails and electronic requests (through the ITSM Portal) are accepted at any moment. Incoming requests are registered as 'Service Calls' in the Service Provider Service Desk management system.

3. INTRODUCTION

This document consists of a Common Communication Network / Common System Interface Service Level Agreement (CCN/CSI SLA) between the European Commission ('Service Provider') and the Kingdom of Norway ('Service Requester'), collectively referred as 'the Parties to the SLA'.

In particular the 'Service Provider' includes the organisational units of DG TAXUD, as listed below:

- DG TAXUD B2 unit coordinating all CCN/CSI activities;
- ITSM3 Operations providing operational services;
- CCN2DEV providing CCN software (evolutionary and corrective maintenance services);
- Trans-European Backbone network provider (CCN/WAN, currently OBS).

Based on the nature of the requested service, one of the Service Providers will fulfil the task.

The 'Service Requester' is the national administration (NA) of the Kingdom of Norway. The concerned organisational units within the NA are:

- the National CCN Support Centre in charge of the support and management of the DG TAXUD CCN Infrastructure equipment located at NA premises as well as the national infrastructure supporting the applications running over the CCN/CSI infrastructure;
- the National Application Support Centre in charge of the national support of the EC applications running in the National Domain and using the CCN/CSI infrastructure services;
- the National Application Development Teams in charge of the development of applications using the CCN/CSI infrastructure including their sub-contractors.

3.1. SCOPE OF THE CCN/CSI SLA

Article 5 of the Agreement specifies that 'A service level agreement ensuring the technical quality and quantity of the services for the functioning of the communication and information exchange systems shall be concluded'.

This CCN/CSI SLA sets out the relationship between and the Commission (Service Provider) and the Kingdom of Norway (Service Requester), concerning the operational phase of the Common Communication Network / Common System Interface system ('CCN/CSI system').

It defines the required level of the service provided to the Service Requester. It also provides for a mutual understanding of service level expectations and the responsibilities of the involved Parties to the SLA.

This document describes the services and service levels provided currently by the Service Provider.

All targets referred to in the CCN/CSI SLA will be applicable under normal working conditions only.

In case of events of *force majeure*, no Party shall be liable for any failure to perform its obligations where such failure is as a result of natural disaster (including fire, flood, earthquake, storm, hurricane or other natural disaster), war, invasion, act of foreign enemies, hostilities (whether war is declared or not), civil war, rebellion, revolution, insurrection, military or usurped power or confiscation, terrorist activities, nationalisation, government sanction, blockage, embargo, labour dispute, strike, lockout or interruption or long-term failure of the commercial electricity grid.

3.2. CCN/CSI SERVICE DEFINITION AND CHARACTERISTICS

The Common Communication Network / Common System Interface is a tool for exchange of tax information between the National Administrations in the field of Taxation and Anti-Fraud. The main characteristics of the CCN/CSI system infrastructure are listed hereafter:

