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Legislation

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Contents

[1] Text with EEA relevance.

EN

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

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

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2019/1844

of 22 October 2019

granting a Union authorisation for the biocidal product family 'BPF_Iodine_VET'

(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 the first subparagraph of Article 44(5) thereof,

Whereas:

(1) On 7 August 2015, Applied Biocide GmbH submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named 'BPF_Iodine_VET' of product-type 3, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Austria had agreed to evaluate the application. The application was recorded under case number BC-XJ019074-33 in the Register for Biocidal Products.

(2) 'BPF_Iodine_VET' 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 22 August 2018, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the European Chemicals Agency ('the Agency').

(4) On 4 April 2019, the Agency submitted to the Commission an opinion ([3]), including the draft summary of the biocidal product characteristics ('SPC') of 'BPF_Iodine_VET' 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 'BPF_Iodine_VET' is a biocidal product family within the meaning of 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, it 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 27 February 2019 on the Union authorisation of 'BPF_Iodine_VET' (ECHA/BPC/219/2019).

(5) On 4 June 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 'BPF_Iodine_VET'.

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

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0020540-0000 is granted to Applied Biocide GmbH for the making available on the market and use of the biocidal product family 'BPF_Iodine_VET', in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 25 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, 22 October 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

Summary of product characteristics for a biocidal product family

BPF_Iodine_VET

Product type 3 - Veterinary hygiene (Disinfectants)

Authorisation number: EU-0020540-0000

R4BP asset number: EU-0020540-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	BPF_Iodine_VET

1.2. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	Applied Biocide GmbH
	Address	Sprl 31, Rue Jules Melotte, 4350, Remicourt, Belgium
Authorisation number	EU-0020540-0000	
R4BP asset number	EU-0020540-0000	
Date of the authorisation	25 November 2019	
Expiry date of the authorisation	31 October 2029	

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

Name of manufacturer	Ewabo Chemikalien GmbH & Co KG
Address of manufacturer	Kolpingstrasse 4, 49835 Wietmarschen Germany
Location of manufacturing sites	Kolpingstrasse 4, 49835 Wietmarschen Germany
Name of manufacturer	FINK TEC GmbH
Address of manufacturer	Oberster Kamp 23, 59069 Hamm Germany
Location of manufacturing sites	Oberster Kamp 23, 59069 Hamm Germany
Name of manufacturer	IRCASERVICE

Address of manufacturer	S.S. Cremasca 591 no. 10, 24040 Fornovo S. Giovanni (BG) Italy
Location of manufacturing sites	S.S. Cremasca 591 no. 10, 24040 Fornovo S. Giovanni (BG) Italy
Name of manufacturer	Laboratorios Maymo SA
Address of manufacturer	Via Augusta, 302, 08017 Barcelona Spain
Location of manufacturing sites	Via Augusta, 302, 08017 Barcelona Spain

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

Active substance	Iodine
Name of manufacturer	Cosayach S.A. Compania de Salitre y Yodo
Address of manufacturer	Amunátegui 178, 7th Floor, 8320000 Santiago Chile
Location of manufacturing sites	S.C.M. Cosayach Cala, 1180000 Pozo Almonte Chile Chile
Active substance	Iodine
Name of manufacturer	ACF Minera S.A.
Address of manufacturer	San Martin 499, 1100000 Iquique Chile
Location of manufacturing sites	Lagunas mine, 1180000 Pozo Almonte Chile
Active substance	Iodine
Name of manufacturer	Sociedad Quimica y Minera SA
Address of manufacturer	Los Militares 4290, 7550000 Las Condes Chile
Location of manufacturing sites	Nueva Victoria, 1180000 Pozo Almonte Chile Pedro de Valdivia, 1240000 Antofagasta 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	0,1	3,0
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	10,0
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-,branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	31,8
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	31,8

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

Formulation(s)	meta SPC 1-5: AL — any other liquid meta SPC 6-8: SL — soluble concentrate

PART II

SECOND INFORMATION LEVEL — META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 1 identifier**

Identifier	Meta SPC 1

1.2. **Suffix to the authorisation number**

Number	1-1

1.3. **Product type(s)**

Product type(s)	PT03 - Veterinary hygiene (Disinfectants)

2. META SPC 1 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,15	0,15
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	0,0
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-,branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	0,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

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

Formulation(s)	AL — any other liquid

3. Hazard and precautionary statements of the meta SPC 1

Hazard statements	May be corrosive to metals.
Precautionary statements	Keep only in original packaging. Absorb spillage to prevent material damage. Store in corrosive resistant container with a resistant inner liner.

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

4.1. **Use description**

Table 1

Use # 1 — Veterinary hygiene — animal husbandry — teat disinfectant — professional — indoors — spraying (post milking)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment Spraying: Manual and automated non-medical disinfection of teats with a ready-to-use spray (on cows, post-milking)
Application rate(s) and frequency	Application rate: 10-15 ml per cow Application frequency: During lactation period: — manual: 2 applications per day (post-milking) — automated: 3 applications per day (post-milking) During dry period: 1 application per day
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle high-density polyethylene (HDPE): 1 liter, cap is made of PP Jerry can HDPE: 5-60 liters Drum HDPE: 200 liters IBC HDPE: 600-1 000 liters

4.1.1. *Use-specific instructions for use*

—

4.1.2. *Use-specific risk mitigation measures*

—

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*

—

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

—

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

—

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

5.1. **Instructions for use**

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

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

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

Immediately after each cow has been milked, spray the entire surface of each teat with the solution. Leave the product until next milking. Do not clean the teats directly after disinfection.

Keep the cows standing until the product has dried (at least 5 minutes).

Product can be applied manually or by means of automatic teat sprayer.

Before the next milking the teats have to be cleaned, preferably with one new wet cloth per cow.

Application frequency must not exceed two applications per cow and day considering manual spraying and must not exceed three applications per cow and day considering automatic teat sprayer (post-milking).

5.2. **Risk mitigation measures**

Keep out of reach of children.

Wear protective chemical resistant gloves, coated coverall and boots during product handling and application phase (material to be specified by the authorisation holder in 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.

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

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Wash skin thoroughly.

After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

[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.

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

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

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

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store the product at room temperature, away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 12 months in HDPE.

6. OTHER INFORMATION

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

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

Trade name(s)	FINK — Io Spray 15 FINK — Euter-DIP PVP-S FINK Pattedyp PVP IOSpray 15 PVP
Authorisation number	EU-0020540-0001 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,15

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 2 identifier**

Identifier	Meta SPC 2

1.2. **Suffix to the authorisation number**

Number	1-2

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 2 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,3	0,5
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	0,0
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	0,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

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

Formulation(s)	AL — any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	May be corrosive to metals. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep only in original packaging. Avoid release to the environment. Absorb spillage to prevent material damage. Store in corrosive resistant container with a resistant inner liner. Dispose of contents to/container in accordance with the local/national regulations.

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

4.1. **Use description**

Table 2

Use # 1 — Veterinary hygiene — animal husbandry — teat disinfectant — professional — indoors — spraying (post milking)

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

Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment Spraying: Manual and automated non-medical disinfection of teats with a ready-to-use spray (on cows, post-milking)
Application rate(s) and frequency	Application rate: 10-15 ml per cow Application frequency: During lactation period: — manual: 2 applications per day (post-milking) — automated: 3 applications per day (post-milking) During dry period: 1 application per day
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5-60 liters Drum HDPE: 200 liters IBC HDPE: 600-1 000 liters

4.1.1. *Use-specific instructions for use*

–

4.1.2. *Use-specific risk mitigation measures*

–

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*

–

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

–

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

–

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

5.1. **Instructions for use**

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

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

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

([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.

Immediately after each cow has been milked, spray the entire surface of each teat with the solution. Leave the product until next milking. Do not clean the teats directly after disinfection.

Keep the cows standing until the product has dried (at least 5 minutes).

Product can be applied manually or by means of automatic teat sprayer.

Before the next milking the teats have to be cleaned, preferably with one new wet cloth per cow.

Application frequency must not exceed two applications per cow and day considering manual spraying and must not exceed three applications per cow and day considering automatic teat sprayer (post-milking).

5.2. **Risk mitigation measures**

Keep out of reach of children.

Wear protective chemical resistant gloves, coated coverall and boots during product handling and application phase (material to be specified by the authorisation holder in 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.

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

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Wash skin thoroughly.

After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

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

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

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store the product at room temperature, away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 12 months in HDPE.

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)	Fink Io Spray - 30 ST-Io Spray DESINTEC MH Iodine S DESINTEC MH Raidip plus Iodine Spray 3000 Iodine Spray
Authorisation number	EU-0020540-0002 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,3

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

Trade name(s)	Fink — Io Spray 50 DESINTEC MH Raidip 5000 Iodine Spray 5000
Authorisation number	EU-0020540-0003 1-2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5

META SPC 3

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 3 identifier**

Identifier	Meta SPC 3

1.2. **Suffix to the authorisation number**

Number	1-3

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 3 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,5	0,5
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	0,0
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-,branched	Non-active substance	69011-36-5	500-241-6	0,0	0,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

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

Formulation(s)	AL — any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	May be corrosive to metals. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep only in original packaging. Avoid release to the environment. Absorb spillage to prevent material damage. Store in corrosive resistant container with a resistant inner liner. Dispose of contents to/container in accordance with the local/national regulations.

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

4.1. **Use description**

Table 3

Use # 1 – Veterinary hygiene - animal husbandry - teat disinfectant - professional - indoors – spraying (post milking)

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

Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment Spraying: Manual and automated non-medical disinfection of teats with a ready-to-use spray (on cows, post-milking)
Application rate(s) and frequency	Application rate: 10-15 ml per cow Application frequency: During lactation period: — manual: 2 applications per day (post-milking) — automated: 3 applications per day (post-milking) During dry period: 1 application per day
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5-60 liters Drum HDPE: 200 liters IBC HDPE: 600-1 000 liters

4.1.1. *Use-specific instructions for use*

–

4.1.2. *Use-specific risk mitigation measures*

—

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*

–

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

—

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

—

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

5.1. **Instructions for use**

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.

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

Immediately after each cow has been milked, spray the entire surface of each teat with the solution. Leave the product until next milking. Do not clean the teats directly after disinfection.

Keep the cows standing until the product has dried (at least 5 minutes).

Product can be applied manually or by means of automatic teat sprayer.

([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.

Before the next milking the teats have to be cleaned, preferably with one new wet cloth per cow.

Application frequency must not exceed two applications per cow and day considering manual spraying and must not exceed three applications per cow and day considering automatic teat sprayer (post-milking).

5.2. **Risk mitigation measures**

Keep out of reach of children.

Wear protective chemical resistant gloves, coated coverall and boots during product handling and application phase (material to be specified by the authorisation holder in 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.

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

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Wash skin thoroughly.

After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

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

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

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store the product at room temperature, away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 12 months in HDPE.

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)	Fink — Io Spray 50 (Jodophor) Fink — Io Spray 50 (Iodophor)
Authorisation number	EU-0020540-0004 1-3

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,5

META SPC 4

1. META SPC 4 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 4 identifier**

Identifier	Meta SPC 4

1.2. **Suffix to the authorisation number**

Number	1-4

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 4 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,1	0,15
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,0	0,0
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-,branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	0,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

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

Formulation(s)	AL — any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 4

Hazard statements	May be corrosive to metals.
Precautionary statements	Keep only in original packaging. Absorb spillage to prevent material damage. Store in corrosive resistant container with a resistant inner liner.

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

4.1. **Use description**

Table 4

Use # 1 – Veterinary hygiene — animal husbandry — teat disinfectant — professional — indoors — dipping (post milking)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor
Application method(s)	Open system: dip treatment Teat-dipping: Manual non-medical disinfection of teats with a ready-to-use liquid (on cows, post-milking)
Application rate(s) and frequency	Application rate: 5-10 ml per cow Application frequency: During lactation period: 2 applications per day (post-milking) During dry period: 1 application per day
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5-60 liters Drum HDPE: 200 liters IBC HDPE: 600-1 000 liters

4.1.1. *Use-specific instructions for use*

—

4.1.2. *Use-specific risk mitigation measures*

—

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*

—

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

—

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

—

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

5.1. **Instructions for use**

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.

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

Fill up a teat dipping cup with 2/3 of product. Immediately after each cow has been milked, dip each teat manually in the solution. Ensure that at least two thirds of the teats, preferably the entire teats, come in contact with the solution.

Do not clean the teats directly after disinfection. Leave the product until next milking. Keep the cows standing until the product has dried (at least 5 minutes).

Refill the cup as necessary.

Teat dipping cups should be emptied after milking and washed before re-use. Before the next milking the teats have to be cleaned, preferably with one new wet cloth per cow.

Application frequency must not exceed two applications per cow and day (post-milking).

5.2. **Risk mitigation measures**

Keep out of reach of children.

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

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

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Wash skin thoroughly.

After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

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

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

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

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store the product at room temperature, away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 12 months in HDPE.

6. OTHER INFORMATION

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

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

Trade name(s)	FINK — Io Dip 10 IODip 10 PVP
Authorisation number	EU-0020540-0005 1-4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,1

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

Trade name(s)	FINK — Io Dip Protect DESINTEC MH Iodine Barrier TvP — Barrier Dip
Authorisation number	EU-0020540-0006 1-4

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,15

META SPC 5

1. META SPC 5 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 5 identifier**

Identifier	Meta SPC 5

1.2. **Suffix to the authorisation number**

Number	1-5

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 5 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	0,3	0,45
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,35	0,4
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-,branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	0,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

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

Formulation(s)	AL — any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 5

Hazard statements	May be corrosive to metals. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep only in original packaging. Avoid release to the environment. Absorb spillage to prevent material damage. Store in corrosive resistant container with a resistant inner liner. Dispose of contents to / container in accordance with the local/national regulations.

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

4.1. **Use description**

Table 5

Use # 1 — Veterinary hygiene — animal husbandry — teat disinfectant — professional — indoors — dipping (post milking)

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts
Field(s) of use	Indoor
Application method(s)	Open system: dip treatment Teat-dipping: Manual non-medical disinfection of teats with a ready-to-use liquid (on cows, post-milking)
Application rate(s) and frequency	Application rate: 5-10 ml per cow Application frequency: During lactation period: 2 applications per day (post-milking) During dry period: 1 application per day
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5-60 liters Drum HDPE: 200 liters IBC HDPE: 600-1 000 liters

4.1.1. Use-specific instructions for use

—

4.1.2. *Use-specific risk mitigation measures*

—

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*

—

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

—

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

—

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

5.1. **Instructions for use**

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

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

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

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

Fill up a teat dipping cup with 2/3 of product. Immediately after each cow has been milked, dip each teat manually in the solution. Ensure that at least two thirds of the teats, preferably the entire teats, come in contact with the solution.

Do not clean the teats directly after disinfection. Leave the product until next milking.

Keep the cows standing until the product has dried (at least 5 minutes).

Refill the cup as necessary.

Teat dipping cups should be emptied after milking and washed before re-use. Before the next milking the teats have to be cleaned, preferably with one new wet cloth per cow.

Application frequency must not exceed two applications per cow and day (post-milking).

5.2. **Risk mitigation measures**

Keep out of reach of children.

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

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

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Wash skin thoroughly.

After eye contact: Rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

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

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

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store the product at room temperature, away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 12 months in HDPE.

6. OTHER INFORMATION

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

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

Trade name(s)	Jodofilm 75/5 4 500 ppm
Authorisation number	EU-0020540-0007 1-5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,45
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,4

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

Trade name(s)	Jodofilm 75/5 3 000 ppm
Authorisation number	EU-0020540-0008 1-5

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	0,3
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	0,35

META SPC 6

1. META SPC 6 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 6 identifier**

Identifier	Meta SPC 6

1.2. **Suffix to the authorisation number**

Number	1-6

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 6 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	1,75	2,4
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	3,0	10,0
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-,branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	0,0	25,6
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	31,8

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

Formulation(s)	SL — soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 6

Hazard statements	May be corrosive to metals. Harmful if swallowed. Causes severe skin burns and eye damage. Causes serious eye damage. May cause damage to thyroid gland through prolonged or repeated exposure. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep only in original packaging. Do not breathe mist. Do not breathe spray. Avoid release to the environment. Wear protective gloves. Wear protective clothing. Wear face protection. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Absorb spillage to prevent material damage. Store locked up. Keep out of reach of children.

