

Official Journal of the European Union

L 28



English edition

Legislation

Volume 65

9 February 2022

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⁽¹⁾ Text with EEA relevance.

EN

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2022/166

of 8 February 2022

on cancelling the registration of protected geographical indication ‘Holsteiner Karpfen’ (PGI)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 54(1) thereof,

Whereas:

- (1) Article 7(1) of Commission Delegated Regulation (EU) No 664/2014 ⁽²⁾ provides that the procedure laid down in Articles 49 to 52 of Regulation (EU) No 1151/2012 apply *mutatis mutandis* to the cancellation of a registration as referred to in Article 54(1) of that Regulation.
- (2) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, in conjunction with Article 7(1) of Delegated Regulation (EU) No 664/2014, application sent by Germany to cancel the registration of the protected geographical indication (PGI) ‘Holsteiner Karpfen’ was published in the *Official Journal of the European Union*. ⁽³⁾
- (3) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name ‘Holsteiner Karpfen’ (PGI) should therefore be cancelled from the register of protected designations of origin and protected geographical indications.
- (4) Pursuant to the last subparagraph of Article 54(1) of Regulation (EU) No 1151/2012 such cancellation is adopted in accordance with the examination procedure referred to in Article 57(2) of that Regulation.
- (5) The measure provided for in this Regulation is in accordance with the opinion of the Agricultural Product Quality Policy Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The registration of the name ‘Holsteiner Karpfen’ (PGI) is hereby cancelled.

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) No 664/2014 of 18 December 2013 supplementing Regulation (EU) No 1151/2012 of the European Parliament and of the Council with regard to the establishment of the Union symbols for protected designations of origin, protected geographical indications and traditional specialties guaranteed and with regard to certain rules on sourcing, certain procedural rules and certain additional transitional rules (OJ L 179, 19.6.2014, p. 17).

⁽³⁾ OJ C 313, 5.8.2021, p. 16.

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 February 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2022/167**of 8 February 2022****on cancelling the registration of protected geographical indication ‘Viande de porc, marque nationale grand-duché de Luxembourg’ (PGI)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 54(1) thereof,

Whereas:

- (1) Article 7(1) of Commission Delegated Regulation (EU) No 664/2014 ⁽²⁾ provides that the procedure laid down in Articles 49 to 52 of Regulation (EU) No 1151/2012 apply *mutatis mutandis* to the cancellation of a registration as referred to in Article 54(1) of that Regulation.
- (2) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, in conjunction with Article 7(1) of Delegated Regulation (EU) No 664/2014, the application sent by Luxembourg to cancel the registration of the protected geographical indication (PGI) ‘Viande de porc, marque nationale grand-duché de Luxembourg’ was published in the *Official Journal of the European Union* ⁽³⁾.
- (3) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name ‘Viande de porc, marque nationale grand-duché de Luxembourg’ (PGI) should therefore be cancelled from the register of protected designations of origin and protected geographical indications.
- (4) Pursuant to the last subparagraph of Article 54(1) of Regulation (EU) No 1151/2012 such cancellation is adopted in accordance with the examination procedure referred to in Article 57(2) of that Regulation.
- (5) The measure provided for in this Regulation is in accordance with the opinion of the Agricultural Product Quality Policy Committee,

HAS ADOPTED THIS REGULATION:

Article 1

The registration of the name ‘Viande de porc, marque nationale grand-duché de Luxembourg’ (PGI) is hereby cancelled.

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*.

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) No 664/2014 of 18 December 2013 supplementing Regulation (EU) No 1151/2012 of the European Parliament and of the Council with regard to the establishment of the Union symbols for protected designations of origin, protected geographical indications and traditional specialities guaranteed and with regard to certain rules on sourcing, certain procedural rules and certain additional transitional rules (OJ L 179, 19.6.2014, p. 17).

⁽³⁾ OJ C 334, 20.8.2021, p. 26.

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

Done at Brussels, 8 February 2022.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2022/168**of 8 February 2022****authorising the placing on the market of pasteurised *Akkermansia muciniphila* as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ establishing a Union list of authorised novel foods was adopted.
- (3) On 24 October 2019, the company A-Mansia Biotech S.A. ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place pasteurised *Akkermansia muciniphila* on the Union market as a novel food. The applicant requested for pasteurised *Akkermansia muciniphila* bacteria to be used as a novel food at levels not exceeding 5×10^{10} cells per day in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council ⁽³⁾ and in foods for special medical purposes as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ⁽⁴⁾, intended for the adult population, excluding pregnant and lactating women.
- (4) On 24 October 2019, the applicant also made a request to the Commission for the protection of proprietary data for a number of studies submitted in support of the application, namely, a bacterial reverse mutation test ⁽⁵⁾, an *in vitro* mammalian cell micronucleus test ⁽⁶⁾, a 14-day dose ranging oral toxicity study in rats ⁽⁷⁾, a 90-day oral toxicity study in rats ⁽⁸⁾, the published toxicity data ⁽⁹⁾, a flow cytometry validation study ⁽¹⁰⁾, and an antimicrobial resistance study ⁽¹¹⁾.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁽³⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

⁽⁴⁾ Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

⁽⁵⁾ Brient, 2019a (unpublished).

⁽⁶⁾ Brient, 2019b (unpublished).

⁽⁷⁾ Bracken, 2019a (unpublished).

⁽⁸⁾ Bracken, 2019b (unpublished).

