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⁽⁶⁾ Text with EEA relevance.

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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.

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⁽⁸⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2020/202**of 4 October 2019****granting a Union authorisation for the biocidal product family 'Iodine Teat Dip Products'****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 44(5) thereof,

Whereas:

- (1) On 20 August 2015, GEA Farm Technologies GmbH, submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'Iodine Teat Dip Products' ('the biocidal product family') of product-type 3, as described in Annex V to that Regulation. The competent authority of United Kingdom 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-AL019223-55 in the Register for Biocidal Products.
- (2) The biocidal product family contains 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 6 June 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 18 January 2019, 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.

⁽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 14 December 2018 on the Union authorisation of 'Iodine Teat Dip Products' (ECHA/BPC/217/2018).

- (5) On 20 May 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.
- (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 GEA Farm Technologies GmbH for the making available on the market and use of the biocidal product family 'Iodine Teat Dip Products' with authorisation number EU-0020125-0000 in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 19 November 2019 until 31 October 2029.

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, 4 October 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Summary of product characteristics for a biocidal product family

Iodine Teat dip products

Product type 3 — Veterinary hygiene (Disinfectants)

Authorisation number: EU-0020125-0000

R4BP asset number: EU-0020125-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	Iodine Teat dip products
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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	GEA Farm Technologies GmbH
	Address	Siemensstraße 25-27, 59199, Bönen, Germany
Authorisation number	EU-0020125-0000	
R4BP asset number	EU-0020125-0000	
Date of the authorisation	19 November 2019	
Expiry date of the authorisation	31 October 2029	

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

Name of manufacturer	GEA Farm Technologies
Address of manufacturer	Wylle Works, BA12 9HT Warminster United Kingdom
Location of manufacturing sites	Wylle Works, Watery Lane, BA12 9HT Warminster United Kingdom Gewerbestraße 5, 5325 Plainfeld Austria ul. Ołowiana 10, 85-461 Bydgoszcz Poland

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

Active substance	Iodine
Name of manufacturer	SQM Europe N.V.
Address of manufacturer	St Pietersvliet 7., bus 8 2000 Antwerp Belgium
Location of manufacturing sites	Sociedad Quimica y Minera SA, Los Militares, Las Condes, 4290 Piso 4 Santiago Chile

Active substance	Iodine
Name of manufacturer	Nihon Tennen Gas Co., Ltd (Via Mitsui & Co Europe PLC)
Address of manufacturer	Chiba Plant, 2508 Minami-Hinata, Shirako-Machi, Chosei-Gun,, 299-4205 Chosei-Gun Japan
Location of manufacturing sites	Chiba Plant, 2508 Minami-Hinata, Shirako-Machi, Chosei-Gun,, 299-4205 Chosei-Gun Japan

Active substance	Iodine
Name of manufacturer	Norkem Ltd
Address of manufacturer	Norkem House, Bexton Lane,, WA16 9FB Knutsford United Kingdom
Location of manufacturing sites	OFICINA CALA CALA S/N, Unknown POZO ALMONTE 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
Iodine		Active Substance	7553-56-2	231-442-4	0,16	2,47
C9-11 Alcohol Ethoxylate	C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Im-bentin C-91-060	Non-active substance	68439-46-3	614-482-0	0,0	2,35

2.2. Type(s) of formulation

Formulation(s)	AL — Any other liquid SL — Soluble concentrate
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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 — Concentrates — Professional concentrates with 1:3, 1:4 and 1:7 dilution rates
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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
Iodine		Active Substance	7553-56-2	231-442-4	1,58	2,47
C9-11 Alcohol Ethoxylate	C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Imbentin C-91-060	Non-active substance	68439-46-3	614-482-0	1,51	2,35

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	Causes serious eye irritation. May cause damage to thyroid gland through prolonged or repeated exposure. May be corrosive to metals. Toxic to aquatic life with long lasting effects.
Precautionary statements	Do not breathe vapours. Wash hands thoroughly after handling. Wear protective gloves. Wear protective clothing. Wear eye protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if you feel unwell. If eye irritation persists: Get medical advice. Collect spillage. Dispose of container according to local regulations. Dispose of contents according to local regulations.

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

4.1. Use description

Table 1

Use # 1 – Concentrates — Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for post milking — Dipping

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
Application method(s)	Open system: dip treatment Application via dip Cup: Using a traditional dip cup with non-return valves, dispense diluted product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material. Dispose of unused material after each milking The same solution can be applied to multiple animals during the same milking session. Cups should be refilled with fresh solution before starting new milking session
Application rate(s) and frequency	Quantity of diluted product to be applied per application: — cows and buffaloes: 3 to 10 ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Product to be diluted by the relevant rate stated on the label. Either: 25 % (1 part product to 3 parts water) 20 % (1 part product to 4 parts water) 12,5 % (1 part product to 7 parts water) In use concentration of products between 0,29 and 0,52 % (w/w) iodine. 2 post milking applications per animal, per day
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.

4.1.1. Use-specific instructions for use

Dip at least 2/3 of the teat length with diluted product immediately after milking

4.1.2. Use-specific risk mitigation measures

Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).

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

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 – Concentrates — Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for post milking — Spraying

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
Application method(s)	Open system: spray treatment Application via pneumatic sprayer: Uptake lance of spray system is placed in the container of the diluted product. The diluted product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two thirds of teats in the diluted product Application via manual trigger spray: Fill trigger spray bottle with diluted product. Use trigger spray to cover the bottom two thirds of each teat with diluted product
Application rate(s) and frequency	Quantity of diluted product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Product to be diluted by the relevant rate stated on the label. Either: 25 % (1 part product to 3 parts water) 20 % (1 part product to 4 parts water) 12,5 % (1 part product to 7 parts water) In use concentration of products between 0,29 and 0,52 % (w/w) iodine. 2 post milking applications per animal, per day
Category(ies) of users	Trained professional Professional

Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.
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4.2.1. *Use-specific instructions for use*

Spray at least 2/3 of the teat length with diluted product immediately after milking

4.2.2. *Use-specific risk mitigation measures*

Wear protective chemical resistant gloves and eye protection when handling the concentrate (glove material to be specified by the authorisation holder within the product information).

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

A protective coverall (at least type 6, EN 13034) shall be worn.

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

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 – Concentrates — Professional concentrates with 1:3, 1:4 and 1:7 dilution rates, for post milking — Foaming

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
Application method(s)	Open system: dip treatment Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the bottom two thirds of the cow's udder The same solution can be applied to multiple animals during the same milking session.

Application rate(s) and frequency	Quantity of diluted product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Product to be diluted by the relevant rate stated on the label. Either: 25 % (1 part product to 3 parts water) 20 % (1 part product to 4 parts water) 12,5 % (1 part product to 7 parts water) In use concentration of products between 0,29 and 0,52 % (w/w) iodine. 2 post milking applications per animal, per day
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.

4.3.1. *Use-specific instructions for use*

Dip at least 2/3 of the teat length with diluted product immediately after milking

4.3.2. *Use-specific risk mitigation measures*

Wear protective chemical resistant gloves and eye protection when handling the concentrate

(glove material to be specified by the authorisation holder within the product information).

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

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.

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

5.1. **Instructions for use**

Keep out of reach of children

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

The product must be brought to a temperature above 20 °C before use.

Dilute product before application according to the ratio specified on the product label

Formanual dilution of the concentrate; Add the ratio of concentrate and water, specified on the product label, to a suitably sized container to achieve the required dilution rate. Mix to a uniform solution.

Before attaching the milking cluster, all teat-dip residues should be removed with either a single use towel or re-usable cloth. One cloth should be used per cow

For effective use against bacteria and yeast, product must be left in contact with the skin for at least 60 seconds

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

Product can be used during the entire lactation period

5.2. **Risk mitigation measures**

See use specific risk mitigation measures

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

Remove and wash contaminated clothing before re-use.

After inhalation: Move to fresh air in case of accidental inhalation of fumes from overheating or combustion.

If you feel unwell, seek medical advice.

After contact with skin: Wash with water and soap as a precaution. Consult a doctor if skin irritation persists.

After contact with eyes: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical treatment by eye specialist.

After ingestion: Rinse out mouth and give plenty of water to drink. Never give anything by mouth to an unconscious person. Consult a physician.

Large spills should be contained using a chemical spill kit, soaked up using absorbent material such as kieselguhr and disposed of as hazardous waste.

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

At the end of the treatment, dispose of 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 farm based waste water treatment plant.

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

Protect from frost

Do not store at temperatures above 30 °C

Shelf life 12 months.

6. OTHER INFORMATION

⁽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.

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)	Ioklene Concentrate. Coars Dual				
Authorisation number	EU-0020125-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub- stance	7553-56-2	231-442-4	1,58
C9-11 Alcohol Ethoxy- late	C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Im- bentin C-91-060	Non-active substance	68439-46-3	614-482-0	1,51

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

Trade name(s)	Clinidip L Concentrate, Maxadine C, Diamond 3:1 Concentrate, Kristal 321, IO Spray 3:1 Concentrate, Coars Shield				
Authorisation number	EU-0020125-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub- stance	7553-56-2	231-442-4	2,06
C9-11 Alcohol Ethoxy- late	C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Im- bentin C-91-060	Non-active substance	68439-46-3	614-482-0	1,96

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

Trade name(s)	Clinidip Superconcentrate, Dunglinson Super IO 421 Concentrate, Ceanodine 4:1, Iodosan				
Authorisation number	EU-0020125-0003 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub- stance	7553-56-2	231-442-4	2,47
C9-11 Alcohol Ethoxy- late	C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Im- bentin C-91-060	Non-active substance	68439-46-3	614-482-0	2,35

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

Trade name(s)	Priodine, Diamond Predip				
Authorisation number	EU-0020125-0004 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub-stance	7553-56-2	231-442-4	2,32
C9-11 Alcohol Ethoxylate	C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Im-bentin C-91-060	Non-active substance	68439-46-3	614-482-0	2,21

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	Meta SPC 2 — RTU Products — Professional RTU Liquid for application pre and post milking
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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
Iodine		Active Substance	7553-56-2	231-442-4	0,16	0,5
C9-11 Alcohol Ethoxylate	C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Im-bentin C-91-060	Non-active substance	68439-46-3	614-482-0	0,0	0,56

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	May be corrosive to metals. Harmful to aquatic life with long lasting effects.
Precautionary statements	Avoid release to the environment. Collect spillage. Dispose of contents in accordance with local regulations. Dispose of container in accordance with local regulations.

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

4.1. Use description

Table 4

Use # 1 – RTU Products — Professional RTU Liquid, for application pre-milking — Dipping

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
Application method(s)	Open system: dip treatment Application via dip Cup: Using a traditional dip cup with non-return valves, dispense RTU product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material. Dispose of unused material after each milking The same solution can be applied to multiple animals during the same milking session.
Application rate(s) and frequency	Quantity of RTU product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Ready to use formulation in use concentration 0,16-0,30 % (w/w) iodine. 2 pre milking applications per animal, per day
Category(ies) of users	Trained professional Professional

Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.
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4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific 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 post milking disinfection

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 5

Use # 2 – RTU Products — Professional RTU Liquid, for application pre milking — Spraying

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast All
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment Application via pneumatic sprayer: Uptake lance of spray system is placed in the container of the RTU product. The RTU product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two thirds of teats in the RTU product Application via manual trigger spray: Fill trigger spray bottle with RTU product. Use trigger spray to cover the bottom two thirds of each teat with RTU product

Application rate(s) and frequency	Quantity of RTU product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Ready to use formulation In use concentration 0,16-0,30 % (w/w) iodine. 2 pre milking applications per animal, per day
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.

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)

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

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 6

Use # 3 – RTU Products — Professional RTU Liquid, for application pre milking – Foaming

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

Field(s) of use	Indoor
Application method(s)	Open system: dip treatment Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the bottom two thirds of the cow's udder The same solution can be applied to multiple animals during the same milking session.
Application rate(s) and frequency	Quantity of RTU product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Ready to use formulation. In use concentration 0,16-0,30 % (w/w) iodine. 2 pre milking applications per animal, per day
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.

4.3.1. *Use-specific instructions for use*

See general directions for use.

4.3.2. *Use-specific 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 post milking disinfection

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 7

Use # 4 – RTU Products — Professional RTU Liquid, for application post milking – Dipping

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
Application method(s)	Open system: dip treatment Application via dip Cup: Using a traditional dip cup with non-return valves, dispense RTU product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material. Dispose of unused material after each milking The same solution can be applied to multiple animals during the same milking session.
Application rate(s) and frequency	Quantity of RTU product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Ready to use formulation. In use concentration 0,16-0,50 % (w/w) iodine. 2 post milking applications per animal, per day
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.

4.4.1. Use-specific instructions for use

Dip at least 2/3 of the teat length with RTU product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

4.4.2. Use-specific 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

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 8

Use # 5 – RTU Products — Professional RTU Liquid, for application post milking – Spraying

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
Application method(s)	Open system: spray treatment Application via pneumatic sprayer: Uptake lance of spray system is placed in the container of the RTU product. The RTU product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two thirds of teats in the RTU product Application via manual trigger spray: Fill trigger spray bottle with RTU product. Use trigger spray to cover the bottom two thirds of each teat with RTU product
Application rate(s) and frequency	Quantity of RTU product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Ready to use formulation. In use concentration 0,16-0,50 % (w/w) iodine. 2 post milking applications per animal, per day
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.

4.5.1. *Use-specific instructions for use*

Spray at least 2/3 of the teat length with RTU product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

4.5.2. *Use-specific risk mitigation measures*

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

A protective coverall (at least type 6, EN 13034) shall be worn

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

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.

4.6. **Use description**

Table 9

Use # 6 – RTU Products — Professional RTU Liquid, for application post milking – Foaming

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
Application method(s)	Open system: dip treatment Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the bottom two thirds of the cow's udder The same solution can be applied to multiple animals during the same milking session.
Application rate(s) and frequency	Quantity of RTU product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Ready to use formulation In use concentration 0,16-0,50 % (w/w) iodine. 2 post milking applications per animal, per day
Category(ies) of users	Trained professional Professional

Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.
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4.6.1. *Use-specific instructions for use*

Dip at least 2/3 of the teat length with RTU product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

4.6.2. *Use-specific 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

4.6.3. *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.

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

See general directions for use.

4.6.5. *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.

4.7. **Use description**

Table 10

Use # 7 – RTU Products — Professional RTU Liquid, for application pre and post milking-Dipping

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
Application method(s)	Open system: dip treatment Application via dip Cup: Using a traditional dip cup with non-return valves, dispense RTU product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material. Dispose of unused material after each milking The same solution can be applied to multiple animals during the same milking session.

Application rate(s) and frequency	Quantity of RTU product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Ready to use formulation In use concentration 0,16-0,30 % (w/w) iodine. 2 pre milking applications per animal, per day 2 post milking applications per animal, per day
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.

4.7.1. *Use-specific instructions for use*

Post milking:

Dip at least 2/3 of the teat length with RTU product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

4.7.2. *Use-specific risk mitigation measures*

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

This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product.

4.7.3. *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.

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

See general directions for use.

4.7.5. *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.

4.8. Use description

Table 11

Use # 8 – RTU Products — Professional RTU Liquid, for application pre and post milking- Spraying

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
Application method(s)	Open system: spray treatment Application via pneumatic sprayer: Uptake lance of spray system is placed in the container of the RTU product. The RTU product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two thirds of teats in the RTU product Application via manual trigger spray: Fill trigger spray bottle with RTU product. Use trigger spray to cover the bottom two thirds of each teat with RTU product
Application rate(s) and frequency	Quantity of RTU product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) – Ready to use formulation In use concentration 0,16-0,30 % (w/w) iodine. 2 pre milking applications per animal, per day 2 post milking applications per animal, per day
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.

4.8.1. Use-specific instructions for use

Post milking:

Spray at least 2/3 of the teat length with RTU product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

4.8.2. Use-specific risk mitigation measures

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

A protective coverall (at least type 6, EN 13034) shall be worn

This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product.

4.8.3. *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.

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

See general directions for use.

4.8.5. *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.

4.9. Use description

Table 12

Use # 9 – RTU Products — Professional RTU Liquid, for application pre and post milking — Foaming

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
Application method(s)	Open system: dip treatment Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the bottom two thirds of the cow's udder The same solution can be applied to multiple animals during the same milking session.
Application rate(s) and frequency	Quantity of RTU product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1.5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Ready to use formulation In use concentration 0,16-0,30 % (w/w) iodine. 2 pre milking applications per animal, per day 2 post milking applications per animal, per day
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.

4.9.1. *Use-specific instructions for use*

Post milking:

Dip at least 2/3 of the teat length with RTU product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

4.9.2. *Use-specific risk mitigation measures*

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

This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product.

4.9.3. *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.

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

See general directions for use.

4.9.5. *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**

Keep out of reach of children

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

The product must be brought to a temperature above 20 °C before use.

Product can be used during the entire lactation period

Before attaching the milking cluster, all teat-dip residues should be removed with either a single use towel or reusable cloth. One cloth should be used per cow

For effective use against bacteria and yeast, product must be left in contact with the skin for at least 60 seconds

5.2. **Risk mitigation measures**

See use specific risk mitigation measures.

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

Remove and wash contaminated clothing before re-use.

After inhalation: Move to fresh air in case of accidental inhalation of fumes from overheating or combustion.

If you feel unwell, seek medical advice.

After contact with skin: Wash with water and soap as a precaution. Consult a doctor if skin irritation persists.

After contact with eyes: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical treatment by eye specialist.

⁽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.

After ingestion: Rinse out mouth and give plenty of water to drink. Never give anything by mouth to an unconscious person. Consult a physician.

Large spills should be contained using a chemical spill kit, soaked up using absorbent material such as kieselguhr and disposed of as hazardous waste.

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

At the end of the treatment, dispose of 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 farm based waste water treatment plant.

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

Protect from frost

Do not store at temperatures above 30 °C

Shelf life 12 months

6. OTHER INFORMATION

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

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

Trade name(s)	LuxSpray 30, Ioklene RTU, Corston Pre/Post Sprayable, Kristal Iocare Plus, PrePost, Autodine, Coars Super Pre				
Authorisation number	EU-0020125-0005 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub-stance	7553-56-2	231-442-4	0,3
C9-11 Alcohol Ethoxylate	C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Imbentin C-91-060	Non-active substance	68439-46-3	614-482-0	0,305

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

Trade name(s)	LuxSpray 50, Silkidip, Ceanodine, IoSpray 10, Maxadine RTU, Diamond Superdip, Kristal Iocare Post, KiwiDip, Superdip Excel, Ioguard RTU, Shepherd's IoSpray 50				
Authorisation number	EU-0020125-0006 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub-stance	7553-56-2	231-442-4	0,5
C9-11 Alcohol Ethoxylate	C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Imbentin C-91-060	Non-active substance	68439-46-3	614-482-0	0,56

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

Trade name(s)	LuxDip 50B, Postguard				
Authorisation number	EU-0020125-0007 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub-stance	7553-56-2	231-442-4	0,5

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

Trade name(s)	LuxDip 25, Kote It, Corston Barracide Post Film Forming Dip, Pro-Tect, Kristal Iocare Film, Coars Iodinegel, Coars Iodogel, LuxDip 20B				
Authorisation number	EU-0020125-0008 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub-stance	7553-56-2	231-442-4	0,25
C9-11 Alcohol Ethoxylate	C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Imbentin C-91-060	Non-active substance	68439-46-3	614-482-0	0,5

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

Identifier	Meta SPC 3 — RTU Products — Professiona RTU Liquid for application pre and post milking (LuxSpray 15)
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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
Iodine		Active Substance	7553-56-2	231-442-4	0,16	0,16
C9-11 Alcohol Ethoxylate	C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Im-bentin C-91-060	Non-active substance	68439-46-3	614-482-0	0.166	0.166

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	May be corrosive to metals.
Precautionary statements	Avoid release to the environment. Collect spillage. Dispose of contents in accordance with local regulations. Dispose of container in accordance with local regulations.

