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Contents

II *Non-legislative acts*

REGULATIONS

- ★ **Commission Delegated Regulation (EU) 2020/1423 of 14 March 2019 on supplementing Directive (EU) 2015/2366 of the European Parliament and of the Council with regard to regulatory technical standards on the criteria for appointing central contact points within the field of payment services and on the functions of those central contact points ⁽¹⁾ 1**
- ★ **Commission Implementing Regulation (EU) 2020/1424 of 8 October 2020 amending Implementing Regulation (EU) 2020/1017 as regards the budgetary ceilings for 2020 applicable to certain direct support schemes in Belgium, Bulgaria, Denmark, Croatia, Luxembourg and Portugal 4**
- ★ **Commission Implementing Regulation (EU) 2020/1425 of 8 October 2020 granting a Union authorisation for the biocidal product family 'PeridoxRTU Product Family' ⁽¹⁾ 8**

DECISIONS

- ★ **Commission Implementing Decision (EU) 2020/1426 of 7 October 2020 on the harmonised use of radio spectrum in the 5 875-5 935 MHz frequency band for safety-related applications of intelligent transport systems (ITS) and repealing Decision 2008/671/EC (notified under document C(2020) 6773) ⁽¹⁾ 19**

⁽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 DELEGATED REGULATION (EU) 2020/1423

of 14 March 2019

on supplementing Directive (EU) 2015/2366 of the European Parliament and of the Council with regard to regulatory technical standards on the criteria for appointing central contact points within the field of payment services and on the functions of those central contact points

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Directive (EU) 2015/2366 of the European Parliament and of the Council of 25 November 2015 on payment services in the internal market, amending Directives 2002/65/EC, 2009/110/EC and 2013/36/EU and Regulation (EU) No 1093/2010, and repealing Directive 2007/64/EC ⁽¹⁾, and in particular Article 29(7) thereof,

Whereas:

- (1) The requirement to appoint a central contact point in accordance with Article 29(4) of Directive (EU) 2015/2366 should be proportionate to achieving the aims pursued by that Directive, without creating unnecessary burdens on payment institutions operating cross-border. Therefore, it is appropriate to specify proportionate criteria in the form of thresholds relating to the volume and value of the transactions carried out in the host Member State through agents and to the number of agents established in the host Member State. As the competent authority of the host Member State can require payment institutions to report on the activities carried out in the territory of that Member State pursuant to Article 29(2) of Directive (EU) 2015/2366, that authority has the means to obtain the information necessary for applying such criteria. Therefore, those thresholds should be laid down to supplement Article 29(4) of Directive (EU) 2015/2366.
- (2) Where the appointment of a central contact point is required by a Member State pursuant to Article 29(4) of Directive (EU) 2015/2366, that central contact point should primarily ensure adequate communication and information reporting on compliance with the requirements laid down in Titles III and IV of that Directive in the host Member State, including the reporting obligations of the appointing payment institution towards the competent authorities of the host Member State. It should also have a central coordinating role between the appointing payment institution and the competent authorities of the home and the host Member States in order to facilitate supervision of the payment services business conducted in the host Member State through agents under the right of establishment. To that end, the payment institution should ensure that the central contact point is given the necessary resources and has access to the relevant reporting data to comply with its obligations under Directive (EU) 2015/2366.
- (3) This Regulation is based on the draft regulatory technical standards submitted by the European Banking Authority (EBA) to the Commission.

⁽¹⁾ OJ L 337, 23.12.2015, p. 35.

- (4) EBA has conducted open public consultations on the draft regulatory technical standards on which this Regulation is based, analysed the potential related costs and benefits and requested the opinion of the Banking Stakeholder Group established in accordance with Article 37 of Regulation (EU) No 1093/2010 of the European Parliament and of the Council ⁽²⁾,

HAS ADOPTED THIS REGULATION:

Article 1

Criteria for determining when the appointment of a central contact point is appropriate

For the purposes of Article 29(4) of Directive (EU) 2015/2366, requiring payment institutions to appoint a central contact point shall only be considered appropriate where one or more of the following criteria is met:

- (a) the total number of agents through which a payment institution provides any of the payment services referred to in Annex I to Directive (EU) 2015/2366 in a host Member State under the right of establishment is equal to or exceeds 10;
- (b) the total value of payment transactions, including payment transactions initiated when providing payment initiation services, carried out by a payment institution in the host Member State in the last financial year through agents located in the host Member State and operating under either the right of establishment or the freedom to provide services, exceeds EUR 3 million and the payment institution has engaged at least two of those agents under the right of establishment;
- (c) the total number of payment transactions carried out by a payment institution in the host Member State in the last financial year through agents located in the host Member State and operating under either the right of establishment or the freedom to provide services, including the number of payment transactions initiated when providing payment initiation services, exceeds 100 000 and the payment institution has engaged at least two of those agents under the right of establishment.