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

4.1. **Use description**

Table 6

Use # 1 — Veterinary hygiene — animal husbandry — hard surface disinfectant — professional — indoors — spraying

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Viruses
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment Disinfectant for hard surfaces in stables (excluding hatcheries). Spraying of diluted concentrate by means of a hand-held knapsack sprayer (4-7 bar)
Application rate(s) and frequency	100 ml/m² — Concentration of Iodine in application solution: 750 ppm (0,075 % w/w). Application frequency per year: Dairy cows: 1 Beef cattle: 1 Veal calves: 4 Sows, in individual pens: 5 Sows in groups: 5 Fattening pigs: 3 Laying hens in battery cages without treatment: 1 Laying hens in battery cages with aeration (belt drying): 1 Laying hens in battery cages with forced drying (deep pit, high rise): 1 Laying hens in compact battery cages: 1 Laying hens in free range with litter floor (partly litter floor, partly slatted): 1 Broilers in free range with litter floor: 7 Laying hens in free range with grating floor (aviery system): 1 Parent broilers in free range with grating floor: 1 Parent broilers in rearing with grating floor: 3 Turkeys in free range with litter floor: 2 Ducks in free range with litter floor: 13 Geese in free range with litter floor: 6
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5-60 liters Drum HDPE: 200 liters IBC HDPE: 600-1 000 liters

4.1.1. *Use-specific instructions for use*

Iodosan 30: Mix 29 ml product with 971 ml water to obtain 1 l application solution.

Iodosan 18: Mix 40 ml product with 960 ml water to obtain 1 l application solution.

4.1.2. *Use-specific risk mitigation measures*

—

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*

—

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

—

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

—

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

5.1. **Instructions for use**

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

To prepare the disinfectant solution, mix the liquid product with water. Always pour in water first and then carefully stir in the product.

Use max. 100 ml application solution per m^2 treated area. Do not prepare more fluid than strictly necessary.

The product shall only be applied in empty (unpopulated) animal houses after surfaces have been thoroughly cleaned with a suitable cleaner.

Pre-cleaning is mandatory. Rinse or wipe the surfaces which will be treated afterwards. Leave them to dry for about 24 up to 36 h before disinfection to obtain earth-moist surfaces. Soak installations and equipment thoroughly with a thin layer of the prepared solution by spraying, using suitable devices (4 to 7 bar). During the process and for the duration of contact time (min. 30 minutes), all openings have to be closed and the ventilation has to be switched off.

5.2. **Risk mitigation measures**

Keep out of reach of children.

The form of the bottle of the product should minimise risk for splashes in order to prevent eye and skin exposure during diluting the product.

During the mixing and loading phase: The use of a face shield and protection gloves (glove material to be specified by the authorisation holder in the product information) is mandatory.

During the application phase of the in use dilution by spraying: Gloves and a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product shall be worn (glove and coverall material to be specified by the authorisation holder in the product information). Use new gloves for each work shift.

Professionals must not carry out animal house disinfection more than 3 times per month. These professionals should not use Iodine products for additional purposes.

Only use one kind of Iodine-containing product per day.

Stable disinfection should not be carried out more than once per year or once per lifetime for calf and pigs. Feeding troughs must be covered during application.

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

After inhalation: Supply fresh air; consult doctor in case of complaints.

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

After skin contact: Immediately take off contaminated clothing and wash skin thoroughly.

After eye contact: Immediately rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

In case of unconsciousness place patient stably in left side position for transportation. Never give anything by mouth to an unconscious individual

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

Methods and material for containment and cleaning up:

Stop leak if safe to do so. Absorb spillage with liquid-binding material (sand, earth, diatomite, acid binders, universal binders, sawdust) and place in container for disposal according to local / national regulations.

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

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

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store the product away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 24 months in HDPE

6. OTHER INFORMATION

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

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

Trade name(s)	IODOSAN 30 IODOSAN IODAT DESINTEC FL-JODES ROTIE-SOL J Disinfect Jod FINK — Jodophos 15 Jod-Reiniger sauer Tankrein extra
Authorisation number	EU-0020540-0009 1-6

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	2,4
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	10,0
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-,branched	Non-active substance	69011-36-5	500-241-6	25,6

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

Trade name(s)	IODOSAN 18
Authorisation number	EU-0020540-0010 1-6

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	1,75
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	3,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	31,8

META SPC 7

1. META SPC 7 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 7 identifier**

Identifier	Meta SPC 7

1.2. **Suffix to the authorisation number**

Number	1-7

1.3. **Product type(s)**

Product type(s)	PT03 — Veterinary hygiene (Disinfectants)

2. META SPC 7 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	3,0	3,0
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	10,0	10,0
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-,branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	31,8	31,8
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

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

Formulation(s)	SL — soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 7

Hazard statements	May be corrosive to metals. Harmful if swallowed. Causes severe skin burns and eye damage. Causes serious eye damage. May cause damage to thyroid gland through prolonged or repeated exposure. Toxic to aquatic life with long lasting effects.
Precautionary statements	Keep only in original packaging. Do not breathe mist. Do not breathe spray. Avoid release to the environment. Wear protective gloves. Wear protective clothing. Wear face protection. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Absorb spillage to prevent material damage. Store locked up. Keep out of reach of children.

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

4.1. **Use description**

Table 7

Use # 1 — Veterinary hygiene — animal husbandry — hard surface disinfectant — professional — indoors — spraying

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Viruses
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment Disinfectant for hard surfaces in stables (excluding hatcheries). Spraying of diluted concentrate by means of a hand-held knapsack sprayer (4-7 bar)
Application rate(s) and frequency	100 ml/m² - Concentration of Iodine in application solution: 750 ppm (0,075 % w/w). Application frequency per year: Dairy cows: 1 Beef cattle: 1 Veal calves: 4 Sows, in individual pens: 5 Sows in groups: 5 Fattening pigs: 3 Laying hens in battery cages without treatment: 1 Laying hens in battery cages with aeration (belt drying): 1 Laying hens in battery cages with forced drying (deep pit, high rise): 1 Laying hens in compact battery cages: 1 Laying hens in free range with litter floor (partly litter floor, partly slatted): 1 Broilers in free range with litter floor: 7 Laying hens in free range with grating floor (aviery system): 1 Parent broilers in free range with grating floor: 1 Parent broilers in rearing with grating floor: 3 Turkeys in free range with litter floor: 2 Ducks in free range with litter floor: 13 Geese in free range with litter floor: 6
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5-60 liters Drum HDPE: 200 liters IBC HDPE: 600-1 000 liters

4.1.1. *Use-specific instructions for use*

Iodosan 30 plus: Mix 23 ml product with 977 ml water to obtain 1 l application solution.

4.1.2. *Use-specific risk mitigation measures*

—

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*

—

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

—

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

—

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

5.1. **Instructions for use**

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

To prepare the disinfectant solution, mix the liquid product with water. Always pour in water first and then carefully stir in the product.

Use max. 100 ml application solution per m^2 treated area. Do not prepare more fluid than strictly necessary.

The product shall only be applied in empty (unpopulated) animal houses after surfaces have been thoroughly cleaned with a suitable cleaner.

Pre-cleaning is mandatory. Rinse or wipe the surfaces which will be treated afterwards. Leave them to dry for about 24 up to 36 h before disinfection to obtain earth-moist surfaces. Soak installations and equipment thoroughly with a thin layer of the prepared solution by spraying, using suitable devices (4 to 7 bar). During the process and for the duration of contact time (min. 30 minutes), all openings have to be closed and the ventilation has to be switched off.

5.2. **Risk mitigation measures**

Keep out of reach of children.

The form of the bottle of the product should minimise risk for splashes in order to prevent eye and skin exposure during diluting the product.

During the mixing and loading phase: The use of a face shield and protection gloves (glove material to be specified by the authorisation holder in the product information) is mandatory.

During the application phase of the in use dilution by spraying: Gloves and a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product shall be worn (glove and coverall material to be specified by the authorisation holder in the product information). Use new gloves for each work shift.

Professionals must not carry out animal house disinfection more than 3 times per month. These professionals should not use Iodine products for additional purposes.

Only use one kind of Iodine-containing product per day.

Stable disinfection should not be carried out more than once per year or once per lifetime for calf and pigs. Feeding troughs must be covered during application.

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

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Immediately take off contaminated clothing and wash skin thoroughly.

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

After eye contact: Immediately rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

In case of unconsciousness place patient stably in left side position for transportation. Never give anything by mouth to an unconscious individual.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

Methods and material for containment and cleaning up:

Stop leak if safe to do so. Absorb spillage with liquid-binding material (sand, earth, diatomite, acid binders, universal binders, sawdust) and place in container for disposal according to local / national regulations.

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

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

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store the product away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 24 months in HDPE

6. OTHER INFORMATION

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

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

Trade name(s)	IODOSAN 30 Plus YODO CONTROL YODIVEN
Authorisation number	EU-0020540-0011 1-7

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	3,0
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	10,0

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-,branched	Non-active substance	69011-36-5	500-241-6	31,8

META SPC 8

1. META SPC 8 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 8 identifier**

Identifier	Meta SPC 8

1.2. **Suffix to the authorisation number**

Number	1-8

1.3. **Product type(s)**

Product type(s)	PT03 - Veterinary hygiene (Disinfectants)

2. META SPC 8 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Iodine		Active Substance	7553-56-2	231-442-4	1,5	1,5
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	3,0	3,0
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-,branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Non-active substance	69011-36-5	500-241-6	18,0	18,0
Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Isotridecanol, ethoxylated 90 %, C 9-11 Alcohol Ethoxylate	Non-active substance	68439-46-3	614-482-0	0,0	0,0

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

Formulation(s)	SL - soluble concentrate

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 8

Hazard statements	May be corrosive to metals. Causes severe skin burns and eye damage. Causes serious eye damage. May cause damage to thyroid gland through prolonged or repeated exposure. Harmful to aquatic life with long lasting effects.
Precautionary statements	Keep only in original packaging. Do not breathe mist. Do not breathe spray. Avoid release to the environment. Wear protective gloves. Wear protective clothing. Wear face protection. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Absorb spillage to prevent material damage. Store locked up. Keep out of reach of children.

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

4.1. **Use description**

Table 8

Use # 1 — Veterinary hygiene — animal husbandry — hard surface disinfectant — professional — indoors — spraying

Product type	PT03 — Veterinary hygiene (Disinfectants)
Where relevant, an exact description of the authorised use	—
Target organism(s) (including development stage)	Bacteria Yeasts Viruses
Field(s) of use	Indoor
Application method(s)	Open system: spray treatment Disinfectant for hard surfaces in stables (excluding hatcheries). Spraying of diluted concentrate by means of a hand-held knapsack sprayer (4-7 bar)
Application rate(s) and frequency	100 ml/m² — Concentration of Iodine in application solution: 750 ppm (0,075 % w/w). Application frequency per year: Dairy cows: 1 Beef cattle: 1 Veal calves: 4 Sows, in individual pens: 5 Sows in groups: 5 Fattening pigs: 3

	Laying hens in battery cages without treatment: 1 Laying hens in battery cages with aeration (belt drying): 1 Laying hens in battery cages with forced drying (deep pit, high rise): 1 Laying hens in compact battery cages: 1 Laying hens in free range with litter floor (partly litter floor, partly slatted): 1 Broilers in free range with litter floor: 7 Laying hens in free range with grating floor (aviery system): 1 Parent broilers in free range with grating floor: 1 Parent broilers in rearing with grating floor: 3 Turkeys in free range with litter floor: 2 Ducks in free range with litter floor: 13 Geese in free range with litter floor: 6
Category(ies) of users	Professional
Pack sizes and packaging material	Bottle HDPE: 1 liter, cap is made of PP Jerry can HDPE: 5-60 liters Drum HDPE: 200 liters IBC HDPE: 600-1 000 liters

4.1.1. *Use-specific instructions for use*

Iodosan 15: Mix 46 ml product with 954 ml water to obtain 1 l application solution.

4.1.2. *Use-specific risk mitigation measures*

—

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*

—

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

—

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

—

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

5.1. **Instructions for use**

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

To prepare the disinfectant solution, mix the liquid product with water. Always pour in water first and then carefully stir in the product.

Use max. 100 ml application solution per m^2 treated area. Do not prepare more fluid than strictly necessary.

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

The product shall only be applied in empty (unpopulated) animal houses after surfaces have been thoroughly cleaned with a suitable cleaner.

Pre-cleaning is mandatory. Rinse or wipe the surfaces which will be treated afterwards. Leave them to dry for about 24 up to 36 h before disinfection to obtain earth-moist surfaces. Soak installations and equipment thoroughly with a thin layer of the prepared solution by spraying, using suitable devices (4 to 7 bar). During the process and for the duration of contact time (min. 30 minutes), all openings have to be closed and the ventilation has to be switched off.

5.2. **Risk mitigation measures**

Keep out of reach of children.

The form of the bottle of the product should minimise risk for splashes in order to prevent eye and skin exposure during diluting the product.

During the mixing and loading phase: The use of a face shield and protection gloves (glove material to be specified by the authorisation holder in the product information) is mandatory.

During the application phase of the in use dilution by spraying: Gloves and a protective coverall (at least type X, EN XXXXX) which is impermeable for the biocidal product shall be worn (glove and coverall material to be specified by the authorisation holder in the product information). Use new gloves for each work shift.

Professionals must not carry out animal house disinfection more than 3 times per month. These professionals should not use Iodine products for additional purposes.

Only use one kind of Iodine-containing product per day.

Stable disinfection should not be carried out more than once per year or once per lifetime for calf and pigs. Feeding troughs must be covered during application.

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

After inhalation: Supply fresh air; consult doctor in case of complaints.

After skin contact: Immediately take off contaminated clothing and wash skin thoroughly.

After eye contact: Immediately rinse opened eye, remove contact lenses, keep rinsing for several minutes under running water. Then consult a doctor.

After swallowing: Rinse out mouth and then drink some water. Do not induce vomiting; call for medical help immediately.

In case of unconsciousness place patient stably in left side position for transportation. Never give anything by mouth to an unconscious individual.

When asking for medical advice keep packaging or label at hand and call your local poison control center [insert local number here].

Environmental emergency measures:

Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). To prevent malfunctioning of an individual wastewater treatment plant, possible residues containing the product must be discharged to the manure storage (for spreading on agricultural soils or fermentation into biogas installation) or to the municipal sewer if legally allowed.

Methods and material for containment and cleaning up:

Stop leak if safe to do so. Absorb spillage with liquid-binding material (sand, earth, diatomite, acid binders, universal binders, sawdust) and place in container for disposal according to local / national regulations.

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

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

European Waste Catalogue: 200130-detergents other than those mentioned in 20 01 29.

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

Store the product away from direct sunlight and in opaque containers. Protect from frost. Keep container tightly closed.

Shelf-life: 24 months in HDPE.

6. OTHER INFORMATION

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

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

Trade name(s)	IODOSAN 15
Authorisation number	EU-0020540-0012 1-8

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Iodine		Active Substance	7553-56-2	231-442-4	1,5
Phosphoric Acid	Trihydroxidooxidophosphorus phosphoric acid	Non-active substance	7664-38-2	231-633-2	3,0
Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-, branched	Poly(oxy-1,2-ethanediyl).alpha.-tridecyl-.omega.-hydroxy-,branched	Non-active substance	69011-36-5	500-241-6	18,0

DIRECTIVES

COMMISSION DELEGATED DIRECTIVE (EU) 2019/1845

of 8 August 2019

amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for bis(2-ethylhexyl) phthalate (DEHP) in certain rubber components used in engine systems

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ([1]) and in particular Article 5(1)(a) thereof,

Whereas:

(1) Directive 2011/65/EU requires Member States to ensure that electrical and electronic equipment placed on the market does not contain the hazardous substances listed in Annex II to that Directive. That requirement does not apply to the applications listed in Annex III to Directive 2011/65/EU.

(2) The different categories of electrical and electronic equipment to which Directive 2011/65/EU applies are listed in Annex I to that Directive.

(3) Bis(2-ethylhexyl) phthalate (DEHP) is a restricted substance listed in Annex II to Directive 2011/65/EU. On 29 June 2017, the Commission received an application made in accordance with Article 5(3) of Directive 2011/65/EU for an exemption, to be listed in Annex III to that Directive, for the use of DEHP in rubber parts such as O-rings, seals, vibration dampers, gaskets, hoses, grommets and cap-plugs that are used in engine systems including exhausts and turbochargers that are designed for use in equipment that is not designed solely for consumer use ('the requested exemption').

(4) The evaluation of the requested exemption included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU.

(5) DEHP is added to rubber material as plasticiser in order to provide flexibility. The rubber components are used as flexible connections between parts of engine systems and assure prevention of leakage, sealing of engine parts and protection from vibration or dirt and fluids over the lifetime of the engines.