Table 5

Characteristics of the services provided by CCN/CSI

TRANS-EUROPEAN	CCN/CSI offers a global WAN access to Service Requesters through a number of Points of Presence (PoP) in every Member State, acceding countries and the Kingdom of Norway. The CCN/CSI network backbone offers the required capacity and resilience to provide the Service Requesters with a high availability rate.
MULTI-PLATFORM	Allows the interoperability between heterogeneous platforms (Windows, Linux, Solaris, AIX, HP-UX, SVR4, IBM MVS, etc.) through a highly portable communication stack (CSI) installed on standard national Application Platforms.
MULTI-PROTOCOL	Supports various protocols and exchange paradigms: — CSI protocol supporting asynchronous and synchronous (request/response) communication paradigms (CCN/CSI channel); — HTTP/S protocol for interactive access to CCN Intranet services (CCN Intranet channel); — POP, IMAP, SMTP protocols for the exchange of e-mail between NA users but also between applications (CCN Mail III channel).
SECURE	Information exchanges over the CCN/CSI network are protected to ensure optimal confidentiality and data integrity. Security services include: — Site-to-site IPSec 256-bits encryption and protection against unwanted accesses enforced by Firewall/encryption devices deployed at every CCN/CSI site; — Access control mechanisms (authentication, authorisation, accounting) at site level enforced at CCN Gateway and supported by local administration tools (ADM3G); — Session-level security enforced by message-level encryption (CSI secure), SSL v.3 mutual authentication and encryption (HTTPS), POP-S and IMAP-S (secure e-mail transport).
MANAGED	The CCN/CSI infrastructure also provides Service Requesters with managed services including: — Central Monitoring; — Event logging; — Production of statistics on CSI and CCN Mail III message exchanges (size, number of messages, matrix) and statistics on CCN gateways and CCN Mail III; — User management (ADM3G) and directory services; — CSI stacks validation; — Portal services: — CCN Portal: on-line access to statistics, on-line remote API proxies (RAP) management; — ITSM Portal: on-line Newsletter, on-line documentation and CSI stack packages, CCN Frequently Asked Questions (FAQ); — ACT (Application Configuration Tool); — Services calls tracking and on-line support.

3.3. AGREEMENT PERIOD

The CCN/CSI SLA is binding on the Parties from the day following its approval by the Joint Committee established by Article 41 of the Agreement ('the Joint Committee').

4. RESPONSIBILITIES

4.1. OBLIGATIONS OF THE SERVICE PROVIDER (OSP)

The Service Provider shall:

Table 6

Obligations of the Service Provider (OSP)

[OSP1]	Operate the CCN/CSI network infrastructure in order to achieve the Service Levels described in section 8.
[OSP2]	Select the various CCN/CSI Infrastructure and Software components.
[OSP3]	Provide Hardware and Software maintenance for the DG TAXUD CCN infrastructure equipment (e.g. CCN Gateways) installed at the Service Requesters premises as well as the central CCN Mail III servers.
[OSP4]	Provide monitoring of the DG TAXUD CCN Infrastructure equipment installed at the Service Requesters premises.
[OSP5]	Manage the CCN/CSI audit files.
[OSP6]	Manage the CCN/CSI addressing plan.
[OSP7]	Respect the rules and recommendations put forward in the 'Security documents': — CCN/CSI General Security Policy RD3; — CCN/CSI Baseline Security Checklist RD4.
[OSP8]	From time to time, the Service Requester needs to make sure that the network availability will not be reduced due to maintenance or other expected unavailability's. In that case, the Service Requester will notify the Service Provider at least 1 month in advance. If the Service Requester cannot respect this delay, DG TAXUD will arbitrate the situation.
[OSP9]	All software licenses running on the CCN gateways will be provided by DG TAXUD.
[OSP10]	Respect the CCN/CSI site backup policy (cfr. RD2).
[OSP11]	Audit the system as defined in RD2.
[OSP12]	Regularly proceed with the System Security Checkup as defined in RD2.

4.2. OBLIGATIONS OF THE SERVICE REQUESTER (OSR)

The Service Requester shall:

Table 7

Obligations of the Service Requester (OSR)

Technical and Infrastructure level	
[OSR1]	House the DG TAXUD CCN Infrastructure equipment provided by the DG TAXUD and provide appropriate: — Rack/Storage space; — electrical power supply; — HVAC.