Article 2

Functions of the central contact point

1. A central contact point that is appointed pursuant to Article 29(4) of Directive (EU) 2015/2366 shall carry out each of the following functions:

- (a) it shall serve as single provider and single point of collection for the purposes of the reporting obligations of the appointing payment institution towards the competent authorities of the host Member State pursuant to Article 29(2) of Directive (EU) 2015/2366 in relation to services provided in the host Member State through agents under the right of establishment;
- (b) it shall serve as single point of contact of the appointing payment institution in communications with the competent authorities of the home and host Member States, in relation to the payment services provided in the host Member State through agents under the right of establishment, including by providing competent authorities with documents and information on request;
- (c) it shall facilitate the on-site inspections by competent authorities of the agents of the appointing payment institution operating in the host Member State under the right of establishment and the implementation of any supervisory measures adopted by the competent authorities of the home or host Member States pursuant to Directive (EU) 2015/2366.

2. Payment institutions shall ensure that a central contact point possesses the necessary resources and has access to all the data necessary for the performance of the functions set out in Article 29(4) of Directive (EU) 2015/2366 and specified in paragraph 1 of this Article.

⁽²⁾ Regulation (EU) No 1093/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Banking Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/78/EC (OJ L 331, 15.12.2010, p. 12).

*Article 3***Entry into force**

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

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

Done at Brussels, 14 March 2019.

For the Commission
The President
Jean-Claude JUNKER

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1424**of 8 October 2020****amending Implementing Regulation (EU) 2020/1017 as regards the budgetary ceilings for 2020 applicable to certain direct support schemes in Belgium, Bulgaria, Denmark, Croatia, Luxembourg and Portugal**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1307/2013 of the European Parliament and of the Council of 17 December 2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy and repealing Council Regulation (EC) No 637/2008 and Council Regulation (EC) No 73/2009 ⁽¹⁾, and in particular Articles 22(1), 36(4), 42(2), 47(3), 51(4) and 53(7) thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) 2020/1017 ⁽²⁾ established the annual budgetary ceilings for certain direct payment schemes for 2020.
- (2) The annual budgetary ceilings set by Implementing Regulation (EU) 2020/1017 are based on the national ceilings laid down in Annex II to Regulation (EU) No 1307/2013 as amended by Commission Delegated Regulation (EU) 2020/756 ⁽³⁾. Delegated Regulation (EU) 2020/756 integrated Member States' decisions as regards the transfers between direct payments and rural development pursuant to Article 14 of Regulation (EU) No 1307/2013 for calendar year 2020.
- (3) However, in order to mitigate the consequences of the COVID-19 pandemic and the ensuing difficulties for the farming sector, Belgium, Bulgaria, Denmark, Croatia, Luxembourg and Portugal notified a review of their decisions as regards the transfers between pillars. The respective ceilings in Annex II to Regulation (EU) No 1307/2013 have subsequently been amended by Commission Delegated Regulation (EU) 2020/1314 ⁽⁴⁾, incorporating the impact of the notified reviewed decisions and amounts.
- (4) Given that the annual budgetary ceilings for 2020 are based on the national ceilings laid down in Annex II to Regulation (EU) No 1307/2013, the changes of the national ceilings entail changes of the annual budgetary ceilings for the Member States concerned. Moreover, some Member States have also reviewed certain allocations to the different schemes to the extent necessary in light of the flexibility review.
- (5) In order to take account of those changes, the budgetary ceilings for the basic payment scheme, the single area payment scheme, the redistributive payment, the payment for agricultural practices beneficial for the climate and the environment, the young farmers scheme and the voluntary coupled support for calendar year 2020 should be recalculated for the Member States concerned.
- (6) Implementing Regulation (EU) 2020/1017 should therefore be amended accordingly.
- (7) As the amendments made by this Regulation affect the application of Implementing Regulation (EU) 2020/1017, which applies from 1 January 2020, this Regulation should apply from the same date.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Committee for Direct Payments,

⁽¹⁾ OJ L 347, 20.12.2013, p. 608.

⁽²⁾ Commission Implementing Regulation (EU) 2020/1017 of 13 July 2020 establishing budgetary ceilings for 2020 applicable to certain direct support schemes provided for in Regulation (EU) No 1307/2013 of the European Parliament and of the Council (OJ L 225, 14.7.2020, p. 1).

⁽³⁾ Commission Delegated Regulation (EU) 2020/756 of 1 April 2020 amending Annexes II and III to Regulation (EU) No 1307/2013 of the European Parliament and of the Council (OJ L 179, 9.6.2020, p. 1).

⁽⁴⁾ Commission Delegated Regulation (EU) 2020/1314 of 10 July 2020 amending Annexes II and III to Regulation (EU) No 1307/2013 of the European Parliament and of the Council as regards the national and net ceilings for direct payments for certain Member States for calendar year 2020 (OJ L 307, 22.9.2020, p.1).

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) 2020/1017 is amended in accordance with the Annex to this Regulation.

Article 2

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

It shall apply from 1 January 2020.

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

Done at Brussels, 8 October 2020.