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

4.1. Use description

Table 13

Use # 1 – RTU Products — Professional RTU Liquid, for application pre-milking — Dipping

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

Application method(s)	Open system: dip treatment Application via dip Cup: Using a traditional dip cup with non-return valves, dispense RTU product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material. Dispose of unused material after each milking The same solution can be applied to multiple animals during the same milking session.
Application rate(s) and frequency	Quantity of RTU product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Ready to use formulation. In use concentration 0,16 % (w/w) iodine. 2 pre milking applications per animal, per day
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific 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 post milking disinfection

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 14

Use # 2 – RTU Products — Professional RTU Liquid, for application pre milking — spraying

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
Application method(s)	Open system: spray treatment Application via pneumatic sprayer: Uptake lance of spray system is placed in the container of the RTU product. The RTU product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two thirds of teats in the RTU product Application via manual trigger spray: Fill trigger spray bottle with RTU product. Use trigger spray to cover the bottom two thirds of each teat with RTU product
Application rate(s) and frequency	Quantity of RTU product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Ready to use formulation In use concentration 0,16 % (w/w) iodine. 2 pre milking applications per animal, per day
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.

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)

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

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 15

Use # 3 – RTU Products — Professional RTU Liquid, for application pre milking – Foaming

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
Application method(s)	Open system: dip treatment Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the bottom two thirds of the cow's udder The same solution can be applied to multiple animals during the same milking session.
Application rate(s) and frequency	Quantity of RTU product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Ready to use formulation In use concentration 0,16 % (w/w) iodine. 2 pre milking applications per animal, per day
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.

4.3.1. *Use-specific instructions for use*

See general directions for use.

4.3.2. *Use-specific 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 post milking disinfection

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 16

Use # 4 – RTU Products — Professional RTU Liquid, for application post milking – Dipping

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
Application method(s)	Open system: dip treatment Application via dip Cup: Using a traditional dip cup with non-return valves, dispense RTU product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material. Dispose of unused material after each milking The same solution can be applied to multiple animals during the same milking session.
Application rate(s) and frequency	Quantity of RTU product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Ready to use formulation In use concentration 0,16 % (w/w) iodine. 2 post milking applications per animal, per day
Category(ies) of users	Trained professional Professional

Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.
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4.4.1. *Use-specific instructions for use*

Dip at least 2/3 of the teat length with diluted product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

4.4.2. *Use-specific 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

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 17

Use # 5 – RTU Products — Professional RTU Liquid, for application post milking – Spraying

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeast All
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment Application via pneumatic sprayer: Uptake lance of spray system is placed in the container of the RTU product. The RTU product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two thirds of teats in the RTU product Application via manual trigger spray: Fill trigger spray bottle with RTU product. Use trigger spray to cover the bottom two thirds of each teat with RTU product

Application rate(s) and frequency	Quantity of RTU product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Ready to use formulation In use concentration 0,16 % (w/w) iodine. 2 post milking applications per animal, per day
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.

4.5.1. Use-specific instructions for use

Spray at least 2/3 of the teat length with RTU product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

4.5.2. Use-specific risk mitigation measures

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

A protective coverall (at least type 6, EN 13034) shall be worn

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

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.

4.6. Use description

Table 18

Use # 6 – RTU Products — Professional RTU Liquid, for application post milking – Foaming

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
Application method(s)	Open system: dip treatment Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the bottom two thirds of the cow's udder The same solution can be applied to multiple animals during the same milking session.
Application rate(s) and frequency	Quantity of RTU product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Ready to use formulation In use concentration 0,16 % (w/w) iodine. 2 post milking applications per animal, per day
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.

4.6.1. Use-specific instructions for use

Dip at least 2/3 of the teat length with RTU product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

4.6.2. Use-specific 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

4.6.3. *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.

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

See general directions for use.

4.6.5. *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.

4.7. Use description

Table 19

Use # 7 – Use # 3.7 – RTU Products — Professional RTU Liquid, for application pre and post milking-Dipping

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
Application method(s)	Open system: dip treatment Application via dip Cup: Using a traditional dip cup with non-return valves, dispense RTU product into the reservoir. Screw down the applicator portion. Squeeze the reservoir to fill the applicator. Cover the bottom two thirds of each teat with material. Dispose of unused material after each milking The same solution can be applied to multiple animals during the same milking session.
Application rate(s) and frequency	Quantity of RTU product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Ready to use formulation In use concentration 0,16 % (w/w) iodine. 2 pre milking applications per animal, per day 2 post milking applications per animal, per day
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.

4.7.1. *Use-specific instructions for use*

Post milking:

Dip at least 2/3 of the teat length with RTU product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

4.7.2. *Use-specific risk mitigation measures*

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

This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product.

4.7.3. *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.

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

See general directions for use.

4.7.5. *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.

4.8. **Use description**

Table 20

Use # 8 – RTU Products — Professional RTU Liquid, for application pre and post milking- Spraying

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
Application method(s)	Open system: spray treatment Application via pneumatic sprayer: Uptake lance of spray system is placed in the container of the RTU product. The RTU product is then pumped to a spray lance located in the milking parlour. The spray lance is then used to cover the bottom two thirds of teats in the RTU product Application via manual trigger spray: Fill trigger spray bottle with RTU product. Use trigger spray to cover the bottom two thirds of each teat with RTU product
Application rate(s) and frequency	Quantity of RTU product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Ready to use formulation In use concentration 0,16 % (w/w) iodine. 2 pre milking applications per animal, per day 2 post milking applications per animal, per day

Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.

4.8.1. *Use-specific instructions for use*

Post milking:

Spray at least 2/3 of the teat length with RTU product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

4.8.2. *Use-specific risk mitigation measures*

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

A protective coverall (at least type 6, EN 13034) shall be worn

This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product.

4.8.3. *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.

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

See general directions for use.

4.8.5. *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.

4.9. **Use description**

Table 21

Use # 9 – RTU Products — Professional RTU Liquid, for application pre and post milking — Foaming

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

Application method(s)	Open system: dip treatment Application via foaming Dip cup: As for dip cup, however, when squeezed, the liquid is forced through a fine mesh, mixing with air and forming foam. This is then applied to the bottom two thirds of the cow's udder The same solution can be applied to multiple animals during the same milking session.
Application rate(s) and frequency	Quantity of RTU product to be applied per application: — cows and buffaloes: 3 to 10ml (5 ml recommended) — sheep 1,5 to 5 ml (1,5 ml recommended) — goats 2,5 to 6 ml (2,5 ml recommended) Ready to use formulation In use concentration 0,16 % (w/w) iodine. 2 pre milking applications per animal, per day 2 post milking applications per animal, per day
Category(ies) of users	Trained professional Professional
Pack sizes and packaging material	Drum, Plastic: HDPE, 10 l Drum, Plastic: HDPE, 20 l Drum, Plastic: HDPE, 25 l Drum, Plastic: HDPE, 200 l IBC (intermediate bulk container), Plastic: HDPE, 1000 l Drum, Plastic: HDPE, 5 l All drums excepting 200 l (200 kg) and 1000 l (1000 kg) could be either silver or natural (white translucent) in colour. 200 l (200 kg) drums are either silver or blue in colour. IBCs are natural coloured. All drums are capped with tamper evident caps or bungs and are UN certified.

4.9.1. *Use-specific instructions for use*

Post milking:

Dip at least 2/3 of the teat length with RTU product immediately after milking

To ensure sufficient contact time, care should be taken that the product is not removed after application (e.g. keep the cows standing at least 5 minutes).

4.9.2. *Use-specific risk mitigation measures*

Wear protective chemical resistant gloves when applying the product by foaming application method

(glove material to be specified by the authorisation holder within the product information).

This product can be used for pre- and post-milking disinfection in combination. However, it should not be used in combination with a different iodine-based product.

4.9.3. *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.

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

See general directions for use.

4.9.5. *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**

Keep out of reach of children

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

The product must be brought to a temperature above 20 °C before use.

Product can be used during the entire lactation period

Before attaching the milking cluster, all teat-dip residues should be removed with either a single use towel or reusable cloth. One cloth should be used per cow

For effective use against bacteria and yeast, product must be left in contact with the skin for at least 60 seconds

5.2. **Risk mitigation measures**

See use specific risk mitigation measures.

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

Remove and wash contaminated clothing before re-use.

After inhalation: Move to fresh air in case of accidental inhalation of fumes from overheating or combustion.

If you feel unwell, seek medical advice.

After contact with skin: Wash with water and soap as a precaution. Consult a doctor if skin irritation persists.

After contact with eyes: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical treatment by eye specialist.

After ingestion: Rinse out mouth and give plenty of water to drink. Never give anything by mouth to an unconscious person. Consult a physician.

Large spills should be contained using a chemical spill kit, soaked up using absorbent material such as kieselguhr and disposed of as hazardous waste.

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

At the end of the treatment, dispose of 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 farm based waste water treatment plant.

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

Protect from frost

Do not store at temperatures above 30 °C

Shelf life 12 months

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

6. OTHER INFORMATION

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

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

Trade name(s)	LuxSpray 15 — Priodine RTU/Kristal Iocare Pre/Super Pre				
Authorisation number	EU-0020125-0009 1-3				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Sub-stance	7553-56-2	231-442-4	0,16
C9-11 Alcohol Ethoxylate	C 9-11 alcohol with 6 moles of ethoxylate. Various brand names available including Imbentin C-91-060	Non-active substance	68439-46-3	614-482-0	0,166

COMMISSION DELEGATED REGULATION (EU) 2020/203
of 28 November 2019
on classification of vehicles, obligations of European Electronic Toll Service users, requirements for
interoperability constituents and minimum eligibility criteria for notified bodies

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive (EU) 2019/520 of the European Parliament and of the Council of 19 March 2019 on the interoperability of electronic road toll systems and facilitating cross-border exchange of information on the failure to pay road fees in the Union ⁽¹⁾, and in particular Articles 8(5), 10(3), 15(4), 15(5), and 19(5) thereof,

Whereas:

- (1) To ensure that the European Electronic Toll Service (EETS) works well, EETS users need to provide correct data and are responsible for the status of the on-board equipment, if an on-board equipment is used.
- (2) In order to increase interoperability of the electronic road toll systems and ensure compatibility with general requirements stemming from EU legislation, as for example data protection, EETS providers and toll chargers need to comply with a minimum set of procedural, technical and operational requirements.
- (3) General infrastructure requirements should be established to ensure that the interoperability constituents provide for accurate data, correct identification of the EETS providers, proper installation of the on board equipment, if one is used, and correct information for the drivers on road fees obligations.
- (4) Standard criteria for nominating the bodies responsible for the assessment of conformity of specifications and suitability for use of interoperability constituents need to be defined so that a minimum level of expertise is ensured and manufacturers can rely on equal treatment in all Member States.
- (5) To ensure consistent application between this Regulation and Directive (EU) 2019/520, it should apply from the date referred to in the Article 32(1) of Directive (EU) 2019/520.

⁽¹⁾ OJ L 91, 29.3.2019, p. 45.

HAS ADOPTED THIS REGULATION:

Article 1

Scope

This Delegated Regulation lays down requirements for:

- (1) the classification of vehicles,
- (2) the detailed obligations of EETS users,
- (3) interoperability constituents,
- (4) the minimum criteria of eligibility for notified bodies.

Article 2

Vehicle classification

1. The parameters used to classify vehicles for determining tolls shall comply with the requirements provided for in Annex I of this Delegated Regulation.
2. Without prejudice to Article 6(2) of Directive (EU) 2019/520, where a toll charger intends to introduce new vehicle classification parameters, the Member State where it is registered must inform the Commission, the other Member States and EETS providers in operation in the EETS domain thereof six months before the new classification parameters are introduced.

Article 3

EETS users' obligations

1. EETS users shall ensure that all user and vehicle data they provide to the EETS providers and the declaration of variable parameters are correct.
2. EETS users shall take all possible measures to ensure that the on-board equipment is operational whilst the vehicle is circulating within an EETS domain requiring on-board equipment.
3. EETS users shall operate on-board equipment in accordance with the EETS provider's instructions, in particular where these apply to the declaration of variable vehicle classification parameters.

Article 4

Interoperability constituents' requirements

Interoperability constituents and roadside infrastructure shall comply with the requirements provided for in Annex II of this Delegated Regulation.

Article 5

Minimum eligibility criteria for notified bodies

The notified bodies referred to in Article 19(1) of Directive (EU) 2019/520 shall comply with the minimum criteria provided for in Annex III of this Delegated Regulation.

Article 6

Entry into force

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

It shall apply from 19 October 2021.

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

Done at Brussels, 28 November 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

PROVISIONS ON VEHICLE CLASSIFICATION

1. General provisions

- 1.1. A toll charger must publish the correspondence between the set of vehicle classification parameters used and its vehicle tariff classes for each tariff scheme applied in an EETS domain under its responsibility at least three months before the use of the tariff scheme. This obligation does not refer to any changes made by the toll charger to specific tariffs within a tariff scheme.
- 1.2. A toll charger must publish the correspondence of its vehicle tariff classes with its tariffs structure for each tariff scheme applied in an EETS domain under its responsibility. It must update the publication immediately when that correspondence changes.

2. Vehicle classification parameters

- 2.1. A toll charger may use vehicle classification parameters according to at least one of the following provisions:
 - (a) any vehicle classification parameter that can be measured by its roadside equipment
 - (b) the vehicle parameters that are listed in vehicles registration documents ⁽¹⁾ and standardised in clause 8.4 of EN ISO 14906:2018 ⁽²⁾;If an OBE is used, the OBE is required only to support storage and transmission of possible vehicle classification parameters that can be retrieved from the OBE using dedicated short-range communication at 5,8 GHz as defined by standards EN 15509:2014 ⁽³⁾ and ETSI ES 200674-1 V2.4.1 ⁽⁴⁾; for GNSS based schemes, in addition, any vehicle parameter may be retrieved from the OBE using CEN-DSRC as defined by EN ISO 12813:2019 ⁽⁵⁾.
- 2.2. When circulating in a toll domain, vehicle on-board equipment must be able to communicate the on-board equipment status information and, where applicable, its vehicle classification parameters to the toll declaration monitoring equipment of the toll charger, as defined in Annex I of Commission Implementing Regulation (EU) 2020/204 ⁽⁶⁾.

3. New tariff schemes

- 3.1. Where a newly introduced tariff scheme is based on vehicle classification parameters already in use in at least one EETS domain, EETS providers must implement the new tariff scheme as of the date of its entry into force.
- 3.2. Where a new tariff scheme introduces one or more new vehicle classification parameters, the procedure under Article 2.2 of the Delegated Regulation must be followed.

⁽¹⁾ Commission Directive 2003/127/EC of 23 December 2003 amending Council Directive 1999/37/EC on the registration documents for vehicles (OJ L 010, 16.1.2004, p. 0029-0053).

⁽²⁾ Electronic fee collection – Application interface definition for dedicated short-range communication.

⁽³⁾ Electronic fee collection — Interoperability application profile for DSRC.

⁽⁴⁾ Intelligent Transport Systems (ITS); Road Transport and Traffic Telematics (RTTT); Dedicated Short Range Communications (DSRC); Part 1: Technical characteristics and test methods for High Data Rate (HDR) data transmission equipment operating in the 5,8 GHz Industrial, Scientific and Medical (ISM) band.

⁽⁵⁾ Electronic fee collection – Compliance check communication for autonomous systems.

⁽⁶⁾ Commission Implementing Regulation (EU) 2020/204 of 28 November 2019 on detailed obligations of European Electronic Toll Service providers, minimum content of the European Electronic Toll Service domain statement, electronic interfaces, requirements for interoperability constituents and repealing Decision 2009/750/EC (OJ L 43 17.2.2020, p. 49).

ANNEX II

REQUIREMENTS FOR INTEROPERABILITY CONSTITUENTS**1. GENERAL REQUIREMENTS****1.1. Reliability and availability**

- 1.1.1. The monitoring and maintenance of fixed or movable components that are used in EETS must be organised, carried out and quantified in such a manner as to maintain their operation under the intended conditions.
- 1.1.2. EETS design should enable the system to continue working if the components malfunction or fail, possibly in a degraded mode, but with the least disruption for EETS users.

1.2. Technical compatibility

Where they are interfacing, the technical characteristics of the equipment of EETS providers and toll chargers must be compatible and in line with the provisions laid down in Annex I of the Implementing Regulation (EU) 2020/204.

1.3. Security/privacy and protection of personal data

- 1.3.1. EETS must provide security features relative to the protection of data stored, handled and transferred between stakeholders in the EETS environment. The security features shall integrate the necessary safeguards into the processing in order to protect the rights and interests of EETS stakeholders, in particular protect them from risks or damage caused by lack of availability, confidentiality, integrity, authentication, non-repudiation and protection from unauthorised access to user data in a European multi-user environment, in compliance with the relevant legislation on the protection of individuals with regard to the processing of personal data.
- 1.3.2. EETS must comply with EU data protection legislation. In particular, compliance with Regulation (EU) 2016/679 and the national laws, regulations or administrative provisions turning Directive 2002/58/EC into national law must be ensured.

2. SPECIFIC REQUIREMENTS**2.1. Infrastructure requirements**

- 2.1.1. EETS infrastructure must allow for the accuracy of toll declaration data to correspond with the toll regime requirements to guarantee equal and fair treatment between EETS users in respect of tolls and charges.
- 2.1.2. The on-board equipment must enable toll chargers to identify the responsible EETS provider. The on-board equipment must regularly monitor this information, invalidate itself if an irregularity is detected and, where possible, inform the EETS provider of the anomaly.
- 2.1.3. Where applicable, EETS equipment must be designed so that its interoperability constituents use standards issued by European Standardisation Organisations.
- 2.1.4. On-board equipment must be integrated in a safe and secure way. Its fitment will be compliant with requirements for vehicles forward vision. ⁽¹⁾
- 2.1.5. Toll chargers must inform drivers, through signalisation or other means chosen by Member States, of the requirement to pay a toll or charge for driving a vehicle in an EETS domain, and of the roads covered by an EETS domain.

⁽¹⁾ Commission Directive 90/630/EEC of 30 October 1990 adapting to technical progress Council Directive 77/649/EEC on the approximation of the laws of the Member States relating to the field of vision of motor vehicle drivers (OJ L 341, 6.12.1990, p. 20).

2.2. Operation and management requirements

- 2.2.1. Toll chargers and EETS providers must determine contingency plans in order to avoid major traffic flow disruptions if the EETS is unavailable.
- 2.2.2. With respect to evaluating the performance of on-board equipment using satellite-positioning technology provided under Article 3.3 of Directive (EU) 2019/520, the EGNOS/Galileo eCall conformance test specifications ⁽²⁾ may be applied

⁽²⁾ Implementation guidelines for On-Board Unit manufacturers, test solution vendors and technical centres, by European Global Navigation Satellite Systems Agency and EC Joint Research Centre (Dec 2017, version 1.0).