⁽⁹⁾ Druart C., Plovier H., Van Hul M., Brient A., Phipps K.R., de Vos W.M., and Cani P.D., 2020. Toxicological Safety evaluation of pasteurized *Akkermansia muciniphila*. *Journal of Applied Toxicology*, 41:276-290.

⁽¹⁰⁾ Jensen, 2019 (unpublished).

⁽¹¹⁾ Gueimonde, 2019 (unpublished).

- (5) On 19 May 2020, the Commission requested, in accordance with Article 10(3) of Regulation (EU) 2015/2283, the European Food Safety Authority ('the Authority') to carry out an assessment of pasteurised *Akkermansia muciniphila* as a novel food.
- (6) On 7 July 2021, the Authority adopted its scientific opinion on the safety of pasteurised *Akkermansia muciniphila* as a novel food pursuant to Regulation (EU) 2015/2283 ⁽¹²⁾.
- (7) In its scientific opinion, the Authority concluded that pasteurised *Akkermansia muciniphila* is safe under the proposed conditions of use for the proposed target populations at levels not exceeding $3,4 \times 10^{10}$ cells/day. Therefore, that scientific opinion gives sufficient grounds to establish that pasteurised *Akkermansia muciniphila*, when used at levels not exceeding $3,4 \times 10^{10}$ cells/day in food supplements and in foods for special medical purposes intended for the adult population, excluding pregnant and lactating women, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (8) In its scientific opinion, the Authority noted that its conclusion on the safety of the novel food was based on the data from the bacterial reverse mutation test, the *in vitro* mammalian cell micronucleus test, the 14-day dose ranging oral toxicity study in rats, the 90-day oral toxicity study in rats, the method validation study for the formulation analysis for the 90-day oral toxicity study in rats, and the antimicrobial resistance study.
- (9) The Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over those data and to clarify their claim to an exclusive right of reference to them in accordance with Article 26(2)(b) of Regulation (EU) 2015/2283.
- (10) The applicant declared that they held proprietary and exclusive rights of reference to the data from the bacterial reverse mutation test, the *in vitro* mammalian cell micronucleus test, the 14-day dose ranging oral toxicity study in rats, the 90-day oral toxicity study in rats, the published toxicity data, the flow cytometry validation study, and the antimicrobial resistance study at the time they submitted the application and therefore third parties could not lawfully have access to or use those studies.
- (11) The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the data from the bacterial reverse mutation test, the *in vitro* mammalian cell micronucleus test, the 14-day dose ranging oral toxicity study in rats, the 90-day oral toxicity study in rats, the published toxicity data, the flow cytometry validation study, and the antimicrobial resistance study contained in the applicant's file on which the Authority based its conclusion on the safety of the novel food and without which it could have not assessed the novel food, should not be used by the Authority for the benefit of any subsequent applicant for a period of five years from the date of entry into force of this Regulation. Accordingly, only the applicant should be authorised to place pasteurised *Akkermansia muciniphila* on the market within the Union during that period.
- (12) However, restricting the authorisation of pasteurised *Akkermansia muciniphila* and the reference to the data contained in the applicant's file for the sole use by the applicant does not prevent other applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting such authorisation.
- (13) The Annex to Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (14) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹²⁾ Safety of pasteurised *Akkermansia muciniphila* as a novel food pursuant to Article 10 of Regulation (EU) 2015/2283; EFSA Journal 2021:19(9):6780.

HAS ADOPTED THIS REGULATION:

Article 1

1. Pasteurised *Akkermansia muciniphila* as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.
2. For a period of five years from the date of entry into force of this Regulation only the initial applicant:
company: A-Mansia Biotech S.A.;
address: rue Granbonpré, 11 Bâtiment H 1435 Mont-Saint-Guibert, Belgium,
is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for that novel food without reference to the data protected pursuant to Article 2 or with the agreement of A-Mansia Biotech S.A.
3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex.

Article 2

The scientific data contained in the application file on the basis of which the novel food referred to in Article 1 have been assessed by the Authority, claimed by the applicant as proprietary and without which the novel food could not have been authorised, shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of A-Mansia Biotech S.A.

Article 3

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

Article 4

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 February 2022.

For the Commission
The President
Ursula VON DER LEYEN

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

(1) in Table 1 (Authorised novel foods), the following entry is inserted:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
	Specified food category	Maximum levels			
'<i>Akkermansia muciniphila</i> (pasteurised)	Foods for special medical purposes as defined under Regulation (EU) No 609/2013 for the adult population, excluding pregnant and lactating women	$3,4 \times 10^{10}$ cells/day	The designation of the novel food on the labelling of the foodstuffs containing it shall be 'pasteurised <i>Akkermansia muciniphila</i> '.		Authorised on 1 March 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.
	Food supplements as defined in Directive 2002/46/EC for the adult population, excluding pregnant and lactating women	$3,4 \times 10^{10}$ cells/day	The labelling of food supplements containing pasteurised <i>Akkermansia muciniphila</i> shall bear a statement that they should be consumed by adults only, excluding pregnant and lactating women.		Applicant: A-Mansia Biotech S.A., rue Granbonpré, 11, Bâtiment H, 1435 Mont-Saint-Guibert, Belgium. During the period of data protection, the novel food pasteurised <i>Akkermansia muciniphila</i> is authorised for placing on the market within the Union only by A-Mansia Biotech S.A., unless a subsequent applicant obtains authorisation for the novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of Mansia Biotech S.A.. End date of the data protection: 1 March 2027.'