[OSR2]	Make sure that the CCN/CSI components are 'electrically' connected to the UPS. Specific adaptations to local standards (e.g. plug adapters) have to be provided by the Service Requester.
Operational and Organisation level	
[OSR3]	Assign personnel in charge of the roles listed in RD5.
[OSR4]	Ensure presence outside of normal working hours whenever deemed necessary and requested by the Service Provider. For some operations performed by the backbone carrier or by the Service Provider, the coordination and/or the presence of the LSA from the Service Consumer may be required. There will be at least one-month notice in order to plan these activities; full cooperation is necessary in order to respect the complex planning due to the number of sites.
[OSR5]	Never stop any of the DG TAXUD CCN Infrastructure equipment without formal authorisation from the Service Provider.
[OSR6]	Ask for the formal authorisation from the Service Provider before installing on the DG TAXUD CCN Infrastructure equipment additional hardware or software components that do not belong to the standard delivery package.
[OSR7]	Provide a clear description of the perceived/reported incidents, reported by the service requester.
[OSR8]	Collaborate actively with the Service Provider and/or his representatives when required for the delivery of services.
Communication level	
[OSR9]	Use exclusively the contact points at the Service Provider and inside their own organisation.
[OSR10]	Notify the Service Provider of any absence of the contact points during the opening hours of the Service Provider, or, at least, provide a backup able to replace the contact points.
[OSR11]	Notify the Service Provider of any modification of its own contact points, at least 5 working days before this modification becomes effective.
[OSR12]	Notify the Service Provider of any scheduled INFRASTRUCTURE maintenance potentially affecting the DG TAXUD CCN Infrastructure equipment hosted at the Service Consumer premises (at least one week in advance for all equipment). e.g.: planned power or network infrastructure outages, DC move, IP-address changes,
[OSR13]	Notify the Service Provider of any external problem such as power failure affecting the good running of the CCN Gateways and application platforms.
[OSR14]	Notify Service Provider, through a formal request, at least six months in advance for any moving of DG TAXUD CCN Infrastructure equipment. The Service Requester takes in charge the costs of the moving operations. Refer to RD6 for more details about the procedure.
[OSR15]	Notify the Service Provider of any outage of the secured links between the DG TAXUD CCN Infrastructure and the Service Requester (NA or peer DG).
[OSR16]	Notify the Service Provider of any outage of the Application Platforms.
[OSR28]	The service requester is requested to communicate any planned local DC/Computer room outage (incl. WAN) 1 (one) working week upfront. This in order for DG TAXUD to be able to put in place the necessary communication to any other involved stakeholders.

Security and User Management level	
[OSR17]	Manage the local user accounts on the CCN Gateway (cf. RD2).
[OSR18]	Grant physical access permission to the equipment and staff mandated by the Service Provider when required.
[OSR19]	Authorise the appropriate TCP ports in the Service Consumer network (National Domain) (cfr. RD2).
[OSR20]	Ensure that the Network Encryption Devices (currently Juniper SSG) at the Service Requester site is located in an access-controlled area.
[OSR21]	Restrict access to all devices of the DG TAXUD CCN Infrastructure to authorised personnel. The access shall be allowed only on request from the CSA. Unwanted access to these devices can jeopardise the security or at least cause network outages.
[OSR22]	Respect the rules and recommendations put forward in the 'Security documents': — CCN/CSI General Security Policy RD5; — CCN/CSI Baseline Security Checklist RD6.
Application Management Development	
[OSR27]	The Service Requester is sole responsible for the development, support and management of its applications. They must conform to the rules defined in RD8.

4.3. SERVICES PROVIDED BY THE SERVICE PROVIDER

4.3.1. IT Service Desk

The Service Provider offers a consolidated IT Service Desk with Incident and Problem Management. The IT Service Desk extends the range of classical help desk services and offers a more global-focused approach, allowing business processes to be integrated into the CCN/CSI service management.

Indeed, the IT Service Desk not only handles incidents, problems and questions, but also provides an interface for other activities such as change requests, maintenance contracts, software licences, service level management, configuration management, availability management, security management and IT service continuity management.

The IT Service Desk also spontaneously notifies the Service Requester of any urgent information, thus acting as an information-dispatching centre for the Service Requester.

A Notification is defined as a message issued by the Service Provider warning Service Requester of an event that may affect the CCN/CSI operations: gateway unavailability, system outage, malfunctions, infrastructure maintenance or software update.