ANNEX III

MINIMUM ELIGIBILITY CRITERIA FOR NOTIFIED BODIES

1. For the purposes of notification, a conformity assessment body, a body entitled to carry out or supervise the conformity assessment procedure on specifications and suitability for use of interoperability constituents, must comply with paragraphs 2 to 11 of this Annex.

The body must be accredited in accordance with Regulation (EC) No 765/2008 ⁽¹⁾ for the harmonised European standard for conformity assessment on requirements for bodies certifying products, processes and services.

2. The body must be established under national law and have legal personality.
3. The body must be a third-party body independent of the organisation or the product it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of products which it assesses, may, if its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. The body, its top-level management and the staff responsible for carrying out the conformity assessment tasks cannot be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products that they assess, nor the authorised representative of any of those parties. This must not preclude the use of assessed products that are necessary for the operations of the conformity assessment body or the use of such products for personal purposes.

The body, its top-level management and the staff responsible for carrying out the conformity assessment tasks must not be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those products, or represent the parties engaged in those activities. They must not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. In particular this must apply to consultancy services.

Conformity assessment bodies must ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their staff must carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field. They must also be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.
6. The body must be capable of carrying out all the conformity assessment tasks assigned to it under Directive 2019/520/EU and the relevant implementing acts and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a conformity assessment body must have at its disposal the necessary:

- (a) staff with technical knowledge and sufficient and relevant experience to perform the conformity assessment tasks;
- (b) descriptions of procedures governing the way a conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It must have appropriate policies and procedures in place that distinguish between the tasks it carries out as a notified body and other activities; and

⁽¹⁾ Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

- (c) procedures for the performance of activities that take account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process.

It shall be able to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and must have access to all necessary equipment or facilities.

7. The staff responsible for carrying out conformity assessment activities must have the following:
 - (a) adequate technical and vocational training covering all the conformity assessment activities for which the conformity assessment body has been notified;
 - (b) satisfactory knowledge of the requirements of the assessments they carry out and sufficient authority to carry out those assessments;
 - (c) sufficient knowledge and understanding of the essential requirements, of the applicable standards and of the relevant provisions of EU harmonisation legislation and of its implementing regulations; and
 - (d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of the conformity assessment bodies, their top-level management and of the assessment personnel must be guaranteed.

The salaries of the top-level management and staff carrying out the assessments cannot depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies must take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.
 10. The conformity assessment body staff must comply with professional secrecy for all information obtained in carrying out their tasks under Directive 2019/520/EU and the relevant implementing acts or any national law giving effect to it. However, this does not apply to the competent authorities of the Member State in which its activities are carried out. Proprietary rights must be protected.
 11. Conformity assessment bodies must participate in, or ensure that staff carrying out the assessment are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under the relevant EU legislation and apply as general guidance the administrative decisions and documents produced by that group.
-

COMMISSION IMPLEMENTING REGULATION (EU) 2020/204**of 28 November 2019****on detailed obligations of European Electronic Toll Service providers, minimum content of the European Electronic Toll Service domain statement, electronic interfaces, requirements for interoperability constituents and repealing Decision 2009/750/EC**

THE EUROPEAN COMMISSION,

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

Having regard to Directive (EU) 2019/520 of the European Parliament and of the Council of 19 March 2019 on the interoperability of electronic road toll systems and facilitating cross-border exchange of information on the failure to pay road fees in the Union ⁽¹⁾, and in particular Articles 5(11), 6(9), 14(3), 15(6) and 15(7) thereof,

After consulting the Electronic Toll Committee,

Whereas:

- (1) In order to complete the legislative framework for ensuring the interoperability of electronic road toll systems, it is necessary to lay down detailed requirements in respect of obligations of European Electronic Toll Service (EETS) providers, the content of the EETS domain statement, electronic interfaces and requirements for interoperability constituents.
- (2) In order to avoid performance problems of the EETS system, EETS providers, should be required to monitor their service and collaborate with the toll charger when performing toll system tests.
- (3) EETS providers should provide specific data to the toll charger so that the verification of the calculation of the toll applied can take place.
- (4) To ensure smooth functioning of the EETS system, EETS providers should provide technical support for the identification of the on-board-equipment.
- (5) Where the measures provided for in this Regulation entail the processing of personal data, they should be carried out in accordance with Union law on the protection of personal data and privacy, in particular Regulation (EU) 2016/679 of the European Parliament and of the Council ⁽²⁾, and, where applicable, Directive 2002/58/EC of the European Parliament and of the Council ⁽³⁾. To this end, EETS providers should not be required to provide more client data to the toll chargers than is necessary to ensure the correct functioning of the EETS.
- (6) In order to provide appropriate information to the users, invoicing should reflect the various service and toll price components in a transparent manner.
- (7) The minimum content of an EETS domain statement should be specified to give EETS providers sufficient clarity regarding the conditions for providing EETS in the corresponding toll domain.
- (8) Seamless functioning of the EETS requires a minimum level of harmonisation of the electronic interfaces, and of the functioning of the interfaces between parties, in particular, between the toll chargers and the EETS providers.
- (9) Specific infrastructure requirements should be laid down to allow for the correct communication and functioning of the equipment of the parties involved and to achieve a smooth and secure functioning of the EETS interoperability and enforcement.
- (10) To make the process of accrediting EETS providers more effective, some harmonisation of the procedure for assessment of conformity to specifications and suitability for use of interoperability constituents across the different EETS domains is needed. Therefore, it is necessary to lay down such a procedure, including the content and format of the EC declarations.

⁽¹⁾ OJ L 91, 29.3.2019, p. 45.

⁽²⁾ 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, OJ L 119, 4.5.2016, p. 1.

⁽³⁾ Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector, OJ L 201, 31.7.2002, p. 37.

- (11) In order to ensure the coherence of the legal framework and the proper functioning of the EETS system, Commission Decision 2009/750/EC (*) should be repealed from the date by which Directive (EU) 2019/520 must be transposed in all Member States, which is the date on which this Regulation and the delegated acts referred to in that Directive will start to apply.
- (12) The measures provided for in this Regulation are in accordance with the opinion of the Electronic Toll Committee, referred to in Article 31(1) of Directive (EU) 2019/520.

HAS ADOPTED THIS REGULATION:

Article 1

Scope

This Regulation lays down detailed obligations for EETS providers, information on the minimum content of the EETS domain statement, specifications for the electronic interfaces between the interoperability constituents, requirements for these constituents, and the procedure to be applied by Member States to assess conformity to specifications and suitability for use of interoperability constituents.

Article 2

Detailed obligations of EETS providers

1. For monitoring the performance of their services, EETS providers shall put in place audited operational processes that provide for appropriate measures when performance problems or integrity breaches are detected.
2. In Global Navigation Satellite System based systems, EETS providers shall monitor the availability of navigation and positioning satellite localisation data. They shall inform toll chargers of any difficulties they may have in establishing toll declaration data that relate to the reception of satellite signals.
3. A toll charger may require the cooperation of an EETS provider to perform unannounced and detailed toll system tests involving vehicles circulating or having recently circulated on the toll charger's EETS domain(s). The number of vehicles submitted to such tests over a year for a particular EETS provider shall be commensurate with the average annual traffic or traffic projections of that EETS provider on the toll charger's EETS domain(s).
4. Unless otherwise agreed, the EETS provider shall provide the toll charger with the following information, which is needed to apply the toll to EETS users' vehicles, or to allow the toll charger to verify the calculation of the toll applied to EETS users' vehicles by the EETS providers:
 - (a) the licence plate number of the EETS user's vehicle, including the international licence plate country code;
 - (b) an identifier of the EETS user's account;
 - (c) an identifier of the OBE, if used in an EETS domain;
 - (d) the vehicle classification parameters necessary to establish the applicable tariff.

The data exchange shall be compliant with the provisions of Annex I of this Implementing Regulation.

5. EETS providers shall provide appropriate service and technical support to ensure correct setting-up of the on-board equipment. EETS providers shall be responsible for fixed vehicle classification parameters stored in on-board equipment or in their back office. Variable vehicle classification parameters, which can vary from trip to trip or within a trip, and are intended to be introduced by in-vehicle intervention shall be configurable through an appropriate human-machine interface.
6. Where applicable, invoicing of individual EETS users by EETS providers shall clearly separate the service charges of the EETS provider from the tolls incurred, and shall at a minimum specify — unless the user decides otherwise — the time and the location of the tolls incurred, and the user-relevant composition of specific tolls.

(*) Commission Decision 2009/750/EC of 6 October 2009 on the definition of the European Electronic Toll Service and its technical elements, OJ L 268, 13.10.2009, p. 11.

7. EETS providers shall inform EETS users immediately of any non-declaration of tolls in relation to their account, offering, the opportunity to regularise the account before any enforcement action is taken, where this is possible under national legislation.

Article 3

EETS domain statement

The EETS domain statement referred to in Article 6(2) of Directive (EU) 2019/520 shall as a minimum contain the elements listed in Annex II of this Implementing Regulation, and shall comply with the requirements provided for in that Annex.

Article 4

EETS stakeholder roles and interfaces

1. Toll chargers and EETS providers shall put in place common interfaces and implement communication protocols in conformity with the requirements of Annex I of this Implementing Regulation. Through interoperable communication channels, EETS providers shall provide toll chargers with secure information relative to tolling operations and control/enforcement in conformity with applicable technical specifications.
2. EETS providers shall ensure that toll chargers are able to easily and unambiguously detect whether a vehicle circulating on their EETS domain requiring the use of an OBE and allegedly using EETS is actually equipped with a validated and properly functioning EETS OBE that provides correct information.
3. EETS OBE shall provide a human-machine interface, that indicates to the user that the OBE is functioning properly, and an interface for declaring variable toll parameters and for indicating the settings of those parameters.

Article 5

Conformity to specifications and suitability for use

Conformity to specification and suitability for use of interoperability constituents shall be assessed in compliance with Annex III of this Implementing Regulation.

Article 6

Repeal

Decision 2009/750/EC is repealed with effect from 19 October 2021.

Article 7

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

It shall apply from 19 October 2021.

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

Done at Brussels, 28 November 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

EUROPEAN ELECTRONIC TOLL SERVICE INTERFACES

European Electronic Toll Service (EETS) providers and toll chargers shall use the following electronic interfaces:

1. Electronic radio interfaces at the roadside between the EETS provider's on-board equipment (OBE) and the toll charger's fixed or mobile equipment. As a minimum, standardised roadside interfaces between OBE and toll chargers' fixed and mobile roadside equipment shall support:
 - (a) Dedicated Short-Range Communication (DSRC) charging transactions, complying with the following requirements:
 - (i) EETS providers' OBE shall support EN 15509:2014 ⁽¹⁾ as well as those clauses of ETSI ES 200674-1 V2.4.1 ⁽²⁾ that relate to interoperability;
 - (ii) toll chargers' fixed and mobile roadside equipment shall support EN 15509:2014. Within Italy, toll chargers' fixed and mobile roadside equipment may support instead those clauses of ETSI ES 200674-1 V2.4.1 that relate to interoperability;
 - (b) real-time compliance checking transactions compliant to EN ISO 12813:2015 ⁽³⁾;
 - (c) localisation augmentation (where applicable) compliant to EN ISO 13141:2015 ⁽⁴⁾.

EETS OBEs shall comply with points 1(a), 1(b) and 1(c). EETS OBEs provided for users of light-duty vehicles must comply with the provisions referred to in point 1(a) as referred to in Article 3(6) of Directive (EU) 2019/520.

Toll chargers may implement any of the provisions referred to in points 1(a), 1(b) 1(c) and 2 in their fixed or mobile roadside equipment according to their requirements.

Where the toll charger implements a new version of a standard for an interface between the roadside equipment and the OBE, the interface shall continue to support the previous version of the standard for a limited period to allow for the continued compatibility of its electronic toll collection system with the OBEs in operation. The duration of this period shall be published by the toll charger in its EETS domain statement and may not be shorter than two years.

2. Electro-optical imaging systems at the toll charger's fixed or mobile equipment at the roadside, providing means for automatic number plate recognition (ANPR), in toll systems where the installation and use of an OBE is not required.
3. Electronic interfaces between the respective back office systems.

Toll chargers shall only implement those aspects of the interface that are linked to the technology used on the EETS domain under their responsibility (GNSS, DSRC and/or ANPR).

- 3.1. The following back office interfaces shall be implemented by both EETS providers and toll chargers independently of the technology used in the EETS toll domain:
 - (a) exchange of information to support exception handling from toll chargers to EETS providers.
 - (b) exchange of EETS user-related lists from EETS providers and toll chargers.
 - (c) exchange of trust objects.
 - (d) exchange of toll context data.
 - (e) optionally, exchange of payment claims according to the adopted business model.
- 3.2. The following back office interfaces shall be additionally implemented by both EETS providers and toll chargers for EETS domains, which implement the GNSS technology:
 - (a) submission and validation of global navigation satellite system (GNSS) toll declarations.
 - (b) optionally, exchange of payment announcements according to the adopted business model.
 - (c) optionally, exchange of billing details according to the adopted business model.

⁽¹⁾ Electronic fee collection — Interoperability application profile for DSRC.

⁽²⁾ Intelligent Transport Systems (ITS); Road Transport and Traffic Telematics (RTTT); Dedicated Short Range Communications (DSRC); Part 1: Technical characteristics and test methods for High Data Rate (HDR) data transmission equipment operating in the 5,8 GHz Industrial, Scientific and Medical (ISM) band.

⁽³⁾ Electronic fee collection — Compliance check communication for autonomous systems.

⁽⁴⁾ Electronic fee collection — Localisation augmentation communication for autonomous systems.

- 3.3. The following back office interfaces shall be additionally implemented by both EETS providers and toll chargers for EETS domains that implement the DSRC technology:
- (a) exchange of billing details.
 - (b) optionally, exchange of payment claims based on dedicated short-range communication (DSRC) charging transactions.
- 3.4. The following back office interfaces shall be additionally implemented by both EETS providers and toll chargers for EETS domains that implement the ANPR technology:
- (a) optionally, exchange of billing details.
 - (b) optionally, exchange of payment claims based on ANPR charging transactions.

The electronic interfaces for DSRC- and GNSS-based schemes between the respective back office systems of the toll charger and those of the EETS provider shall comply with CEN/TS 16986:2016 ⁽³⁾, as corrected by CEN/TS 16986:2016/AC:2017, at the latest five years from date of applicability of this Implementing Regulation. Where the toll charger or EETS provider implements a new version of a standard, it shall continue to support, for a limited period, lasting not less than two years, data exchange compatible with the previous version of the standard to ensure the continuous compatibility of the back offices.

⁽³⁾ Electronic Fee Collection — Interoperable application profiles for information exchange between Service Provision and Toll Charging.

ANNEX II

MINIMUM CONTENTS OF A EUROPEAN ELECTRONIC TOLL SERVICE DOMAIN STATEMENT

A European Electronic Tolling Service (EETS) domain statement shall contain the following information:

1. A section on procedural conditions, which shall be non-discriminatory and shall include at least:
 - (a) the toll transaction policy (including authorisation parameters, toll context data, black lists);
 - (b) the procedures and Service Level Agreement, including the format for communicating toll declaration data or billing data, times and frequency for the transfer of toll declaration data, accepted percentage of missed/erroneous tolls, accuracy of toll declaration data, operational availability performance;
 - (c) the invoicing policy;
 - (d) the payment policy;
 - (e) a reference to the relevant conciliation body and its competences related to disputes concerning the remuneration of EETS-providers and of the main service provider;
 - (f) the commercial conditions.
- 1.1. The section on the commercial conditions shall include at least the following elements applicable to the EETS providers:
 - (a) any applicable fixed charge based on the costs incurred by the toll charger, for providing, operating and maintaining an EETS compliant system. The toll charger may not impose on EETS providers the fixed charge based on these costs if the costs of providing, operating and maintaining an EETS compliant system are included in the toll;
 - (b) any applicable fixed charge to be paid by EETS providers based on the cost of the accreditation procedure, as referred to in Article 2(20) of Directive (EU) 2019/520, including the cost of the assessment of conformity to specifications or suitability for use of interoperability constituents;
 - (c) any applicable requirements for a bank guarantee or equivalent financial instrument, which may not exceed the average monthly toll transaction amount paid by the EETS provider for this toll domain. This amount shall be determined based on the total toll transaction amount paid by the EETS provider for this toll domain in the previous year. For new EETS providers and for new toll domains, the amount shall be based on the expected average toll transactions payable by the EETS provider for this toll domain within the invoicing period based on the number of contracts and average toll per contract estimated in the EETS provider's business plan for the specific toll domain.
- 1.2. The commercial conditions shall also include, as a minimum, a description of the elements used to define the fixed and/or variable remuneration paid by the toll charger to the EETS provider. The remuneration may vary according to the following elements:
 - (a) the amount of the toll collected by the EETS provider on behalf of the toll charger;
 - (b) the number of active pieces of on-board-equipment (OBE) provided by the EETS provider, which are in use in the EETS domain of the toll charger concerned;
 - (c) where applicable, the number of toll transactions, or another indication of the cost of mobile communications between the OBE and the back office of the EETS provider;
 - (d) the invoices issued by the EETS provider to EETS users for tolls due for the use of the EETS domain concerned;
 - (e) the nature of other services outsourced by the toll charger to the EETS provider.
- 1.3. The domain statement shall also include a description of the specific requirements and obligations of the main service provider, which differ from the ones of the EETS providers and, which justify any differences in the remuneration of the main service provider compared to that of the EETS providers.
2. A section defining *ex ante* the steps of the accreditation of an EETS provider to the EETS domain and an indicative duration of the accreditation procedure. This section shall set out the complete procedure for the assessment of the conformity to specifications and the suitability for use of interoperability constituents. It shall include a list of required certificates, laboratory and field tests and their indicative costs, and measurable criteria or parameters indicating conformity to specifications.

The section shall contain references to all applicable international or European standards related to electronic tolling and exceptions to their application in the EETS domain. It shall also specify all technical requirements that are specific to the EETS domain and not covered by the international or European standards.

The same acceptance procedure shall apply to all EETS providers.

3. A section on the toll context data.
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ANNEX III

CONFORMITY TO SPECIFICATIONS AND SUITABILITY FOR USE OF INTEROPERABILITY CONSTITUENTS

CONFORMITY TO SPECIFICATIONS

Compliance of interoperability constituents (including road side equipment and interfaces) with the requirements referred to in Article 15(4) and 15(5) of Directive (EU) 2019/520 and with all relevant technical specifications and standards shall, prior to their placing on the market, be demonstrated by means of either of the following conformity assessment procedures, adapted to the specificity of the sector based on the modules provided by Decision No 768/2008/EC ⁽¹⁾:

- (a) internal production control as set out in section I (module A);
- (b) EU type examination as set out in section II (Module B) which is followed by Conformity to type based on internal production control set out in section III (Module C).

I. Module A — Internal production control

Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points (a), (b) and (c), and ensures and declares on his sole responsibility that the interoperability constituents concerned satisfy the requirements referred to in Article 15(4) and 15(5) of Directive (EU) 2019/520.