(2) in Table 2 (Specifications), the following entry is inserted:

Authorised novel food	Specification
<p>'<i>Akkermansia muciniphila</i> (pasteurised)</p>	<p>Description: Pasteurised <i>Akkermansia muciniphila</i> (strain ATCC BAA-835, CIP 107961) is produced by anaerobic growth of the bacteria followed by pasteurisation, concentration of the cells, cryopreservation, and freeze drying.</p> <p>Characteristics/Composition: Total <i>A. muciniphila</i> cell count (cells/g): $2,5 \times 10^{10}$ to $2,5 \times 10^{12}$ Viable <i>A. muciniphila</i> cell count (CFU/g): < 10 (LoD)(*) Water activity: $\leq 0,43$ Moisture (%): $\leq 12,0$ Protein (%): $\leq 35,0$ Fat (%): $\leq 4,0$ Crude ash (%): $\leq 21,0$ Carbohydrates (%): 36,0 – 86,0</p> <p>Microbiological criteria: Aerobic mesophilic total count: ≤ 500 CFU(**)/g Sulphite reducing anaerobes: ≤ 50 CFU/g Coagulase⁺ Staphylococci: ≤ 10 CFU/g Enterobacteriaceae: ≤ 10 CFU/g Yeast: ≤ 10 CFU/g Mould: ≤ 10 CFU/g <i>Bacillus cereus</i>: ≤ 100 CFU/g <i>Listeria</i> spp.: Absence in 25 g <i>Salmonella</i> spp.: Absence in 25 g <i>Escherichia coli</i>: Absence in 1 g</p> <p>(*) LoD: Limit of Detection; (**) Colony Forming Units.'</p>

COMMISSION IMPLEMENTING REGULATION (EU) 2022/169**of 8 February 2022****authorising the placing on the market of frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) 2017/2470****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ establishing a Union list of authorised novel foods was adopted.
- (3) On 28 December 2018, the company Fair Insects BV ('the applicant') submitted an application to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) on the Union market as a novel food. The applicant requested frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) to be used in a number of foods intended for the general population.
- (4) The applicant also submitted a request to the Commission for the protection of proprietary data for a number of data submitted in support of the application. Namely, detailed description of the production process ⁽³⁾, analytical data on the composition ⁽⁴⁾, stability studies ⁽⁵⁾, protein digestibility study ⁽⁶⁾, cytotoxicity study, including full study reports ⁽⁷⁾, list of analytical data on the composition ⁽⁸⁾, intake assessment and proposed uses and use levels ⁽⁹⁾.
- (5) In accordance with Article 10(3) of Regulation (EU) 2015/2283, the Commission consulted the European Food Safety Authority ('the Authority') on 9 August 2019, asking it to provide a scientific opinion by carrying out an assessment for frozen and dried preparations from yellow mealworm (*Tenebrio molitor* larva) as a novel food.

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁽³⁾ Section 2.3_Production process, including updates; Appendix C11; Appendix C17 – Fair Insects BV, 2020 (unpublished).

⁽⁴⁾ Section 2.4_Compositional data, including updates; Section 2.9_Nutritional information, including updates; Appendix B4, including updates; Appendix B5, including updates; Appendix C20; Appendix D1, including updates; Appendix D2, including updates; Appendix D6, including updates – Fair Insects BV, 2020 (unpublished).

⁽⁵⁾ Section 2.4.4_Stability, including updates; Appendix C21; Appendix C22; Appendix D7, including updates – Fair Insects BV, 2020 (unpublished).

⁽⁶⁾ Appendix D4, including updates, Fair Insects BV, 2020 (unpublished); DIASS study (section 2.8_upd, section 2.9_upd, section 2.11_upd).

⁽⁷⁾ Section 2.10 Toxicological information, including updates; Appendix D5, including updates – Fair Insects BV, 2020 (unpublished).

⁽⁸⁾ Appendix B2, Fair Insects BV, 2020 (unpublished).

⁽⁹⁾ Intake assessment by Schuttelaar & Partners (section 2.7_upd); Proposed use and use levels data estimated by Schuttelaar & Partners (section 2.7_upd) – Fair Insects BV, 2020 (unpublished);