The IT Service Desk interface to Service Requester is achieved through the Service Provider contact point or through the ITSM Web portal, which provides on-line services to the Service Requester such as service call tracking; ACT and the CCN Web portal which provides CSI packages download area, access to statistics and monitoring information, etc.

4.3.1.1. Incident and problem management

This service deals with incidents originating from Service Desk users (including system operations). An incident may be defined as a simple request for information or clarification, but may also be categorized as the reporting of non-compliant behaviour of a specific component.

An incident is defined as an unexpected event that is not part of the standard operation of the infrastructure or a failure that degrades an operational CCN/CSI service. An incident is solved when the service is restored.

The incident can be related to the following Configuration Items (CI):

- the hardware under responsibility of the Service Provider: CCN gateways, security devices, Customer Premises Routers (CPR) and other network connectivity devices on the EuroDomain (DG TAXUD CCN Infrastructure) LAN;
- the software running on the encryption devices;
- the system software running on the gateways: Operating System, basic communication software such as TCP/IP, etc.;
- the third-party software running on the gateways such as Tuxedo, MQSeries, Sun ONE Directory Server, PostgreSQL, Apache, etc.;
- the CCN Mail III;
- the CCN/CSI software running on the gateways;
- the CSI software running on the Application Platforms;
- SIAP (Secure Internet Access Point) – Unified Defence.

A problem is identified either from a single incident which has an extremely adverse impact on the user service and for which the cause is unknown, or from multiple incidents exhibiting common symptoms. A problem is solved when the cause is identified and removed.

When an incident occurs, the situation is investigated in order to restore the operational CCN/CSI services (if needed) and to find the root cause of the incident. The Service Provider helps to resolve incidents in the NA application software, at the level of the interface with CCN/CSI, as long as this has no impact on the other services to be provided by the Service Provider. The Service Provider assistance consists in providing information about the correct usage of CCN/CSI. It does not consist in participating in the debugging of NA application software.

4.3.2. Tools supporting the Service Management

The monitoring of the CCN gateway infrastructure, applications and CCN queues is supported by the IBM® Tivoli Monitoring (Tivoli Monitoring) and IBM Tivoli Composite Application Manager (ITCAM) product family.

The CCN Tivoli Monitoring and Reporting service, based on IBM Tivoli Monitoring suite, provides the following functionalities:

- monitor the applications queues located on the CCN Gateways (WebSphere MQ);
- monitor the operating system status of the CCN Gateways;
- CPU usage, Disk space, Memory usage, Network usage, Processes;
- Out of Band HW monitoring;
- monitor the running processes of the CCN components located on the CCN Gateways;
- monitor the CCN Mail III infrastructure;
- provide to the CCN Tivoli users a view on the previous monitored information;
- generate pre-defined alerts on the previous monitored components;
- provide reports based on collected historical data (CCN Tivoli Data Warehouse);
- give information about the availability and performance of the CCN/CSI infrastructure over time, reporting important trends in a consistent and integrated manner.

4.3.3. ICT Infrastructure Management and Operations

The Service Provider is called upon to install, operate, and maintain the CCN/CSI operational infrastructure so as to guarantee the agreed availability levels.

The CCN/CSI operational infrastructure is composed of the EuroDomain relay devices (CCN Gateways), security devices, customer premises router and telecommunications.

This service covers:

- Availability Management;
- Contingency Management;
- Application Configuration Data management;
- Security Management.

And also includes:

- the coordination of the moving of CCN/CSI equipment;
- the coordination of deployment of new sites;
- the capacity planning of the CCN infrastructure;
- follow-up of the above-requested activity during the monthly progress meeting. This meeting is QA'ed and consists of all contracting parties contributing to the CCN/CSI service;
- facilitation of 'freeze' requests. These can be requested only by authorized users to a DG TAXUD dedicated official;
- design, planning, deployment, operations, technical support & retirement of HW, OS and COTS;
- Network Services;
- HW& OS & COTS Services;
- Backup & Restore;
- Job Management Service;
- Production & Maintenance of ICT Infrastructure Management Related Plans i.e. ICT Infrastructure Plan, Availability Plan, Capacity Plan, Continuity Plan;
- Feasibility Studies linked to Infrastructure.