(6) Currently, there are no DEHP-free alternatives available on the market which would provide sufficient level of reliability for applications in engines where long life and special properties such as resistance to any contact material (e.g. fuel, lubricant oil, coolants, gases, or dirt), temperature and vibration are required.

(7) Due to the lack of reliable alternatives, a substitution or elimination of DEHP is still scientifically and technically impracticable for certain rubber parts used in engine systems. The requested exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([2]) and thus does not weaken the environmental and health protection afforded by it.

(8) It is, therefore, appropriate to grant the requested exemption by including the applications covered by it in Annex III to Directive 2011/65/EU with respect to electrical and electronic equipment of category 11 of Annex I to Directive 2011/65/EU.

([1]) OJ L 174, 1.7.2011, p. 88.
([2]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency (OJ L 396, 30.12.2006, p. 1).

(9) The exemption should be granted for the maximum validity period of 5 years starting from 22 July 2019, in accordance with Article 4(3) and the first subparagraph of Article 5(2) of Directive 2011/65/EU. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.

(10) Directive 2011/65/EU should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex III to Directive 2011/65/EU is amended as set out in the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 30 April 2020 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 May 2020.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 8 August 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Annex III to Directive 2011/65/EU, the following entry 43 is added:

'43	Bis(2-ethylhexyl) phthalate in rubber components in engine systems, designed for use in equipment that is not intended solely for consumer use and provided that no plasticised material comes into contact with human mucous membranes or into prolonged contact with human skin and the concentration value of bis(2-ethylhexyl) phthalate does not exceed: (a) 30 % by weight of the rubber for (i) gasket coatings; (ii) solid-rubber gaskets; or (iii) rubber components included in assemblies of at least three components using electrical, mechanical or hydraulic energy to do work, and attached to the engine. (b) 10 % by weight of the rubber for rubber-containing components not referred to in point (a). For the purposes of this entry, "prolonged contact with human skin" means continuous contact of more than 10 minutes duration or intermittent contact over a period of 30 minutes, per day.	Applies to category 11 and expires on 21 July 2024.'

COMMISSION DELEGATED DIRECTIVE (EU) 2019/1846

of 8 August 2019

amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead in solders used in certain combustion engines

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ([1]) and in particular Article 5(1)(a) thereof,

Whereas:

(1) Directive 2011/65/EU requires Member States to ensure that electrical and electronic equipment placed on the market does not contain the hazardous substances listed in Annex II to that Directive. That requirement does not apply to the applications listed in Annex III to Directive 2011/65/EU.

(2) The different categories of electrical and electronic equipment to which Directive 2011/65/EU applies are listed in Annex I to that Directive.

(3) Lead is a restricted substance listed in Annex II to Directive 2011/65/EU. On 29 June 2017, the Commission received an application made in accordance with Article 5(3) of Directive 2011/65/EU for an exemption to be listed in Annex III to Directive 2011/65/EU, for the use of lead in solders of sensors, actuators and engine control units that are used to monitor and control engine systems including turbochargers and exhaust emission controls of internal combustion engines used in equipment that are not intended to be used solely by consumers ('the requested exemption').

(4) The evaluation of the requested exemption included stakeholder consultations in accordance with Article 5(7) of Directive 2011/65/EU.

(5) Each engine within scope of the requested exemption is equipped with specific types of sensors, actuators and engine control units that monitor and control its emissions to ensure compliance with Regulation (EU) 2016/1628 of the European Parliament and of the Council ([2]). The conditions experienced in and close to such engine and an exhaust system can be so severe in terms of elevated temperatures and vibration levels that they may cause early failure of solder bonds.

(6) Currently, for the applications of lead covered by the requested exemption, additional time is needed for testing to ensure the reliability of available lead-free substitutes.

(7) Due to the lack of reliable alternatives, a substitution or elimination of lead is scientifically and technically impracticable in certain combustion engines. The requested exemption is consistent with Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([3]) and thus does not weaken the environmental and health protection afforded by it.

(8) It is, therefore, appropriate to grant the requested exemption by including the applications covered by it in Annex III to Directive 2011/65/EU with respect to electrical and electronic equipment of category 11 of Annex I to Directive 2011/65/EU.

(9) The exemption should be granted for the maximum validity period of 5 years starting from 22 July 2019, in accordance with Article 4(3) and the first subparagraph of Article 5(2) of Directive 2011/65/EU. In view of the results of the ongoing efforts to find a reliable substitution, the duration of the exemption is unlikely to have adverse impacts on innovation.

(10) Directive 2011/65/EU should therefore be amended accordingly,

([1]) OJ L 174, 1.7.2011, p. 88.

([2]) Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC (OJ L 252, 16.9.2016, p. 53).

([3]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency (OJ L 396, 30.12.2006, p. 1).

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex III to Directive 2011/65/EU is amended as set out in the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by 30 April 2020 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions.

They shall apply those provisions from 1 May 2020.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 8 August 2019.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Annex III to Directive 2011/65/EU, the following entry 44 is added:

'44	Lead in solder of sensors, actuators, and engine control units of combustion engines within the scope of Regulation (EU) 2016/1628 of the European Parliament and of the Council (*) , installed in equipment used at fixed positions while in operation which is designed for professionals, but also used by non-professional users	Applies to category 11 and expires on 21 July 2024.

(*) Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC (OJ L 252, 16.9.2016, p. 53).'

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2019/1847

of 31 July 2019

amending Implementing Decision 2014/190/EU as regards the annual breakdown of the resources from the specific allocation for the Youth Employment Initiative by Member State together with the list of eligible regions

(notified under document C(2019) 5438)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1303/2013 of the European Parliament and of the Council of 17 December 2013 laying down common provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund, the European Agricultural Fund for Rural Development and the European Maritime and Fisheries Fund and laying down general provisions on the European Regional Development Fund, the European Social Fund, the Cohesion Fund and the European Maritime and Fisheries Fund and repealing Council Regulation (EC) No 1083/2006 ([1]), and in particular Article 91(2) thereof,

Whereas:

(1) Commission Implementing Decision 2014/190/EU ([2]) sets out, among others, the annual breakdown by Member State of resources from the specific allocation for the Youth Employment Initiative ('YEI'), together with the list of eligible regions for the YEI pursuant to Article 91(2) of Regulation (EU) No 1303/2013.

(2) By Regulation (EU) 2019/711 of the European Parliament and of the Council ([3]) amending Regulation (EU) No 1303/2013, the specific allocation for the YEI for 2019 has been increased.

(3) The regions eligible for the increase of the resources for the specific allocation for the YEI for 2019 are determined in accordance with Article 16 of Regulation (EU) No 1304/2013 of the European Parliament and of the Council ([4]) by making reference, however, to the latest available annual data on youth unemployment. Pursuant to Article 65(2) of Regulation (EU) No 1303/2013, expenditure under the YEI is eligible until 31 December 2023, both for the regions already listed in the two lists of Annex IV to Implementing Decision 2014/190/EU and for the regions eligible for the increase of the resources for the specific allocation for the YEI for 2019. The existing lists should therefore continue to apply and should be complemented with a list of the regions eligible for the increase of the resources for the specific allocation for the YEI for 2019. For reasons of clarity and transparency, Annex IV to Implementing Decision 2014/190/EU should therefore be amended accordingly.

([1]) OJ L 347, 20.12.2013, p. 320.

([2]) Commission Implementing Decision 2014/190/EU of 3 April 2014 setting out the annual breakdown by Member State of global resources for the European Regional Development Fund, the European Social Fund and the Cohesion Fund under the Investment for growth and jobs goal and the European territorial cooperation goal, the annual breakdown by Member State of resources from the specific allocation for the Youth Employment Initiative together with the list of eligible regions, and the amounts to be transferred from each Member State's Cohesion Fund and Structural Funds allocations to the Connecting Europe Facility and to aid for the most deprived for the period 2014-2020 (OJ L 104, 8.4.2014, p. 13).

([3]) Regulation (EU) 2019/711 of the European Parliament and of the Council of 17 April 2019 amending Regulation (EU) No 1303/2013 as regards the resources for the specific allocation for the Youth Employment Initiative (OJ L 123, 10.5.2019, p. 1).

([4]) Regulation (EU) No 1304/2013 of the European Parliament and of the Council of 17 December 2013 on the European Social Fund and repealing Council Regulation (EC) No 1081/2006 (OJ L 347, 20.12.2013, p. 470).

(4) In accordance with Annex VIII to Regulation (EU) No 1303/2013 the breakdown by Member State of the increased resources for 2019 should follow the same steps applied for the initial allocation and the allocation of the resources for 2017-2020. The annual breakdown of the specific allocation for the YEI set out in 2011 prices in Annex III to Implementing Decision 2014/190/EU should therefore be amended accordingly.

(5) In order to allow Member States to plan ahead, the annual breakdown should also be provided in current prices to reflect the indexation of 2 % per year in accordance with Article 91(1) of Regulation (EU) No 1303/2013. Annex X to Implementing Decision 2014/190/EU should therefore be amended accordingly.

(6) Implementing Decision 2014/190/EU should therefore be amended,

HAS ADOPTED THIS DECISION:

Article 1

Implementing Decision 2014/190/EU is amended as follows:

(1) Annexes III and IV are replaced by the text set out in Annex I to this Decision;

(2) Annex X is replaced by the text set out in Annex II to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 31 July 2019.

For the Commission
Johannes HAHN
Member of the Commission

ANNEX I

'ANNEX III

YOUTH EMPLOYMENT INITIATIVE — SPECIFIC ALLOCATION

(EUR, 2011 prices)

	2014	2015	2016	2017	2018	2019	2020	Total
BE	22 464 896	17 179 038	0	7 569 546	5 194 787	5 740 441	1 664 356	59 813 064
BG	29 216 622	22 342 123	0	0	0	0	0	51 558 745
CZ	0	12 564 283	0	0	0	0	0	12 564 283
DK	0	0	0	0	0	0	0	0
DE	0	0	0	0	0	0	0	0
EE	0	0	0	0	0	0	0	0
IE	36 075 815	27 587 388	0	0	0	0	0	63 663 203
EL	90 800 184	69 435 434	0	29 193 451	20 034 721	21 102 150	6 418 916	236 984 856
ES	499 481 827	381 956 689	0	154 715 855	106 177 548	109 838 027	34 018 181	1 286 188 127
FR	164 197 762	125 562 994	0	59 683 863	40 959 513	39 706 031	13 123 002	443 233 165
HR	35 033 821	26 790 569	0	12 993 208	8 916 907	9 001 567	2 856 884	95 592 956
IT	300 437 373	229 746 226	0	126 913 692	87 097 632	83 831 742	27 905 173	855 931 838
CY	6 126 207	4 684 747	0	2 428 857	1 666 863	1 089 453	534 046	16 530 173
LV	15 358 075	11 744 410	0	0	0	0	0	27 102 485
LT	16 825 553	12 866 600	0	0	0	0	0	29 692 153
LU	0	0	0	0	0	0	0	0
HU	26 345 509	20 146 566	0	0	0	0	0	46 492 075
MT	0	0	0	0	0	0	0	0
NL	0	0	0	0	0	0	0	0
AT	0	0	0	0	0	0	0	0

(EUR, 2011 prices)

	2014	2015	2016	2017	2018	2019	2020	Total
PL	133 639 212	102 194 692	0	6 060 353	4 159 066	4 181 837	1 332 522	251 567 682
PT	85 111 913	65 085 581	0	23 156 678	15 891 838	13 327 866	5 091 580	207 665 456
RO	56 112 815	42 909 800	0	16 695 447	11 457 659	7 488 666	3 670 915	138 335 302
SI	4 876 537	3 729 117	0	0	0	0	0	8 605 654
SK	38 209 190	29 218 793	0	4 574 741	3 139 529	3 413 850	1 005 873	79 561 976
FI	0	0	0	0	0	0	0	0
SE	23 379 703	17 878 597	0	0	0	0	0	41 258 300
UK	24 516 103	166 367 414	0	0	0	0	0	190 883 517
EU 28	1 608 209 117	1 389 991 061	0	443 985 691	304 696 063	298 721 630	97 621 448	4 143 225 010

ANNEX IV

YOUTH EMPLOYMENT INITIATIVE — LIST OF ELIGIBLE REGIONS

List of eligible regions based on 2012 youth unemployment data

BE10 – Région de Bruxelles-Capitale/Brussel Hoofdstedelijk Gewest

BE32 – Prov. Hainaut

BE33 – Prov. Liège

BG31 – Severozapaden

BG32 – Severen tsentralen

BG33 – Severoiztochen

BG34 – Yugoiztochen

BG42 – Yuzhen tsentralen

CZ04 – Severozápad

IE01 – Border, Midland and Western

IE02 – Southern and Eastern

EL11 – Anatoliki Makedonia, Thraki

EL12 – Kentriki Makedonia

EL13 – Dytiki Makedonia

EL14 – Thessalia

EL21 – Ipeiros

EL23 – Dytiki Ellada

EL24 – Sterea Ellada

EL25 – Peloponnisos

EL30 – Attiki

EL41 – Voreio Aigaio

EL42 – Notio Aigaio

EL43 – Kriti

ES11 – Galicia

ES12 – Principado de Asturias

ES13 – Cantabria

ES21 – País Vasco

ES22 – Comunidad Foral de Navarra

ES23 – La Rioja

ES24 – Aragón

ES30 – Comunidad de Madrid

ES41 – Castilla y León

ES42 – Castilla-La Mancha

ES43 – Extremadura

ES51 – Cataluña

ES52 – Comunidad Valenciana

ES53 – Illes Balears

ES61 – Andalucía

ES62 – Región de Murcia

ES63 – Ciudad Autónoma de Ceuta

ES64 – Ciudad Autónoma de Melilla

ES70 – Canarias

FR61 – Aquitaine

FR21 – Champagne-Ardenne

FR22 – Picardie

FR23 – Haute-Normandie

FR24 – Centre

FR30 – Nord-Pas-de-Calais

FR72 – Auvergne

FR81 – Languedoc-Roussillon

FR91 – Guadeloupe

FR92 – Martinique

FR93 – Guyane

FR94 – Réunion

FRA5 – Mayotte

HR03 – Jadranska Hrvatska

HR04 – Kontinentalna Hrvatska

ITC1 – Piemonte

ITC2 – Valle d'Aosta/Vallée d'Aoste

ITC3 – Liguria

ITC4 – Lombardia

ITF1 – Abruzzo

ITF2 – Molise

ITF3 – Campania

ITF4 – Puglia

ITF5 – Basilicata

ITF6 – Calabria

ITG1 – Sicilia

ITG2 – Sardegna

ITH5 – Emilia-Romagna

ITH4 – Friuli-Venezia Giulia

ITI1 – Toscana

ITI2 – Umbria

ITI3 – Marche

ITI4 – Lazio

CY00 – Kýpros

LV00 – Latvija

LT00 – Lietuva

HU23 – Dél-Dunántúl

HU31 – Észak-Magyarország

HU32 – Észak-Alföld

HU33 – Dél-Alföld

PL11 – Łódzkie

PL21 – Małopolskie

PL31 – Lubelskie

PL32 – Podkarpackie

PL33 – Świętokrzyskie

PL42 – Zachodniopomorskie

PL43 – Lubuskie

PL51 – Dolnośląskie

PL61 – Kujawsko-Pomorskie

PL62 – Warmińsko-Mazurskie

PT11 – Norte

PT15 – Algarve

PT16 – Centro (PT)

PT17 – Lisboa

PT18 – Alentejo

PT20 – Região Autónoma dos Açores

PT30 – Região Autónoma da Madeira

RO12 – Centru

RO22 – Sud-Est

RO31 – Sud-Muntenia

SI01 – Vzhodna Slovenija

SK02 – Západné Slovensko

SK03 – Stredné Slovensko

SK04 – Východné Slovensko

SE22 – Sydsverige

SE31 – Norra Mellansverige

SE32 – Mellersta Norrland

UKC1 – Tees Valley and Durham

UKD7 – Merseyside

UKG3 – West Midlands

UKI1 – Inner London

UKM3 – South Western Scotland

List of eligible regions based on 2016 youth unemployment data

BE10 – Région de Bruxelles-Capitale/Brussel Hoofdstedelijk Gewest

BE32 – Prov. Hainaut

BE34 – Prov. Luxembourg (BE)