- (6) On 7 July 2021 the Authority, in accordance with the requirements of Article 11 of Regulation (EU) 2015/2283 adopted its scientific opinion on the ‘Safety of frozen and dried formulations from whole yellow mealworm (*Tenebrio molitor* larva) as a novel food pursuant to Regulation (EU) 2015/2283’⁽¹⁰⁾.
- (7) In its opinion, the Authority concluded that frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) are safe under the proposed uses and use levels. Therefore, the opinion of the Authority gives sufficient grounds to establish that frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) under the specific conditions of use fulfils the requirements for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (8) In that opinion and the Authority’s opinion on the ‘Scientific Opinion on the safety of dried yellow mealworm (*Tenebrio molitor* larva) as a novel food pursuant to Regulation (EU) 2015/2283’⁽¹¹⁾, the Authority also concluded on the basis of limited published evidence on food allergy related to insects, that the consumption of the novel food may induce primary sensitisation and allergic reactions to yellow mealworm proteins. In accordance with the Authority’s recommendation to carry out research on the allergenicity to *Tenebrio molitor* larva, the Commission is currently exploring the ways to carry out the necessary research. Until the data is generated by the research and assessed by the Authority, and considering that, to date, only the few allergic cases have been reported according to data available to the insect industry of *Tenebrio molitor* larva⁽¹²⁾, the Commission considers that no specific labelling requirements concerning the potential of *Tenebrio molitor* larva to cause primary sensitisation should be included in the Union list of authorised novel foods.
- (9) In those opinions, the Authority also concluded that the consumption of the novel food may cause allergic reactions in persons that are allergic to crustaceans and dust mites due to cross-reactivity. Furthermore, the Authority noted that additional allergens may end up in the novel food, if these allergens are present in the substrate feed to the insects. This may include allergens, listed in the Annex II to Regulation (EU) No 1169/2011 of the European Parliament and of the Council⁽¹³⁾. Therefore, it is appropriate that frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) made available to the consumer as such and foods containing these preparations are appropriately labelled following the requirements in accordance with Article 9 of Regulation (EU) 2015/2283 and Regulation (EU) No 1169/2011.
- (10) In its opinion, the Authority noted that the detailed description of the production process, analytical data on the composition, stability studies, protein digestibility study, cytotoxicity study, including full study reports, served as a basis to establish the safety of the novel food. The Authority also noted that it could not have reached its conclusion without those data, claimed by the applicant as proprietary.
- (11) The Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over those data and to clarify their claim to an exclusive right of reference to those data, as required under Article 26(2)(b) of Regulation (EU) 2015/2283.
- (12) The applicant declared that, at the time of the submission of the application, they held proprietary and exclusive rights of reference to those data under national law, and that therefore third parties cannot lawfully access, use or refer to those data.

⁽¹⁰⁾ EFSA Journal 2021;19(8):6778.

⁽¹¹⁾ EFSA Journal 2021;19(1):6343.

⁽¹²⁾ *Tenebrio molitor* larva is marketed in a number of Member States under the transitional measures laid down in Article 35(2) of Regulation (EU) 2015/2283.

⁽¹³⁾ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

- (13) The Commission assessed all the information provided by the applicant and considered that the applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, detailed description of the production process ⁽¹⁴⁾, analytical data on the composition ⁽¹⁵⁾, stability studies ⁽¹⁶⁾, protein digestibility study ⁽¹⁷⁾, cytotoxicity study, including full study reports ⁽¹⁸⁾, contained in the applicant's file, on which the Authority based its conclusion on the safety of the novel food and without which it could not have assessed the novel food, should not be used by the Authority for the benefit of any subsequent applicant for a period of five years from the date of entry into force of this Regulation. Accordingly, only the applicant should be authorised to place frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) on the market within the Union during that period.
- (14) However, restricting the authorisation of frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva) and of the reference to the data contained in the applicant's file for the sole use of the applicant, does not prevent other applicants from applying for an authorisation to place on the market the same novel food, provided that their application is based on legally obtained information supporting such authorisation under Regulation (EU) 2015/2283.
- (15) The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (16) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed.

HAS ADOPTED THIS REGULATION:

Article 1

1. Frozen, dried and powder forms of yellow mealworm (*Tenebrio molitor* larva), as specified in the Annex to this Regulation, shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.

2. For a period of five years from the date of entry into force of this Regulation, only the initial applicant:

company: Fair Insects BV;

address: Industriestraat 3, 5107 NC Dongen, the Netherlands,

is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for the novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of Fair Insects BV.

3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex to this Regulation.

⁽¹⁴⁾ Section 2.3_Production process, including updates; Appendix C11; Appendix C17 – Fair Insects BV, 2020 (unpublished).

⁽¹⁵⁾ Section 2.4_Compositional data, including updates; Section 2.9_Nutritional information, including updates; Appendix B4, including updates; Appendix B5, including updates; Appendix C20; Appendix D1, including updates; Appendix D2, including updates; Appendix D6, including updates – Fair Insects BV, 2020 (unpublished).

⁽¹⁶⁾ Section 2.4.4_Stability, including updates; Appendix C21; Appendix C22; Appendix D7, including updates – Fair Insects BV, 2020 (unpublished).

⁽¹⁷⁾ Appendix D4, including updates, Fair Insects BV, 2020 (unpublished); DIASS study (section 2.8_upd, section 2.9_upd, section 2.11_upd).

⁽¹⁸⁾ Section 2.10 Toxicological information, including updates; Appendix D5, including updates – Fair Insects BV, 2020 (unpublished).

Article 2

The studies contained in the application file on the basis of which the novel food referred to in Article 1 have been assessed by the Authority, claimed by the applicant as proprietary and without which the novel food could not have been authorised, shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of Fair Insects BV.

Article 3

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

Article 4

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 February 2022.