For the Commission

The President

Ursula VON DER LEYEN

ANNEX

The Annex to Implementing Regulation (EU) 2020/1017 is amended as follows:

- (1) in point I, the entries for Belgium, Denmark, Croatia, Luxembourg and Portugal are replaced by the following:

Belgium	225 124
Denmark	522 054
Croatia	157 075
Luxembourg	24 004
Portugal	290 208'

- (2) in point II, the entry for Bulgaria is replaced by the following:

Bulgaria	412 836'
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- (3) in point III, the entries for Bulgaria, Croatia and Portugal are replaced by the following:

Bulgaria	60 844
Croatia	34 828
Portugal	55 320'

- (4) in point IV, the entries for Belgium, Bulgaria, Croatia, Luxembourg and Portugal are replaced by the following:

Belgium	151 580
Bulgaria	260 016
Croatia	104 484
Luxembourg	10 583
Portugal	205 307'

- (5) in point VI, the entries for Belgium, Bulgaria, Croatia, Luxembourg and Portugal are replaced by the following:

Belgium	9 563
Bulgaria	3 016
Croatia	6 966
Luxembourg	529
Portugal	13 687'

- (6) in point VII, the entries for Belgium, Bulgaria, Croatia, Luxembourg and Portugal are replaced by the following:

Belgium	10 105
Bulgaria	17 334
Croatia	6 966
Luxembourg	706
Portugal	13 687'

(7) in point VIII, the entries for Belgium, Bulgaria, Denmark, Croatia and Portugal are replaced by the following:

Belgium	83 510
Bulgaria	130 008
Denmark	32 863
Croatia	52 242
Portugal	134 204'

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1425**of 8 October 2020****granting a Union authorisation for the biocidal product family ‘PeridoxRTU Product Family’****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

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

Whereas:

- (1) On 26 September 2017, Contec Europe submitted an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for authorisation of a biocidal product family named ‘PeridoxRTU Product Family’ of product-type 2, as described in Annex V to that Regulation, providing written confirmation that the competent authority of Belgium had agreed to evaluate the application. The application was recorded under case number BC-HT057172-25 in the Register for Biocidal Products.
- (2) ‘PeridoxRTU Product Family’ contains peracetic acid, as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012.
- (3) On 27 August 2019, 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 7 April 2020, the Agency submitted to the Commission an opinion ⁽²⁾, including the draft summary of the biocidal product characteristics (‘SPC’) of ‘PeridoxRTU Product Family’ and the final assessment report on the biocidal product family in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that ‘PeridoxRTU Product Family’ 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.
- (6) On 27 April 2020, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for ‘PeridoxRTU Product Family’.
- (8) 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-0023658-0000 is granted to Contec Europe for the making available on the market and use of the biocidal product family ‘PeridoxRTU Product Family’ in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 29 October 2020 until 30 September 2030.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ ECHA opinion of 5 March 2020 on the Union authorisation of ‘PeridoxRTU Product Family’ (ECHA/BPC/247/2020), <https://echa.europa.eu/bpc-opinions-on-union-authorisation>.

Article 2

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

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

Done at Brussels, 8 October 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

PeridoxRTU Product Family

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

Authorisation number: EU-0023658-0000

R4BP asset number: EU-0023658-0000

PART I

FIRST INFORMATION LEVEL**1. ADMINISTRATIVE INFORMATION****1.1. Family name**

Name	PeridoxRTU Product Family
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1.2. Product type(s)

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
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1.3. Authorisation holder

Name and address of the authorisation holder	Name	Contec Europe
	Address	ZI Du Prat, Avenue Paul Duplaix, 56 000 Vannes, France
Authorisation number	EU-0023658-0000	
R4BP asset number	EU-0023658-0000	
Date of the authorisation	29 October 2020	
Expiry date of the authorisation	30 September 2030	

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	Enviro Tech Chemical Services, Inc.
Address of manufacturer	500 Winmoore Way, CA 95 358 Modesto United States
Location of manufacturing sites	500 Winmoore Way, CA 95 358 Modesto United States 724 Phillips Rd 411, AR 72 342 Helena United States

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

Active substance	Peracetic acid
Name of manufacturer	Evonik Peroxid GmbH
Address of manufacturer	Industriestraße 1, 9721 Weißenstein Austria
Location of manufacturing sites	Industriestraße 1, 9721 Weißenstein Austria

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
Peracetic acid		Active Substance	79-21-0	201-186-8	0,23	0,23
Hydrogen Peroxide	Hydrogen Peroxide	Non-active Sub- stance	7722-84-1	231-765-0	4,4	4,4
Acetic Acid	Acetic Acid	Non-active Sub- stance	64-19-7	200-580-7	5,0	5,0

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

Formulation(s)	AL – Any other liquid
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PART II

SECOND INFORMATION LEVEL – META SPC(S)**META SPC 1**1. **META SPC 1 ADMINISTRATIVE INFORMATION**1.1. **Meta SPC 1 identifier**

Identifier	Contec PeridoxRTU
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1.2. **Suffix to the authorisation number**

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

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
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2. **META SPC 1 COMPOSITION**2.1. **Qualitative and quantitative information on the composition of the meta SPC 1**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Peracetic acid		Active Substance	79-21-0	201-186-8	0,23	0,23
Hydrogen Peroxide	Hydrogen Peroxide	Non-active Sub- stance	7722-84-1	231-765-0	4,4	4,4
Acetic Acid	Acetic Acid	Non-active Sub- stance	64-19-7	200-580-7	5,0	5,0

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

Formulation(s)	AL – Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Causes severe skin burns and eye damage. May be corrosive to metals. Harmful to aquatic life with long lasting effects.
Precautionary statements	Do not breathe vapours. Do not breathe spray. Keep only in original packaging. Wash hands thoroughly after handling. Avoid release to the environment. Wear protective gloves. Wear protective clothing. Wear eye protection. Wear face protection. IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTRE or doctor/physician. Specific treatment (see information on this label). Wash contaminated clothing before reuse. Absorb spillage to prevent material damage. Store locked up. Dispose of contents to in accordance with local/regional/national/international regulations (to be specified). Dispose of container to in accordance with local/regional/national/international regulations (to be specified).