BE35 – Prov. Namur

EL51 – Anatoliki Makedonia, Thraki

EL52 – Kentriki Makedonia

EL53 – Dytiki Makedonia

EL54 – Ipeiros

EL61 – Thessalia

EL62 – Ionia Nisia

EL63 – Dytiki Ellada

EL64 – Sterea Ellada

EL65 – Peloponnisos

EL30 – Attiki

EL41 – Voreio Aigaio

EL42 – Notio Aigaio

EL43 – Kriti

ES11 – Galicia

ES12 – Principado de Asturias

ES13 – Cantabria

ES21 – País Vasco

ES22 – Comunidad Foral de Navarra

ES23 – La Rioja

ES24 – Aragón

ES30 – Comunidad de Madrid

ES41 – Castilla y León

ES42 – Castilla-la Mancha

ES43 – Extremadura

ES51 – Cataluña

ES52 – Comunidad Valenciana

ES53 – Illes Balears

ES61 – Andalucía

ES62 – Región de Murcia

ES63 – Ciudad Autónoma de Ceuta (ES)

ES64 – Ciudad Autónoma de Melilla (ES)

ES70 – Canarias (ES)

FR21 – Champagne-Ardenne

FR22 – Picardie

FR23 – Haute-Normandie

FR24 – Centre (FR)

FR26 – Bourgogne

FR30 – Nord-Pas-de-Calais

FR42 – Alsace

FR81 – Languedoc-Roussillon

FRA1 – Guadeloupe

FRA2 – Martinique

FRA3 – Guyane

FRA4 – La Réunion

FRA5 – Mayotte

HR03 – Jadranska Hrvatska

HR04 – Kontinentalna Hrvatska

ITC1 – Piemonte

ITC2 – Valle d'Aosta/Vallée d'Aoste

ITC3 – Liguria

ITC4 – Lombardia

ITF1 – Abruzzo

ITF2 – Molise

ITF3 – Campania

ITF4 – Puglia

ITF5 – Basilicata

ITF6 – Calabria

ITG1 – Sicilia

ITG2 – Sardegna

ITH4 – Friuli-Venezia Giulia

ITI1 – Toscana

ITI2 – Umbria

ITI3 – Marche

ITI4 – Lazio

CY00 – Kypros

PL32 – Podkarpackie

PT11 – Norte

PT16 – Centro (PT)

PT17 – Área Metropolitana de Lisboa

PT18 – Alentejo

PT20 – Região Autónoma dos Açores (PT)

PT30 – Região Autónoma da Madeira (PT)

RO22 – Sud-Est

RO31 – Sud-Muntenia

RO41 – Sud-Vest Oltenia

SK04 – Východné Slovensko

List of eligible regions based on 2017 youth unemployment data

BE10 Région de Bruxelles-Capitale/Brussel Hoofdstedelijk Gewest

BE32 – Prov. Hainaut

BE33 – Prov. Liège

EL30 – Attiki

EL41 – Voreio Aigaio

EL42 – Notio Aigaio

EL43 – Kriti

EL51 – Anatoliki Makedonia, Thraki

EL52 – Kentriki Makedonia

EL53 – Dytiki Makedonia

EL54 – Ipeiros

EL61 – Thessalia

EL62 – Ionia Nisia

EL63 – Dytiki Ellada

EL64 – Sterea Ellada

EL65 – Peloponnisos

ES11 – Galicia

ES12 – Principado de Asturias

ES13 – Cantabria

ES21 – País Vasco

ES22 – Comunidad Foral de Navarra

ES23 – La Rioja

ES24 – Aragón

ES30 – Comunidad de Madrid

ES41 – Castilla y León

ES42 – Castilla-La Mancha

ES43 – Extremadura

ES51 – Cataluña

ES52 – Comunidad Valenciana

ES53 – Illes Balears

ES61 – Andalucía

ES62 – Región de Murcia

ES63 – Ciudad Autónoma de Ceuta (ES)

ES64 – Ciudad Autónoma de Melilla (ES)

ES70 – Canarias (ES)

FR21 – Champagne-Ardenne

FR22 – Picardie

FR30 Nord – Pas-de-Calais

FR61 – Aquitaine

FR81 – Languedoc-Roussillon

FRA1 – Guadeloupe

FRA2 – Martinique

FRA3 – Guyane

FRA4 – Réunion

FRA5 – Mayotte

HR03 – Jadranska Hrvatska

HR04 – Kontinentalna Hrvatska

ITC1 – Piemonte

ITC3 – Liguria

ITF1 – Abruzzo

ITF2 – Molise

ITF3 – Campania

ITF4 – Puglia

ITF5 – Basilicata

ITF6 – Calabria

ITG1 – Sicilia

ITG2 – Sardegna

ITH4 – Friuli-Venezia Giulia

ITI2 – Umbria

ITI4 – Lazio

PL32 – Podkarpackie

PT11 – Norte

PT20 – Região Autónoma dos Açores

PT30 – Região Autónoma da Madeira

SK04 – Východné Slovensko'

ANNEX II

'ANNEX X

YOUTH EMPLOYMENT INITIATIVE – SPECIFIC ALLOCATION

(EUR current prices)

	2014	2015	2016	2017	2018	2019	2020	Total
BE	23 839 927	18 595 143	0	8 524 538	5 967 177	6 725 841	1 989 059	65 641 685
BG	31 004 913	24 183 832	0	0	0	0	0	55 188 745
CZ	0	13 599 984	0	0	0	0	0	13 599 984
DK	0	0	0	0	0	0	0	0
DE	0	0	0	0	0	0	0	0
EE	0	0	0	0	0	0	0	0
IE	38 283 943	29 861 476	0	0	0	0	0	68 145 419
EL	96 357 882	75 159 147	0	32 876 567	23 013 597	24 724 532	7 671 199	259 802 924
ES	530 054 111	413 442 204	0	174 235 182	121 964 627	128 692 755	40 654 875	1 409 043 754
FR	174 247 979	135 913 423	0	67 213 724	47 049 606	46 521 944	15 683 202	486 629 878
HR	37 178 171	28 998 973	0	14 632 462	10 242 723	10 546 771	3 414 241	105 013 341
IT	318 826 544	248 684 704	0	142 925 430	100 047 801	98 222 247	33 349 267	942 055 993
CY	6 501 180	5 070 921	0	2 735 288	1 914 702	1 276 468	638 234	18 136 793
LV	16 298 112	12 712 527	0	0	0	0	0	29 010 639
LT	17 855 411	13 927 222	0	0	0	0	0	31 782 633
LU	0	0	0	0	0	0	0	0
HU	27 958 065	21 807 291	0	0	0	0	0	49 765 356
MT	0	0	0	0	0	0	0	0
NL	0	0	0	0	0	0	0	0
AT	0	0	0	0	0	0	0	0

(EUR current prices)

	2014	2015	2016	2017	2018	2019	2020	Total
PL	141 819 001	110 618 821	0	6 824 942	4 777 460	4 899 688	1 592 486	270 532 398
PT	90 321 443	70 450 726	0	26 078 181	18 254 727	15 615 719	6 084 909	226 805 705
RO	59 547 368	46 446 947	0	18 801 785	13 161 249	8 774 166	4 387 083	151 118 598
SI	5 175 020	4 036 516	0	0	0	0	0	9 211 536
SK	40 547 898	31 627 361	0	5 151 901	3 606 331	3 999 869	1 202 111	86 135 471
FI	0	0	0	0	0	0	0	0
SE	24 810 728	19 352 368	0	0	0	0	0	44 163 096
UK	26 016 685	180 081 439	0	0	0	0	0	206 098 124
EU 28	1 706 644 381	1 504 571 025	0	500 000 000	350 000 000	350 000 000	116 666 666	4527882072’

DECISION (EU) 2019/1848 OF THE EUROPEAN CENTRAL BANK

of 29 October 2019

amending Decision ECB/2007/7 concerning the terms and conditions of TARGET2-ECB (ECB/2019/32)

THE EXECUTIVE BOARD OF THE EUROPEAN CENTRAL BANK,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first and fourth indents of Article 127(2) thereof,

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular Article 11.6 and Articles 17, 22 and 23 thereof,

Whereas:

(1) On 4 October 2019, the Governing Council amended ([1]) Guideline ECB/2012/27 ([2]), in order to: (a) introduce a new SSP functionality, enabling the processing of very critical and critical payments in a contingency, to which Eurosystem central banks must adhere; (b) clarify the conditions under which investment firms may participate in TARGET2, including the requirement for a legal opinion regarding investment firms established outside the European Economic Area (EEA) and applying for direct participation in a TARGET2 component system; (c) clarify that participants in TARGET2 component systems must adhere to the TARGET2 self-certification requirement and to the endpoint security requirements of TARGET2 network service providers, and inform the relevant Eurosystem central bank of any crisis prevention or management measures to which they are subject; and (d) clarify and update certain other aspects of Guideline ECB/2012/27.

(2) Amendments made to Guideline ECB/2012/27 which affect the terms and conditions of TARGET2-ECB should be reflected in Decision ECB/2007/7 ([3]).

(3) Therefore, Decision ECB/2007/7 should be amended accordingly,

HAS ADOPTED THIS DECISION:

Article 1

Amendments

Annexes I, II and III to Decision ECB/2007/7 are amended in accordance with the Annex to this Decision.

([1]) Guideline (EU) 2019/… of 4 October 2019 amending Guideline ECB/2012/27 on a Trans-European Automated Real-time Gross settlement Express Transfer system (TARGET2) (ECB/2019/30) (see page XX of this Official Journal).
([2]) Guideline ECB/2012/27 of 5 December 2012 on a Trans-European Automated Real-time Gross settlement Express Transfer system (TARGET2) (OJ L 30, 30.1.2013, p. 1).
([3]) Decision ECB/2007/7 of 24 July 2007 concerning the terms and conditions of TARGET2-ECB (OJ L 237, 8.9.2007, p. 71).

Article 2

Final provisions

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

It shall apply from 17 November 2019.

Done at Frankfurt am Main, 29 October 2019.

The President of the ECB
Mario DRAGHI

ANNEX

Annexes I, II and III to Decision ECB/2007/7 are amended as follows:

1. Annex I is amended as follows:

(a) in Article 1, the definition of Contingency Module is deleted;

(b) in Article 1, the definition of 'Information and Control Module (ICM)' is replaced by the following:

— '"Information and Control Module (ICM)" means the SSP module that allows PM account holders to obtain online information and gives them the possibility to submit liquidity transfer orders, manage liquidity and, if applicable, initiate backup payment orders or payment orders to the Contingency Solution in a contingency,';

(c) in Article 1, the following definition is added:

— '"Contingency Solution" means the SSP functionality that processes very critical and critical payments in contingency,';

(d) Article 9(8) is replaced by the following:

'8. Participants shall immediately inform the ECB if an event of default occurs in relation to themselves or if they are subject to crisis prevention measures or crisis management measures within the meaning of Directive 2014/59/EU of the European Parliament and of the Council (*) or any other equivalent applicable legislation.

(*) Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014 establishing a framework for the recovery and resolution of credit institutions and investment firms and amending Council Directive 82/891/EEC, and Directives 2001/24/EC, 2002/47/EC, 2004/25/EC, 2005/56/EC, 2007/36/EC, 2011/35/EU, 2012/30/EU and 2013/36/EU, and Regulations (EU) No 1093/2010 and (EU) No 648/2012, of the European Parliament and of the Council (OJ L 173, 12.6.2014, p. 190).';

(e) Article 21 is replaced by the following:

'Article 21

Business continuity and contingency procedures

1. In the event of an abnormal external event or any other event which affects the operation of the SSP, the business continuity and contingency procedures described in Appendix IV shall apply.

2. The Eurosystem provides a Contingency Solution if the events described in paragraph 1 occur. Connection to and use of the Contingency Solution shall be mandatory for participants considered by the ECB to be critical. Other participants may, on request, connect to the Contingency Solution.';

(f) Article 22 is amended as follows:

(i) paragraph 3 is replaced by the following:

'3. The ECB may impose additional security requirements, in particular with regard to cybersecurity or the prevention of fraud, on all participants and/or on participants that are considered critical by the ECB.';

(ii) the following paragraph 4 is added:

'4. Participants shall provide the ECB with their TARGET2 self-certification and their attestation of adherence to the TARGET2 network service provider's endpoint security requirements. In the event of non-adherence to the latter, participants shall provide a document describing alternative mitigating measures to the satisfaction of the ECB.';

(g) in Article 23(1), point (c) is replaced by the following:

'(c) allows participants to initiate backup liquidity redistribution and backup contingency payments or payment orders to the Contingency Solution in the event of a failure of the participant's payment infrastructure.';

(h) in Article 32(2), point (c) is replaced by the following:

'(c) supervisory, resolution and oversight authorities of Member States and the Union, including CBs, to the extent that this is necessary for the performance of their public tasks, and provided in all such cases that the disclosure is not in conflict with the applicable law.';

(i) Appendix I is amended as follows:

(i) the fifth line of the table in paragraph 2(1) is replaced by the following:

'MT 202COV	Mandatory	Cover payment';

(ii) paragraph 8(7) is replaced by the following:

'If a participant has technical problems and is unable to submit any payment order, it may generate preformatted backup liquidity redistribution and backup contingency payments by using the ICM. The ECB shall open such functionality upon request of the participant';

(j) in Appendix III, under the heading 'Terms of reference for country opinions for non-EEA participants in TARGET2', paragraph 3.2 entitled 'General insolvency issues' is replaced by the following:

'3.2. **General insolvency and crisis management issues**

Types of insolvency and crisis management proceedings

The only types of insolvency proceedings (including composition or rehabilitation) which, for the purpose of this Opinion, shall include all proceedings in respect of the Participant's assets or any branch it may have in [jurisdiction] to which the Participant may become subject in [jurisdiction], are the following: [list proceedings in original language and English translation] (together collectively referred to as "Insolvency Proceedings").

In addition to Insolvency Proceedings, the Participant, any of its assets, or any branch it may have in [jurisdiction] may become subject in [jurisdiction] to [list any applicable moratorium, receivership, or any other proceedings as a result of which payments to and/or from the Participant may be suspended, or limitations can be imposed in relation to such payments, or similar proceedings, including crisis prevention and crisis management measures equivalent to those defined in Directive 2014/59/EU, in original language and English translation] (hereinafter collectively referred to as "Proceedings").

Insolvency treaties

[jurisdiction] or certain political subdivisions within [jurisdiction], as specified, is/are party to the following insolvency treaties: [specify, if applicable which have or may have an impact on this Opinion].';

(k) in Appendix IV, paragraph 6 is amended as follows:

(i) points (a) and (b) are replaced by the following:

'(a) If the ECB deems it necessary to do so, it shall initiate the contingency processing of payment orders using the Contingency Solution of the SSP. In such cases, only a minimum service level shall be provided to participants. The ECB shall inform its participants of the start of contingency processing by any available means of communication.

(b) In contingency processing, payment orders shall be submitted by the participants and authorised by the ECB. In addition, the participants may submit files containing payment instructions, which may be uploaded into the Contingency Solution by the ECB.';

(ii) points (d) and (e) are replaced by the following:

'(d) Payments required to avoid systemic risk shall be considered as "critical" and the ECB may decide to initiate contingency processing in relation to them.

(e) Participants shall submit payment orders for contingency processing directly into the Contingency Solution and information to payees shall be provided through encrypted and authenticated email, as well as via authenticated fax Participants shall submit files which contain payment instructions to the ECB for uploading into the Contingency Solution and which authorise the ECB to do so. The ECB may, exceptionally, also manually input payments on behalf of participants. Information concerning account balances and debit and credit entries may be obtained via the ECB.';

(l) in Appendix IV, points (a) and (b) of paragraph 7 are replaced by the following:

'(a) In the event that a participant has a problem that prevents it from settling payments in TARGET2 it shall be its responsibility to resolve the problem. In particular, a participant may use in-house solutions or the ICM functionality, i.e. backup liquidity redistribution and backup contingency payments (e.g. CLS, EURO1).