For the Commission
The President
Ursula VON DER LEYEN

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

(1) in Table 1 (Authorised novel foods), the following entry is inserted:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data protection	
'Frozen, dried and powder forms of yellow mealworm (<i>Tenebrio molitor</i> larva)	Specified food category	Maximum levels (g/100g) (marketed as such or reconstituted according to the instructions)	<p>1. Depending on the form used, the designation of the novel food on the labelling of the foodstuffs containing it shall be 'frozen yellow mealworm (<i>Tenebrio molitor</i> larva)', 'dried yellow mealworm (<i>Tenebrio molitor</i> larva)', or 'yellow mealworm (<i>Tenebrio molitor</i> larva) powder'.</p> <p>2. The labelling of the foodstuffs containing frozen, dried and powder forms of yellow mealworm (<i>Tenebrio molitor</i> larva) shall bear a statement that this ingredient may cause allergic reactions to consumers with known allergies to crustaceans and products thereof and to dust mites. This statement shall appear in close proximity to the list of ingredients.</p>		<p>Authorised on 1 March 2022. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283.</p> <p>Applicant: Fair Insects BV, Industriestraat 3, 5107 NC Dongen, the Netherlands.</p> <p>During the period of data protection, the novel food is authorised for placing on the market within the Union only by Fair Insects BV, unless a subsequent applicant obtains authorisation for that novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283, or with the agreement of Fair Insects BV.</p> <p>End date of the date protection: 1 March 2027.'</p>	
		Frozen				Dried or powder
	Frozen, dried and powder forms of yellow mealworm (<i>Tenebrio molitor</i> larva)					
	Multigrain bread and rolls; crackers and breadsticks	30				10
	Cereal bars	30				15
	Dried pasta based products; pasta based dishes (excluding dried puffed pasta); pizza and pizza-like dishes	15				10
	Dried stuffed pasta based products	30				15
	Pre-mixes (dry) for baked products	30				15
	Sauces	30				10
	Potato, legumes based dishes	15				10
	Whey powder	40				20
	Meat analogues	80				50
	Soups and salads	20				5
	Chips/crisps	40				20
	Beer-like beverages; mixed alcoholic drinks; alcoholic drink mixes	1				1
Chocolate confectionary	30	10				
Nuts, oilseeds and chickpeas	40	30				

	Frozen fermented milk-based products	15	5			
	Meat preparations	40	16			

(2) in Table 2 (Specifications), the following entry is inserted:

Authorised Novel Food	Specification		
'Frozen, dried and powder forms of yellow mealworm (<i>Tenebrio molitor</i> larva)	Description/Definition:		
	The novel food are frozen, dried and powder forms of yellow mealworm (<i>Tenebrio molitor</i> larva). The term 'mealworm' refers to the larval form of <i>Tenebrio molitor</i> , an insect species that belongs to the family of Tenebrionidae (darkling beetles). Another identified scientific synonym is <i>Tenebrio molitor</i> Linnaeus.		
	The entire mealworms are meant for human consumption, no parts are removed. A minimum 24 hours fasting period is required before killing the insects by freezing, to allow the larvae to discard their bowel content.		
	The novel food is intended to be placed on the market in three different forms, namely: whole, blanched and frozen <i>T. molitor</i> larva (frozen); whole, blanched and freeze-dried <i>T. molitor</i> larva (dried) which may be in powder form (powder).		
	Parameters	Frozen	Dried or powder
	Characteristics/Composition		
	Ash	0,9-1,10	3,6-4,1
	Moisture (% w/w)	69-75	≤ 5
	Crude protein (N x 6,25) (% w/w)	14-19	54-60
	Fat (% w/w)	7-12,5	27-30
— of which saturated fatty acids (% fat)	20-29	20-29	
Digestible carbohydrates (% w/w)	1-2	4-8	
Dietary fibre (% w/w)	1,2-3,5	4-6	
Chitin(*) (% w/w)	≤ 3	4-9	

Peroxide value (Meq O ₂ /kg fat)	≤ 5	≤ 5
Contaminants		
<i>Heavy metals</i>		
Lead (mg/kg)	≤ 0,01	≤ 0,075
Cadmium (mg/kg)	≤ 0,05	≤ 0,1
<i>Mycotoxins</i>		
Aflatoxins (Sum of B1, B2, G1, G2) (µg/kg)	≤ 4	≤ 4
Aflatoxin B1 (µg/kg)	≤ 2	≤ 2
Deoxynivalenol (µg/kg)	≤ 200	≤ 200
Ochratoxin A (µg/kg)	≤ 1	≤ 1
<i>Dioxins and PCBs</i>		
Sum of dioxins and dl-PCBs (UB, WHO-TEQ2005)(**) (pg/g fat)	≤ 0,75	≤ 0,75
Microbiological criteria		
Total aerobic colony count (CFU/g)	≤ 10 ⁵	≤ 10 ⁵
Enterobacteriaceae (presumptive) (CFU/g)	≤ 100	≤ 100
<i>Escherichia coli</i> (CFU/g)	≤ 50	≤ 50
<i>Listeria monocytogenes</i>	Absence in 25g	Absence in 25g
<i>Salmonella</i> spp.	Absence in 25g	Absence in 25g
<i>Bacillus cereus</i> (presumptive) (CFU/g)	≤ 100	≤ 100
Coagulase positive Staphylococci (CFU/g)	≤ 100	≤ 100
Sulfite-reducing Anaerobes (CFU/g)	≤ 30	≤ 30
Yeasts and moulds (CFU/g)	≤ 100	≤ 100
(*) Chitin calculated as the difference between the Acid Detergent Fibre fraction and the Acid Detergent Lignin fraction (ADF-ADL), as described by Hahn et al. (2018).		
(**) Upper bound sum of polychlorinated dibenzo-para-dioxins (PCDDs)-polychlorinated dibenzofurans (PCDFs) and dioxin-like polychlorinated biphenyls (PCBs) expressed as World Health Organization toxic equivalent (using WHO-TEFs of 2005)).		
CFU: colony forming units.		