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

4.1. Use description

Table 1. Use # 1 – Application by trigger spray onto a suitable cleanroom wipe and use of the wipe to distribute the liquid on the surface

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Fungi

	Yeast Bacterial spores
Field(s) of use	Indoor Surface disinfection of clean, hard non-porous surfaces in cleanrooms not associated with food or feed areas, by spraying onto a suitable cleanroom wipe and using the wipe to distribute the liquid on the surface.
Application method(s)	Spraying Spray onto a suitable cleanroom wipe and use the wipe to distribute the liquid on the surface. Uniform distribution of the biocidal product should be ensured.
Application rate(s) and frequency	50,0 mL/m ² – Ready-to-use product Ensure the surface is uniformly covered with the product and leave for the required contact time. Contact time for bacteria – 2-minutes. Contact time for fungi, yeasts and bacterial spores – 3-minutes.
Category(ies) of users	Professional
Pack sizes and packaging material	900 ml High density polyethylene (HDPE) bottle, delivered with a poly propylene screw cap which is replaced with the poly propylene trigger.

4.1.1. *Use-specific instructions for use*

For use only on visibly clean surfaces. Cleaning prior to disinfection is required. Physically remove contaminants from the surface before disinfection using a suitable cleanroom wipe and a recommended wiping technique for optimum contamination control.

Spray directly onto a suitable cleanroom wipe. Use a wipe to distribute the liquid on the surface.

Ensure the surface is uniformly covered with the product and leave for the required contact time indicated to kill bacteria, fungi, yeast and bacterial spores.

Do not apply more than 50 ml/m².

Leave for required contact time and wipe to dry afterwards.

For use at room temperature (20 ± 2 °C).

Suitable cleanroom wipe materials should be used in order to minimise interaction with the product.

Used wipes must be disposed in a closed container.

4.1.2. *Use-specific risk mitigation measures*

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

A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).

A ventilation rate of at least 20/hr is mandatory when handling the product.

The product must only be applied for disinfection of small surfaces.

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*

Inhalation: Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. Maintain an open airway. Loosen tight clothing such as collar, tie or belt. When breathing is difficult, properly trained personnel may assist affected person by administering oxygen. Get medical attention. Place unconscious person on their side in the recovery position and ensure breathing can take place.

Skin contact: It is important to remove the substance from the skin immediately. Rinse immediately with plenty of water. Continue to rinse for at least 15 minutes and get medical attention. Chemical burns must be treated by a physician.

Eye contact: Rinse immediately with plenty of water. Do not rub eye. Remove any contact lenses and open eyelids wide apart. Continue to rinse for at least 15 minutes and get medical attention.

Ingestion: Rinse mouth thoroughly with water. Give a few small glasses of water or milk to drink. Stop if the affected person feels sick as vomiting may be dangerous. Never give anything by mouth to an unconscious person. Place unconscious person on their side in the recovery position and ensure breathing can take place. Keep affected person under observation. Get medical attention if symptoms are severe or persist.

Indication of any immediate medical attention and special treatment needed: Treat symptomatically.

Environmental precautions: Prevent from entering into soil, ditches, sewers, waterways and/or groundwater. Spills or discharge to natural waterways is likely to kill aquatic organisms.

Personal precautions, protective equipment and emergency procedures in case of accidental release measures: Evacuate area.

Keep upwind of spill. Ventilate area of leak or spill. Only trained and properly protected personnel may be involved in clean-up operations. Use appropriate safety equipment.

Methods and materials for containment and cleaning up: Avoid making contact with spilled material. When cleaning up a spill always wear the appropriate protective equipment, including respiratory protection, gloves and protective clothing. A self-contained breathing apparatus or respirator and absorbents may be necessary, depending on the size of the spill and the adequacy of ventilation.

Small spills: Wear the correct protective equipment and cover the liquid with absorbent material. Collect and seal the material and the dirt that has absorbed the spilled material in polyethylene bags and place in a drum for transit to an approved disposal site. Rinse away the remaining spilled material with water to reduce odour and discharge the rinsate into a municipal or industrial sewer, not into a natural waterway.

Large spills: In case of nasal and respiratory irritation, vacate the room immediately. Personnel cleaning up should be trained and equipped with a self-contained breathing apparatus, or an officially approved or certified full-face respirator equipped with an organic vapour cartridge, gloves, and clothing impervious, including rubber boots or shoe protection.

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

This biocidal product, when being disposed of in its unused and uncontaminated state should be treated as a hazardous waste according to Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3). Any disposal practices must be in compliance with all national and provincial laws and any municipal or local by-laws governing hazardous waste.

Do not dump into any sewers, on the ground, or into any body of water. Avoid release to the environment.

High-temperature incineration is an acceptable practice.

Containers are non-refillable. Do not reuse or refill the containers. Containers should be triple or pressure rinsed with water promptly after they are emptied. They can then be offered for recycling or reconditioning for biocidal products, or they can be punctured and disposed of in a sanitary landfill or by other procedures approved by national and local authorities. Send waste liquid from rinsing of used containers to an approved waste handling facility.