(b) If a participant decides to use the ICM functionality for making backup liquidity redistribution, the ECB shall, if the participant so requests, open this functionality via the ICM. If the participant so requests, the ECB shall transmit an ICM broadcast message to inform other participants about the participant's use of backup liquidity redistribution. The participant shall be responsible for sending such backup liquidity redistribution exclusively to other participants with which it has bilaterally agreed on the use of such payments and for any further steps in relation to such payments.';

(m) in Appendix VI, the third and fourth lines of the table in point 5 are replaced by the following:

'T2S DCA to T2S DCA liquidity transfer orders	14,1	per transfer
Intra-balance movement (i.e. blocking, unblocking, reservation of liquidity etc.)	9,4	per transaction';

2. Annex II is amended as follows:

(a) Article 1 is amended as follows:

(i) the definition of 'Information and Control Module (ICM)' is replaced by the following:

— '"Information and Control Module (ICM)" means the SSP module that allows PM account holders to obtain online information and gives them the possibility to submit liquidity transfer orders, manage liquidity and, if applicable, initiate backup payment orders or payment orders to the Contingency Solution in a contingency,';

(ii) the following definition is added:

— '"Contingency Solution" means the SSP functionality that processes very critical and critical payments in contingency,';

(b) Article 10(9) is replaced by the following:

'9. T2S DCA holders shall immediately inform the ECB if an event of default occurs in relation to themselves or if they are subject to crisis prevention measures or crisis management measures within the meaning of Directive 2014/59/EU or any other equivalent applicable legislation.';

(c) Article 18(3) is replaced by the following:

'3. The ECB may impose additional security requirements, in particular with regard to cybersecurity or the prevention of fraud, on all T2S DCA holders and/or on T2S DCA holders that are considered critical by the ECB.';

(d) in Article 27(2), point (c) is replaced by the following:

'(c) supervisory, resolution and oversight authorities of Member States and the Union, including CBs, to the extent that this is necessary for the performance of their public tasks, and provided in all such cases that the disclosure is not in conflict with the applicable law.';

(e) in Appendix III, under the heading 'Terms of reference for country opinions for non-EEA T2S DCA holders in TARGET2', paragraph 3.2 entitled 'General insolvency issues' is replaced by the following:

'3.2. **General insolvency and crisis management issues**

Types of insolvency and crisis management proceedings

The only types of insolvency proceedings (including composition or rehabilitation) which, for the purpose of this Opinion, shall include all proceedings in respect of the T2S DCA holder's assets or any branch it may have in [jurisdiction] to which the T2S DCA holder may become subject in [jurisdiction], are the following: [list proceedings in original language and English translation] (together collectively referred to as "Insolvency Proceedings").

In addition to Insolvency Proceedings, the T2S DCA holder, any of its assets, or any branch it may have in [jurisdiction] may become subject in [jurisdiction] to [list any applicable moratorium, receivership, or any other proceedings as a result of which payment orders to and/or from the T2S DCA holder may be suspended, or limitations can be imposed in relation to such payment orders, or similar proceedings, including crisis prevention and crisis management measures equivalent to those defined in Directive 2014/59/EU, in original language and English translation] (hereinafter collectively referred to as "Proceedings").

Insolvency treaties

[jurisdiction] or certain political subdivisions within [jurisdiction], as specified, is/are party to the following insolvency treaties: [specify, if applicable which have or may have an impact on this Opinion].';

(f) in Appendix VI, the third and fourth lines of the table are replaced by the following:

'T2S DCA to T2S DCA liquidity transfer orders	14,1 euro cent	per transfer
Intra-balance movement (i.e. blocking, unblocking, reservation of liquidity etc.)	9,4 euro cent	per transaction';

3. Annex III is amended as follows:

(a) Article 14(8) is replaced by the following:

'8. TIPS DCA holders shall immediately inform the ECB if an event of default occurs in relation to themselves or if they are subject to crisis prevention measures or crisis management measures within the meaning of Directive 2014/59/EU or any other equivalent applicable legislation.';

(b) Article 21 is amended as follows:

(i) paragraph 5 is replaced by the following:

'5. The ECB may impose additional security requirements, in particular with regard to cybersecurity or the prevention of fraud, on all TIPS DCA holders.';

(ii) the following paragraph 6 is added:

'6. TIPS DCA holders using instructing parties in line with Article 7(2) or (3), or allowing access to their TIPS DCA as set out in Article 8(1), shall be deemed to have addressed the risk stemming from such use or access in accordance with the additional security requirements imposed upon them.';

(c) Article 26(4) is replaced by the following:

'4. In the event that the ECB suspends or terminates a TIPS DCA holder's participation in TARGET2-ECB under paragraph 1 or 2, the ECB shall immediately inform, by means of a ICM broadcast message, other CBs and PM account holders in all of the TARGET2 component systems of such suspension or termination. Such message shall be deemed to have been issued by the home CB of the PM account holder that received the message.

Linked PM account holders shall have the responsibility to inform their Linked TIPS DCA holders of the suspension or termination of any TIPS DCA holder's participation in TARGET2-ECB.

In the event that the suspension or termination of a TIPS DCA holder's participation in TARGET2-ECB occurs during the technical maintenance window, the ICM broadcast message shall be sent after the start of daytime processing on the next TARGET2 business day.';

(d) in Article 29(3), point (c) is replaced by the following:

'(c) supervisory, resolution and oversight authorities of Member States and the Union, including CBs, to the extent that this is necessary for the performance of their public tasks, and provided in all such cases that the disclosure is not in conflict with the applicable law.';

(e) in Appendix II, under the heading 'Terms of reference for country opinions for non-EEA TIPS DCA holders in TARGET2, paragraph 3.2 entitled 'General insolvency issues' is replaced by the following:

'3.2. **General insolvency and crisis management issues**

3.2.a. *Types of insolvency and crisis management proceedings*

The only types of insolvency proceedings (including composition or rehabilitation) which, for the purpose of this Opinion, shall include all proceedings in respect of the TIPS DCA holder's assets or any branch it may have in [jurisdiction] to which the TIPS DCA holder may become subject in [jurisdiction], are the following: [list proceedings in original language and English translation] (together collectively referred to as "Insolvency Proceedings").

In addition to Insolvency Proceedings, the TIPS DCA holder, any of its assets, or any branch it may have in [jurisdiction] may become subject in [jurisdiction] to [list any applicable moratorium, receivership, or any other proceedings as a result of which payment orders to and/or from the TIPS DCA holder may be suspended, or limitations can be imposed in relation to such payment orders, or similar proceedings, including crisis prevention and crisis management measures equivalent to those defined in Directive 2014/59/EU, in original language and English translation] (hereinafter collectively referred to as "Proceedings").

3.2.b. *Insolvency treaties*

[jurisdiction] or certain political subdivisions within [jurisdiction], as specified, is/are party to the following insolvency treaties: [specify, if applicable which have or may have an impact on this Opinion].'.

GUIDELINES

GUIDELINE (EU) 2019/1849 OF THE EUROPEAN CENTRAL BANK

of 4 October 2019

amending Guideline ECB/2012/27 on a Trans-European Automated Real-time Gross settlement Express Transfer system (TARGET2)

(ECB/2019/30)

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first and fourth indents of Article 127(2) thereof,

Having regard to the Statute of the European System of Central Banks and of the European Central Bank, and in particular Article 3.1 and Articles 17, 18 and 22 thereof,

Whereas:

(1) On 26 April 2007, the Governing Council of the European Central Bank adopted Guideline ECB/2007/2 [1] governing TARGET2, which is characterised by a single technical platform, the Single Shared Platform (SSP). That Guideline was amended and recast as Guideline ECB/2012/27 [2].

(2) A new SSP functionality has been established, enabling the processing of very critical and critical payments in a contingency, to which Eurosystem central banks must adhere.

(3) There is a need to clarify the conditions under which investment firms may participate in TARGET2, including the requirement for a legal opinion regarding investment firms established outside the European Economic Area (EEA) and applying for direct participation in a TARGET2 component system.

(4) It is necessary to clarify that participants in TARGET2 component systems must adhere to the TARGET2 self-certification requirement and to the endpoint security requirements of TARGET2 network service providers, and inform the relevant Eurosystem central bank of any crisis prevention or management measures to which they are subject.

(5) It is also necessary to clarify and update certain other aspects of Guideline ECB/2012/27.

(6) Therefore, Guideline ECB/2012/27 should be amended accordingly,

HAS ADOPTED THIS GUIDELINE:

Article 1

Amendments

Guideline ECB/2012/27 is amended as follows:

1. Article 2 is amended as follows:

   (a) point (44) is replaced by the following:

   '(44) "Information and Control Module (ICM)" means the SSP module that allows PM account holders to obtain online information and gives them the possibility to submit liquidity transfer orders, manage liquidity and, if applicable, initiate backup payment orders or payment orders to the Contingency Solution in a contingency;';

[1] Guideline ECB/2007/2 of 26 April 2007 on a Trans-European Automated Real-time Gross settlement Express Transfer system (TARGET2) (OJ L 237, 8.9.2007, p. 1).

[2] Guideline ECB/2012/27 of 5 December 2012 on a Trans-European Automated Real-time Gross settlement Express Transfer system (TARGET2) (OJ L 30, 30.1.2013, p. 1).

(b) the following point (86) is added:

'(86) "Contingency Solution" means the SSP functionality that processes very critical and critical payments in contingency.';

2. in Article 21, the following paragraph 6 is added:

'6. The Eurosystem CBs shall connect to the Contingency Solution.';

3. Annexes II, IIa, IIb, III, IV and V are amended in accordance with the Annex to this Guideline.

Article 2

Taking effect and implementation

1. This Guideline shall take effect on the day of its notification to the national central banks of the Member States whose currency is the euro.

2. The national central banks of the Member States whose currency is the euro shall take the necessary measures to comply with this Guideline and apply them from 17 November 2019. They shall notify the ECB of the texts and means relating to those measures by 17 October 2019 at the latest.

Article 3

Addressees

This Guideline is addressed to all Eurosystem central banks.

Done at Frankfurt am Main, 4 October 2019.

For the Governing Council of the ECB
The President of the ECB
Mario DRAGHI

ANNEX

Annexes II, IIa, IIb, III, IV and V to Guideline ECB/2012/27 are amended as follows:

1. Annex II is amended as follows:

(a) in Article 1, the definition of Contingency Module is deleted;

(b) in Article 1, the definition of 'Information and Control Module (ICM)' is replaced by the following:

— "'Information and Control Module (ICM)" means the SSP module that allows PM account holders to obtain online information and gives them the possibility to submit liquidity transfer orders, manage liquidity and, if applicable, initiate backup payment orders or payment orders to the Contingency Solution in a contingency,';

(c) in Article 1, the following definition is added:

— "'Contingency Solution" means the SSP functionality that processes very critical and critical payments in contingency,';

(d) in Article 4(2), point (a) is replaced by the following:

'(a) treasury departments of central or regional governments of Member States;';

(e) in Article 4(2), point (c) is replaced by the following:

'(c) (i) investment firms established in the Union or the EEA, including when they act through a branch established in the Union or the EEA; and

(ii) investment firms established outside the EEA, provided that they act through a branch established in the Union or the EEA;';

(f) in Article 8(1)(b), point (ii) is replaced by the following:

'(ii) for the entities referred to in Article 4(1)(b) and in Article 4(2)(c)(ii), provide a country opinion in the form specified in Appendix III, unless the information and representations to be provided in such country opinion have already been obtained by the [insert name of CB] in another context.';

(g) Article 11(9) is replaced by the following:

'9. Participants shall immediately inform the [insert name of CB] if an event of default occurs in relation to themselves or if they are subject to crisis prevention measures or crisis management measures within the meaning of Directive 2014/59/EU of the European Parliament and of the Council ([1]) or any other equivalent applicable legislation.';

(h) Article 27 is replaced by the following:

'Article 27

Business continuity and contingency procedures

1. In the event of an abnormal external event or any other event which affects the operation of the SSP, the business continuity and contingency procedures described in Appendix IV shall apply.

2. The Eurosystem provides a Contingency Solution if the events described in paragraph 1 occur. Connection to and use of the Contingency Solution shall be mandatory for participants considered by the [insert name of CB] to be critical. Other participants may, on request, connect to the Contingency Solution.';

(i) Article 28 is amended as follows:

(i) paragraph 3 is replaced by the following:

'3. The [insert name of CB] may impose additional security requirements, in particular with regard to cybersecurity or the prevention of fraud, on all participants and/or on participants that are considered critical by the [insert name of CB].';

([1]) Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014 establishing a framework for the recovery and resolution of credit institutions and investment firms and amending Council Directive 82/891/EEC, and Directives 2001/24/EC, 2002/47/EC, 2004/25/EC, 2005/56/EC, 2007/36/EC, 2011/35/EU, 2012/30/EU and 2013/36/EU, and Regulations (EU) No 1093/2010 and (EU) No 648/2012, of the European Parliament and of the Council (OJ L 173, 12.6.2014, p. 190).

(ii) the following paragraphs 4 and 5 are added:

'4. Participants shall provide the [insert name of CB] with their TARGET2 self-certification and their attestation of adherence to the TARGET2 network service provider's endpoint security requirements. In the event of non-adherence to the latter, participants shall provide a document describing alternative mitigating measures to the satisfaction of the [insert name of CB].

5. Participants allowing access to their PM account by third parties as set out in Article 5(2), (3) and (4) shall address the risk stemming from allowing such access in accordance with the security requirements set out in paragraphs 1 to 4. The self-certification referred to in paragraph (4) shall specify that the participant imposes the TARGET2 network service provider's endpoint security requirements on third parties who have access to that participant's PM account.';

(j) in Article 29(1), point (c) is replaced by the following:

'(c) allows participants to initiate backup liquidity redistribution and backup contingency payments or payment orders to the Contingency Solution in the event of a failure of the participant's payment infrastructure.';

(k) in Article 38(2), in the first sentence, point (c) is replaced by the following:

'(c) supervisory, resolution and oversight authorities of Member States and the Union, including CBs, to the extent that this is necessary for the performance of their public tasks, and provided in all such cases that the disclosure is not in conflict with the applicable law.';

(l) in Appendix I, the fifth line of the table in point 2(1) is replaced by the following:

'MT 202COV	Mandatory	Cover payment';

(m) in Appendix III, under the heading 'Terms of reference for country opinions for non-EEA participants in TARGET2', paragraph 3.2 is replaced by the following:

'3.2. General insolvency and crisis management issues

3.2.a. *Types of insolvency and crisis management proceedings*

The only types of insolvency proceedings (including composition or rehabilitation) which, for the purpose of this Opinion, shall include all proceedings in respect of the Participant's assets or any branch it may have in [jurisdiction] to which the Participant may become subject in [jurisdiction], are the following: [list proceedings in original language and English translation] (together collectively referred to as 'Insolvency Proceedings').

In addition to Insolvency Proceedings, the Participant, any of its assets, or any branch it may have in [jurisdiction] may become subject in [jurisdiction] to [list any applicable moratorium, receivership, or any other proceedings as a result of which payments to and/or from the Participant may be suspended, or limitations can be imposed in relation to such payments, or similar proceedings, including crisis prevention and crisis management measures equivalent to those defined in Directive 2014/59/EU, in original language and English translation] (hereinafter collectively referred to as 'Proceedings').

3.2.b. *Insolvency treaties*

[jurisdiction] or certain political subdivisions within [jurisdiction], as specified, is/are party to the following insolvency treaties: [specify, if applicable which have or may have an impact on this Opinion].';

(n) in Appendix IV, paragraph 6 is amended as follows:

(i) points (a) and (b) are replaced by the following:

'(a) If [insert name of CB] deems it necessary to do so, it shall initiate the contingency processing of payment orders using the Contingency Solution of the SSP. In such cases, only a minimum service level shall be provided to participants and ancillary systems. The [insert name of CB] shall inform its participants and ancillary systems of the start of contingency processing by any available means of communication.

(b) In contingency processing, payment orders shall be submitted by the participants and authorised by the [insert name of CB]. In addition, the ancillary systems may submit files containing payment instructions, which may be uploaded into the Contingency Solution by [insert name of CB].';

(ii) points (d) and (e) are replaced by the following:

'(d) Payments required to avoid systemic risk shall be considered as 'critical' and the [insert name of CB] may decide to initiate contingency processing in relation to them.