DECISIONS

POLITICAL AND SECURITY COMMITTEE DECISION (CFSP) 2022/170

of 8 February 2022

on the appointment of the EU Mission Force Commander of the European Union military mission to contribute to the training of Somali security forces (EUTM Somalia) and repealing Decision (CFSP) 2020/1072 (EUTM Somalia/1/2022)

THE POLITICAL AND SECURITY COMMITTEE,

Having regard to the Treaty on European Union, and in particular Article 38 thereof,

Having regard to Council Decision 2010/96/CFSP of 15 February 2010 on a European Union military mission to contribute to the training of Somali security forces ⁽¹⁾, and in particular Article 5 thereof,

Whereas:

- (1) Pursuant to Article 5(1) of Decision 2010/96/CFSP, the Council authorised the Political and Security Committee (PSC), in accordance with Article 38 of the TEU, to take the relevant decisions concerning the political control and strategic direction of the European Union military mission to contribute to the training of Somali security forces (EUTM Somalia), including decisions to appoint the subsequent EU Mission Force Commanders.
- (2) On 16 July 2020, the PSC adopted Decision (CFSP) 2020/1072 ⁽²⁾ appointing Brigadier General Fabiano ZINZONE as the EU Mission Force Commander of EUTM Somalia.
- (3) On 18 January 2022, the Italian military authorities proposed the appointment of Brigadier General Roberto VIGLIETTA to succeed Brigadier General Fabiano ZINZONE as the EU Mission Force Commander of EUTM Somalia.
- (4) On 21 January 2022, the EU Military Committee agreed to recommend that the PSC approve the proposal made by the Italian military authorities.
- (5) A decision on the appointment of Brigadier General Roberto VIGLIETTA should be taken and Decision (CFSP) 2020/1072 should be repealed.
- (6) In accordance with Article 5 of Protocol No 22 on the position of Denmark, annexed to the TEU and to the Treaty on the Functioning of the European Union, Denmark does not participate in the elaboration and the implementation of decisions and actions of the Union which have defence implications,

HAS ADOPTED THIS DECISION:

Article 1

Brigadier General Roberto VIGLIETTA is hereby appointed as the EU Mission Force Commander of the European Union military mission to contribute to the training of Somali security forces (EUTM Somalia) from 9 February 2022.

⁽¹⁾ OJ L 44, 19.2.2010, p. 16.

⁽²⁾ Political and Security Committee Decision (CFSP) 2020/1072 of 16 July 2020 on the appointment of the EU Mission Force Commander of the European Union military mission to contribute to the training of Somali security forces (EUTM Somalia) and repealing Decision (CFSP) 2019/1264 (EUTM Somalia/1/2020) (OJ L 234, 21.7.2020, p. 18).

Article 2

Decision (CFSP) 2020/1072 is hereby repealed from 9 February 2022.

Article 3

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

Done at Brussels, 8 February 2022.

For the Political and Security Committee
The Chairperson
D. PRONK

COMMISSION IMPLEMENTING DECISION (EU) 2022/171**of 2 February 2022****on the request for registration of the European citizens' initiative entitled 'Win It On The Pitch' pursuant to Regulation (EU) 2019/788 of the European Parliament and of the Council***(notified under document C(2022) 630)***(Only the English text is authentic)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/788 of the European Parliament and of the Council of 17 April 2019 on the European citizens' initiative ⁽¹⁾, and in particular Article 6(2) and (3) thereof,

Whereas:

- (1) A request for registration of a European citizens' initiative entitled 'Win It On The Pitch' was submitted to the Commission on 30 September 2021.
- (2) The initiative had three objectives, namely the adoption of (1) a Council recommendation to protect the model of football in Europe based on values, solidarity, sustainability and open competitions, by providing an EU framework and guidelines for Member State action to protect the model of football in Europe; (2) Commission guidelines on the application of EU competition rules to sport; and (3) a Commission communication to 'build the strongest possible model of European sport for the future, including reference to what European fans and citizens expect from sport in Europe'.
- (3) In accordance with Article 1 of Regulation (EU) 2019/788, initiatives can be registered when they invite the Commission to propose a legal act of the Union within the framework of its powers for the purpose of implementing the Treaties. While the Commission has the power under Article 165 of the Treaty on the Functioning of the European Union to adopt a proposal for a Council recommendation as indicated under objective 1 of the initiative, objectives 2 and 3, as initially drafted, did not call upon the Commission to adopt 'a proposal for a legal act of the Union'. They only asked the Commission to adopt guidelines and a Commission communication.
- (4) On 27 October 2021, in accordance with Article 6(4) of Regulation (EU) 2019/788, the Commission informed the group of organisers of its assessment that the requirements for registration set out in Article 6(3), points (a), (d) and (e), of that Regulation were fulfilled and that the requirement set out in Article 6(3), point (b) was not applicable. However, the Commission also indicated that the text of the initiative as formulated in the request of 30 September 2021 did not allow it to conclude that it fulfilled the requirement set out in Article 6(3), point (c) of Regulation (EU) 2019/788.
- (5) As a result, an amended version of the initiative was submitted to the Commission on 3 January 2022.
- (6) The initiative invites the Commission to adopt a proposal for a Council recommendation providing an EU framework and guidelines for Member State action to protect the model of football in Europe, to recognise the social value of sport in European society and the specific nature of sport in the EU competition rules and to strengthen the EU vision and long-term policy on the future and governance of European sport.
- (7) An annex provides further details on the subject matter, objectives and background to the initiative. The organisers have also provided further information on their initiative in an additional document.