(a) Technical documentation

The manufacturer shall prepare the technical documentation. The documentation shall make it possible to assess the interoperability constituent's conformity to the relevant requirements, and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the interoperability constituent. The technical documentation shall, wherever applicable, contain at least the following elements:

- (i) a general description of the interoperability constituent,
- (ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.
- (iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the interoperability constituent,
- (iv) reference to the category of interfaces as set out in Annex I,
- (v) a list of the standards and/or other relevant technical specifications, applied in full or in part, and descriptions of the solutions adopted to meet the requirements referred to in Section I,
- (vi) results of design calculations made, examinations carried out, etc., and
- (vii) test reports.

(b) Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured interoperability constituents with the technical documentation referred to in point (a) and with the requirements of the legislative instruments that apply to them.

(c) 'EC' declaration of conformity

The manufacturer shall draw up a written 'EC' declaration of conformity for an interoperability constituent model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the interoperability constituent has been placed on the market. The 'EC' declaration of conformity shall identify the interoperability constituent for which it has been drawn up.

A copy of the 'EC' declaration of conformity shall be made available to the relevant authorities upon request.

(d) Authorised representative

The manufacturer's obligations set out in point (b) may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

⁽¹⁾ Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products and repealing Council Decision 93/465/EEC (Text with EEA relevance).

II. Module B — EU-type examination

1. EU-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of an interoperability constituent and verifies and attests that the technical design of the interoperability constituent meets the requirements of the legislative instrument that apply to it.
2. EU-type examination may be carried out in one of the following ways:
 - examination of a specimen, representative of the production envisaged, of the complete interoperability constituent (production type),
 - assessment of the adequacy of the technical design of the interoperability constituent through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the interoperability constituent (combination of production type and design type),
 - assessment of the adequacy of the technical design of the interoperability constituent through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).
3. The manufacturer shall lodge an application for EU-type examination with a single notified body of his choice.

The application shall include:

 - (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well,
 - (b) a written declaration that the same application has not been lodged with any other notified body,
 - (c) the technical documentation, which shall make it possible to assess the interoperability constituent's conformity with the applicable requirements of the legislative instrument and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the interoperability constituent. The technical documentation shall contain, wherever applicable, at least the following elements:
 - (i) a general description of the interoperability constituent,
 - (ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
 - (iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the interoperability constituent,
 - (iv) a list of the harmonised standards and/or other relevant technical specifications the references of which have been published in the *Official Journal of the European Union*, applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the legislative instrument where those harmonised standards have not been applied. In the event of partly applied harmonised standards, the technical documentation shall specify the parts which have been applied,
 - (v) results of design calculations made, examinations carried out, etc., and
 - (vi) test reports,
 - (d) the specimens representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme,
 - (e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant harmonised standards and/or technical specifications have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.
4. The notified body shall:

With regard to the interoperability constituent:

 - 4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the interoperability constituent;

With regard to the specimen(s):

- 4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;
- 4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards and/or technical specifications, these have been applied correctly;
- 4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential requirements of the legislative instrument;
- 4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.
6. Where the type meets the requirements of the specific legislative instrument that apply to the interoperability constituent concerned, the notified body shall issue an EU-type examination certificate to the manufacturer. The certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured interoperability constituents with the examined type to be evaluated and to allow for in-service control.

Where the type does not satisfy the applicable requirements of the legislative instrument, the notified body shall refuse to issue an EU-type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of the legislative instrument, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.

The manufacturer shall inform the notified body that holds the technical documentation relating to the EU-type examination certificate of all modifications to the approved type that may affect the conformity of the interoperability constituent with the essential requirements of the legislative instrument or the conditions for validity of the certificate. Such modifications shall require additional approval in the form of an addition to the original EU-type examination certificate.

8. Each notified body shall inform its notifying authorities concerning the EU-type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authorities the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU-type examination certificates and/or any additions thereto, which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU-type examination certificates and/or additions thereto. On request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body. The notified body shall keep a copy of the EU-type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer shall keep a copy of the EU-type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the interoperability constituent has been placed on the market.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

III. Module C — Conformity to type based on internal production control

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the interoperability constituents concerned are in conformity with the type described in the EU-type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured interoperability constituents with the approved type described in the EU-type examination certificate and with the requirements of the legislative instrument that apply to them.

3. Conformity marking and declaration of conformity

- 3.1. The manufacturer shall affix the required conformity marking set out in the legislative instrument to each individual interoperability constituent that is in conformity with the type described in the EC-type examination certificate and satisfies the applicable requirements of the legislative instrument.

- 3.2. The manufacturer shall draw up a written declaration of conformity for a interoperability constituent model and keep it at the disposal of the national authorities for 10 years after the interoperability constituent has been placed on the market. The declaration of conformity shall identify the interoperability constituent model for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the relevant authorities upon request.

4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

IV. Tests specifications

The conformity evaluation of implementation to the requirements referred under point 1 of Annex I of this Implementing Regulation and in Article 5(4) of Directive (EU) 2019/520 may be evaluated by applying the following tests specifications:

- Annex I 1(a) of this Implementing Regulation related to the DSRC charging transactions: EN 15876-1:2016 ^(?), ETSI TS 102 708-1-1:2010 ^(?), ETSI TS 102 708-1-2:2010 ^(?), ETSI TS 102 708-2-1:2013 ^(?) and ETSI TS 102 708-2-2:2018 ^(?), respectively;
- Annex I 1(b) of this Implementing Regulation related to the real-time compliance checking transactions: EN ISO 13143-1:2016 ^(?);
- Annex I 1(c) of this Implementing Regulation related to the localisation augmentation: EN ISO 13140-1:2016 ^(?).

^(?) Electronic fee collection — Evaluation of on-board and roadside equipment for conformity to EN 15509

^(?) Intelligent Transport Systems (ITS); RTTT; Test specifications for High Data Rate (HDR) data transmission equipment operating in the 5,8 GHz ISM band; Part 1: Data Link Layer; Sub-Part 1: Protocol Implementation Conformance Statement (PICS) proforma specification.

^(?) Intelligent Transport Systems (ITS); RTTT; Test specifications for High Data Rate (HDR) data transmission equipment operating in the 5,8 GHz ISM band; Part 1: Data Link Layer; Sub-Part 2: Test Suite Structure and Test Purposes (TSS&TP).

^(?) Intelligent Transport Systems (ITS); RTTT; Test specifications for High Data Rate (HDR) data transmission equipment operating in the 5,8 GHz ISM band; Part 2: Application Layer; Sub-part 1: Protocol Implementation Conformance Statement (PICS) proforma specification.

^(?) Intelligent Transport Systems (ITS); RTTT; Test specifications for High Data Rate (HDR) data transmission equipment operating in the 5,8 GHz ISM band; Part 2: Application Layer; Sub-Part 2: Test Suite Structure and Test Purposes (TSS & TP).

^(?) Electronic fee collection — Evaluation of on-board and roadside equipment for conformity to ISO 12813 — Part 1: Test suite structure and test purposes.

^(?) Electronic fee collection — Evaluation of on-board and roadside equipment for conformity to ISO 13141 — Part 1: Test suite structure and test purposes.

V. Suitability for use (interoperability of service)

The suitability for use of interoperability constituents is assessed by operation or use of the constituents in service, integrated representatively into the EETS toll system (including test environments) of the toll charger(s) on whose domain the on-board equipment must circulate over a specified operation time. The assessment of suitability for use may include tests predefined in the EETS domain statement or pilots with real users. The toll charger or its authorised representative as well as the EETS provider, the manufacturer or an authorised representative and the notified body to which the EETS provider applied to, shall comply with each step of the suitability-for-use assessment based on measurable criteria or parameters defined in the EETS domain statement in accordance with Annex II.

To carry out such an assessment by means of in-service experience for demonstrating the in-service interoperability of the constituents, the manufacturer, EETS provider or an authorised representative shall either collaborate directly with the toll charger(s) or apply to a notified body, subject to requirements in points (a) and (b). The relevant toll charger may require that tests and/or pilots are carried out by means of the infrastructure provided for by the toll charger, regardless of whether the EETS provider chooses to directly collaborate with the toll charger or applies to a notified body.

- (a) Where the EETS provider collaborates directly with the toll charger(s) on whose domain the on-board equipment shall circulate:

The manufacturer, EETS provider or an authorised representative shall:

- (1) provide for tests or place in service one or more specimens representative of the interoperability constituent(s), as required by the toll charger(s);
- (2) monitor the in-service behaviour of the interoperability constituent(s) by a procedure agreed and surveyed by the toll charger(s);
- (3) give evidence to the toll charger(s) that the interoperability constituents meet all the interoperability requirements of this (these) Toll Charger(s);
- (4) draw up a declaration of suitability for use, conditional to obtaining a suitability for use attestation delivered by the toll charger(s). The declaration of suitability for use covers the assessment by the toll charger(s) of the suitability for use of the EETS interoperability constituents within the EETS environment of this (these) Toll Charger(s);

The toll charger shall:

- (1) clearly define the programme for validation by in-service experience
- (2) approve the monitoring procedure of the in-service behaviour in its toll domains and carry out specific verifications;
- (3) assess the in-service interoperability with its system;
- (4) attest the suitability for use on its toll domains in cases where the behaviour of the interoperability constituents is successful.

- (b) Where the EETS provider applies to a notified body, the manufacturer, EETS provider or an authorised representative shall:

- (1) provide for tests or place in service one or more specimens representative of the interoperability constituent(s), as required and specified by the toll charger(s);
- (2) monitor the in-service behaviour of the interoperability constituents using a procedure approved and surveyed by the notified body.
- (3) provide evidence to the notified body that the interoperability constituent(s) meet(s) all the interoperability requirements of the toll charger(s), including the results of in-service experience;
- (4) draw up the 'EC' declaration of suitability-for-use, conditional to obtaining a suitability-for-use certificate delivered by the notified body. The 'EC' declaration of suitability for use covers the assessment/judgement by the notified body of the suitability for use of the EETS interoperability constituents, considered within the EETS domain and environment of the selected toll charger(s) and, particularly in cases where interfaces are involved, in relation to the technical specifications, particularly those of a functional nature, which are to be checked;

The notified body shall:

- (1) take into consideration the 'EC' declaration of conformity to specifications as well as the requirements laid down in the EETS domain statement of the toll charger(s).
- (2) organise collaboration with the relevant toll charger(s);
- (3) verify the technical documentation and the programme for validation by in-service experience;
- (4) approve the monitoring procedure of the in-service behaviour and carry out specific surveillance;
- (5) assess in-service interoperability with toll charger systems and operational processes;
- (6) issue a suitability-for-use certificate in cases where the behaviour of the interoperability constituents is successful;
- (7) issue an explanatory report in case where the behaviour of the interoperability constituent(s) is unsuccessful. The report shall also consider problems that may arise because of non-compliance of a toll charger's systems and processes with relevant standards and technical specifications. If appropriate, the report shall make recommendations with a view to resolving the problems.

VI. Content and format of the declarations of conformity to specifications and declarations of suitability for use

1. Content of the 'EC' Declaration of conformity

The EC declaration of conformity shall state that the fulfilment of requirements set out in Article 15(4), (5) and (6) of Directive (EU) 2019/520 has been demonstrated.

The EC declaration of conformity shall have the model structure set out in point 2 of this Section. It shall contain the elements specified in the relevant modules set out in this Annex and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which market the interoperability constituent is placed or made available.

By drawing up the EC declaration of conformity, the manufacturer shall assume responsibility for the compliance of the interoperability constituent.

2. Model the EC Declaration of conformity

- (1) No (unique identification of the interoperability constituent):
- (2) Name and address of the manufacturer or his authorised representative:
- (3) This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):
- (4) Object of the declaration (identification of interoperability constituent allowing traceability. It may include a photograph, where appropriate):
- (5) The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:
- (6) References to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared:
- (7) Where applicable, the notified body (name, number) performed (description of intervention) and issued the certificate:
- (8) Additional information:

Signed for and on behalf of:

(place and date of issue):

(name, function) (signature):

'EC' declarations of suitability for use and the accompanying documents must be dated and signed.

The declarations shall be written in the same language as the instructions and must contain the following:

- (a) references to the relevant legislation;
- (b) the name and address of the manufacturer, EETS provider or authorised representative established within the Union (provide the trade name and full address of the authorised representative and the trade name of the manufacturer);
- (c) description of interoperability constituent(s) (make, type, version, etc.);

- (d) description of the procedure followed in order to declare conformity to specifications or suitability for use;
 - (e) all the relevant requirements met by the interoperability constituents and, in particular, their conditions of use;
 - (f) where applicable, name and address of the toll charger(s)/notified body(ies) involved in the procedure followed for the assessment of conformity to specifications or suitability for use;
 - (g) where appropriate, reference to the technical specifications;
 - (h) identification of the signatory empowered to enter into commitments on behalf of the manufacturer or of the manufacturer's authorised representative established within the Union.
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COMMISSION REGULATION (EU) 2020/205
of 14 February 2020
amending Regulation (EC) No 2073/2005 as regards *Salmonella* in reptile meat
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ⁽¹⁾, and in particular Article 4(4) thereof,

Whereas:

- (1) Commission Regulation (EC) No 2073/2005 ⁽²⁾ lays down the microbiological criteria for certain micro-organisms and the implementing rules to be complied with by food business operators in respect of the general and specific hygiene requirements referred to in Article 4 of Regulation (EC) No 852/2004.
- (2) In particular, Regulation (EC) No 2073/2005 lays down food safety criteria which define the acceptability of a product or a batch of foodstuff applicable to products placed in the market. That Regulation does not provide for food safety criteria for reptile meat.
- (3) The 'European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2016' ⁽³⁾ published by the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control states that human salmonellosis is the second most reported human food-borne illness in the Union with around 95 000 cases reported annually.
- (4) In 2007, EFSA adopted a scientific opinion on public health risks involved in the human consumption of reptile meat ⁽⁴⁾ according to which reptiles are well-known reservoirs for *Salmonella* species. The scientific opinion reviews farming practices and observes a documented high intestinal carrier rate in live crocodilians that is reflected in an equally high contamination rate in their fresh and frozen meat. The scientific opinion concludes that *Salmonella* is considered to be the most relevant bacterial hazard that may occur in reptile meat and it constitutes a significant public health risk.
- (5) Production of reptile meat in the Union is limited, but according to data available in Eurostat's reference database for detailed statistics on international trade in goods (Comext) ⁽⁵⁾, imports from third countries of fresh, chilled or frozen meat and edible offal of reptiles have shown an upward trend over the last 10 years with an increase of over 50 % in the quantity imported during the period 2007-2017 and an average yearly import in the Union of nearly 100 tons.
- (6) Considering the potential significant health risk posed by the possible presence of *Salmonella* in reptile meat, a food safety criterion should be laid down in Regulation (EC) No 2073/2005 for reptile meat. This food safety criterion should oblige food business operators to take measures at previous stages of reptile meat production contributing to the reduction of the presence of all serotypes of *Salmonella* with public health significance.
- (7) The international standard EN/ISO 6579-1 is the horizontal method for the detection of *Salmonella* in food and animal feeding stuffs. Annex I to Regulation (EC) No 2073/2005 provides for that standard to be the analytical reference method for *Salmonella* food safety criteria. It should, therefore, be laid down as the analytical reference method to verify the compliance of a *Salmonella* in reptile meat food safety criterion.

⁽¹⁾ OJ L 139, 30.4.2004, p. 1.

⁽²⁾ Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

⁽³⁾ EFSA Journal 2017;15(12):5077.

⁽⁴⁾ EFSA Journal (2007) 578, 1-55.

⁽⁵⁾ Combined nomenclature codes 0208 50 00 and 0210 93 00 as defined in Commission Implementing Regulation (EU) 2017/1925 amending Annex I to Council Regulation (EEC) No 2658/87 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 282, 31.10.2017, p. 1).

- (8) Regulation (EC) No 2073/2005 should therefore be amended accordingly.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 2073/2005 is amended as follows:

- (1) in Article 2, the following point (q) is added:

‘(q) “reptile meat” means reptile meat as laid down in point (16) of Article 2 of Commission Delegated Regulation (EU) 2019/625 (*).

(*) Commission Delegated Regulation (EU) 2019/625 of 4 March 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption (OJ L 131, 17.5.2019, p. 18).’;

- (2) Annex I is amended in accordance with the Annex to this Regulation.

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, 14 February 2020.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX

Annex I to Regulation (EC) No 2073/2005 is amended as follows:

(1) in Chapter 1, the following row 1.30 is added:

Food category	Micro-organisms/their toxins, metabolites	Sampling plan		Limits		Analytical reference method	Stage where the criterion applies
		n	c	m	M		
1.30 Reptile meat	<i>Salmonella</i>	5	0	Not detected in 25 g		EN ISO 6579-1	Products placed on the market during their shelf-life'

(2) in Chapter 1, footnote 2 is replaced by the following:

‘(2) For points 1.1-1.24, 1.27a, 1.28-1.30 m = M.’

COMMISSION IMPLEMENTING REGULATION (EU) 2020/206**of 14 February 2020****authorising the placing on the market of fruit pulp, pulp juice, concentrated pulp juice from *Theobroma cacao* L. as a traditional food from a third country under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Implementing Regulation (EU) 2017/2470****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 15(4) thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union. Traditional food from a third country is a novel food defined in Article 3 of Regulation (EU) 2015/2283.
- (2) Commission Implementing Regulation (EU) 2017/2468 ⁽²⁾ lays down administrative and scientific requirements concerning traditional foods from third countries.
- (3) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽³⁾ establishing a Union list of authorised novel foods was adopted.
- (4) Pursuant to Article 15(4) of Regulation (EU) 2015/2283, the Commission is to decide on the authorisation and on the placing on the Union market of a traditional food from a third country.
- (5) On 30 January 2019 and 28 March 2019, the companies Nestec York Ltd. and Cabosse Naturals NV. ('the applicants') submitted a notification to the Commission of the intention to place fruit pulp, pulp juice, concentrated pulp juice from *Theobroma cacao* L. ('Cocoa pulp') on the Union market as a traditional food from a third country within the meaning of Article 14 of Regulation (EU) 2015/2283. The applicants request for fruit pulp, pulp juice, concentrated pulp juice from *Theobroma cacao* L. to be consumed as such or as an ingredient by the general population.
- (6) Pursuant to Article 7(2) of Implementing Regulation (EU) 2017/2468, the Commission requested additional information from the applicants as regards the validity of the notification. The requested information was submitted on 12 April 2019 and 20 June 2019.
- (7) The data presented by the applicants demonstrates that fruit pulp, pulp juice, concentrated pulp juice from *Theobroma cacao* L. have a history of safe food use in Brazil.
- (8) Pursuant to Article 15(1) of Regulation (EU) 2015/2283, on 22 May 2019 and 20 June 2019, the Commission forwarded the valid notifications to the Member States and to the European Food Safety Authority ('the Authority').
- (9) No duly reasoned safety objections to the placing on the market within the Union of fruit pulp, pulp juice, concentrated pulp juice from *Theobroma cacao* L. were submitted to the Commission by Member States or the Authority within the four-months period laid down in Article 15(2) of Regulation (EU) 2015/2283.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2468 of 20 December 2017 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 55).

⁽³⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

- (10) The Commission should therefore authorise the placing on the market within the Union of fruit pulp, pulp juice, concentrated pulp juice from *Theobroma cacao* L. and update the Union list of novel foods.
- (11) Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

1. Fruit pulp, pulp juice, concentrated pulp juice from *Theobroma cacao* L. as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.
2. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

Article 2

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 3

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, 14 February 2020.