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

Store in a cool, well ventilated area.

Keep this product in the original container tightly closed.

Container must be stored and transported in an upright position to prevent spilling the contents.

Keep away from direct sunlight.

Do not freeze.

Store below 30 °C.

The shelf-life is 12 months (unopened).

4.2. Use description

Table 2. Use # 2 – Application by pouring into a container and then using a suitable cleanroom mop/wipe to apply the liquid on the surface

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Bacteria Fungi Yeast Bacterial spores
Field(s) of use	Indoor Surface disinfection of clean, hard non-porous surfaces in cleanrooms not associated with food or feed areas, by pouring into a container and then applying the liquid on the surface with a suitable cleanroom mop/wipe.
Application method(s)	Pouring Pour into a container and then apply with a suitable cleanroom mop/wipe.
Application rate(s) and frequency	50,0 mL/m ² – Ready-to-use product Ensure the surface is uniformly covered with the product and leave for the required contact time. Contact time for bacteria – 2-minutes. Contact time for fungi, yeasts and bacterial spores – 3-minutes.
Category(ies) of users	Professional
Pack sizes and packaging material	3 750 ml HDPE bottle with a poly propylene screw cap 900 ml HDPE bottle, delivered with a poly propylene screw cap which is replaced with the poly propylene push/pull cap

4.2.1. Use-specific instructions for use

For use only on visibly clean surfaces. Cleaning prior to disinfection is required. Physically remove contaminants from the surface before disinfection using a suitable cleanroom mop/wipe and a recommended wiping technique for optimum contamination control.

Pour the product into a container and then mop onto the surface.

Ensure the surface is uniformly covered with the product and leave for the required contact time indicated to kill bacteria, fungi, yeast and bacterial spores. Do not apply more than 50 ml/m².

Leave for required contact time and wipe to dry afterwards. For use at room temperature (20 ± 2 °C).

Suitable cleanroom wipe and mop materials should be used in order to minimise interaction with the product.

Used wipes must be disposed in a closed container.

4.2.2. *Use-specific risk mitigation measures*

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

A protective coverall which is impermeable for the biocidal product shall be worn (coverall material to be specified by the authorisation holder within the product information).

Application of technical or engineering controls to remove airborne residues is mandatory (e.g. room ventilation or local exhaust ventilation (LEV)) during product application. A minimum ventilation rate of 100 air change per hour is mandatory.

Technical or engineering controls to remove airborne residues is mandatory (e.g. ventilation or LEV) before operatives are permitted to enter into treated areas after surface disinfection. Where necessary, a waiting restriction of sufficient duration must be set to allow time for the removal of airborne residues.

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

Inhalation: Move affected person to fresh air and keep warm and at rest in a position comfortable for breathing. Maintain an open airway. Loosen tight clothing such as collar, tie or belt. When breathing is difficult, properly trained personnel may assist affected person by administering oxygen. Get medical attention. Place unconscious person on their side in the recovery position and ensure breathing can take place.

Skin contact: It is important to remove the substance from the skin immediately. Rinse immediately with plenty of water. Continue to rinse for at least 15 minutes and get medical attention. Chemical burns must be treated by a physician.

Eye contact: Rinse immediately with plenty of water. Do not rub eye. Remove any contact lenses and open eyelids wide apart. Continue to rinse for at least 15 minutes and get medical attention.

Ingestion: Rinse mouth thoroughly with water. Give a few small glasses of water or milk to drink. Stop if the affected person feels sick as vomiting may be dangerous. Never give anything by mouth to an unconscious person. Place unconscious person on their side in the recovery position and ensure breathing can take place. Keep affected person under observation. Get medical attention if symptoms are severe or persist.

Indication of any immediate medical attention and special treatment needed: Treat symptomatically.

Environmental precautions: Prevent from entering into soil, ditches, sewers, waterways and/or groundwater. Spills or discharge to natural waterways is likely to kill aquatic organisms.

Personal precautions, protective equipment and emergency procedures in case of accidental release measures: Evacuate area.

Keep upwind of spill. Ventilate area of leak or spill. Only trained and properly protected personnel may be involved in clean-up operations. Use appropriate safety equipment.

Methods and materials for containment and cleaning up: Avoid making contact with spilled material. When cleaning up a spill always wear the appropriate protective equipment, including respiratory protection, gloves and protective clothing. A self-contained breathing apparatus or respirator and absorbents may be necessary, depending on the size of the spill and the adequacy of ventilation.

Small spills: Wear the correct protective equipment and cover the liquid with absorbent material. Collect and seal the material and the dirt that has absorbed the spilled material in polyethylene bags and place in a drum for transit to an approved disposal site. Rinse away the remaining spilled material with water to reduce odour and discharge the rinsate into a municipal or industrial sewer, not into a natural waterway.

Large spills: In case of nasal and respiratory irritation, vacate the room immediately. Personnel cleaning up should be trained and equipped with a self-contained breathing apparatus, or an officially approved or certified full-face respirator equipped with an organic vapour cartridge, gloves, and clothing impervious, including rubber boots or shoe protection.