(e) Participants shall submit payment orders for contingency processing directly into the Contingency Solution and information to payees shall be provided through [insert communication means]. Ancillary systems shall submit files which contain payment instructions to [insert name of CB] for uploading into the Contingency Solution and which authorise [insert name of CB] to do so. [insert name of CB] may, exceptionally, also manually input payments on behalf of participants. Information concerning account balances and debit and credit entries may be obtained via the [insert name of CB].';

(o) in Appendix IV, point (a) of paragraph 7 is replaced by the following:

'(a) In the event that a participant has a problem that prevents it from settling payments in TARGET2 it shall be its responsibility to resolve the problem. In particular, a participant may use in-house solutions or the ICM functionality, i.e. backup liquidity redistribution payments and backup contingency payments (e.g. CLS, EURO1).';

(p) in Appendix VI, the third and fourth lines of the table in point 13 are replaced by the following:

'T2S DCA to T2S DCA liquidity transfer orders	14,1 euro cent	per transfer
Intra-balance movement (i.e. blocking, unblocking, reservation of liquidity etc.)	9,4 euro cent	per transaction';

2. Annex IIa is amended as follows:

(a) Article 1 is amended as follows:

(i) the definition of 'Information and Control Module (ICM)' is replaced by the following:

— '"Information and Control Module (ICM)" means the SSP module that allows PM account holders to obtain online information and gives them the possibility to submit liquidity transfer orders, manage liquidity and, if applicable, initiate backup payment orders or payment orders to the Contingency Solution in a contingency,';

(ii) the following definitions are added:

— '"investment firm" means an investment firm within the meaning of [insert national law provisions implementing Article 4(1)(1) of Directive 2014/65/EU], excluding the institutions specified in [insert national law provisions implementing Article 2(1) of Directive 2014/65/EU], provided that the investment firm in question is:

(a) authorised and supervised by a recognised competent authority, which has been designated as such under Directive 2014/65/EU; and

(b) entitled to carry out the activities referred to under [insert national law provisions implementing items 2, 3, 6 and 7 of Section A of Annex I to Directive 2014/65/EU],';

— '"Contingency Solution" means the SSP functionality that processes very critical and critical payments in contingency,';

(b) in Article 5(2), point (a) is replaced by the following:

'(a) treasury departments of central or regional governments of Member States;';

(c) in Article 5(2), point (c) is replaced by the following:

'(c) (i) investment firms established in the Union or the EEA, including when they act through a branch established in the Union or the EEA; and

(ii) investment firms established outside the EEA, provided that they act through a branch established in the Union or the EEA;';

(d) in Article 6(1)(b), point (ii) is replaced by the following:

'(ii) for credit institutions or investment firms established outside the EEA, acting through a branch established in the Union or the EEA, provide a country opinion in the form specified in Appendix III, unless the information and representations to be provided in such country opinion have already been obtained by the [insert name of CB] in another context.';

(e) Article 10(9) is replaced by the following:

'9. T2S DCA holders shall immediately inform the [insert name of CB] if an event of default occurs in relation to themselves or if they are subject to crisis prevention measures or crisis management measures within the meaning of Directive 2014/59/EU or any other equivalent applicable legislation.'

(f) Article 18(3) is replaced by the following:

'3. The [insert name of CB] may impose additional security requirements, in particular with regard to cybersecurity or the prevention of fraud, on all T2S DCA holders and/or on T2S DCA holders that are considered critical by the [insert name of CB].';

(g) in Article 27(2), in the first sentence, point (c) is replaced by the following:

'(c) supervisory, resolution and oversight authorities of Member States and the Union, including CBs, to the extent that this is necessary for the performance of their public tasks, and provided in all such cases that the disclosure is not in conflict with the applicable law.';

(h) in Appendix III, under the heading 'Terms of reference for country opinions for non-EEA T2S DCA holders in TARGET2', paragraph 3.2 is replaced by the following:

'3.2. General insolvency and crisis management issues

3.2.a. *Types of insolvency and crisis management proceedings*

The only types of insolvency proceedings (including composition or rehabilitation) which, for the purpose of this Opinion, shall include all proceedings in respect of the T2S DCA holder's assets or any branch it may have in [jurisdiction] to which the T2S DCA holder may become subject in [jurisdiction], are the following: [list proceedings in original language and English translation] (together collectively referred to as 'Insolvency Proceedings').

In addition to Insolvency Proceedings, the T2S DCA holder, any of its assets, or any branch it may have in [jurisdiction] may become subject in [jurisdiction] to [list any applicable moratorium, receivership, or any other proceedings as a result of which payment orders to and/or from the T2S DCA holder may be suspended, or limitations can be imposed in relation to such payment orders, or similar proceedings, including crisis prevention and crisis management measures equivalent to those defined in Directive 2014/59/EU, in original language and English translation] (hereinafter collectively referred to as 'Proceedings').

3.2.b. *Insolvency treaties*

[jurisdiction] or certain political subdivisions within [jurisdiction], as specified, is/are party to the following insolvency treaties: [specify, if applicable which have or may have an impact on this Opinion].';

(i) in Appendix VI, the third and fourth lines of the table are replaced by the following:

'T2S DCA to T2S DCA liquidity transfer orders	14,1 euro cent	per transfer
Intra-balance movement (i.e. blocking, unblocking, reservation of liquidity etc.)	9,4 euro cent	per transaction';

3. Annex IIb is amended as follows:

(a) in Article 5(2), point (a) is replaced by the following:

'(a) treasury departments of central or regional governments of Member States;';

(b) in Article 5(2), point (c) is replaced by the following:

'(c) (i) investment firms established in the Union or the EEA, including when they act through a branch established in the Union or the EEA; and

(ii) investment firms established outside the EEA, provided that they act through a branch established in the Union or the EEA;';

(c) in Article 6(1)(b), point (ii) is replaced by the following:

'(ii) for credit institutions or investment firms established outside the EEA, acting through a branch established in the Union or the EEA, provide a country opinion in the form specified in Appendix II, unless the information and representations to be provided in such country opinion have already been obtained by the [insert name of CB] in another context; and';

(d) Article 14(8) is replaced by the following:

'8. TIPS DCA holders shall immediately inform the [insert name of CB] if an event of default occurs in relation to themselves or if they are subject to crisis prevention measures or crisis management measures within the meaning of Directive 2014/59/EU or any other equivalent applicable legislation.';

(e) Article 21 is amended as follows:

(i) paragraph 5 is replaced by the following:

'5. The [insert name of CB] may impose additional security requirements, in particular with regard to cybersecurity or the prevention of fraud, on all TIPS DCA holders.';

(ii) the following paragraph 6 is added:

'6. TIPS DCA holders using instructing parties in line with Article 7(2) or (3), or allowing access to their TIPS DCA as set out in Article 8(1), shall be deemed to have addressed the risk stemming from such use or access in accordance with the additional security requirements imposed upon them.';

(f) Article 26(4) is replaced by the following:

'4. In the event that the [insert name of CB] suspends or terminates a TIPS DCA holder's participation in TARGET2-[insert CB/country reference] under paragraph 1 or 2, the [insert name of CB] shall immediately inform, by means of a ICM broadcast message, other CBs and PM account holders in all of the TARGET2 component systems of such suspension or termination. Such message shall be deemed to have been issued by the home CB of the PM account holder that received the message.

Linked PM account holders shall have the responsibility to inform their Linked TIPS DCA holders of the suspension or termination of any TIPS DCA holder's participation in TARGET2-[insert CB/country reference].

In the event that the suspension or termination of a TIPS DCA holder's participation in TARGET2-[insert CB/country reference] occurs during the technical maintenance window, the ICM broadcast message shall be sent after the start of daytime processing on the next TARGET2 business day.';

(g) in Article 29(3), point (c) is replaced by the following:

'(c) supervisory, resolution and oversight authorities of Member States and the Union, including CBs, to the extent that this is necessary for the performance of their public tasks, and provided in all such cases that the disclosure is not in conflict with the applicable law.';

(h) in Appendix II, under the heading 'Terms of reference for country opinions for non-EEA TIPS DCA holders in TARGET2, paragraph 3.2 is replaced by the following:

'3.2. General insolvency and crisis management issues

3.2.a. *Types of insolvency and crisis management proceedings*

The only types of insolvency proceedings (including composition or rehabilitation) which, for the purpose of this Opinion, shall include all proceedings in respect of the TIPS DCA holder's assets or any branch it may have in [jurisdiction] to which the TIPS DCA holder may become subject in [jurisdiction], are the following: [list proceedings in original language and English translation] (together collectively referred to as 'Insolvency Proceedings').

In addition to Insolvency Proceedings, the TIPS DCA holder, any of its assets, or any branch it may have in [jurisdiction] may become subject in [jurisdiction] to [list any applicable moratorium, receivership, or any other proceedings as a result of which payment orders to and/or from the TIPS DCA holder may be suspended, or limitations can be imposed in relation to such payment orders, or similar proceedings, including crisis prevention and crisis management measures equivalent to those defined in Directive 2014/59/EU, in original language and English translation] (hereinafter collectively referred to as 'Proceedings').

3.2.b. *Insolvency treaties*

[jurisdiction] or certain political subdivisions within [jurisdiction], as specified, is/are party to the following insolvency treaties: [specify, if applicable which have or may have an impact on this Opinion].';

4. Annex III is amended as follows:

in paragraph 2, point (c) is replaced by the following:

'(c) treasury departments of central or regional governments of Member States and public sector bodies of Member States authorised to hold accounts for customers;';

5. Annex IV is amended as follows:

(a) in paragraph 1 (Definitions), point (7) is replaced by the following:

'(7) "Information and Control Module (ICM)" means the SSP module that allows PM account holders to obtain online information and gives them the possibility to submit liquidity transfer orders, manage liquidity and, if applicable, initiate backup payment orders or payment orders to the Contingency Solution in a contingency,';

(b) in paragraph 1 (Definitions), the following point (15) is added:

'(15) "Contingency Solution" means the SSP functionality that processes very critical and critical payments in contingency.';

(c) in point (1)(d)(iii) of paragraph 18, the third and fourth lines of the table are replaced by the following:

'T2S DCA to T2S DCA liquidity transfer orders	14,1 euro cent	per transfer
Intra-balance movement (i.e. blocking, unblocking, reservation of liquidity etc.)	9,4 euro cent	per transaction';

6. Annex V is amended as follows:

(a) in Article 4, point (14) is replaced by the following:

'(14) Article 28 is modified as follows:

(a) paragraph 1 is replaced by the following:

'1. Participants using internet-based access shall implement adequate security controls, in particular those specified in Appendix IA to Annex V, to protect their systems from unauthorised access and use. Participants shall be exclusively responsible for the adequate protection of the confidentiality, integrity and availability of their systems.';

(b) paragraph 4 is replaced by the following:

'4. Participants using internet-based access shall provide the [insert name of CB] with their TARGET2 self-certification.'; and

(c) the following paragraph 6 is added:

'6. Participants using internet-based access shall inform [insert name of CB] immediately of any event that may affect the validity of the certificates, in particular those events specified in Appendix IA to Annex V, including, without limitation, any loss or improper use.'..

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

Only the original UN/ECE texts have legal effect under international public law. The status and date of entry into force of this Regulation should be checked in the latest version of the UN/ECE status document TRANS/WP.29/343, available at:

http://www.unece.org/trans/main/wp29/wp29wgs/wp29gen/wp29fdocstts.html

Regulation No 29 of the Economic Commission for Europe of the United Nations (UN/ECE) — Uniform provisions concerning the approval of vehicles with regard to the protection of the occupants of the cab of a commercial vehicle [2019/1850]

Incorporating all valid text up to:
Supplement 4 to the 03 series of amendments — Date of entry into force: 28 May 2019

Contents

1. SCOPE

This Regulation applies to vehicles of category N ([1]) with regard to the protection of the occupants of the cab.

2. DEFINITIONS

For the purposes of this Regulation:

2.1. 'Approval of a vehicle' means the approval of a vehicle type pursuant to the requirements of this Regulation, with regard to the protection of the occupants of the cab of a vehicle in the event of head-on impact or of overturning.

2.2. 'Vehicle type' means a category of motor vehicle which does not differ in such essential respects as:

2.2.1. The dimensions, shapes and materials of the components of the vehicle cab; or

2.2.2. The manner of attachment of the cab to the chassis frame;

2.3. 'Transverse plane' means a vertical plane perpendicular to the longitudinal plane of the vehicle;

2.4. 'Longitudinal plane' means a plane parallel to the median longitudinal plane of the vehicle;

2.5. 'Cab-over-engine vehicle' means a vehicle where more than half of the engine length is rearward of the foremost point of the windshield base and the steering wheel hub is in the forward quarter of the vehicle length.

2.6. 'R point' means the seating reference point as defined in Annex 4, paragraph 2.4.

2.7. 'H-point' means the point defined in Annex 4, paragraph 2.3.

2.8. 'Test A' means a frontal impact test intended to evaluate the resistance of a cab in frontal impact accident.

2.9. 'Test B' means an impact test to the A-pillars of the cab intended to evaluate the resistance of a cab in a 90° rollover accident with subsequent impact.

2.10. 'Test C' means a cab roof strength test intended to evaluate the resistance of a cab in a 180° rollover accident.

2.11. 'A-pillar' means the foremost and outermost roof support.

2.12. 'Windscreen' means the frontal glazing of the vehicle situated between the A-pillars.

([1]) As defined in the Consolidated Resolution on the Construction of Vehicles (R.E.3.), document ECE/TRANS/WP.29/78/Rev.6, para. 2.

2.13. 'Vehicles of category N_1 derived from M_1"means those vehicles of N_1 category which, forward of the A-pillars, have the same general structure and shape as a pre-existing M_1 category vehicle.'

2.14. 'Separate cab' means a cab attached to the vehicle's frame by specific links and which has no common part with the cargo area.

3. APPLICATION FOR APPROVAL

3.1. The application for approval of a vehicle type with regard to the protection of the occupants of the cab of a vehicle shall be submitted by the vehicle manufacturer or by his duly accredited representative.

3.2. It shall be accompanied by drawings of the vehicle, showing the position of the cab on the vehicle and the manner of its attachment, and by sufficiently detailed drawings relating to the structure of the cab, all the said drawings being submitted in triplicate. A model for the information document relating to the construction features is given in Annex 1, Part 1.

4. APPROVAL

4.1. If the vehicle type submitted for approval pursuant to this Regulation meets the requirements of paragraph 5 hereof, approval of that vehicle type shall be granted.

4.2. An approval number shall be assigned to each type approved. Its first two digits (at present 03 corresponding to the 03 series of amendments) shall indicate the series of amendments incorporating the most recent major technical amendments made to the Regulation at the time of issue of the approval. The same Contracting Party may not assign the same number to another vehicle type within the meaning of paragraph 2.2 above.

4.3. Notice of approval or of extension or of refusal or of withdrawal of approval or production definitely discontinued of a vehicle type pursuant to this Regulation shall be communicated by the Parties to the Agreement which apply this Regulation by means of a form conforming to the model in annex 1 to this Regulation.

4.4. There shall be affixed, conspicuously and in a readily accessible place specified on the approval form, to every vehicle conforming to a vehicle type approved under this Regulation, an international approval mark consisting of:

4.4.1. A circle surrounding the letter 'E' followed by the distinguishing number of the country which has granted the approval ([2]) and

4.4.2. the number of this Regulation, followed by the letter 'R', a dash and the approval number, to the right of the circle prescribed in paragraph 4.4.1;

4.5. If the vehicle conforms to a vehicle type approved, under one or more other Regulations annexed to the Agreement, in the country which has granted approval under this Regulation, the symbol prescribed in paragraph 4.4.1 need not be repeated; in such a case the additional numbers and symbols of all the Regulations under which approval has been granted in the country which has granted approval under this Regulation shall be placed in vertical columns to the right of the symbol prescribed in paragraph 4.4.1.

4.6. The approval mark shall be clearly legible and be indelible.

4.7. The approval mark shall be placed close to or on the vehicle data plate.

4.8. Annex 2 to this Regulation gives examples of arrangements of approval marks.

5. REQUIREMENTS

5.1. General requirements

5.1.1. The cab of the vehicle shall be so designed and so attached to the vehicle as to eliminate to the greatest possible extent the risk of injury to the occupants in the event of an accident.

([2]) The distinguishing numbers of the Contracting Parties to the 1958 Agreement are reproduced in Annex 3 to the Consolidated Resolution on the Construction of Vehicles (R.E.3), document ECE/TRANS/WP.29/78/Rev. 6 — http://www.unece.org/trans/main/wp29/wp29wgs/wp29gen/wp29resolutions.html

5.1.2. Vehicles of categories N_1 and vehicles of categories N_2 with a gross vehicle mass not exceeding 7,5 t shall be subjected to the tests A and C, as described in Annex 3, paragraphs 5 and 7.

However a vehicle type which meets the frontal impact requirements of Regulation No 12 or Regulation No 33 or Regulation No 94, and vehicles of category N_1, derived from M_1 approved to Regulation No 94, may be considered to have satisfied the requirements on frontal impact (test A).

Test C shall only be conducted on vehicles which have a separate cab.

5.1.3. Vehicles of categories N_3 and vehicles of categories N_2 with a gross vehicle mass exceeding 7,5 t shall be subjected to the tests A, B, and C, as described in Annex 3, paragraphs 5, 6, and 7.

Test C shall only be conducted on vehicles which have a separate cab.

5.1.4. Test A (frontal impact) shall only be conducted on cab-over-engine vehicles.

5.1.5. One, two or three cabs, at the manufacturer's choice, may be used for the purpose of demonstrating compliance with paragraphs 5.1.2 or 5.1.3 above. However both phases in test C, if applicable, shall be conducted on the same cab.