For the Commission
The President
Ursula VON DER LEYEN

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

(1) The following entry is inserted in Table 1 (Authorised novel foods) in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used	Additional specific labelling requirements	Other requirements
'Fruit pulp, pulp juice, concentrated pulp juice from <i>Theobroma cacao</i> L. (Traditional food from a third country)	Not specified	The designation of the novel food on the labelling of the foodstuffs containing it shall be "cocoa (<i>Theobroma cacao</i> L.) pulp", "cocoa (<i>Theobroma cacao</i> L.) pulp juice" or "cocoa (<i>Theobroma cacao</i> L.) concentrated pulp juice" depending on the form used.'	

(2) The following entry is inserted in Table 2 (Specifications) in alphabetical order:

Authorised Novel Food	Specifications
'Fruit pulp, pulp juice, concentrated pulp juice from <i>Theobroma cacao</i> L. (Traditional food from a third country)	Description/Definition The traditional food is the fruit pulp from the cocoa (<i>Theobroma cacao</i> L) plant, which is the "aqueous, mucilaginous and acidic substance in which the seeds are embedded". Cocoa fruit pulp is obtained by splitting cocoa pods followed by separation from husks and beans; the pulp is then subject to pasteurisation and freezing. Cocoa pulp juice and/or cocoa concentrated pulp juice are produced following processing (enzymatic treatment, pasteurization, filtration, and concentration). Typical compositional data of cocoa fruit pulp, pulp juice, concentrated pulp juice Protein (g/100 g): 0,0 to 2,0 Total fat (g/100 g): 0,0 to 0,2 Total sugars (g/100 g): > 11,0 Brix level (° Brix): ≥ 14 pH: 3,3 to 4,0 Microbiological criteria Total Plate Count (aerobic): < 10 000 cfu (°)/g Enterobacteriaceae: ≤ 10 cfu/g <i>Salmonella</i>: Absence in 25 g

(°) Cfu: Colony forming unit.'

COMMISSION IMPLEMENTING REGULATION (EU) 2020/207
of 14 February 2020
amending Regulation (EU) No 142/2011 as regards imports of petfood from Saudi Arabia
(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 ⁽¹⁾, and in particular Article 41(4), thereof,

Whereas:

- (1) Commission Regulation (EU) No 142/2011 ⁽²⁾ lays down rules implementing Regulation (EC) No 1069/2009 including public and animal health conditions for imports of petfood.
- (2) The requirements for the importation into and transit through the Union of petfood including dogchews are set out in Section 1 of Chapter II of Annex XIV to Regulation (EU) No 142/2011, including the list of third countries in row 12 of Table 2 thereof.
- (3) The competent authorities of the Kingdom of Saudi Arabia provided the Commission with assurances that the Kingdom of Saudi Arabia can comply with the relevant health conditions and sufficient guarantees for the controls they carry out on the production of petfood obtained from poultry. It is therefore justified to add Saudi Arabia to the list of third countries from where processed petfood of poultry origin may be imported into and transit through the Union.
- (4) Table 2 of Section 1 of Chapter II of Annex XIV to Regulation (EU) No 142/2011 should therefore be amended accordingly.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Table 2 of Section 1 of Chapter II of Annex XIV to Regulation (EU) No 142/2011 is amended in accordance with the text set out in the Annex to this Regulation.

⁽¹⁾ OJ L 300, 14.11.2009, p. 1.

⁽²⁾ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

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, 14 February 2020.

For the Commission
The President
Ursula VON DER LEYEN

In Table 2 of Section 1 of Chapter II of Annex XIV to Regulation (EU) No 142/2011, row 12 is replaced by the following:

'12	Petfood, including dogchews	(a) In the case of processed petfood and of dogchews: materials referred to in Article 35(a)(i) and (ii). (b) In the case of raw petfood: materials referred to in Article 35(a)(iii).	The petfood and the dogchews must have been produced in accordance with Chapter II of Annex XIII.	(a) In the case of raw petfood: Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010 or in Annex I to Regulation (EC) No 798/2008, from which Member States authorise imports of fresh meat from the same species and where only bone-in meat is authorised. In the case of fish materials, third countries listed in Annex II to Decision 2006/766/EC. (b) In the case of dogchews and petfood other than raw petfood: Third countries listed in Part 1 of Annex II to Regulation (EU) No 206/2010, and the following countries: (JP) Japan (EC) Ecuador (LK) Sri Lanka (TW) Taiwan (SA) Saudi Arabia (only processed petfood of poultry origin) In the case of processed petfood derived from fish materials, third countries listed in Annex II to Decision 2006/766/EC.	(a) In the case of canned petfood: Annex XV, Chapter 3(A). (b) In the case of processed petfood other than canned petfood: Annex XV, Chapter 3(B). (c) In the case of dogchews: Annex XV, Chapter 3(C). (d) In the case of raw petfood: Annex XV, Chapter 3(D).'
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COMMISSION IMPLEMENTING REGULATION (EU) 2020/208
of 14 February 2020
amending Regulation (EC) No 29/2009 laying down requirements on data link services for the single European sky

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 ⁽¹⁾, and in particular point (a) of Article 44(1) thereof,

Whereas:

- (1) Commission Regulation (EC) No 29/2009 ⁽²⁾ laying down requirements on data link services for the single European sky requires the use of specific operational methods related to the exchange of data between airborne and ground equipment. Such operational methods have to be implemented in a uniform way to ensure interoperability and seamless operations.
- (2) EUROCAE ED-120 'Safety and Performance Requirements Standard for Air Traffic Data Link Services in Continental Airspace' was recently revised to remove any reference to Downlink Message (DM) 89 'MONITORING [unit name] [frequency]' as being required to support data link operations. The current reference to ED-120 included in Regulation (EC) No 29/2009 is no longer appropriate to reflect the evolution of standards and operational principles, and to support the data link operation of certified aircraft with increased ATM functionalities.
- (3) Therefore, the minimum technical standards laid down in Regulation (EC) No 29/2009, to which aircraft operators are to comply, should be amended accordingly.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 127(1) of Regulation (EU) 2018/1139,

HAS ADOPTED THIS REGULATION:

Article 1

Annex III to Regulation (EC) No 29/2009 is amended in accordance with the Annex to this Regulation.

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, 14 February 2020.

For the Commission
The President
Ursula VON DER LEYEN

⁽¹⁾ OJ L 212, 22.8.2018, p. 1.

⁽²⁾ Commission Regulation (EC) No 29/2009 of 16 January 2009 laying down requirements on data link services for the single European sky (OJ L 13, 17.1.2009, p. 3).

ANNEX

In Annex III to Regulation (EC) No 29/2009, paragraph 11 is replaced by the following:

‘11. Eurocae ED-120 Safety and Performance Requirements Standard for Air Traffic Data Link Services in Continental Airspace, published in May 2004, including:

(a) for operators:

- Change 1, published in April 2007, and Change 2, published in October 2007, or
- Change 1, published in April 2007, Change 2, published in October 2007, and Change 3, published in September 2019;

(b) for ATS providers:

- Change 1, published in April 2007, Change 2, published in October 2007, and Change 3, published in September 2019.’
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DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2020/209

of 14 February 2020

concerning certain protective measures relating to African swine fever in Greece

(notified under document C(2020) 962)

(Only the Greek text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ⁽¹⁾, and in particular Article 9(4) thereof,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary checks applicable in intra-Union trade in certain live animals and products with a view to the completion of the internal market ⁽²⁾, and in particular Article 10(4) thereof,

Whereas:

- (1) African swine fever is an infectious viral disease affecting domestic and feral pig populations and can have a severe impact on the profitability of pig farming causing disturbance to trade within the Union and exports to third countries.
- (2) In the event of an outbreak of African swine fever, there is a risk that the disease agent might spread to other pig holdings and to feral pigs. As a result, it may spread from one Member State to another Member State and to third countries through trade in live pigs or their products.
- (3) Council Directive 2002/60/EC ⁽³⁾ lays down minimum measures to be applied within the Union for the control of African swine fever. Article 9 of Directive 2002/60/EC provides for the establishment of protection and surveillance zones in the event of outbreaks of that disease, where the measures laid down in Articles 10 and 11 of that Directive are to apply.
- (4) Following an outbreak of African swine fever in the regional unit of Serres in Greece, that Member State informed the Commission of the African swine fever situation in its territory, and in accordance with Article 9 of Directive 2002/60/EC, it established protection and surveillance zones where the measures referred to in Articles 10 and 11 of that Directive are applied.
- (5) Commission Implementing Decision (EU) 2020/181 ⁽⁴⁾ was adopted following the establishment of the protection and surveillance zones in Greece, in accordance with Article 9 of Directive 2002/60/EC.
- (6) Since the date of adoption of Implementing Decision (EU) 2020/181, the epidemiological situation in Greece has not evolved with respect to African swine fever in the regional unit of Serres, and accordingly Greece has implemented the required control measures and it has collected additional surveillance data.

⁽¹⁾ OJ L 395, 30.12.1989, p. 13.

⁽²⁾ OJ L 224, 18.8.1990, p. 29.

⁽³⁾ Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever (OJ L 192, 20.7.2002, p. 27).

⁽⁴⁾ Commission Implementing Decision (EU) 2020/181 of 7 February 2020 concerning certain interim protective measures relating to African swine fever in Greece (OJ L 37, 10.2.2020, p. 8).

- (7) In order to prevent any unnecessary disturbance to trade within the Union and to avoid unjustified barriers to trade being imposed by third countries, it is necessary to describe at Union level the areas established as protection and surveillance zones for African swine fever in Greece in collaboration with that Member State. These surveillance and protection zones take account of the current epidemiological scenario in that Member State.
- (8) Accordingly, the areas identified as protection and surveillance zones in Greece should be set out in the Annex to this Decision and the duration of that regionalisation fixed.
- (9) In addition, Implementing Decision (EU) 2020/181 should be repealed and replaced by this Decision.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

Greece shall ensure that the protection and surveillance zones established in accordance with Article 9 of Directive 2002/60/EC comprise at least the areas listed as the protection and surveillance zones in the Annex to this Decision.

Article 2

Implementing Decision (EU) 2020/181 is repealed.

Article 3

This Decision shall apply until 6 April 2020.

Article 4

This Decision is addressed to the Hellenic Republic.

Done at Brussels, 14 February 2020.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

Greece	Areas as referred to in Article 1	Date applicable until
Protection zone	Municipality of Visaltias (Serres Regional Unit)	6 April 2020
Surveillance zone	In Thessaloniki Regional Unit: — Municipality of Lagada, — Municipality of Volvis. In Serres Regional Unit: — Municipality of Iraklia, — Municipality of Serron, — Municipality of Amfipolis, — Municipality of Emmanouil Pappa, — Municipality of Neas Zichnis.	6 April 2020

COMMISSION IMPLEMENTING DECISION (EU) 2020/210**of 14 February 2020****amending the Annex to Implementing Decision (EU) 2020/47 on protective measures in relation to highly pathogenic avian influenza of subtype H5N8 in certain Member States***(notified under document C(2020) 963)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ⁽¹⁾, and in particular Article 9(4) thereof,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary checks applicable in intra-Union trade in certain live animals and products with a view to the completion of the internal market ⁽²⁾, and in particular Article 10(4) thereof,

Whereas:

- (1) Commission Implementing Decision (EU) 2020/47 ⁽³⁾ was adopted following outbreaks of highly pathogenic avian influenza of subtype H5N8 in holdings where poultry are kept in certain Member States and the establishment of protection and surveillance zones by those Member States in accordance with Council Directive 2005/94/EC ⁽⁴⁾.
- (2) Implementing Decision (EU) 2020/47 provides that the protection and surveillance zones established by the Member States listed in the Annex to that Implementing Decision, in accordance with Directive 2005/94/EC, are to comprise at least the areas listed as protection and surveillance zones in that Annex.
- (3) The Annex to Implementing Decision (EU) 2020/47 was recently amended by Commission Implementing Decision (EU) 2020/175 ⁽⁵⁾, following instances of highly pathogenic avian influenza of subtype H5N8 in poultry in Poland that needed to be reflected in that Annex.
- (4) Since the date of adoption of Implementing Decision (EU) 2020/175, Poland has notified the Commission of additional outbreaks of highly pathogenic avian influenza of subtype H5N8 in holdings where poultry are kept, in the Ostrodzki district.
- (5) In addition, Germany has notified the Commission of an outbreak of highly pathogenic avian influenza of subtype H5N8 in a holding where poultry are kept in the Hohenlohe district.
- (6) The new outbreaks in Poland and Germany are outside the areas currently listed in the Annex to Implementing Decision (EU) 2020/47, and the competent authorities of those Member States have taken the necessary measures required in accordance with Directive 2005/94/EC, including the establishment of protection and surveillance zones around those new outbreaks.
- (7) The Commission has examined the measures taken by Poland and Germany in accordance with Directive 2005/94/EC and it is satisfied that the boundaries of the protection and surveillance zones, established by the competent authorities of those Member States, are at a sufficient distance to the holdings where the recent outbreaks of highly pathogenic avian influenza of subtype H5N8 have been confirmed.

⁽¹⁾ OJ L 395, 30.12.1989, p. 13.

⁽²⁾ OJ L 224, 18.8.1990, p. 29.

⁽³⁾ Commission Implementing Decision (EU) 2020/47 of 20 January 2020 on protective measures in relation to highly pathogenic avian influenza of subtype H5N8 in certain Member States (OJ L 16, 21.1.2020, p. 31).

⁽⁴⁾ Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC (OJ L 10, 14.1.2006, p. 16).

⁽⁵⁾ Commission Implementing Decision (EU) 2020/175 of 6 February 2020 amending the Annex to Implementing Decision (EU) 2020/47 on protective measures in relation to highly pathogenic avian influenza of subtype H5N8 in certain Member States (OJ L 35, 7.2.2020, p. 23).

- (8) In order to prevent any unnecessary disturbance to trade within the Union and to avoid unjustified barriers to trade being imposed by third countries, it is necessary to rapidly describe at Union level, in collaboration with Poland and Germany, the new protection and surveillance zones established by those Member States in accordance with Directive 2005/94/EC. Therefore, the protection and surveillance zones listed for Poland, in the Annex to Implementing Decision (EU) 2020/47, should be amended, and new protection and surveillance zones should be listed for Germany.
- (9) Accordingly, the Annex to Implementing Decision (EU) 2020/47 should be amended to update regionalisation at Union level to include the new protection and surveillance zones established by Poland and Germany, in accordance with Directive 2005/94/EC, and the duration of the restrictions applicable therein.
- (10) Implementing Decision (EU) 2020/47 should therefore be amended accordingly.
- (11) Given the urgency of the epidemiological situation in the Union as regards the spread of highly pathogenic avian influenza of subtype H5N8, it is important that the amendments made to the Annex to Implementing Decision (EU) 2020/47 by this Decision should take effect as soon as possible.
- (12) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Implementing Decision (EU) 2020/47 is replaced by the text set out in the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 14 February 2020.

For the Commission
Stella KYRIAKIDES
Member of the Commission

ANNEX

The Annex to Implementing Decision (EU) 2020/47 is replaced by the following:

‘ANNEX

PART A

Protection zones in the concerned Member States as referred to in Articles 1 and 2:

Member State: Czechia

Area comprising:	Date until applicable in accordance with Article 29(1) of Directive 2005/94/EC
Region of Vysočina:	
Borovec (763446), Dolní Čepí (773514), Horní Čepí (773522), Kozlov u Lesoňovic (680257), Lískovec u Nedvědice (773557), Olešnička (763454), Štěpánov nad Svratkou (763462), Švařec (669601), Ujčov (773565), Vrtěžář (763471)	10.2.2020

Member State: Germany

Area comprising:	Date until applicable in accordance with Article 29(1) of Directive 2005/94/EC
BADEN-WÜRTTEMBERG, Kreis Hohelohenkreis:	
Folgende Gemarkungen sind vollständig enthalten: — Bretzfeld — Adolzfurt — Scheppach — Rappach Teilweise enthalten sind die Gemarkungen — Bitzfeld — Verrenberg — Windischenbach — Pfedelbach — Geddelsbach — Unterheimbach — Obersulm — Waldbach — Dimbach — Schwappach — Beginnend im Nordosten an der Gemarkungsgrenze Bitzfeld Schnittpunkt A6 weiter an der Gemarkungsgrenze südlich bis zur L 1036 — Nach Osten entlang Feldweg am Gewann Unteress Gässle entlang zum Schnittpunkt der Eisenbahnlinie HN-Waldenberg und der K2336 — Auf der K2336 durch Verrenberg bis zur T-Kreuzung — auf Höhe des Funkturms abbiegend auf einem Feldweg nach Süden Richtung Golberhöfe — Bis Einmündung auf die Golbergstraße — Auf der Golbergstraße in Windischenbach bis zur Einmündung auf die L1036 — Auf der L1036 nach Süden bis zum Ortsausgang Windischenbach bis zur Kreuzung Adolzfurter Straße — Weiter auf Adolzfurter Straße nach Osten bis zur Einmündung Burghofstraße — Auf der Burghofstraße 350 m nach Süden — An der Kreuzung auf einem Feldweg 250 m weiter Richtung Südosten — Weiter auf dem Feldweg zwischen den Gewannen Wolfsbühl und Holzbühl Richtung Süden — Auf diesem Feldweg weiter durch das Waldgebiet Spörershölzle bis zum Feldweg In der Lohklinge	28.2.2020

Area comprising:	Date until applicable in accordance with Article 29(1) of Directive 2005/94/EC
— Auf dem Feldweg In der Lohklinge bis zur K 2346 in Buchhorn — Abbiegend auf die K2346 nach Südwesten durch Buchhorn — Auf der K2346 bis zum Aussiedlerhof Fleisch am Höhenweg — Dort abbiegend auf einen Feldweg Richtung Westen 500 m zwischen den Gewannen Große Äcker und Hintere Halden — Nach 500 m Abbiegend nach Süden — An der Gemarkungsgrenze Pfdelbach und Geddelsbach nach Westen auf einem Feldweg nordwestlich vorbei an den Ausiedlerhöfen Hintere Halden — Am Gebäude Geddelsbacher Helden 28 auf den Weg Richtung Westen bis zum Haus Geddelsbacher Helden 24 — Am Haus Geddelsbacher Helden 24 abbiegend Richtung Süden auf einem Feldweg bis zur Einmündung auf die K 2345 — Querung der K2345 — Weiter auf dem Feldweg Richtung Unterheimbach bis zur Einmündung auf die L 1090 in Unterheimbach — Auf der L1090 Richtung Südosten bis zur Schulstraße am Sportplatz — Nach der Sporthalle auf einer gedachten Linie 1,3 Km Richtung Westen bis zu einem Bach — An dem Bach 80 m entlang Richtung Süden von dort 280 m auf einer gedachten Linie nach Südwest zum nächsten Waldweg — Auf dem Waldweg 130 m nach Nordwesten im Wald Sandrain — Zwischen dem Wald Sandrain und Salenwald 1 km Richtung Südosten — Durch die Otterklinge nach Südwest bis zum Bach in der Rauchklinge — Entlang der der Gemarkungsgrenze Adolzfurt einschließlich bis zur Gemeindegrenze Obersulm — Entlang der Gemeindegrenze Bretzfeld/Obersulm nach Nordwest, Bretzfeld einschließlich, bis zur Feldwegkreuzung Steigwald und Eulenklinge — Von dort auf einem Feldweg Richtung Ortseingang Affaltrach — Von dort entlang eines Bachlaufs nach Norden zur L 1035, Affaltrach ausschließend — Querung der L 1035 — Weiter entlang am Mittelbach bis zum Ortseingang Affaltrach, dort am Ortsrand entlang nach Norden zur K 2110, Affaltrach ausschließend — Auf der K1035 Richtung Nordosten bis zur Gemeindegrenze Obersulm/Bretzfeld, Bretzfeld einschließend — Auf einer gedachten Linie 300 m in Nordwestlicher Richtung zum Waldrand Buchhau, Gewann Sperbelhau nördlich einschließend — Am Waldrand entlang Richtung Nordwesten bis zur Querung eines Wassergrabens — Von hier auf einer gedachten Linie nach Norden, westlich der Ortschaft Waldbach, Waldbach einschließend bis zur K 2341 — Querung der K 2341 — Auf einer gedachten Linie Richtung Nord-Nordost bis zum Dimbach — Auf einem Feldweg 300 m nach Nordwest, von dort auf einem Feldweg nach Nordosten bis zur A6 — Querung der A6 — Auf der Schwarzenbergstraße bis zur Ringstraße, Ostliche Teile von Schwappach einschließend — Auf der Ringstraße nach Norden bis zur Kreuzung L1089 — Weiter auf der Moosbachstraße Richtung Norden bis zum Kreisverkehr der L1036 — Vom Kreisverkehr Richtung Osten auf L1036 bis zur A6 — Auf der A6 Richtung Osten bis Startpunkt	
BADEN-WÜRTTEMBERG, Kreis Heilbronn:	
Teilweise enthalten sind die Flur Eschenau: — Von Landkreisgrenze Heilbronn Landkreis entlang Köberleweg Richtung Eschenau — entlang des Michelbach bis zur Straße Eschenauer Berg — östlich der Bebauung zur K2110 — entlang der K2110 bis zur Landkreisgrenze	28.2.2020