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

This biocidal product, when being disposed of in its unused and uncontaminated state should be treated as a hazardous waste according to Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3). Any disposal practices must be in compliance with all national and provincial laws and any municipal or local by-laws governing hazardous waste.

Do not dump into any sewers, on the ground, or into any body of water. Avoid release to the environment.

High-temperature incineration is an acceptable practice.

Containers are non-refillable. Do not reuse or refill the containers. Containers should be triple or pressure rinsed with water promptly after they are emptied. They can then be offered for recycling or reconditioning for biocidal products, or they can be punctured and disposed of in a sanitary landfill or by other procedures approved by national and local authorities. Send waste liquid from rinsing of used containers to an approved waste handling facility.

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

Store in a cool, well ventilated area.

Keep this product in the original container tightly closed.

Container must be stored and transported in an upright position to prevent spilling the contents.

Keep away from direct sunlight.

Do not freeze.

Store below 30 °C.

The shelf-life is 12 months (unopened).

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

5.1. Instructions for use

See Use-specific instructions for use.

5.2. Risk mitigation measures

See Use-specific risk mitigation measures.

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

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

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

See, where specific to the use, the instructions for safe disposal of the product and its packaging.

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

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

⁽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.

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)		Contec Sterile PeridoxRTU			
Authorisation number	EU-0023658-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Peracetic acid		Active Substance	79-21-0	201-186-8	0,23
Hydrogen Peroxide	Hydrogen Peroxide	Non-active Sub- stance	7722-84-1	231-765-0	4,4
Acetic Acid	Acetic Acid	Non-active Sub- stance	64-19-7	200-580-7	5,0

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

Trade name(s)		Contec PeridoxRTU			
Authorisation number	EU-0023658-0002 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Peracetic acid		Active Substance	79-21-0	201-186-8	0,23
Hydrogen Peroxide	Hydrogen Peroxide	Non-active Sub- stance	7722-84-1	231-765-0	4,4
Acetic Acid	Acetic Acid	Non-active Sub- stance	64-19-7	200-580-7	5,0

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2020/1426

of 7 October 2020

on the harmonised use of radio spectrum in the 5 875-5 935 MHz frequency band for safety-related applications of intelligent transport systems (ITS) and repealing Decision 2008/671/EC

(notified under document C(2020) 6773)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Decision No 676/2002/EC of the European Parliament and of the Council of 7 March 2002 on a regulatory framework for radio spectrum policy in the European Community (Radio Spectrum Decision) ⁽¹⁾, and in particular Article 4(3) thereof,

Whereas:

- (1) Intelligent transport systems (ITS) encompass road ITS and urban rail ITS. Road ITS include cooperative systems based on real-time communications between the vehicle (including cars, trucks, bicycles, motor bicycles, tramways, construction equipment, agricultural equipment, as well as pedestrian and cycling equipment) and its environment (other vehicles, infrastructure, etc.). In certain cases, such road ITS equipment may also be used off-road (e.g. on industrial, agricultural, or construction sites). Urban rail ITS consist of public transport systems permanently guided by at least one control and management system, intended to operate local, urban and suburban passenger services separated from general road and pedestrian traffic. ITS have the potential to offer major improvements in transport system efficiency, in traffic safety and in comfort while travelling.
- (2) Commission Decision 2008/671/EC ⁽²⁾ harmonised the use of radio spectrum in the 5 875-5 905 MHz (or 5,9 GHz) frequency band for safety-related applications of ITS. It recognised the role of ITS as being central to an integrated approach in road safety by adding information and communication technologies to transport infrastructure and vehicles to avoid potentially dangerous traffic situations and reduce the number of accidents.
- (3) Directive 2010/40/EU of the European Parliament and of the Council ⁽³⁾ established a framework to deploy ITS in road transport and for interfaces with other modes of transport.
- (4) On 14 September 2016, following the adoption of a set of measures for a European gigabit society ⁽⁴⁾ (including the 5G action plan ⁽⁵⁾), the Commission stressed the link between the development and deployment of 5G in Europe and key application areas, in particular smart mobility (connected and automated mobility).

⁽¹⁾ OJ L 108, 24.4.2002, p. 1.

⁽²⁾ Commission Decision 2008/671/EC of 5 August 2008 on the harmonised use of radio spectrum in the 5 875-5 905 MHz frequency band for safety-related applications of Intelligent Transport Systems (ITS) (OJ L 220, 15.8.2008, p. 24).

⁽³⁾ Directive 2010/40/EU of the European Parliament and of the Council of 7 July 2010 on the framework for the deployment of Intelligent Transport Systems in the field of road transport and for interfaces with other modes of transport (OJ L 207, 6.8.2010, p. 1).

⁽⁴⁾ Connectivity for a European gigabit society,
<https://ec.europa.eu/digital-single-market/en/policies/improving-connectivity-and-access>

⁽⁵⁾ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 14 September 2016 '5G for Europe: An Action Plan' (COM(2016) 588 final).