4.3.3.1. Availability Management

The main service that the Service Provider has to provide is to ensure that the CCN/CSI system is 'up and running' at the required availability level.

The Service Provider ensures that all CCN/CSI sites are interconnected through a Wide Area Network (WAN) offering the necessary resilience and capacity to ensure the proper functioning of critical business applications using the CCN/CSI infrastructure and services.

The availability management service covers the following items:

- global access in all connected NAs;
- the provision of the local loop (+ a backup line) between the WAN local access point (PoP) and the National Administration premises;
- the Customer Premises Router (CPR) installation, configuration, and maintenance;
- the Security Device (i.e. SSG encryption-firewall box) installation and maintenance;
- communication gateways located on the DMZ, at every local site (i.e. CCN Gateways);
- the central CCN Mail III system.

The Service Provider also provides statistical information on the availability collected under operational circumstances and a monitoring service, both for pro-active problem tracking and statistical purposes.

4.3.3.2. Contingency Management

The Service Provider is responsible for the CCN/CSI components located in the DG TAXUD CCN Infrastructure at each CCN/CSI site.

The Contingency service aims at restoring the agreed service levels within an agreed timeframe in case of partial or complete dysfunction or destruction of the CCN/CSI system by providing the Service Requesters with help and items such as:

- software backup of CCN gateways (at every site);
- central CCN backup site;
- redundant encryption devices;
- switching capabilities between production and backup gateways;
- spare units for hardware devices;
- dual telecom access lines to the CCN backbone (at every site);
- assistance in installation and configuration of CCN/CSI items in the DG TAXUD CCN Infrastructure;
- recovery procedures.

4.3.3.3. Application Configuration Data Management

This service concerns the management of configuration data, required by CCN/CSI applications, by the Service Provider.

These configuration data are stored in the central CCN/CSI Directory. The central CCN/CSI Directory management is shared between the Service Provider and the National Administrations. Each National Administration is in charge of the management of its local CCN/CSI users. The rest is managed by the Service Provider.

Examples of configurations subject to an Administration Service Request are:

- definition of a local admin profile;
- registration of an application service;
- registration of an application queue;
- registration of a message type;
- validation of application configuration data;
- registration of administration roles;
- contact list management.

4.3.4. Security Management

This service concerns the management of the security items, required by CCN/CSI environment, by the Service Provider.

Security is managed as well on the level of the involved server equipment (OS), network equipment and on operational level.

Information exchanges over the CCN/CSI network are protected to ensure optimal confidentiality and data integrity.

Security services include:

- site-to-site encryption and protection against unwanted accesses enforced by firewall/encryption devices;
- access control mechanisms (authentication, authorisation, accounting) at site level enforced at CCN Gateway and supported by local administration tools (ADM3G);
- session-level security enforced by message-level encryption (CSI secure), SSL mutual authentication and encryption (HTTPS & NJCSI), POP-S and IMAP-S (secure e-mail transport);
- SIAP unified defence mechanism for secured internet access to CCN services.

4.3.5. Documentation management

The Service Provider maintains the whole CCN/CSI technical documentation (i.e. technical document, user guides, frequently asked questions, newsletters, upcoming events, etc.) up-to-date, which acts as Documentation Centre.

This includes the documentation related to the CCN/CSI infrastructure: Oracle-Tuxedo, IBM-MQ, CCN Gateways, CCN Mail III, CSI software, procedures, reports, history of communication with partners, etc.

The Service Provider manages a list of documentation, related to the CCN/CSI that can be communicated to Service Requester. These documents are available on CIRCABC, and the ITSM Portal.

The Service Provider automatically updates the list with the newly approved version of the documents.