⁽¹⁾ OJ L 130, 17.5.2019, p. 55.

- (8) Insofar as the initiative seeks the adoption of a Council recommendation aiming to achieve the objective that the Union contribute to the promotion of European sporting issues, while taking account of the specific nature of sport, its structures based on voluntary activity and its social and educational function, the Commission has the power to present a proposal for a legal act on the basis of Article 165 of the Treaty.
- (9) For those reasons, none of the parts of the initiative manifestly falls outside the framework of the Commission's powers to submit a proposal for a legal act of the Union for the purpose of implementing the Treaties.
- (10) This conclusion is without prejudice to the assessment of whether the concrete factual and substantive conditions required for the Commission to act, including compliance with the principles of proportionality and subsidiarity and compatibility with fundamental rights, would be met in this case.
- (11) The group of organisers has provided appropriate evidence that it fulfils the requirements laid down in Article 5(1) and (2) of Regulation (EU) 2019/788 and has designated the contact persons in accordance with Article 5(3), first subparagraph, of that Regulation.
- (12) The initiative is not manifestly abusive, frivolous or vexatious, nor is it manifestly contrary to the values of the Union as set out in Article 2 of the Treaty on European Union and rights enshrined in the Charter of Fundamental Rights of the European Union.
- (13) The initiative entitled 'Win It On The Pitch' should therefore be registered.
- (14) The conclusion that the conditions for registration under Article 6(3) of Regulation (EU) 2019/788 are fulfilled does not imply that the Commission in any way confirms the factual correctness of the content of the initiative, which is the sole responsibility of the group of organisers of the initiative. The content of the initiative only expresses the views of the group of organisers, and can in no way be taken to reflect the views of the Commission,

HAS ADOPTED THIS DECISION:

Article 1

The European citizens' initiative entitled 'Win It On The Pitch' shall be registered.

Article 2

This Decision is addressed to the group of organisers of the citizens' initiative entitled 'Win It On The Pitch', represented by Mr Ronan EVAÏN and Ms Martha MESTRE GENS VIDA DA CONCEIÇÃO acting as contact persons.

Done at Brussels, 2 February 2022.

For the Commission
Věra JOUROVÁ
Vice-President

COMMISSION IMPLEMENTING DECISION (EU) 2022/172**of 7 February 2022****amending Implementing Decision (EU) 2018/1538 on the harmonisation of radio spectrum for use by short-range devices within the 874-876 and 915-921 MHz frequency bands***(notified under document C(2022) 608)***(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) Short-range devices are typically mass-market or portable products or both which can easily be taken and used across borders. Differences in spectrum access conditions may prevent their free movement, increase their production costs and create risks of harmful interference with other radio applications and services due to unauthorised use. Commission Decision 2006/771/EC ⁽²⁾ harmonised the technical conditions for use of spectrum for a wide variety of short-range devices which, as a result, are subject to a very light regulatory regime and to no more than a general authorisation under national law.
- (2) Commission Implementing Decision (EU) 2018/1538 ⁽³⁾ harmonised the technical conditions for the use of the 874-876 and 915-921 MHz frequency bands by technically advanced radio frequency identification ('RFID') solutions as well as 'Internet of Things' applications based on networked short-range devices in data networks. In those frequency bands, the sharing environment is different compared to that applicable under Decision 2006/771/EC, therefore, a specific regulatory regime is required.
- (3) While the 873-874,4 MHz and 918-919,4 MHz bands are not harmonised for usage of the global system for mobile communications for -railway ('GSM -R') s by Union law or by a Decision of the European Communications Committee ('ECC'), these frequency bands may be used for this purpose on a national basis subject to a national decision in line with the Radio Regulations of the International Telecommunication Union. Therefore, where harmonised technical conditions would not be sufficient to protect the use of these bands for a national extension of GSM for Railways ('E-GSM-R'), concerned Member States are allowed to subject the use of short-range devices to additional requirements without impacting the harmonised technical conditions for access to spectrum for short-range devices within the bands. Such restrictions, where needed in a particular Member State, should notably ensure that coordination between spectrum users takes place in order to enable geographic sharing between E-GSM-R on the one hand and RFID devices and networked short-range devices on the other.
- (4) The harmonised use for railway mobile radio of the paired frequency bands 874,4-880,0 MHz and 919,4-925,0 MHz, which are adjacent to sub-bands 874-874,4 MHz and 917,4-919,4 MHz harmonised for short-range devices by this Decision, is subject to Commission Implementing Decision (EU) 2021/1730 ⁽⁴⁾. The coexistence between

⁽¹⁾ OJ L 108, 24.4.2002, p. 1.

⁽²⁾ Commission Decision 2006/771/EC of 9 November 2006 on harmonisation of the radio spectrum for use by short-range devices (OJ L 312, 11.11.2006, p. 66).

⁽³⁾ Commission Implementing Decision (EU) 2018/1538 of 11 October 2018 on the harmonisation of radio spectrum for use by short-range devices within the 874-876 and 915-921 MHz frequency bands (OJ L 257, 15.10.2018, p. 57).