- (5) On 30 November 2016, the Commission published the Communication — A European strategy on cooperative ITS ⁽⁶⁾. On spectrum, the strategy proposes to keep the designation of spectrum used by European Telecommunications Standards Institute (ETSI) wireless short range communications (ITS-G5) for safety-related ITS services and to support measures to protect the 5,9 GHz frequency band from harmful interference. The strategy also proposes that cooperative intelligent transport systems deployment initiatives should implement the relevant mitigation techniques for co-existence according to ETSI standards and procedures.
- (6) On 17 May 2018, the Commission adopted the third Mobility package ⁽⁷⁾, which integrated the strategy on road safety in a broader European sustainable mobility ecosystem focusing on safe, connected and clean mobility. In that package, driverless vehicles and advanced connectivity systems are expected to make vehicles safer and easier to share, and open up access to mobility services for more users.
- (7) Under that evolving political and regulatory framework on road safety, the Member States and industry carried out various initiatives related to the use of the 5,9 GHz band, to develop and deploy road safety applications. Such initiatives include the Car-2-Car Communications Consortium ⁽⁸⁾, the C-Roads platform ⁽⁹⁾, the establishment of the 5G Automotive Association (5GAA) ⁽¹⁰⁾ and increased activities within the 3rd Generation Partnership Project (3GPP) ⁽¹¹⁾ and standardisation bodies such as ETSI. Industry efforts resulted in the development of two competing technologies for short range communication of vehicles with their environment, namely the ITS-G5 and the long term evolution – vehicle-to-everything (LTE-V2X) technology.
- (8) The urban rail community considers that at least 20 MHz of harmonised spectrum ⁽¹²⁾ is necessary in order to operate urban rail communication based train control (CBTC) systems. Such systems enable urban rail operations to be managed safely and efficiently, in particular by shortening intervals between successive trains, which increases throughput in public transportation infrastructures. Based on local authorisations, a number of metro lines in the Union already use parts of the 5 905–5 935 MHz frequency band or beyond. It is therefore important to harmonise spectrum for such use Union-wide in order to ensure a single market also in urban rail and to contribute to Europe's environmental objectives.
- (9) Pursuant to Article 4(2) of Decision No 676/2002/EC, on 18 October 2017 the Commission issued a mandate to the European Conference of Postal and Telecommunications Administrations (CEPT) to study the possibility of extending the upper edge of the safety-related ITS band harmonised at Union level (5 875-5 905 MHz) by 20 MHz up to 5 925 MHz and admitting other means of transport, in addition to road transport, such as urban rail using CBTC in that band.
- (10) In response to the mandate, CEPT published a report on 11 March 2019 (CEPT Report 71 – ITS at 5,9 GHz) reviewing the technical conditions and extension of the 5,9 GHz band. The proposals in the report include broadening the definition of ITS, harmonising the frequency band 5 875-5 925 MHz for safety-related ITS applications and harmonising the frequency band 5 925-5 935 MHz for safety-related urban rail ITS applications, subject to national coordination with fixed service and/or studies to determine the sharing conditions. The report also proposes giving priority to road ITS applications below 5 915 MHz and to urban rail ITS applications above 5 915 MHz. In the frequency band 5 915-5 925 MHz use by road ITS applications is proposed to be limited to infrastructure to vehicle (I2V) until road ITS applications are able to protect urban rail ITS applications. In the

⁽⁶⁾ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 30 November 2016 'A European strategy on Cooperative Intelligent Transport Systems, a milestone towards cooperative, connected and automated mobility' (COM(2016) 766 final).

⁽⁷⁾ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of 17 May 2018 'Europe on the move — Sustainable Mobility for Europe: safe, connected, and clean' (COM(2018) 293 final).

⁽⁸⁾ <https://www.car-2-car.org/>

⁽⁹⁾ <https://www.c-roads.eu/platform.html>

⁽¹⁰⁾ <http://5gaa.org/>

⁽¹¹⁾ <https://www.3gpp.org>

⁽¹²⁾ ETSI Technical Report 103 111 V1.1.1 (2014-10) – part on spectrum requirements for urban rail systems in the 5,9 GHz range.

frequency band 5 915-5 935 MHz use by urban rail ITS is proposed to be on a shared basis and subject to national circumstances and stakeholder demand for urban rail ITS. Individual authorisations for urban rail ITS (5 915-5 935 MHz), road ITS infrastructure (5 915-5 925 MHz) and fixed service (above 5 925 MHz) should enable national coordination, where appropriate.

- (11) When making the frequency band 5 915-5 935 MHz available for urban rail ITS as soon as reasonably practicable after its designation in accordance with this Decision, Member States should give due consideration to existing urban rail systems operating in the band (or part of it) with different technical conditions, in order to allow for a sufficient time frame to adapt the existing train and network equipment to the harmonised technical conditions.
- (12) The results of the work carried out by CEPT in cooperation with ETSI constitute the technical basis for this Decision.
- (13) ITS and radio local area network (RLAN) are both supported by Union policies. CEPT is defining technical conditions for RLAN operating above 5 935 MHz to address the protection of safety-related urban rail ITS applications below 5 935 MHz and safety-related road ITS below 5 925 MHz (e.g. out-of-band emission limit requirements and blocking scenario).
- (14) Standardised solutions for ensuring co-channel sharing mechanisms and implementation of priority rules between road ITS and urban rail ITS applications are being defined by ETSI.
- (15) ETSI is currently working on two technical reports dealing with the definition and evaluation of co-channel and adjacent-channel co-existence methods between ITS G5 and LTE-V2X. Relevant standards may be available at the earliest by mid-2021 and could take until mid-2022.
- (16) Taking into account the developments in ETSI, this Decision may need to be reviewed in the future.
- (17) This Decision should build upon and develop the rules set out in Decision 2008/671/EC. In the interest of legal clarity, Decision 2008/671/EC should be repealed.
- (18) The measures provided for in this Decision are in accordance with the opinion of the Radio Spectrum Committee established by Decision No 676/2002/EC,

HAS ADOPTED THIS DECISION:

Article 1

The purpose of this Decision is to harmonise the conditions for the availability and efficient use of frequency band 5 875-5 935 MHz for safety-related applications of Intelligent Transport Systems (ITS).