4.3.6. Reporting and statistics

The Service Provider provides the Service Requester with the following reporting facilities through the CCN and ITSM Web Portal:

- on-line availability figures for CCN Gateways and CCN Mail III servers;
- on-line newsletters;
- statistics on CCN/CSI exchanges.

The Service Provider also regularly holds IT Tech & Infra meeting, where the reporting and statistics are presented.

4.3.7. Training

The Service Provider works out courses and performs training related to the technical aspects of the CCN/CSI system. The standard courses are organised in training packages divided into modules. As a general rule, training sessions are organised every year. The standard training packages are distributed twice a year via DG TAXUD and available online on the ITSM Portal.

5. SERVICE LEVEL MEASUREMENT

5.1. SERVICE LEVEL

The Service Level is a measure of the quality of the services provided by the Service Provider. It is computed by a Service Quality Indicator or SQI.

It is expected that the Service Requester complies with its obligations (see §4.2) to achieve the agreed Service Level.

5.2. APPLICABLE SERVICE QUALITY INDICATORS

5.2.1. Individual CCN/CSI Site Availability

This SQI provides the lowest measured availability of an individual site during the 'Full Period', i.e. 24/7, for a given month. The CCN/CSI SLA limit is defined as follows:

LIMIT	>= 97,0 % availability
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5.2.2. SQI on the Duty Period

The Service Provider's 'Duty Period' is the hours of coverage of the Service Desk function. The duty is ensured by the Service Provider SD 24/24, 7 days a week including public holidays.

Depending of the CI's Service Window, there is an immediate action (24/7) or the intervention is scheduled for the next Service Window. Letter, fax, e-mails and electronic requests (through the ITSM Portal) are accepted at any moment. Incoming requests are registered as 'Service Calls' in the Service Provider Service Desk management system.

The SLA limit is defined as follows:

LIMIT	Service Desk shall not be unreachable during the duty period more than 2 times / month
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5.2.3. SQI on the Notification Service

The Service Provider provides notifications services to the Service Requester.

There are two types of notifications, for Urgent Notifications and for Normal Notifications:

- URGENT NOTIFICATIONS (when there isn't enough time to notify the CCN/CSI community at least 7 calendar days in advance): the notifications are disseminated to the appropriate audience at the latest, 2 hours after reception of an urgent notification request.
- NORMAL NOTIFICATIONS (or planned interventions): the notifications are disseminated to the appropriate audience at least one week (7 calendar days) before the interventions and a reminder is sent at least 24 hours before the events.

This indicator measures the respect of deadline for announcement (via mass mails) of scheduled unavailability.

5.2.4. SQI on the Contingency Management

Cold Standby (Switch Procedure, Backup & Restore or CCN over Internet)

The appropriate type of switch to be performed depends on a thorough analysis of the specific national administration setup and the problem at hand.

The maximum delay to switch from any national administration Production Gateway to an appropriate CCN Backup Gateway solution is defined as follows:

LIMIT	Max 5 working hours following the agreement with the Service Requester to perform the switch
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5.2.5. SQI on the Application Configuration Data management

The maximum delay to implement an Application Configuration Request via the ACT (Application Configuration Tool) for a single site is defined as follows:

LIMIT	5 working days
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5.2.6. SQI on the Acknowledgment Delay

The maximum delay between the time a request is received by the Service Desk and the time an acknowledgment (i.e. Service Call number) is sent to the service requester, is defined as follows:

LIMIT	30 minutes
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Incidents are classified according to their priority levels.

The priority of an incident is a number between 1 and 4:

Table 8

Priorities of incidents

1	CRITICAL
2	HIGH
3	MEDIUM
4	LOW

5.2.7. SQI on the Resolution Delay

The resolution delay is the elapsed time between the moment the incident is acknowledged by the Service Provider and the moment the Service Provider repairs the root cause of the incident or implements a workaround.