Member State: Hungary

Area comprising:	Date until applicable in accordance with Article 29(1) of Directive 2005/94/EC
Komárom-Esztergom megye:	
Ács és Bábolna települések közigazgatási területeinek a 47.687049 és a 17.989846, a 47.690195 és a 17.995825, valamint a 47.686220 és a 17.987319 GPS-koordináták által meghatározott pont körüli 3 km sugarú körön belül eső területei	17.2.2020
Hajdú-Bihar megye:	
Kokad és Létavértes települések közigazgatási területeinek a 47.387114 és a 21.9118493 GPS-koordináták által meghatározott pont körüli 3 km sugarú körön belül eső területei	8.2.2020

Member State: Slovakia

Area comprising:	Date until applicable in accordance with Article 29(1) of Directive 2005/94/EC
Nitra region:	
Municipalities: Zbehy, Čajakovce	30.1.2020
Trnava region:	
Municipality: Cífer	10.2.2020
Pezinok region:	
Municipality: Jablonec	10.2.2020
Čadca region:	
Municipalities: Stará Bystrica, Radôstka	18.2.2020

Member State: Poland

Area comprising:	Date until applicable in accordance with Article 29(1) of Directive 2005/94/EC
W województwie lubelskim, w powiecie lubartowskim:	
W gminie Uścimów miejscowości: Stary Uścimów, Nowy Uścimów, Drozdówka, Głębokie, Maśluchy, Orzechów Kolonia; Nowy Orzechów, Stary Orzechów	29.1.2020
W województwie lubelskim, w powiecie krasnostawskim:	
1. W gminie Izbica miejscowości: Wólka Orłowska, Topola, Orłów Drewniany, Orłów Drewniany Kolonia, Wał, Dworzyska, część miejscowości Izbica położona na północ od ulic Stokowej, Cichej, Targowej i Gminnej, północno – wschodnia część miejscowości Tarnogóra położona na wschód od rzeki Wieprz, część miejscowości Romanów położona na wschód od drogi 2141L; 2. W gminie Krasnostaw miejscowości: Łatyczów, Małochwiej Mały; 3. W gminie Żółkiewka miejscowości: Borówek, Borówek Kolonia, Makowiska, Olchowiec Wieś, Olchowiec Kolonia, Poperczyn, Wola Żółkiewska; 4. W gminie Gorzków miejscowości: Czysta Dębina, Borów.	29.1.2020

Area comprising:	Date until applicable in accordance with Article 29(1) of Directive 2005/94/EC
W województwie wielkopolskim, w powiecie ostrowskim:	
Część gmin Ostrów Wielkopolski i Przygodzice odgraniczone: od północy od przejazdu kolejowego na ulicy Gorzyckiej w Ostrowie Wielkopolskim, dalej ulicą Gorzycką w kierunku zachodnim do kościoła w miejscowości Gorzyce Wielkie. W kierunku południowym mijając od wschodu wsie Radziwiłłów do miejscowości Gorzyce Małe. Następnie do drogi nr 445 i ciekim wodnym przez las i niezamieszkałą część ulicy Kwiatowej w miejscowości Tarchały Wielkie. Następnie na wschód ulicą długą w miejscowości Topola Wielka do miejscowości Janków Przygodzki wzdłuż ulicy Długiej do skrzyżowania z ulicą Zębcowską. Na północ wzdłuż ulicy Zębcowskiej w Jankowie Przygodzkim do ulicy Staroprzygodzkiej w Ostrowie Wielkopolskim. Wzdłuż ulicy Staroprzygodzkiej do ulicy Siewnej, następnie na północny zachód ulicą Długą w miejscowości Ostrów Wielkopolski do ulicy Krętej, dalej wzdłuż ulicy Krętej i dalej ulicy Bocznej do przejazdu kolejowego na ulicy Gorzyckiej w miejscowości Ostrów Wielkopolski.	26.1.2020
W województwie wielkopolskim, w powiecie ostrowskim:	
W gminie Ostrów Wielkopolski miejscowości: Słaborowice, Lewków, Szczury, Kwiatków, Kołatajew, Franklinów, Młynów, Będzieszyn, Michałków, Czekanów	8.2.2020
W województwie wielkopolskim, w powiecie ostrowskim:	
1. W gminie Ostrów Wielkopolski miejscowość: Wysocko Wielkie 2. W gminie Przygodzice miejscowości: Janków Przygodzki, Przygodzice, Wysocko Małe	8.2.2020
W województwie wielkopolskim, w powiecie ostrowskim:	
1. W gminie Raszków miejscowości: Rąbczyn, Jelitów, Jaskółki, Radłów, południowa część miejscowości Przybysławice od numeru 144 do nr 35 2. W gminie Ostrów Wielkopolski miejscowości: Zacharzew, Lamki, Zalesie, Świeligów 3. Część północno - zachodnia miasta Ostrów Wielkopolski od ulicy Miodowej nr 5, Radłowskiej 65 przez ulice Profesora Jachimka, Przymiejską, Krotoszyńską, Owsianą do ulicy Topolowej 62	13.2.2020
W województwie wielkopolskim w powiecie wolsztyńskim:	
1. W gminie Wolsztyn miejscowości: Berzyna, Stary Widzim Piekiełko, Adamowo Piekiełko, Kębłowo Kolonia, część miejscowości Niałek Wielki położona na południe od drogi nr 32	20.2.2020
W województwie wielkopolskim, w powiecie kolskim:	
1. W gminie Olszówka miejscowości: Drzewce, Młynik, Łubianka, Ostrów Kolonia, Adamin, 2. W gminie Dąbie miejscowości: Tarnówka Wiesiołowska, Baranowiec, Tarnówka, Zalesie	5.2.2020
W województwie wielkopolskim, w powiecie szamotulskim	
W gminie Ostroróg miejscowości: Zapust, Wielonek, Klemensowo, Rudki Huby, Ostroróg	15.2.2020
W województwie wielkopolskim w powiecie wolsztyńskim:	
1. W gminie Wolsztyn miejscowości: Berzyna, Stary Widzim Piekiełko, Adamowo Piekiełko, Kębłowo Kolonia, część miejscowości Niałek Wielki położona na południe od drogi nr 32	20.2.2020
W województwie zachodniopomorskim w powiecie myśliborskim:	
1. W gminie Myślibórz miejscowości: Rościn, Rościnko, Rokicienko, Gryżyno, Dąbrowa-osada, Nawrocko, Iłowo, Wrzelewo, Pszczelnik; 2. W gminie Dębno miejscowość: Junczewo	8.2.2020

Area comprising:	Date until applicable in accordance with Article 29(1) of Directive 2005/94/EC
W województwie dolnośląskim w powiatach legnickim i złotoryjskim:	
1. W powiecie legnickim w gminie Chojnów miejscowości: Strupice, Budziwojów, Dzwonów, Gołocin, Pawlikowice; 2. W powiecie złotoryjskim w gminie Zagrodno miejscowość: Brochocin; 3. W powiecie złotoryjskim w gminie Złotoryja miejscowości: Podolany, Kolonia Kwiatów m. Lubiaków,	9.2.2020
W województwie warmińsko – mazurskim w powiecie iławskim	
W gminie Zalewo: Rąbity, Międzychód, Zatyki, Surbajny, Koziny, Kupin, Rudnia	20.2.2020
W województwie warmińsko – mazurskim w powiecie ostródzkim	
W gminie Grunwald miejscowości: Góry Lubiańskie, Zybułtowo, Lubian, Mielno, Stębark	4.3.2020
W województwie śląskim w powiecie raciborskim:	
W gminie Kuźnia Raciborska, miejscowości: Ruda Kozielska, część miejscowości Rudy położona na zachód od drogi nr 919	20.2.2020

Member State: Romania

Area comprising:	Date until applicable in accordance with Article 29(1) of Directive 2005/94/EC
Județul Maramureș	
Oraș Seini Oraș Seini - localitatea Săbișă	13.2.2020
Județul Satu Mare	
Comuna Pomi, localitatea Pomi	13.2.2020

PART B

Surveillance zones in the concerned Member States as referred to in Articles 1 and 3:

Member State: Czechia

Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
Region of Vysočina:	
Blažejovice u Rozsoch (742414), Bolešín (781037), Bor u Nedvědice (747114), Bratrušín (617008), Brťoví (733407), Bukov na Moravě (615757), Bystřice nad Pernštejnem (616958), Býšovec (617211), Čtyři Dvory (733415), Dolní Rožínka (630098), Domanín u Bystřice nad Pernštejnem (630616), Domanínek (617075), Dvořiště u Bystřice nad Pernštejnem (616982), Hluboké u Dalečína (624471), Horní Rožínka (643980), Hrdá Ves (782483), Chlébské (748498), Chlum (651605), Jablůňov (781363), Josefov u Rožné (742881), Karasín (794970), Kobylnice nad Svratkou (669580), Korouhvice (651613), Koroužné (669598), Kovářová (773549), Lesoňovice (680265), Malé Tresné (741981), Milasín (615765), Moravecké Pavlovice (698571), Pivonice u Lesoňovic (680273), Prosetín u Bystřice nad Pernštejnem (733423), Rodkov (630110), Rovečné (741990), Rozsochy (742431), Rožná (742899), Sejřek (747131), Skorotice (748501), Smrček (617229), Střítež u Bukova (615773), Věchnov (777544), Velké Tresné (742007), Věstín (781045), Věstínek (781053), Věžná na Moravě (781380), Vír (782491), Vojetín u Rozsoch (742449), Zlatkov (742902), Ždánice u Bystřice nad Pernštejnem (794988)	17.2.2020

Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
Borovec (763446), Dolní Čepí (773514), Horní Čepí (773522), Kozlov u Lesoňovic (680257), Lískovec u Nedvědice (773557), Olešnička (763454), Štěpánov nad Svratkou (763462), Švařec (669601), Ujčov (773565), Vrtěžř (763471)	From 11.2.2020 until 17.2.2020
Southern Moravian region:	
Bedřichov (601373), Běleč u Lomnice (601918), Brumov u Lomnice (613053), Crhov u Olešnice (617920), Černovice u Kunštátu (620602), Černvř (620661), Doubravnřk (631388), Hluboké u Kunštátu (639672), Hodonřn u Kunštátu (640409), Klokočí u Olří (711128), Křeptov (601926), Křřžovice (676675), Křřtřnov u Olešnice (676691), Lhota u Olešnice (681202), Louka (687189), Mařnová (719358), Nedvědice pod Pernštejnem (702307), Ochoz u Tiřnova (709441), Olešnice na Moravě (710415) – řást katastrálního území západně od komunikace ř. 362 (ul. Roveřínská-Generála řápka), Olří u Tiřnova (711144), Osiky (713112), Pernštejn (702315), Rakové (711152), Rozseř nad Kunštátem (742317), Strhaře (756881), Synalov (761753), Tasovice (765112)	17.2.2020

Member State: Germany

Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
BADEN-WÜRTTEMBERG, Kreis Hohelohenkreis:	
Folgende Gemarkungen sind vollständig enthalten: — Bretzfeld — Adolzfurt — Scheppach — Rappach Teilweise enthalten sind die Gemarkungen — Bitzfeld — Verrenberg — Windischenbach — Pfdelbach — Geddelsbach — Unterheimbach — Obersulm — Waldbach — Dimbach — Schwappach — Beginnend im Nordosten an der Gemarkungsgrenze Bitzfeld Schnittpunkt A6 weiter an der Gemarkungsgrenze südlich bis zur L 1036 — Nach Osten entlang Feldweg am Gewinn Interess Gässle entlang zum Schnittpunkt der Eisenbahnlinie HN-Waldenberg und der K2336 — Auf der K2336 durch Verrenberg bis zur T-Kreuzung — auf Höhe des Funkturms abbiegend auf einem Feldweg nach Süden Richtung Golberhöfe — Bis Einmündung auf die Golbergstraße — Auf der Golbergstraße in Windischenbach bis zur Einmündung auf die L1036 — Auf der L1036 nach Süden bis zum Ortsausgang Windischenbach bis zur Kreuzung Adolzfurter Straße — Weiter auf Adolzfurter Straße nach Osten bis zur Einmündung Burghofstraße — Auf der Burghofstraße 350 m nach Süden — An der Kreuzung auf einem Feldweg 250 m weiter Richtung Südosten — Weiter auf dem Feldweg zwischen den Gewannen Wolfsbül und Holzbühl Richtung Süden — Auf diesem Feldweg weiter durch das Waldgebiet Spörershölzle bis zum Feldweg In der Lohklinge — Auf dem Feldweg In der Lohklinge bis zur K 2346 in Buchhorn — Abbiegend auf die K2346 nach Südwesten durch Buchhorn — Auf der K2346 bis zum Aussiedlerhof Fleisch am Höhenweg	From 29.2.2020 until 8.3.2020

Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
— Dort abbiegend auf einen Feldweg Richtung Westen 500 m zwischen den Gewannen Große Äcker und Hintere Halden — Nach 500 m Abbiegend nach Süden — An der Gemarkungsgrenze Pfdelbach und Geddelbach nach Westen auf einem Feldweg nordwestlich vorbei an den Ausiedlerhöfen Hintere Halden — Am Gebäude Geddelbacher Helden 28 auf den Weg Richtung Westen bis zum Haus Geddelbacher Helden 24 — Am Haus Geddelbacher Helden 24 abbiegend Richtung Süden auf einem Feldweg bis zur Einmündung auf die K 2345 — Querung der K2345 — Weiter auf dem Feldweg Richtung Unterheimbach bis zur Einmündung auf die L 1090 in Unterheimbach — Auf der L1090 Richtung Südosten bis zur Schulstraße am Sportplatz — Nach der Sporthalle auf einer gedachten Linie 1,3 Km Richtung Westen bis zu einem Bach — An dem Bach 80 m entlang Richtung Süden von dort 280 m auf einer gedachten Linie nach Südwest zum nächsten Waldweg — Auf dem Waldweg 130 m nach Nordwesten im Wald Sandrain — Zwischen dem Wald Sandrain und Salenwald 1 km Richtung Südosten — Durch die Otterklinge nach Südwest bis zum Bach in der Rauchklinge — Entlang der der Gemarkungsgrenze Adolzfurt einschließlich bis zur Gemeindegrenze Obersulm — Entlang der Gemeindegrenze Bretzfeld/Obersulm nach Nordwest, Bretzfeld einschließlich, bis zur Feldwegkreuzung Steigwald und Eulenklinge — Von dort auf einem Feldweg Richtung Ortseingang Affaltrach — Von dort entlang eines Bachlaufs nach Norden zur L 1035, Affaltrach ausschließend — Querung der L 1035 — Weiter entlang am Mittelbach bis zum Ortseingang Affaltrach, dort am Ortsrand entlang nach Norden zur K 2110, Affaltrach ausschließend — Auf der K1035 Richtung Nordosten bis zur Gemeindegrenze Obersulm/Bretzfeld, Bretzfeld einschließend — Auf einer gedachten Linie 300 m in Nordwestlicher Richtung zum Waldrand Buchhau, Gewann Sperbelhau nördlich einschließend — Am Waldrand entlang Richtung Nordwesten bis zur Querung eines Wassergrabens — Von hier auf einer gedachten Linie nach Norden, westlich der Ortschaft Waldbach, Waldbach einschließend bis zur K 2341 — Querung der K 2341 — Auf einer gedachten Linie Richtung Nord-Nordost bis zum Dimbach — Auf einem Feldweg 300 m nach Nordwest, von dort auf einem Feldweg nach Nordosten bis zur A6 — Querung der A6 — Auf der Schwarzenbergstraße bis zur Ringstraße, Ostliche Teile von Schwappach einschließend — Auf der Ringstraße nach Norden bis zur Kreuzung L1089 — Weiter auf der Moosbachstraße Richtung Norden bis zum Kreisverkehr der L1036 — Vom Kreisverkehr Richtung Osten auf L1036 bis zur A6 — Auf der A6 Richtung Osten bis Startpunkt	
Folgende Gemarkungen sind vollständig enthalten: — Westernbach (Gemeinde Zweiflingen) — Baumerlenbach, Unterohrn, Verrenberg, Öhringen, Büttelbronn, Eckartsweiler, Cappel (Stadt Öhringen) — Pfdelbach, Windischenbach, Oberohrn, Harsberg (Gemeinde Pfdelbach) — Siebeneich (Gemeinde Bretzfeld) Folgende Gemarkungen sind teilweise im Beobachtungsgebiet und im Sperrbezirk enthalten, die genaue Abgrenzung ist der Beschreibung des Sperrbezirks zu entnehmen: — Bitzfeld, Geddelbach, Unterheimbach, Waldbach, Dimbach, Schwabbach (Gemeinde Bretzfeld) — Verrenberg (Stadt Öhringen) — Windischenbach, Pfdelbach (Gemeinde Pfdelbach)	8.3.2020

Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
Teilweise enthalten sind die Gemarkungen Möglingen und Ohrnberg (Gemeinde Öhringen): — Beginnend ab der Gemarkungsgrenze Möglingen-Kochersteinsfeld-Ohrnberg — vorbei an den Gewannen Hummeläcker und Streich — weitergedacht bis zum nördlichsten Punkt der Kleingartensiedlung (Gewann Streichberg) — Linie weitergedacht bis zur L1045 Teilweise enthalten ist die Gemarkung Zweiflingen: — über die Gewanne Schießäcker einmündend in den Feldweg am Waldrand unterhalb des Gewanns Weite Gruben dann in gleicher Richtung weiterführend bis zur Schießhofer Straße, die Schießhofer Straße Richtung Süden bis Pfahlbach — dann entlang der K2330 bis zum Limes Blick Zweiflingen — nach Osten abbiegend entlang der Kärcher Straße am Golfplatz vorbei bis zum Kreisel L1050 — weiter nach Süden auf der L1050 bis zur Einmündung K2354 — weiter entlang der K2354, die A6 querend Teilweise enthalten sind die Gemarkungen Neuenstein und Obersöllbach: — bis nach dem Gewann Wachtbaumäcker in Richtung Neuenstein, — dann abbiegend in Richtung Südwesten, — dann 2. Feldweg links abbiegend — dann entlang des Wegs zwischen den Baugebieten Riedweg Teil 1 und Teil 2 nach Süden, die Bahnlinie queren, südlich vorbei am Wohngebiet Steigerbrünle — Linie weiter gedacht am Sportgelände vorbei bis zur Brücke über den Epbach (Bergstraße) — dann die L1051 und L1036 queren, dann auf die K2357 bis zur Gemarkungsgrenze Obersöllbach-Eschelbach — entlang des Gewanns Obere Halde die K2355 und das Gewann Bühl querend — dann weiter Richtung Süden in Richtung Pfaffenberg — östlich vorbei am Pfaffenberg, die Gemeindegrenze nach Öhringen querend Teilweise enthalten ist die Gemarkung Michelbach: — den Weg weiter bis Rohrklänge — dann weiter Richtung Süden durch die Gewanne Brenntenholz und Erlen — dann die K2387 kreuzen, weiter in Richtung Süden nach Mittelsteinbach durch das Gewann Koppenwiesenschlag, Teilweise enthalten ist die Gemarkung Untersteinbach: — weiter in Richtung Süden durch die Gewanne Holderberg und Göttele — östlich an Mittelsteinbach vorbei auf den Herdenweg, dann bis zum Wasserhochbehälter vor Untersteinbach — dann Weiter Richtung Süden an der Siedlungsgrenze bis zur Straße In der Heid — dann weiter entlang des Wegs in Richtung Süden bis zur Schuppacher Straße (K2360) — auf K2360 weiter bis Floßholz, dann entlang des Wegs parallel zum Lohklingenbach in Richtung Südwesten bis ca. 150 m vor der Kehre zur Kreisgrenze SHA	
BADEN-WÜRTTEMBERG, Kreis Heilbronn:	
Teilweise enthalten sind die Flur Eschenau: — Von Landkreisgrenze Heilbronn Landkreis entlang Köberleweg Richtung Eschenau — entlang des Michelbach bis zur Straße Eschenauer Berg — östlich der Bebauung zur K2110 — entlang der K2110 bis zur Landkreisgrenze	From 29.2.2020 until 8.3.2020
Folgende Gemeinden sind vollständig enthalten: — Löwenstein — Lehensteinsfeld — Ellhofen — Langenbrettach — Eberstadt — Wüstenrot Folgende Gemarkungen sind vollständig enthalten: — Grantschen (Gemeinde Weinsberg) — Wimmmental (Gemeinde Weinsberg) — Cleversulzbach (Gemeinde Neuenstadt)	8.3.2020

Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
Teilweise enthalten ist die Gemeinde Obersulm: — ausgenommen: der im Sperrbezirk liegende Teil Teilweise enthalten ist die Gemarkung Unterheinriet (Gemeinde Untergruppenbach): — An der Gemeindegrenze zwischen Sandberg und Vorhof in westlicher Richtung bis zur Forststraße; — auf Feldweg nördlich von Vorhof Richtung Waldrand, entlang bis zur Schozach; — nördlich am Braunenwald entlang Zufluss zur Schozach; — westlich entlang Waldrand bis zur Wegkreuzung unterhalb Hagelsberg; — entlang Forstweg in nördlicher Richtung bis zur Gemeindegrenze Lehensteinsfeld Teilweise enthalten ist die Gemarkung Weinsberg (Gemeinde Weinsberg): — Gemeindegrenze zu Lehensteinsfeld an der A81 entlang in nördlicher Richtung bis zur Gemeindegrenze Eberstadt Teilweise enthalten ist die Gemarkung Neuenstadt (Gemeinde Neuenstadt): — Gemeindegrenze Eberstadt Feld/Forstweg von Buchhorn Richtung Neuenstadt – Daistler; — bei den Aussiedlerhöfen in westlicher Richtung bis zum Limbach; — vom Limbach zur Cleversulzbacherstraße weiter zur K2007 bis zur Öhringerstraße über die A81 bis zur Kocher Teilweise enthalten ist die Gemarkung Gochsen (Gemeinde Hardthausen): — von der A81 zur Kocher am Fluss entlang bis Buchsmühle; — Feldweg nördlich des Sportplatz Richtung Hintere Berge – Dörnet – Bühl – Lampoldshausenerstraße – Feldweg westlich zur K2014; — südlich des Gänskirchhofs in westlicher Richtung zur Landkreisgrenze	

BADEN WÜRTTEMBERG, Kreis Schwäbisch-Hall:

Folgende Gemarkungen sind vollständig enthalten: Ammertsweiler (Gemeinde Mainhardt) Teilweise enthalten ist die Gemarkung Geißelhardt (Gemeinde Mainhardt): — Von der Gemarkungsgrenze (Ammertsweiler/Geißelhardt) links entlang der L1050 bis zur Abzweigung Streithag — gesamter Ortsteil Streithag — von Streithag Richtung Waldrand Lohklingen Wald, links entlang des Waldrandes bis zur Kreisgrenze Schwäbisch-Hall	8.3.2020
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Member State: Hungary

Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
Komárom-Esztergom megye:	
Bana, Bábolna, Csém, Kisigmánd, Komárom, Mocs, Nagyigmánd és Tárkány települések közigazgatási területének a 47.687049 és a 17.989846, a 47.690195 és a 17.995825, valamint a 47.686220 és a 17.987319 GPS-koordináták által meghatározott pont körüli 10 km sugarú kör által határolt területen belül és a védőkörzeten kívül eső területei	26.2.2020
Ács és Bábolna települések közigazgatási területeinek a 47.687049 és a 17.989846, a 47.690195 és a 17.995825, valamint a 47.686220 és a 17.987319 GPS-koordináták által meghatározott pont körüli 3 km sugarú körön belül eső területei	From 18.2.2020 until 26.2.2020
Győr-Moson-Sopron megye:	
Bőny, Nagyszentjános és Réta települések közigazgatási területeinek a 47.687049 és a 17.989846 valamint a 47.690195 és a 17.995825 GPS-koordináták által meghatározott pont körüli 10 km sugarú körön belül eső területei	26.2.2020

Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
Hajdú-Bihar megye:	
Álmosd, Bagamér, Monostorpályi, Pocsaj, Újléta és Vámospércs és települések közigazgatási területeinek a 47.387114 és a 21.9118493 GPS-koordináták által meghatározott pont körüli 10 km sugarú körön belül és a védőközvetlen kívül eső területei	17.2.2020
Kokad és Létavértes települések közigazgatási területeinek a 47.387114 és a 21.9118493 GPS-koordináták által meghatározott pont körüli 3 km sugarú körön belül eső területei	From 9.2.2020 until 17.2.2020
Member State: Slovakia	
Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
Nitra region:	
Municipalities in region Nitra: Čab, Nové Sady, Malé Zálužie, Kapince, Šurianky, Hruboňovo, Jelšovce, Ľudovítová, Výčapy-Opatovce, Podhorany, Lužianky, Lehota, Alekšince, Lukáčovce, Rišňovce Parts of town Nitra: Dražovce, Zobor, Chrenová, Kynek	8.2.2020
Municipalities in region Nitra: City Komárno part of Nová Stráž, part of municipality Žitná na Ostrove	26.2.2020
Municipalities: Zbehy, Čajakovce	From 31.1.2020 until 8.2.2020
Topoľčany region:	
Municipality: Koniarovce	8.2.2020
Trnava region:	
Municipality: Cífer	From 11.2.2020 until 17.2.2020
Municipalities: Trnava city, Hrnčiarovce nad Parnou, Zeleneč, Biely Kostol, Ružindol, Zvončín, Suchá nad Parnou, Borová, Voderady, Slovenská Nová Ves, Pavlice	17.2.2020
Senec region:	
Municipalities: Blatné, Kaplná, Igram, Čataj	17.2.2020
Pezinok region:	
Municipality : Jablonec	From 11.2.2020 until 17.2.2020
Municipalities: Báhoň, Štefanová, Budmerice, Vištuk, Šenkvice	17.2.2020
Galanta region:	
Municipality: Veľký Grob	19.2.2020
Čadca region:	
Municipalities: Stará Bystrica, Radôstka, Vychylovka	From 19.2.2020 until 27.2.2020
Municipalities: Klubina, Zborov nad Bystricou, Krásno nad Kysucou, Nová Bystrica, Dunajov	27.2.2020
Žilina region:	
Municipality: Lutiše, Horná Tižiná	27.2.2020
Kysucké Nové Mesto region:	
Municipality: Lodno, part of municipalities: Kysucký Lieskovec, Horný Vadičov	27.2.2020

Member State: Poland

Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
W województwie lubelskim, w powiatach: lubartowskim, łączyńskim, parczewskim, włodawskim:	
1. W powiecie lubartowskim w gminie Uścimów miejscowości: Krasne, Nowa Jedlanka, Ochoża, Rudka Starościńska, Stara Jedlanka; 2. W powiecie lubartowskim w gminie Ostrów Lubelski miejscowości: Ostrów Lubelski, Bójki, Jamy, Kolechowice, Kolechowice Folwark; Kolechowice Kolonia, Rozkopaczew, Rudka Kijańska; 3. W powiecie łączyńskim w gminie Ludwin miejscowości: Dratów Kolonia, Jagodno, Krzcień, Piaseczno, Rogóźno, Rozpłucie Pierwsze, Rozpłucie Drugie; 4. W powiecie parczewskim w gminie Sosnowica miejscowości: Stary Orzechów, Nowy Orzechów, Lejno, Komarówka, Zienki, Górki, Sosnowica, Libiszów, Bohutyn, Lipniak, Pasieka, Zbójno; 5. W powiecie parczewskim w gminie Dębowa Kłoda miejscowości: Białka, Makoszka, Uhnin, 6. W powiecie parczewskim w gminie Parczew: miejscowości: Babianka, Tyśmienica; 7. W powiecie włodawskim w gminie Urszulin: miejscowości: Jamniki, Łomnica, Zawadówka	7.2.2020
W województwie lubelskim, w powiecie lubartowskim:	
W gminie Uścimów miejscowości: Stary Uścimów, Nowy Uścimów, Drozdówka, Głębokie, Maśluchy, Orzechów Kolonia, Nowy Orzechów, Stary Orzechów	From 30.1.2020 until 7.2. 2020
W województwie lubelskim, w powiatach: krasnostawskim, zamojskim	
1. W powiecie krasnostawskim miasto Krasnystaw; 2. W powiecie krasnostawskim w gminie Gorzków miejscowości: Piaski Szlacheckie, Widniówka; 3. W powiecie krasnostawskim gmina Izbica (bez obszaru zapowietrzonego); 4. W powiecie krasnostawskim w gminie Krasnystaw miejscowości: Białka, Łany, Małochwiej Duży, Niemienice, Niemienice Kolonia, Siennica Nadolna, Tuligłowy, Rońsko, Widniówka, Zastawie Kolonia, Zażółkiew; 5. W powiecie krasnostawskim w gminie Krasnystaw miejscowości: Anielpol, Brzeziny, Czajki, Franciszków, Majdan Surhowski, Łukaszówka, Surhów, Surhów Kolonia; 6. W powiecie krasnostawskim w gminie Siennica Różana miejscowości: Rudka, Siennica Królewska Duża; 7. W powiecie zamojskim w gminie Skierbieszów miejscowości: Kalinówka, Kolonia Wiszenki, Wiszenki, Zabytów; 8. W powiecie zamojskim w gminie Stary Zamość miejscowości: Krasne, Majdan Sitanecki, Podkrasne, Podstary Zamość, Stary Zamość, Wierzba Druga.	7.2.2020
W województwie lubelskim, w powiecie krasnostawskim:	
1. W gminie Izbica miejscowości: Wólka Orłowska, Topola, Orłów Drewniany, Orłów Drewniany Kolonia, Wał, Dworzyska, część miejscowości Izbica położona na północ od ulic Stokowej, Cichej, Targowej i Gminnej, północno – wschodnia część miejscowości Tarnogóra położona na wschód od rzeki Wieprz, część miejscowości Romanów położona na wschód od drogi 2141L; 2. W gminie Krasnystaw miejscowości: Łatyczów, Małochwiej Mały; 3. W gminie Żółkiewka miejscowości: Borówek, Borówek Kolonia, Makowiska, Olchowiec Wieś, Olchowiec Kolonia, Poperczyn, Wola Żółkiewska; 4. W gminie Gorzków miejscowości: Czysa Dębina, Borów.	From 30.1.2020 until 7.2. 2020

Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
W województwie lubelskim, w powiatach: krasnostawskim, lubelskim, świdnickim	
1. W powiecie krasnostawskim w gminie Żółkiewka miejscowości: Dąbie, Dąbie Kolonia, Tokarówka, Celin, Siniec, Adamówka, Makowiska Małe, Żółkiewka, Rożki, Rożki Kolonia, Huta, Żółkiew Wieś, Żółkiew Kolonia, Zaburze, Zaburze Kolonia, Markiewiczów, Gany, Koszarsko, Chruściechów, Majdan Wierzychowski, Wierzychowin, Chłaniów, Chłaniów Kolonia, Średnia Wieś, Władysławin; 2. W powiecie krasnostawskim w gminie Rudnik: Majdan Borowski Pierwszy, Majdan Borowski Drugi, Suszeń, Joanin, Potasznia, Majdan Średni, Majdan Kobylański, Majdan Łuczyci, Majdan Borowski, Suche Lipie, Rudnik, Równianki, Wierzbica, Wierzbica Kolonia, Międzyłaz, Mościska Kolonia, Mościska, Płonka, Maszów, Romanówek, Bzowiec, Kaszuby; 3. W powiecie krasnostawskim w gminie Gorzków miejscowości: Antoniówka, Bogusław, Orchowiec, Kolonia Orchowiec, Bobrowe, Felicjan, Baranica, Wielkopole, Zamostek, Gorzków, Gorzków Wieś, Gorzków Osada, Piaszki Szlacheckie, Chorupnik, Chorupnik Kolonia, Borsuk, Józefów, Czysta Debina Kolonia, Borów Kolonia, Góry, Olesin, Wielobycz, Wiśniów; 4. W powiecie krasnostawskim w gminie Izbica miejscowości: Bobliwo, Wirkowice Drugie; 5. W powiecie lubelskim w gminie Krzczonów miejscowości: Sobieska Wola Pierwsza, Sobieska Wola Druga; 6. W powiecie lubelskim w gminie Wysokie miejscowość: Antoniówka; 7. W powiecie świdnickim w gminie Rybczewice miejscowości: Bazar, Częstoborowice, Izdebnio, Izdebnio Kolonia, Pilaszkowice Pierwsze, Pilaszkowice Drugie, Zygmuntów.	7.2.2020
W województwie wielkopolskim, w powiecie ostrowskim:	
1. Pozostała część gminy Przygodzice bez obszaru zapowietrzonego, 2. Pozostała część gminy Ostrów Wielkopolski bez obszaru zapowietrzonego, 3. gmina Raszków, 4. gmina Odolanów.	4.2.2020
W województwie wielkopolskim, w powiecie ostrowskim:	
1. W gminie Ostrów Wielkopolski miejscowości: Sobótka, Borowiec, Gutów, Górzeńko, Górzno, Biniew, Szczury, Kwiatków, Lewkowiec, Stary Staw, Karski, Ostrów Wielkopolski, Wtorek, Sadowie, Nowe Kamienice, Wysocko Wielkie, Smardowskie Olendry 2. W gminie Raszków miejscowości: Grudzielec, Nowy Grudzielec, Korytnica, Szczurawice, 3. W gminie Nowe Skalmierzyce miejscowości: Pawłówek, Gałązki Wielkie, Kotowiecko, Żakowice, Głóski, Droszew, Gałązki Małe, Trkusów, Miedzianów, Boczków, Kurów, Kościuszków, Gniazdów, Fabian, Ociąż, Skalmierzyce, Śliwniki, Nowe Skalmierzyce, Biskupice Ołoboczne, Bilczew 4. W gminie Sieroszewice miejscowości: Latowice, Latowice-Kęszyce, Parczew, Bibianki 5. W gminie Przygodzice miejscowości: Topola Osiedle, Strugi, Trzcieliny, Szkudlarka, Dębica, Olendry, Smardów, Boguśałów, Chynowa, Chynowa Lipie, Kłady, Opłotki; 6. W gminie Odolanów miejscowości: Chujary, Pustkowie, Gorzyce Małe, Egipt, Madera I, Parcele, Harych, Zieluchowiec, Chałupki, Huta, Żuraw, Szmata, Nadstawki, Grochowiska, Papiernia 7. W gminie Sieroszewice miejscowości: Parczew, Westrza, Zmysłona 8. W gminie Ostrów Wielkopolski miejscowości: Sadowie, Smardowskie Olendry, Nowe Kamienice, Wtorek, Trąba, Kąkolewo, Bagatela, Czekanów, Baby, Michałków, Gręblów, Madera II, Biedrusko,	17.2.2020

Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
Część gmin Ostrów Wielkopolski i Przygodzice odgraniczone: od północy od przejazdu kolejowego na ulicy Gorzyckiej w Ostrowie Wielkopolskim, dalej ulicą Gorzycką w kierunku zachodnim do kościoła w miejscowości Gorzyce Wielkie. W kierunku południowym mijając od wschodu wieś Radziwiłłów do miejscowości Gorzyce Małe. Następnie do drogi nr 445 i ciekim wodnym przez las i niezamieszkałą część ulicy Kwiatowej w miejscowości Tarchały Wielkie. Następnie na wschód ulicą długą w miejscowości Topola Wielka do miejscowości Janków Przygodzki wzdłuż ulicy Długiej do skrzyżowania z ulicą Zębcowską. Na północ wzdłuż ulicy Zębcowskiej w Jankowie Przygodzkim do ulicy Staroprzygodzkiej w Ostrowie Wielkopolskim. Wzdłuż ulicy Staroprzygodzkiej do ulicy Siewnej, następnie na północny zachód ulicą Długą w miejscowości Ostrów Wielkopolski do ulicy Krętej, dalej wzdłuż ulicy Krętej i dalej ulicy Bocznej do przejazdu kolejowego na ulicy Gorzyckiej w miejscowości Ostrów Wielkopolski.	From 26.1.2020 until 4.2. 2020
W gminie Ostrów Wielkopolski miejscowości: Słaborowice, Lewków, Szczury, Kwiatków, Kołatajew, Franklinów, Młynów, Będzieszyn, Michałków, Czekanów	From 9.2.2020 until 17.2. 2020
1. W gminie Ostrów Wielkopolski miejscowość: Wysocko Wielkie 2. W gminie Przygodzice miejscowości: Janków Przygodzki, Przygodzice, Wysocko Małe	From 9.2.2020 until 17.2. 2020
W województwie wielkopolskim, w powiecie ostrowskim:	
1. W gminie Raszków miejscowości: Rąbczyn, Jelitów, Jaskółki, Radłów, południowa część miejscowości Przybysławice od numeru 144 do nr 35 2. W gminie Ostrów Wielkopolski miejscowości: Zacharzew, Lamki, Zalesie, Świeligów 3. Część północno - zachodnia miasta Ostrów Wielkopolski od ulicy Miodowej nr 5, Radłowskiej 65 przez ulice Profesora Jachimka, Przymiejską, Krotoszyńską, Owsianą do ulicy Topolowej 62	From 14.2.2020 until 23.2. 2020
W województwie wielkopolskim, w powiatach ostrowskim i krotoszyńskim:	
W powiecie ostrowskim: 1. W gminie Raszków miejscowości: Rąbczyn, Raszków, Pogrzebów, Głogowa, Skrzebowa, Moszczanka, Biniew, Bieganin, Szczurawice, Walentynów, Niemojewiec, Janków Zalesny, Sulisław, pozostała część miejscowości Przybysławice poza obszarem zapowietrzonym, południowa część miejscowości Korytnica do ulicy Jarocińskiej 6; 2. W gminie Ostrów Wielkopolski miejscowości: Łąkociny, Daniszyn, Gorzyce Wielkie, Radziwiłłów, Topola Mała, Słaborowice, Franklinów, Lewków, Szczury, Wysocko Wielkie, Cegły, Kołatajew, Karski, Stary Staw, Mazury- część wschodnia do numeru 8, Czekanów- zachodnia część od ulicy Kaliskiej 12, Kwiatków- zachodnia część od numeru 7A 3. Pozostała część miasta Ostrów Wielkopolski poza obszarem zapowietrzonym 4. W gminie Przygodzice miejscowości: Topola Wielka, Topola Osiedle, Janków Przygodzki, Wysocko Małe 5. W gminie Odolanów miejscowości: Nabyszyce, Wierzbno, Tarchały Wielkie, Tarchały Małe, Gorzyce Małe W powiecie krotoszyńskim: W gminie Krotoszyn miejscowości: Baszyny, Ugrzele, Janów, Orpizew, Świnków	23.2.2020
W województwie wielkopolskim, w powiecie kolskim:	
1. W gminie Olszówka miejscowości: Drzewce, Młynik, Łubianka, Ostrów Kolonia, Adamin; 2. W gminie Dąbie miejscowości: Tarnówka Wiesiołowska, Baranowiec, Tarnówka, Zalesie	From 6.2.2020 until 14.2. 2020
W województwie wielkopolskim, w powiecie kolskim:	

Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
1. W gminie Koło miejscowości: Przybylów, Skobielice; 2. W gminie Olszówka miejscowości: Zawadka, Krzewata, Przybyszew, Nowa Wioska, Grabina, Dębowniczi, Mniewo, Ponętów Górny Pierwszy, Ponętów Górny Drugi, Szczepanów, Tomaszew, Głębokie, Olszówka, Umień, Złota; 3. W gminie Kłodawa miejscowości: Górki, Podgajew, 4. W gminie Dąbie miejscowości: Rośle, Lisice, Krzewo, Karszew, Kupinin, Wiesiołów, Domanin, Cichmiana, Chruscin, Augustynów, Krzykosy, Bród, Lutomirów, Gaj, Rzuchów, Majdany, Ladorudz, Grabina Mała, Chełmno Parcele, Chełmno, Grabina Wielka, Sobótka, Dąbie; 5. W gminie Grzegorzew miejscowości: Ladorudzek, Ponętów Dolny, Grodna, Tarnówka;	14.2.2020
W województwie wielkopolskim, w powiecie szamotulskim:	
W gminie Ostroróg miejscowości: Zapust, Wielonek, Klemensowo, Rudki Huby, Ostroróg	From 16.2.2020 until 25.2.2020.
W województwie wielkopolskim, w powiecie szamotulskim:	
1. W gminie Kaźmierz miejscowości: Sokolniki Wielkie, Sokolniki Małe, Wierzchaczewo; 2. W gminie Ostroróg miejscowości: Bobulczyn, Oporowo, Kluczewo, Kluczewo Huby, Szczepankowo, Karolewo, Rudki, Piaskowo, Forestowo, Bielejewo, Binino, Dobrojewo; 3. W gminie Obrzycko miejscowości: Gaj Mały, Karolin, Pęckowo, Ordzin, Koźmin, Dobrogostowo, Lizbona; 4. W gminie Pniewy miejscowości: Przystanki, Dębina, Buszewko, Buszewo, Dęborzyce, Mielno, Szymanowo, Zajączkowo, Psarski, Nojewo, Psarki, Nosalewo 5. W gminie Wronki miejscowości: Samołęż, Nowa Wieś, Huby Oporowo, Marianowo, Wierzchocin, Głuchowo 6. W gminie Szamotuły miejscowości: Czyściec, Krzeszkowice, Kamionka, Otorowo, Lipnickie Huby, Lipnica, Brodziszewo, Emilianowo, Gałowo, Jastrowo, Ostrolesie, Koźle, Śmiłowo, Szamotuły	25.2.2020
W województwie wielkopolskim, w powiecie międzychodzkim	
W gminie Chrzypsko Wielkie miejscowość Orle Wielkie	25.2.2020
W województwie wielkopolskim w powiecie wolsztyńskim:	
W gminie Wolsztyn miejscowości: Berzyna, Stary Widzim Piekiełko, Adamowo Piekiełko, Kębłowo Kolonia, część miejscowości Niałek Wielki położona na południe od drogi nr 32	From 21.2.2020 until 29.2.2020
W województwie wielkopolskim w powiatach wolsztyńskim i grodziskim:	
W powiecie wolsztyńskim: 1. W gminie Wolsztyn miejscowości: Stary Widzim, Świętno, Stradyń, Obra, Wroniawy, Stara Dąbrowa, Adamowo, Gościeszyn, Błocko, Tłoki, Wolsztyn, Karpicko, Nowe Tłoki, Chorzemin, Powodowo, Nowa Obra, Nowa Dąbrowa, Krutla, Nowy Młyn, Zdrogowo, Świętno, część miejscowości Niałek Wielki położona na północ od drogi nr 32; 2. W gminie Przemęt miejscowości: Solec, Solec Nowy, Mochy; 3. W gminie Siedlec miejscowości: Jaromierz, Jazyniec, Kielkowo, Żodyń, Siedlec, Kiełpiny Kolonia W powiecie grodziskim: W gminie Rakoniewice miejscowości: Głodno, Cegielsko Adolfowo, Łąkie, część miejscowości Rostarzewo położona na zachód od ulic Topolowej i Ogrodowej	29.2.2020
W województwie lubuskim w powiecie zielonogórskim	

Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
W gminie Kargowa miejscowości: Obra Dolna, Nowy Jaromierz	29.2.2020
W województwie łódzkim, w powiatach łączyskim, poddębickim:	
1. W powiecie łączyskim w gminie Świnice Warckie miejscowości: Chęciny, Chorzepin, Chorzepinek, Chorzepinek, Chwałborzyce, Góry Chwałborskie, Hektary, Kaznów, Kaznówek, Kozanki Podleśne, Kraski, Miniszew, Odrada, Polusin, Wyganów, Wylazłów, Zbylczyce; 2. W powiecie łączyskim w gminie Grabów miejscowości: Besiekiery, Besiekiery-Kolonia, Biała Góra, Bugaj, Bujak, Byszew, Byszew-Parcele, Celinów, Ciasna, Goszczędza, Goszczędza-Parcele, Grabinka, Grabów-Cegielnia, Grabów-Dwór, Jamy, Janów, Jastrzębia, Kadzidłowa, Kadzidłowa-Adamów, Kadzidłowa-Borki, Kadzidłowa-Brzezinka, Kadzidłowa-Grabinka, Kadzidłowa-Karolewo, Kępina, Kobyle, Kontrowers, Kotowice, Leszno, Osiny, Ostrówek, Ostrówek-Kolonia, Pieczew, Pieczew Poduchowny, Pokrzywnia, Polamy, Probstowo, Pruchyniec, Rybnik, Smardzew, Smardzew-Osada, Stanisławki, Zachciałki, Żrebięta; 3. W powiecie poddębickim w gminie Uniejów miejscowości: Brzozówka, Czepów, Czepów Górny, Czepów Średni, Grodzisko, Jaszczurów, Kozia nóżka, Lekaszyn, Osina, Rożniatów, Rożniatów-Kolonia, Sachalina, Skotniki, Wilamów, Wilamówka, Żabieniec	14.2.2020
W województwie zachodniopomorskim w powiecie myśliborskim:	
1. W gminie Myślibórz miejscowości: Rościn, Rościnko, Rokiczenko, Gryżyno, Dąbrowa-osada, Nawrocko, Iłowo, Wrzelewo, Pszczelnik; 2. W gminie Dębno miejscowość: Junczewo	From 9.2.2020 until 17.2.2020
W województwie zachodniopomorskim w powiatach myśliborskim i gryfińskim:	
1. W powiecie myśliborskim w gminie Myślibórz miejscowości: Wierzbica, Myślibórz, Myśliborzyce, Kolonia Myśliborzyce, Klicko, Dąbrowa, Zgoda, Sobienice, Listomie, Kruszwin, Golenice, Jezierzycze, Pacynowo, Straszyn, Golenicki Młyn, Pniów, Chłopowo, Dalsze, Golczew, Podłążek, Wierzbówek, Pluty, Płośno, Turzyniec, Mirawno, Zarzece, Jaruzyn, Nawojczyn, Czerników, Sarbinowo, Mączlino, Utonie, Chłopówko, 2. W powiecie myśliborskim w gminie Dębno miejscowości: Dolsk, Borne, Turze, Różańsko, Ostrowiec, Dyszno, Warnice, Krężelin, Borówno, Przyłuszczka, Grzybno, Pioletek, Radzicz, Sulisław; 3. W powiecie gryfińskim w gminie Trzcińsko-Zdrój: Piaseczno, Stołeczna, Tchorzno, Dobropole, Wesoła, Babin	17.2.2020
W województwie lubuskim w powiecie gorzowskim:	
W gminie Lubiszyn miejscowości: Mystki, Smoliny, Staw, Podlesie, Zacisze, Gajewo	17.2.2020
W województwie dolnośląskim w powiatach legnickim i zlotoryjskim:	
1. W powiecie legnickim w gminie Chojnów miejscowości: Strupice, Budziwojów, Dzwonów, Gołocin, Pawlikowice; 2. W powiecie zlotoryjskim w gminie Zagrodno miejscowość: Brochocin; 3. W powiecie zlotoryjskim w gminie Złotoryja miejscowości: Podolany, Kolonia Kwiatów m. Lubiatów,	From 10.2.2020 until 18.2.2020
1. W powiecie legnickim miasto Chojnów, 2. W powiecie legnickim w gminie Chojnów miejscowości: Biała, Dobroszów, Goliszów, Gołaczów, Jerzmanowice, Konradówka, Michów, Niedźwiedzice, Osetnica, Piotrowice, 3. w powiecie legnickim w gminie Miłkowice miejscowości: Goślinów, Gniewomirowice, Jezierzany, Miłkowice, Siedliska, Studnica, Ulesie, 4. W powiecie legnickim w gminie Krotoszyce miejscowości: Czerwony Kościół, Jasków, Krotoszyce, Pawłowice Małe, Szymanowice, Wilczyce, 5. W powiecie zlotoryjskim w gminie Zagrodno miejscowości: Jadwisin, Łukaszów, Modlikowice, Wojciechów, Zagrodno, 6. W powiecie zlotoryjskim w gminie Złotoryja miejscowości: Brennik, Ernestynów, Gierałowiec, Kopacz, Kozów, Lubiatów bez kolonii Kwiatów, Nowa Wieś Złotoryjska, Pyskowice, Rokitnica, Rzymówka, Wyskok, Wysocko.	18.2.2020

Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
W województwie warmińsko – mazurskim w powiecie iławskim	
W gminie Zalewo miejscowości: Rąbity, Międzychód, Zatyki, Surbajny, Koziny, Kupin, Rudnia	From 21.2.2020 until 29.2.2020
W województwie warmińsko – mazurskim w powiatach iławskim, ostródzkim:	
Powiat iławski: W gminie Zalewo miejscowości: Karpowo, Śliwa, Dajny, Barty, Pozorty, Girgajny, Mazanki, Janiki Wielkie, Janiki Małe, Jaśkowo, Wielowieś, Boreczno, Duba, Mozgowo, Huta Wielka, Skitławki, Urowo, Gubławki, Wieprz, Matyty, Polajny, Jerzwałd, Rucewo, Kiemiany, Dobrzyki, Witoszewo, Gajdy, Półwieś, Zalewo, Bajdy, Sadławki, Bądky, Bednarzówka, Brzeziniak, Jezierce, Bukowiec, Likszajny, Tarpno, Nowe Chmielówko Powiat ostródzki: 1. W gminie Małdyty miejscowości: Wielki Dwór, Jarnołtowo, Fiugajki, Drynki, Pleśno, Leszczynka Mała, Linki, Klonowy Dwór, Płkity, Smolno, Kanty, Bagnity, Wodziany, Surzyki Małe, Surzyki Wielkie; 2. W gminie Miłomłyn miejscowości: Skarpa, Ligi	29.2.2020
W województwie pomorskim w powiecie sztumskim:	
W gminie Stary Dzierżoń od granicy województwa pomorskiego wzdłuż drogi łączącej miejscowości Bajdy-Przezmark do miejscowości Przezmark, następnie po drugiej stronie drogi wojewódzkiej 519 wzdłuż jeziora Motława Wielka do miejscowości Danielówka, dalej drogą leśną do jeziora Witoszewskiego w województwie warmińsko-mazurskim.	29.2.2020
W województwie warmińsko – mazurskim w powiecie ostródzkim:	
W gminie Grunwald miejscowości: Góry Lubiańskie, Zybułtowo, Lubian, Mielno, Stębark	From 5.3.2020 until 13.3.2020
W województwie warmińsko – mazurskim w powiatach: ostródzkim, działdowskim, nidzickim, olsztyńskim:	
1. w powiecie ostródzkim: — w gminie Grunwald miejscowości: Dylewko, Dąbrowo, Frygnowo, Grabiczki, Gierzwałd, Grunwald, Kiersztanowo, Kitnowo, Korsztyn, Lipowa Góra, Lubianek, Łącko, Łodwigowo, Marcinkowo, Omin, Pacółtowo, Pacółtówko, Rzepki, Tymawa, Ulnowo, Wróble, Zapieka, — w gminie Dąbrówno miejscowości: Gardyny, Łogdowo, Osiekowo, Ostrowite, Samin, Saminek; 2. w powiecie działdowskim w gminie Działdowo miejscowość Jankowice; 3. w powiecie nidzickim w gminie Kozłowo miejscowości: Browina, Turowo, Turówko, Wronowo; 4. w powiecie olsztyńskim w gminie Olsztynek miejscowości: Czarci Jar, Dębowa Góra, Drwęck, Gąsiorowo Olsztyńskie, Gibała, Gierdałki, Jadamowo, Juńcza, Królikowo, Lichtajny, Lutek, Nowa Wieś Ostródzka, Pawłowo, Sitno, Waplewo, Warglewo	13.3.2020
W województwie śląskim w powiecie raciborskim:	
W gminie Kuźnia Raciborska, miejscowości: Ruda Kozielska, część miejscowości Rudy położona na zachód od drogi nr 919	From 21.2.2020 until 29.2.2020
W województwie śląskim w powiatach raciborskim, rybnickim, gliwickim, w powiecie miejskim Rybnik:	
W powiecie raciborskim: 1. W gminie Kuźnia Raciborska miejscowości: Kuźnia Raciborska, Jankowice, Siedliska, część miejscowości Budziska położona na wschód od ulic Leśnej, Szkolnej, Główniej i Fabrycznej, część miejscowości Rudy położona na wschód od drogi nr 919; 2. W gminie Nędza, miejscowości: Szymocice, Górki Śląskie, część miejscowości Nędza położona na wschód od linii kolejowej łączącej miejscowości Racibórz – Kędzierzyn Koźle; W powiecie rybnickim: 1. W gminie Lyski miejscowości: Bogunice, Zwonowice, Sumina, Lyski, część miejscowości Adamowice położona na północ od ulic: Jana III Sobieskiego, Rybnickiej i Rolnej, część miejscowości Nowa Wieś położona na północ od ulicy Rybnickiej do drogi nr 923;	29.2.2020

Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
2. W gminie Gaszowice: część miejscowości Gaszowice położona na północ od ulic: Łąkowej, Wiejskiej, Rybnickiej, część miejscowości Szczerbice położona na północ od ulic: Rybnickiej, Głównej, Dworcowej; 3. W gminie Jejkowice: część miejscowości Jejkowice położona na północ od ulic: Głównej oraz Dworcowej; W powiecie miejskim Rybnik dzielnice: Stodoły, Grabownia, Chwałęcice, Ochojec, część dzielnicy Rybnicka Kuźnia położona na północ od ulicy Podmiejskiej, część dzielnicy Golejów położona na zachód od drogi nr 78 oraz na północ od ulicy Komisji Edukacji Narodowej; W powiecie gliwickim: 1. W gminie Sośnicowice miejscowości: Tworóg Mały, Kuźniczka, Trachy, Bargłówka, część miejscowości Sierakowice położona na zachód od ulicy Sierakowskiej na terenach leśnych oraz ulicy Długiej, część miejscowości Smolnica położona na zachód od ulicy Łęgowskiej, część miejscowości Sośnicowice położona na zachód od ulicy Raciborskiej; 2. W gminie Pilchowice miejscowości: Stanica, część miejscowości Leboszowice położona na zachód od ulic: Smolnickiej i Wiejskiej, część miejscowości Pilchowice na zachód od ulic: Leboszowskiej, Wielopole, Dworcowej oraz ulicy Dolna Wieś, część miejscowości Wilcza położona na północny-zachód od drogi nr 78;	
W województwie opolskim w powiecie kędzierzyńsko-kozielskim:	
W gminie Bierawa miejscowości: Solarnia, Koblarnia, Goszyce, Dziergowice	29.2.2020

Member State: Romania

Area comprising:	Date until applicable in accordance with Article 31 of Directive 2005/94/EC
Județul Maramureș	
Oraș Seini Oraș Seini - localitatea Săbișa	From 14.2.2020 until 22.2.2020
Comuna Cicârlău- Localitatea Cicârlău Comuna Cicârlău - Localitatea Bârgău Comuna Cicârlău - Localitatea Handalu Ilbei Comuna Cicârlău - Localitatea Ilba Oraș Seini- Localitatea Viile Apei Comuna Ardușat- Localitatea Ardușat	22.2.2020
Județul Satu Mare	
Comuna Pomi, localitatea Pomi	From 14.2.2020 until 22.2.2020
Comuna Orașu Nou- Localitatea Orașu Nou Vii Comuna Orașu Nou- Localitatea Racșa Vii Comuna Pomi- Localitatea Acuia Comuna Pomi- Localitatea Bicău Comuna Pomi- Localitatea Borlești Comuna Apa- Localitatea Apa Comuna Apa- Localitatea Someșeni Comuna Crucișor- Localitatea Crucișor Comuna Crucișor- Localitatea Iegheriște Comuna Valea Vinului- Localitatea Valea Vinului Comuna Valea Vinului- Localitatea Roșiori Comuna Medieșu Auriu- Localitatea Medieș Rături Comuna Medieșu Auriu-Localitatea Medieș Vii Comuna Orașu Nou- Racșa	22.2.2020
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