Article 2

For the purposes of this Decision, the following definitions shall apply:

- (1) 'intelligent Transport Systems' or 'ITS' means a range of systems and services, based on information and communications technologies, including processing, control, positioning, communication and electronics, that are applied to a road transportation system or an urban rail transportation system, or both;
- (2) 'road intelligent transport systems' or 'road ITS' means intelligent transport systems applied to any kind of road-based transport (including in off-road use cases) that enable safety communications between vehicles (V2V) and between infrastructure and vehicles (I2V). ITS applied to railway lines not separated from road or pedestrian traffic (such as tramways and light rail) are also considered a part of road ITS;
- (3) 'urban rail intelligent transport systems' or 'urban rail ITS' means intelligent transport systems applied to urban or suburban railway lines permanently guided by at least one control and management system, separated from road and pedestrian traffic;

- (4) ‘mean equivalent isotropically radiated power’ or ‘mean e.i.r.p.’ means e.i.r.p. during the transmission burst which corresponds to the highest power.

Article 3

1. Member States shall, no later than 30 June 2021, designate the frequency band 5 875-5 935 MHz for intelligent transport systems and limit it to urban rail ITS in 5 925-5 935 MHz. Following that designation, Member States shall, as soon as reasonably practicable, make that frequency band available on a non-exclusive basis.

Such designation shall comply with the parameters set out in the Annex.

2. Road ITS applications shall have priority below 5 915 MHz and urban rail ITS applications shall have priority above 5 915 MHz, so that protection is afforded to the application having priority.

3. Access by road ITS to the frequency range 5 915-5 925 MHz shall be limited to applications involving infrastructure-to-vehicle (I2V) connectivity only, coordinated, where appropriate, with urban rail ITS.

4. Access by urban rail ITS to the frequency range 5 925-5 935 MHz shall be on a shared basis and subject to national circumstances and demand for urban rail ITS including coordination with fixed service.

Article 4

The scope and means of application of this Decision shall be reviewed as soon as market developments and evolution of standards and technology justify such a review or at the latest by 30 September 2023.

Article 5

Member States shall report to the Commission on the implementation of Article 3 of this Decision by 30 September 2022.

Article 6

Decision 2008/671/EC is repealed.

Article 7

This Decision is addressed to the Member States.

Done at Brussels, 7 October 2020.

For the Commission
Thierry BRETON
Member of the Commission

ANNEX

**Technical parameters for safety related applications of intelligent transport systems in the
5 875-5 935 MHz band**

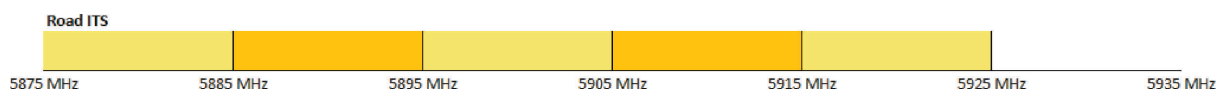
Parameter	Value
Maximum spectral power density (mean e.i.r.p.)	23 dBm/MHz
Maximum total transmit power (mean e.i.r.p.)	33 dBm with a transmit power control (TPC) range of at least 30 dB

Techniques to access spectrum and mitigate interference that provide an appropriate level of performance shall be used in line with Directive 2014/53/EU of the European Parliament and of the Council ⁽¹⁾. If relevant techniques are described in harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* under Directive 2014/53/EU, performance at least equivalent to the performance level associated to those techniques shall be ensured.

Frequency arrangement

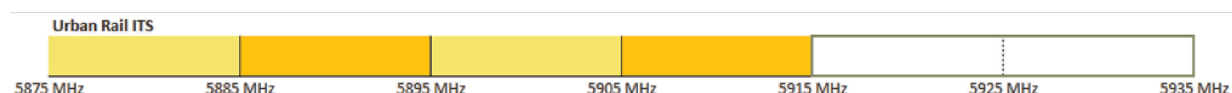
The frequency arrangement is based on block sizes of 10 MHz starting at the lower edge of the band, at 5 875 MHz.

For road ITS:



In the 5 875-5 925 MHz band, road ITS applications shall use channels within the boundaries of each 10 MHz block. Channel bandwidth may be less than 10 MHz.

For urban rail ITS:



In 5 875-5 915 MHz, urban rail ITS applications shall use channels within the boundaries of each 10 MHz block. Channel bandwidth may be lower than 10 MHz.

In 5 915-5 935 MHz, the maximum channel bandwidth shall be 10 MHz for urban rail ITS applications. The dotted line shows the preferred harmonised frequency arrangement but, at national level, rollouts may use a channel centred at 5 925 MHz.

⁽¹⁾ Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62).

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