5.1.6. None of the tests A, B, C, need be carried out if the manufacturer can show by computer simulation or calculations of the strength of the component parts of the cab or by other means to the satisfaction of the Technical Service that the cab will not undergo deformation dangerous to the occupants (penetration into the survival space) if subjected to the conditions of the tests.

5.2. Survival space required after the test or tests

5.2.1. After undergoing each of the tests referred to in paragraphs 5.1.2 or 5.1.3, the cab of the vehicle shall exhibit a survival space allowing accommodation of the manikin defined in Annex 3, Appendix 2, on the seat, when the latter is in its median position, without contact between the test manikin and non-resilient parts with a Shore-Hardness of 50 or more. No account shall be taken of non-resilient parts which can be moved away without any tools from the test manikin by using a force of less than 100 N. To facilitate installation, the manikin may be inserted in dismantled form and assembled in the cab. For this purpose, the seat shall be adjusted to its most rearward position and the manikin completely assembled and so placed that its H point coincides with the R point. The seat shall then be moved forward to its median position for the assessment of the survival space. As an alternative to the test manikin defined in Annex 3, Appendix 2, a fiftieth percentile Hybrid II or III male dummy, with or without measuring instrumentation, the description of which is given in Regulation No 94, may be used.

5.2.2. The space so defined shall be verified for every seat provided by the manufacturer.

5.3. Other conditions

5.3.1. During the tests the components by which the cab is secured to the chassis frame may be distorted or broken, provided that the cab remains attached to the chassis frame by standard fixture attachments and does not unintentionally move, shift or rotate about the attachment points.

5.3.2. None of the doors shall open during the tests, but the doors shall not be required to open after testing.

6. MODIFICATION AND EXTENSION OF APPROVAL OF THE VEHICLE TYPE

6.1. Every modification of the vehicle type shall be notified to the Type Approval Authority which approved the vehicle type. The Type Approval Authority may then either:

6.1.1. Consider that the modifications made are unlikely to have an appreciable adverse effect, and that in any case the vehicle still complies with the requirements;

6.1.2. Or require a further test report from the Technical Service responsible for conducting the tests.

6.2. Confirmation or refusal of approval, specifying the alterations, shall be communicated by the procedure specified in paragraph 4.3 above to the Contracting Parties to the Agreement which apply this Regulation.

6.3. The competent authority issuing an extension of approval shall assign a series number for such an extension and inform thereof the other Parties to the 1958 Agreement applying this Regulation by means of a communication form conforming to the model in Annex 1 to this Regulation.

7. CONFORMITY OF PRODUCTION

The conformity of production procedures shall comply with those set out in the Agreement, (Schedule 1, E/ECE/TRANS/505/Rev.3), with the following requirements:

7.1. A vehicle approved pursuant to this Regulation shall be so manufactured as to conform to the type approved by meeting the requirements of paragraph 5 above.

7.2. The Competent Authority which has granted approval may at any time verify the conformity of control methods applicable to each production unit. The normal frequency of such inspections shall be once every two years.

8. PENALTIES FOR NON-CONFORMITY OF PRODUCTION

8.1. The approval granted in respect of a vehicle type, pursuant to this Regulation, may be withdrawn if the requirement laid down in paragraph 7.1 above is not complied with.

8.2. If a Party to the Agreement which applies this Regulation withdraws an approval it has previously granted, it shall forthwith so notify the other Contracting Parties applying this Regulation by means of a communication form conforming to the model in Annex 1 to this Regulation.

9. PRODUCTION DEFINITELY DISCONTINUED

If the holder of the approval completely ceases to manufacture a type of vehicle approved in accordance with this Regulation, he shall so inform the authority which granted the approval. Upon receiving the relevant communication, that authority shall inform thereof the other Parties to the 1958 Agreement which apply this Regulation by means of a communication form conforming to the model in Annex 1 to this Regulation.

10. TRANSITIONAL PROVISIONS

10.1. As from the official date of entry into force of the 02 series of amendments, no Contracting Party applying this Regulation shall refuse to grant ECE approval under this Regulation as amended by the 02 series of amendments.

10.2. As from 1 October 2002 Contracting Party applying this Regulation shall grant ECE approvals only if the requirements of this Regulation, as amended by the 02 series of amendments are satisfied.

10.3. As from 1 October 2006 Contracting Party applying this Regulation may refuse to recognise approvals which were not granted in accordance with the 02 series of amendments to this Regulation.

10.4. As from the official date of entry into force of the 03 series of amendments, no Contracting Party applying this Regulation shall refuse to grant ECE approval under this Regulation as amended by the 03 series of amendments.

10.5. As from 72 months after the date of entry into force of the 03 series of amendments Contracting Parties applying this Regulation shall grant ECE approval under this Regulation to the new types of cabs only if the requirements of this Regulation, as amended by the 03 series of amendments, are satisfied.

10.6. Contracting Parties applying this Regulation shall not refuse to grant extensions of approval to the preceding series of amendments to this Regulation.

10.7. Contracting Parties applying this Regulation shall continue to grant approvals to those types of vehicles which comply with the requirements of this Regulation as amended by the preceding series of amendments during the 72 months' period which follows the date of entry into force of the 03 series of amendments.

10.8. No Contracting Party applying this Regulation shall refuse national or regional type approval of a vehicle type approved to the 03 series of amendments to this Regulation.

10.9. Even after the entry into force of the 03 series of amendments to this Regulation, approvals of the vehicles to the preceding series of amendments to this Regulation shall remain valid and Contracting Parties applying this Regulation shall continue to accept them.

11. NAMES AND ADDRESSES OF TECHNICAL SERVICES RESPONSIBLE FOR CONDUCTING APPROVAL TESTS AND OF TYPE APPROVAL AUTHORITIES

The Parties to the Agreement which apply this Regulation shall communicate to the Secretariat of the United Nations the names and addresses of the Technical Services conducting approval tests, and of the Type Approval Authorities which grant approval and to which forms certifying approval or extension, or refusal or withdrawal of approval, issued in other countries, are to be sent.

ANNEX 1

ECE TYPE-APPROVAL DOCUMENTATION

PART 1

MODEL INFORMATION DOCUMENT

Pursuant to Regulation No 29 relating to type-approval of the cab

The following information, if applicable, must be supplied in triplicate and include a list of contents. Any drawings must be supplied in appropriate scale and in sufficient detail on size A4 or on a folder of A4 format. Photographs, if any, must show sufficient detail.

1. General …

1.1. Make (trade name of manufacturer): …

1.2. Type: …

1.3. Means of identification of type, if marked on the vehicle: …

1.3.3. Location of that marking: …

1.4. Category of vehicle ([1]): …

1.5. Name and address of manufacturer: …

1.6. Address(es) of assembly plant(s): …

2. General Construction Characteristics of the Vehicle …

2.1. Photographs and/or drawings of a representative vehicle: …

2.2. Dimensional drawing of the whole vehicle: …

2.3. Number of axles and wheels: …

2.6. Position and arrangement of the engine: …

2.7. Driving cab (cab-over-engine or bonnet) ([2]) …

2.8. Hand of drive: …

3. Masses and Dimensions (in kg and mm) (refer to drawing where applicable) …

3.1. Technically permissible maximum laden mass stated by the manufacturer: …

3.2. Technical permissible maximum mass for the front axle or axles of the vehicle: …

4. Cab …

4.1. Type of cab: (normal/sleeper/top-sleeper) ([3]): …

4.2. Materials used and methods of construction: …

([1]) As defined in the Consolidated Resolution on the Construction of Vehicles (R.E.3.), document ECE/TRANS/WP.29/78/Rev.6, para. 2

([2]) Cab-over-engine means a configuration in which more than half of the engine length is rearward of the foremost point of the windshield base and the steering wheel hub in the forward quarter of the vehicle length.

([3]) Delete where not applicable (there are cases where nothing needs to be deleted when more than one entry is applicable).

4.3. Door configuration and number of doors: …

4.4. Drawings of door latches and retention components and their position in the doors: …

4.5. Number of seats: …

4.6. R-points: …

4.7. Detailed description of the cab of the vehicle type including its dimensions, configuration and constituent materials and its attachment to any chassis frame: …

4.8. Drawings of the cab and those parts of its interior arrangement which have an influence on the residual space: …

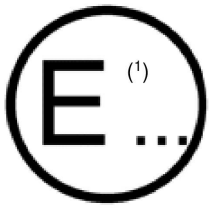
5. Steering …

5.1. Schematic diagram(s) of the steering control(s): …

5.2. Range and method of adjustment (if any), of the steering control: …

PART 2

Communication
(maximum format: A4 (210 × 297 mm))



Issued by: Name of administration:

.....

.....

concerning (2): Approval granted

Approval extended

Approval refused

Approval withdrawn

Production definitively discontinued

of a vehicle type with regard to protection of the occupants of the cab of a vehicle pursuant to Regulation No 29.

Approval No: ..... Extension No: .....

1. Trade name or mark of the vehicle: .....
2. Vehicle type:.....
3. Manufacturer's name and address:.....
4. If applicable, name and address of manufacturer's representative:.....
5. Brief description of the cab's design and method of attachment:.....
6. Vehicle submitted for approval on:.....
7. Technical Service responsible for conducting approval tests: .....
8. Date of report issued by that service: .....
9. Number of report issued by that service:.....
10. Approval granted/refused/extended/withdrawn (2).....
11. Position of approval mark on the vehicle:.....
12. Place: .....
13. Date: .....
14. Signature:.....

The list of documents deposited with the Type Approval Authority which has granted approval is annexed to this communication and may be obtained on request.

(1) Distinguishing number of the country which has granted, extended, refused or withdrawn approval (see approval provisions in the Regulation).
(2) Strike out which does not apply.

ANNEX 2

ARRANGEMENTS OF APPROVAL MARKS

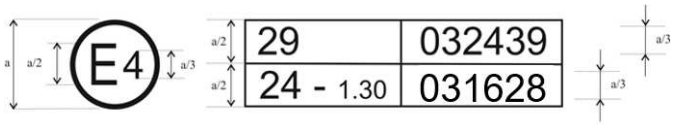
MODEL A

(See paragraph 4.4 of this Regulation)

a = 8 mm min.

The above approval mark affixed to a vehicle shows the vehicle type concerned has with regard to the protection of the occupants of the cab of a commercial vehicle, been approved in the Netherlands (E 4), under the number 03249. The first two digits of the approval number indicate the Regulation No 29 already included the 03 series of amendments when the approval was given.

MODEL B



a = 8 mm min.

The above approval mark affixed to a vehicle shows that the vehicle type concerned has been approved in the Netherlands (E 4) pursuant to Regulations Nos 29 and 24 ([1]) (In the case of the latter Regulation the corrected absorption coefficient is 1,30 m-1). The approval numbers indicate that on the dates on which these approvals were granted, Regulations Nos 29 and 24 included the 03 series of amendments.

([1]) The second number is given merely as an example.

ANNEX 3

TEST PROCEDURE

1. Doors

Before the tests the doors of the cab shall be closed but not locked.

2. Engine

For test A the engine, or a model equivalent thereto in mass, dimensions and mounting, shall be fitted to the vehicle.

3. Cab

The cab shall be equipped with the steering mechanism, steering wheel, instrument-panel and the driver and passenger seats. The steering wheel and the seating position shall be adjusted to their positions for normal use as prescribed by the manufacturer.

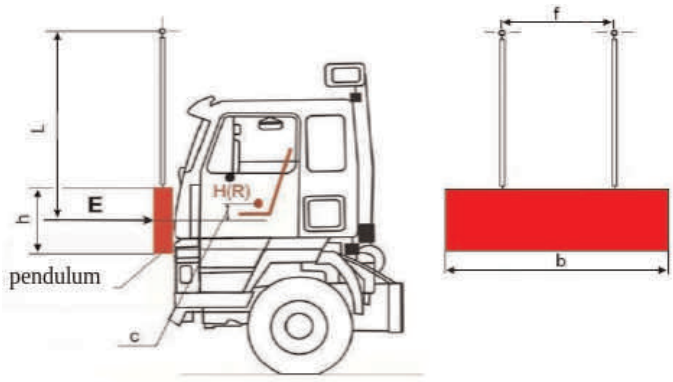
4. Anchorage of the cab

For test A, the cab shall be mounted on a vehicle. For tests B, C the cab shall, at the manufacturer's choice, be mounted either on a vehicle or on a separate frame. The vehicle or frame shall be secured in the manner prescribed in Appendix 1 to this annex.

5. Front impact test (test A)

Figure 1

Front impact test (test A)



5.1. The impactor shall be made of steel and its mass shall be evenly distributed; its mass shall not be less than 1 500 kg. Its striking surface, rectangular and flat, shall be 2 500 mm wide and 800 mm high (see b and h on Figure 1). Its edges shall be rounded to a radius of curvature of 10 mm ±5 mm.

5.2. The impactor assembly shall be of rigid construction. The impactor shall be freely suspended by two beams rigidly attached to it and spaced not less than 1 000 mm apart (see f on Figure 1). The beams shall be not less than 3 500 mm long from the axis of suspension to the geometric centre of the impactor (L on Figure 1).

5.3. The impactor shall be so positioned that in the vertical position:

5.3.1. Its striking face is in contact with the foremost part of the vehicle;

5.3.2. Its centre of gravity is c = 50 + 5/− 0 mm below the R point of the driver's seat, and

5.3.3. its centre of gravity is in the median longitudinal plane of the vehicle.

5.4. The impactor shall strike the cab at the front in the direction towards the rear of the cab. The direction of impact shall be horizontal and shall be parallel to the median longitudinal plane of the vehicle.

5.5. The impact energy shall be:

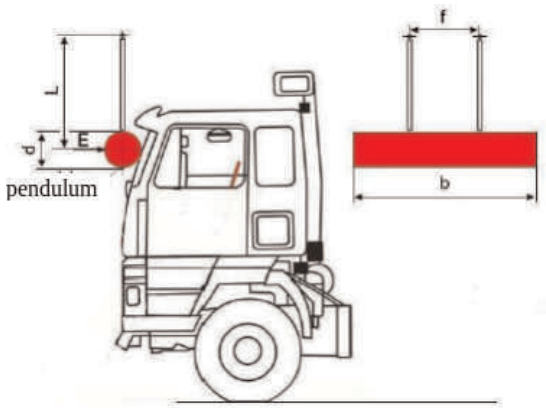
5.5.1. 29,4 kJ in the case of vehicles of category N_1 and of vehicles of category N_2 with a gross vehicle mass not exceeding 7,5 t.

5.5.2. 55 kJ in the case of vehicles of category N_3 and of vehicles of category N_2 with a gross vehicle mass exceeding 7,5 t.

6. Front pillar impact test (Test B)

Figure 2

Front pillar impact test (Test B)



6.1. The impactor shall be rigid and its mass shall be evenly distributed; its mass shall not be less than 1 000 kg. The impactor shall be cylindrical with a diameter d of the cylinder of 600 ±50 mm and a length b of not less than 2 500 mm. Its edges shall be rounded to a radius of curvature of not less than 1,5 mm.

6.2. The impactor assembly shall be of rigid construction. The impactor shall be freely suspended by two beams rigidly attached to it and spaced not less than f = 1 000 mm apart. The beams shall not be less than L = 3 500 mm long from the axis of suspension to the geometric centre of the impactor.

6.3. The impactor shall be so positioned that when its suspension is in the vertical position:

6.3.1. Its striking face is in contact with the foremost part of the cab;

6.3.2. Its median longitudinal line is horizontal and perpendicular to the median longitudinal vertical plane of the cab;

6.3.3. Its centre of gravity is midway between the lower and the upper windscreen frame, as measured along the windscreen and along the median longitudinal vertical plane of the cab;

6.3.4. Its centre of gravity is in the median longitudinal plane of the cab;

6.3.5. Its length is equally distributed over the width of the vehicle, overlapping the full width of both A-pillars.

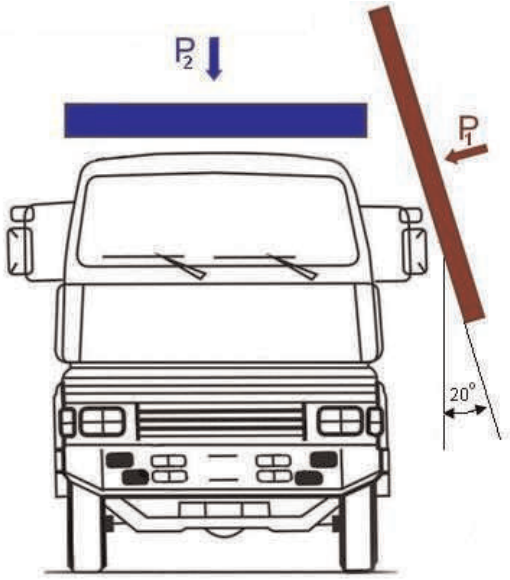
6.4. The impactor shall strike the cab at the front in the direction towards the rear of the cab. The direction of impact shall be horizontal and shall be parallel to the median longitudinal plane of the vehicle.