According to the priority, the resolution delay is defined as follows:

Table 9

Resolution Delays

PRIORITY	RESOLUTION DELAY
CRITICAL	5 Working Hours
HIGH	13 Working Hours
MEDIUM	39 Working Hours
LOW	65 Working Hours

Table 10

Limit of Resolution Delays for Incidents

PRIORITY	LIMIT
CRITICAL	>= 95,00 % of CRITICAL incidents must be solved within the agreed resolution delay (5 Working Hours).
HIGH	>= 95,00 % of HIGH incidents must be solved within the agreed resolution delay (13 Working Hours).
MEDIUM	>= 95,00 % of MEDIUM incidents must be solved within the agreed resolution delay (39 Working Hours).

6. APPROVAL OF THE SLA

The Service Level Agreement has to be approved by the Joint Committee in order to be applicable.

7. CHANGES TO THE SLA

The CCN/CSI SLA will be reviewed following a written request from the Commission or the Kingdom of Norway to the Joint Committee.

Until the Joint Committee decides on the proposed changes, the provisions of the CCN/CSI SLA in force are applicable. The Joint Committee acts as the decision making body for the current CCN/CSI SLA.

8. CONTACT POINT

For all operational services, the ITSM3 Operations acts as single point of contact. Its coordinates are provided below:

ITSM3 Operations - IBM

 Toll free: + 800 777 4477

 Caller paid: + 40 214 058 422

✉ support@itsmtaxud.europa.eu

🌐 <http://portal.ccntc.ccncsi.int:8080/portal>

(CCN Web Portal - for CCN Registered users)

🌐 <https://itsmtaxud.europa.eu/smt/ess.do>

(ITSM Web Portal - for Service Calls)

DRAFT

**DECISION No 4/2019 OF THE JOINT COMMITTEE ESTABLISHED BY THE AGREEMENT
BETWEEN THE EUROPEAN UNION AND THE KINGDOM OF NORWAY ON ADMINISTRATIVE
COOPERATION, COMBATING FRAUD AND RECOVERY OF CLAIMS IN THE FIELD OF VALUE
ADDED TAX**

of ...

**on the amount and modalities of the financial contribution to be made by Norway to the general
budget of the Union in respect of the cost generated by its participation in the European
Information Systems**

THE JOINT COMMITTEE,

Having regard to the Agreement between the European Union and the Kingdom of Norway on administrative cooperation, combating fraud and recovery of claims in the field of the value added tax ⁽¹⁾ ('the Agreement'), and in particular Article 41(1) thereof,

Whereas:

- (1) Regulation (EU) No 1286/2013 of the European Parliament and the Council ⁽²⁾ lays down the rules for the development, operation and maintenance of the European Information Systems, which are set out in point A of the Annex to that Regulation.
- (2) The Common Communication Network / Common System Interface ('CCN/CSI') and the electronic forms to be adopted pursuant to point (d) of Article 41(2) of the Agreement are Union components of the European Information Systems.
- (3) Pursuant to Article 9(3) of Regulation (EU) No 1286/2013, the use of the Union components of the European Information Systems by non-participating countries is subject to agreements with those countries to be concluded in accordance with Article 218 of the Treaty on the Functioning of the European Union.
- (4) It is necessary to adopt practical arrangements for the implementation of point (f) of Article 41(2) of the Agreement,

HAS ADOPTED THIS DECISION:

Article 1

Installation costs

The initial amount to be paid by the Kingdom of Norway for the establishment of virtual private network (VPN) access is 20 000 EUR.

The amount shall be paid within 60 days following adoption of this Decision.

Article 2

Yearly financial contribution

The yearly financial contribution that the Kingdom of Norway shall pay to the general budget of the Union shall be 20 000 EUR. The amount shall be paid each year by 1 September.

The contribution shall cover expenditure related to the development, maintenance and upgrade of IT solutions (CCN/CSI, e-forms, etc.).

⁽¹⁾ OJ L 195, 1.8.2018, p. 3.

⁽²⁾ Regulation (EU) No 1286/2013 of the European Parliament and of the Council of 11 December 2013 establishing an action programme to improve the operation of taxation systems in the European Union for the period 2014-2020 (Fiscalis 2020) and repealing Decision No 1482/2007/EC (OJ L 347, 20.12.2013, p. 25).

*Article 3***Method of payment**

The contributions under Articles 1 and 2 shall be paid in euros into the euro-denominated bank account of the Commission indicated in the debit note.

Article 4

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

Done at ..., ...

For the Joint Committee
The Chair

COUNCIL DECISION (EU) 2019/426**of 12 March 2019****appointing a member and two alternate members, proposed by the Kingdom of Belgium, of the Committee of the Regions**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to the proposal of the Belgian Government,

Whereas:

- (1) On 26 January 2015, 5 February 2015 and 23 June 2015, the Council adopted Decisions (EU) 2015/116 ⁽¹⁾, (EU) 2015/190 ⁽²⁾ and (EU) 2015/994 ⁽³⁾ appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020.
- (2) A member's seat on the Committee of the Regions has become vacant following the end of the term of office of Mr Michel LEBRUN.
- (3) Two alternate members' seats on the Committee of the Regions have become vacant following the end of the terms of office of Ms Anne-Marie CORBISIER and Mr Antoine TANZILLI,

HAS ADOPTED THIS DECISION:

Article 1

The following are hereby appointed to the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2020:

- (a) as a member:
 - Mr Willy BORSUS, *Conseiller communal de Marche-en-Famenne*,
- (b) as alternate members:
 - Mr Laurent HACKEN, *Conseiller communal à Forest*,
 - Mr Etienne SERMON, *Conseiller communal d'Andenne*.

Article 2

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

Done at Brussels, 12 March 2019.

For the Council
The President
E.O. TEODOROVICI

⁽¹⁾ Council Decision (EU) 2015/116 of 26 January 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 20, 27.1.2015, p. 42).

⁽²⁾ Council Decision (EU) 2015/190 of 5 February 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 31, 7.2.2015, p. 25).

⁽³⁾ Council Decision (EU) 2015/994 of 23 June 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 159, 25.6.2015, p. 70).

COUNCIL DECISION (EU) 2019/427**of 12 March 2019****appointing a member and an alternate member, proposed by the United Kingdom, of the Committee of the Regions**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 305 thereof,

Having regard to the proposal of the United Kingdom Government,

Whereas:

- (1) On 26 January 2015, 5 February 2015 and 23 June 2015, the Council adopted Decisions (EU) 2015/116 ⁽¹⁾, (EU) 2015/190 ⁽²⁾ and (EU) 2015/994 ⁽³⁾ appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020.
- (2) A member's seat on the Committee of the Regions has become vacant following the passing away of Mr Paul WATSON.
- (3) An alternate member's seat on the Committee of the Regions has become vacant following the end of the term of office of Ms Suzanne Ellen GROCOTT,

HAS ADOPTED THIS DECISION:

Article 1

The following are hereby appointed to the Committee of the Regions for the remainder of the current term of office, which runs until 25 January 2020 or until the date of withdrawal of the UK from the EU, whichever date comes first:

(a) as a member:

— Mr Simon BLACKBURN, *Councillor, Blackpool Council*,
and

(b) as an alternate member:

— Ms Joanne LABAN, *Councillor, Enfield Council*.

Article 2

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

Done at Brussels, 12 March 2019.

For the Council
The President
E.O. TEODOROVICI

⁽¹⁾ Council Decision (EU) 2015/116 of 26 January 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 20, 27.1.2015, p. 42).

⁽²⁾ Council Decision (EU) 2015/190 of 5 February 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 31, 7.2.2015, p. 25).

⁽³⁾ Council Decision (EU) 2015/994 of 23 June 2015 appointing the members and alternate members of the Committee of the Regions for the period from 26 January 2015 to 25 January 2020 (OJ L 159, 25.6.2015, p. 70).