6.5. The impact energy shall be 29,4 kJ

7. Roof strength test (Test C)

Figure 3

Roof strength test (Test C)



7.1. For vehicles of category N_2 with a gross vehicle mass exceeding 7,5 t and of category N_3, both tests as described in paragraphs 7.3 and 7.4 below, in that order, shall be conducted on the same cab.

7.2. For vehicles of category N_2 with a gross vehicle mass not exceeding 7,5 t and of category N_1, only the test as described in paragraph 7.4 below shall be conducted.

7.3. Dynamic pre-loading of vehicles of category N_2 with a gross vehicle mass exceeding 7,5 t and of category N_3 (see P_1 on Figure 3).

7.3.1. The impactor shall be rigid and its mass shall be evenly distributed; its mass shall not be less than 1 500 kg.

7.3.2. The striking surface of the impactor shall be rectangular and flat. Its dimensions shall be sufficiently large such that, when positioned in accordance with paragraph 7.3.3 below, no contact will occur between the cab and the edges of the impactor.

If a pendulum is used as an impactor, it shall be freely suspended by two beams rigidly attached to it and spaced not less than 1 000 mm apart. The distance from the axis of suspension to the geometric centre of the impactor shall not be less than 3 500 mm.

7.3.3. The impactor and/or the cab shall be so positioned that, at the moment of impact:

7.3.3.1. The striking face of the impactor is at an angle of 20° to the median longitudinal plane of the cab. Either the impactor or the cab may be tilted. If the impactor is a pendulum, the cab shall not be tilted and shall be installed in a horizontal position;

7.3.3.2. The striking face of the impactor covers the whole length of the top side of the cab;

7.3.3.3. The median longitudinal line of the impactor is horizontal and parallel to the median longitudinal plane of the cab.

7.3.4. The impactor shall strike the upper side of the cab such that at the time of the impact the prescriptions of paragraph 7.3.3 above are satisfied. The direction of impact shall be perpendicular to the surface of the impactor and perpendicular to the median longitudinal line of the cab. Either the impactor or the cab may be moving, as long as the positioning requirements are satisfied at the moment of impact.

7.3.5. The impact energy shall be minimum 17,6 kJ.

7.4. Roof strength test (see P_2 on Figure 3)

7.4.1. The loading device shall be made of steel and its mass shall be evenly distributed.

7.4.2. The loading face of the device shall be rectangular and flat. Its dimensions shall be sufficiently large such that, when positioned in accordance with paragraph 7.4.4 below, no contact will occur between the cab and the edges of the device.

7.4.3. A linear bearing system may be included between the device and its supporting structure to allow for lateral motion of the cab roof away from the side that was impacted in the pre-load phase of paragraph 6.3, if applicable.

7.4.4. The loading device shall be so positioned that, during the test:

7.4.4.1. It is parallel to the x-y plane of the chassis;

7.4.4.2. It moves parallel to the vertical axis of the chassis;

7.4.4.3. Its loading face covers the whole area of the cab roof.

7.4.5. A static load shall be applied by the loading device to the roof of the cab, corresponding to the maximum mass authorised for the front axle or axles of the vehicle, subject to a maximum of 98 kN.

Appendix 1

INSTRUCTIONS FOR SECURING VEHICLES TO THE TEST BED

1. General instructions for securing

1.1. Measures shall be taken to ensure that the vehicle does not shift appreciably during the test. For this purpose the hand-brake shall be applied, a gear engaged and the front wheels wedged with chocks.

1.2. Anchoring chains or ropes

Each anchoring chain or rope shall be of steel and shall be capable of withstanding a tractive load of at least 10 tons.

1.3. Blocking of the chassis frame

The longitudinal members of the chassis frame shall be supported on wooden blocks, rigid composite blocks and/or adjustable metal brackets across their full width and over a length of not less than 150 mm. The front edges of the blocks must not be situated forward of the rearmost point of the cab, nor rearward of the mid-point of the wheel base (see Figure 1 below). At the manufacturer's request the chassis frame shall be set in the attitude it takes up when loaded.

1.4. Longitudinal attachment

Rearward movement of the chassis frame shall be limited by chains or ropes A attached to the front of the chassis frame symmetrically in relation to its longitudinal axis, the points of attachment being not less than 600 mm apart. The chains or ropes shall when tensioned form a downward angle of not more than 25° with the horizontal and their projection on a horizontal plane shall form an angle of not more than 10° with the longitudinal axis of the vehicle (see Figure 1 below). The chains or ropes may cross one another.

1.5. Tensioning of chains or ropes and rear attachment

For tests A and B, the chain or rope C shall, to begin with, be placed under a load of approximately 1 kN. All slack in the four chains or ropes A and B shall then be taken up and chain or rope C shall be subjected to a tensile stress of not less than 10 kN. The angle of chain or rope C with the horizontal shall not exceed 15°. A vertical blocking force of not less than 500 N shall be applied at point D between the chassis frame and the ground (see Figure 1 below). For test C, the chains or ropes B as described above shall be replaced by the chains or ropes E and F (see Figure 2 below).

1.6. Equivalent mounting

At the request of the manufacturer the test may be carried out with the cab mounted on a special frame, on condition that this method of mounting is shown to be equivalent to mounting on the vehicle.

2. Frontal impact

2.1. Cab mounted on the vehicle

Test A shall be applied to a cab mounted on the vehicle as described in paragraph 1.

2.1.1. Lateral attachment

Lateral movement shall be limited by chains or ropes B attached to the chassis frame symmetrically in relation to its longitudinal axis. The points of attachment to the chassis shall be not more than 5 m and not less than 3 m from the front of the vehicle. The chains or ropes shall when tensioned form a downward angle of not more than 20° with the horizontal and their projection on a horizontal plane shall form an angle of not less than 25° and not more than 45° with the longitudinal axis of the vehicle (see Figure 1 below).

2.2. Cab mounted on a frame

Measures shall be taken to ensure that the cab does not shift appreciably during the test.

3. Front pillars impact

3.1. Cab mounted on the vehicle.

Test B shall be applied to a cab mounted on the vehicle as described in paragraph 1.

3.1.1. Lateral attachment

Lateral movement shall be limited by chains or ropes B attached to the chassis frame symmetrically in relation to its longitudinal axis. The points of attachment to the chassis shall be not more than 5 m and not less than 3 m from the front of the vehicle. The chains or ropes shall when tensioned form a downward angle of not more than 20° with the horizontal and their projection on a horizontal plane shall form an angle of not less than 25° and not more than 45° with the longitudinal axis of the vehicle (see Figure 1 below).

3.2. Cab mounted on a frame

Measures shall be taken to ensure that the cab does not shift appreciably during the test.

4. Roof strength

4.1. Cab mounted on the vehicle

Test C shall be applied to a cab mounted on the vehicle as described in paragraph 1.

4.1.1. Blocking of the chassis frame

Notwithstanding paragraph 1.3 an additional support shall be placed under both sides of the longitudinal members of the chassis frame's front end.

4.1.2. Lateral attachment

Lateral movement shall be limited by chains or ropes E and F attached to the chassis frame symmetrically in relation to its longitudinal axis.

The points of attachment of chains or rope E to the chassis shall be not more than 5 m and not less than 3 m from the front of the vehicle.

The points of attachment of chains or rope F to the chassis shall be between the centre of the front axle and the front of the vehicle.

The chains or ropes shall when tensioned form a downward angle of not more than 20° with the horizontal and their projection on a horizontal plane shall form an angle 90°±5° with the longitudinal axis of the vehicle (see Figure 2 below).

4.2. Cab mounted on a frame

Measures shall be taken to ensure that the frame does not shift appreciably during the test.

Figure 1

Front impact test and front pillars impact test

The cab is mounted on the vehicle

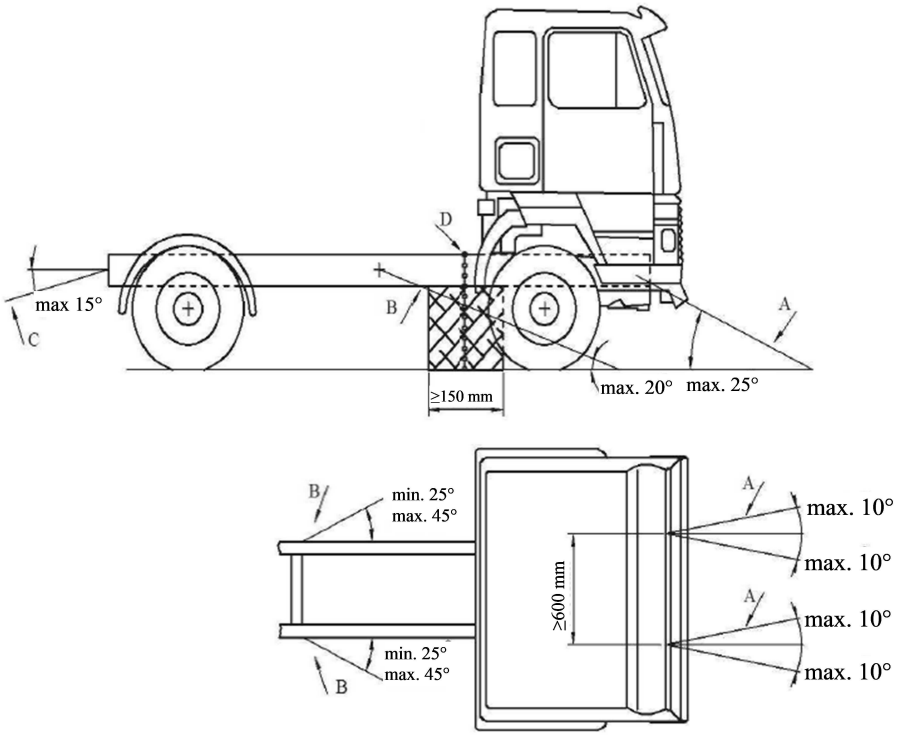
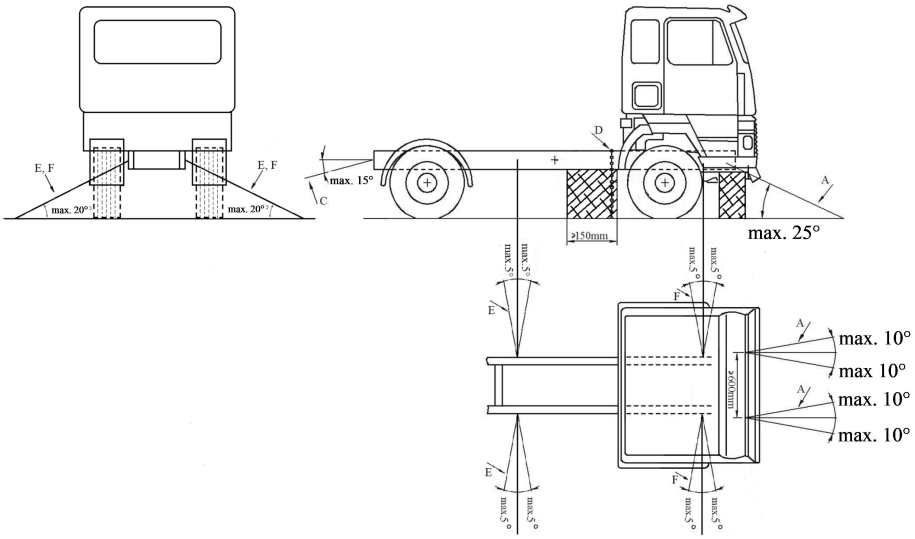


Figure 2

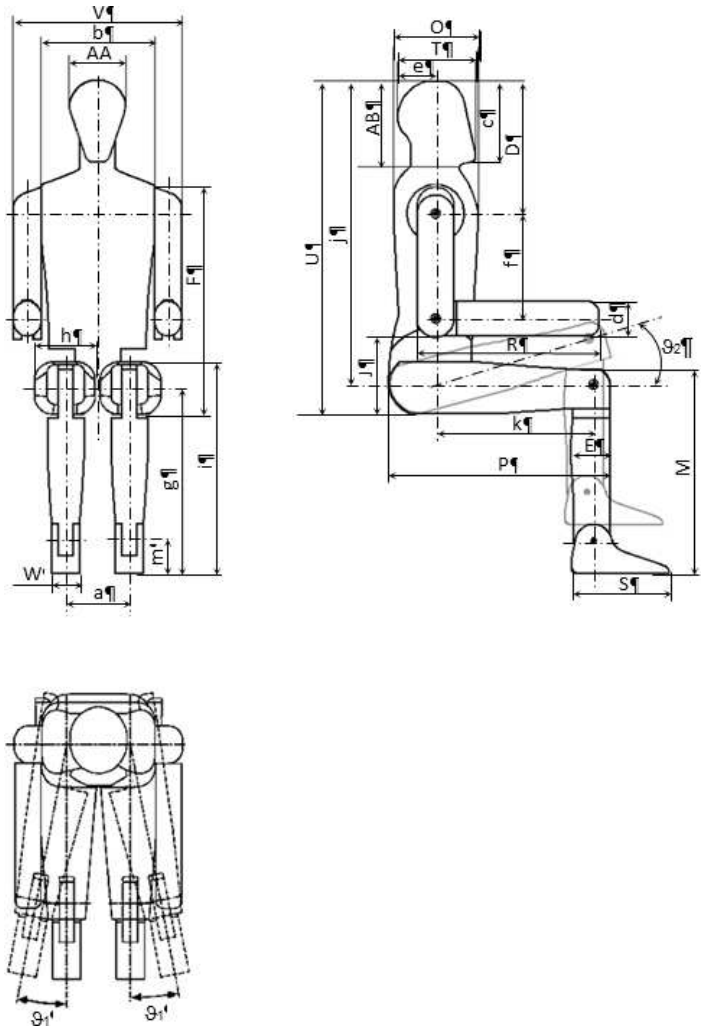
Roof strength test

The cab is mounted on the vehicle



Appendix 2

MANIKIN TO BE USED TO VERIFY THE SURVIVAL SPACE



Dimensions		
Name	Description	Dimensions in mm
AA	Breadth of head	153
AB	Combined height of head and neck	244
D	Distance from top of head to shoulder pivot	359
E	Calf depth	106
F	Height from seat to top of shoulder	620
J	Height of elbow rest	210
M	Knee height	546
O	Chest depth	230
P	Distance from seat back to knee	595
R	Distance from elbow to fingertip	490

Dimensions		
Name	Description	Dimensions in mm
S	Length of foot	266
T	Length of head	211
U	Height from seat to top of head	900
V	Shoulder breadth	453
W	Breadth of foot	77
a	Distance between hip point centres	172
b	Chest breadth	305
c	Height of head and chin	221
d	Forearm thickness	94
e	Distance between vertical centreline of torso and rear of head	102
f	Distance between shoulder pivot and elbow pivot	283
g	Knee pivot height from ground	505
h	Thigh breadth	165
i	Lap height (Sitting)	565
j	Distance from top of head to 'H' point	819
k	Distance between hip pivot and knee pivot	426
m	Ankle pivot height from ground	89
ϑ_1	Lateral rotation of the legs	20°
ϑ_2	Upward rotation of the legs	45°

ANNEX 4

PROCEDURE FOR DETERMINING THE 'H' POINT AND THE ACTUAL TORSO ANGLE FOR SEATING POSITIONS IN MOTOR VEHICLES [1]

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[1] The procedure is described in Annex 1 to the Consolidated Resolution on the Construction of Vehicles (R.E.3), document ECE/TRANS/WP.29/78/Rev.6.

Appendix 1

DESCRIPTION OF THE THREE-DIMENSIONAL 'H' POINT MACHINE (3-D H MACHINE) [1]

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[1] The 3-D H point machine is described in Annex 1, Appendix 1 to the Consolidated Resolution on the Construction of Vehicles (R.E.3), document ECE/TRANS/WP.29/78/Rev.6.

Appendix 2

THREE-DIMENSIONAL REFERENCE SYSTEM [1]

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[1] As described in Annex 1 Appendix 2 to the Consolidated Resolution on the Construction of Vehicles (R.E.3), document ECE/TRANS/WP.29/78/Rev.6.

ANNEX 5

REFERENCE DATA CONCERNING SEATING POSITIONS [1]

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[1] As described in Annex 1, Appendix 3 to the Consolidated Resolution on the Construction of Vehicles (R.E.3), document ECE/TRANS/WP.29/78/Rev.6.

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