⁽⁴⁾ Commission Implementing Decision (EU) 2021/1730 of 28 September 2021 on the harmonised use of the paired frequency bands 874,4-880,0 MHz and 919,4-925,0 MHz and of the unpaired frequency band 1 900-1 910 MHz for Railway Mobile Radio (OJ L 346, 30.9.2021, p. 1).

short-range devices in the 874-874,4 MHz and 917,4-919,4 MHz frequency bands and railway mobile radio in the adjacent frequency bands 874,4-880,0 MHz and 919,4-925,0 MHz was assessed in Report 74 of the European Conference of Postal and Telecommunications Administrations ('CEPT').

- (5) In accordance with Article 1(4) of Decision No 676/2002/EC, Member States retain the right to organise and use their radio spectrum for public order and public security purposes and defence, and remain free, in that context, to protect the existing and future use of the 874-876 and 915-921 MHz frequency bands and of adjacent bands for military and other public security and public order purposes while pursuing the aim of making available the minimum harmonised core bands for networked short-range devices in accordance with the technical conditions defined in this Decision and in compliance notably with the general principles of EU law.
- (6) In order to reflect technological and market developments in the area of short-range devices, a permanent mandate was issued in July 2006 to the CEPT⁷ pursuant to Article 4(2) of Decision No 676/2002/EC, to update the Annex to Decision 2006/771/EC. The work carried out on the basis of the permanent mandate (seventh update cycle) was also the basis for Implementing Decision (EU) 2018/1538 which provided additional spectrum for short-range devices within the 874-876 and 915-921 MHz frequency bands.
- (7) On 16 July 2019, the Commission issued its guidance letter for the eighth update cycle of Decision 2006/771/EC. In response to the permanent mandate and in accordance with that guidance, the CEPT submitted to the Commission its Report 77 on 5 March 2021 which contains several proposals for the amendment of Implementing Decision (EU) 2018/1538. Those include the amendment of definitions in relation to short-range devices, in order to avoid ambiguity and ensure consistency with Decision 2006/771/EC. They also propose re-assessment of some technical parameters for categories of short-range devices covered by Implementing Decision (EU) 2018/1538. CEPT Report 77 constitutes the technical basis for this Decision.
- (8) Short-range devices operating within the conditions set out in this Decision should also comply with Directive 2014/53/EU of the European Parliament and of the Council⁽⁸⁾.
- (9) Implementing Decision (EU) 2018/1538 should therefore be amended.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Radio Spectrum Committee,

HAS ADOPTED THIS DECISION:

Article 1

- (1) Decision (EU) 2018/1538 is amended as follows:

Article 2 is replaced by the following:

'Article 2

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

- (1) "short-range device" means a radio device which provides either unidirectional or bidirectional communication and which receives and/or transmits over a short distance at low power;
- (2) "non-interference and non-protected basis" means that no harmful interference may be caused to any radio communication service and that no claim may be made for protection of these devices against interference originating from radio communication services;

⁽⁸⁾ 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).

- (3) “category of short-range devices” means a group of short-range or networked short-range devices that use spectrum with similar technical spectrum access mechanisms or based on common usage scenarios;”
- (2) The Annex is replaced by the text in the Annex to this Decision

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 7 February 2022.

For the Commission
Thierry BRETON
Member of the Commission

Frequency bands with corresponding harmonised technical conditions and implementation deadlines for short-range devices

The following table specifies different combinations of frequency band and category of short-range devices (as defined in Article 2(6)), and the harmonised technical conditions for spectrum access and implementation deadlines applicable thereto.

General technical conditions applicable to all bands and short-range devices that fall in the scope of this Decision:

- Member States must allow the usage of spectrum up to the **transmit power, field strength or power density** given in this table. In accordance with Article 3(3), they may impose less restrictive conditions, i.e. allow the use of spectrum with higher transmit power, field strength or power density, provided that this does not reduce or compromise the appropriate coexistence between short-range devices in bands harmonised by this Decision;
- Member States may only impose the **'additional parameters'** (channelling and/or channel access and occupation rules) identified in the table, and shall not add other parameters or spectrum access and mitigation requirements. Less restrictive conditions within the meaning of Article 3(3), mean that Member States may completely omit the 'additional parameters (channelling and/or channel access and occupation rules)' in a given cell or allow higher values, provided that the appropriate sharing environment in the harmonised band is not compromised.
- Member States may only impose the **'other usage restrictions'** identified in the table and shall not add additional usage restrictions unless the conditions mentioned in Article 3(2) apply. As less restrictive conditions may be introduced within the meaning of Article 3(3), Member States may omit one or all of these restrictions, provided that the appropriate sharing environment in the harmonised band is not compromised.

Terms used:

'Duty cycle' is defined as the ratio, expressed as a percentage, of $\Sigma(\text{Ton})/(\text{Tobs})$ where Ton is the 'on' time of a single transmitter device and Tobs is the observation period. Ton is measured in an observation frequency band (Fobs). Unless otherwise specified in this technical annex, Tobs is a continuous one hour period and Fobs is the applicable frequency band in this Annex. Less restrictive conditions within the meaning of Article 3(3), mean that Member States may allow a higher value for 'duty cycle'.

Band no	Frequency band	Category of short-range devices	Transmit power limit/field strength limit/power density limit	Additional parameters (channelling and/or channel access and occupation rules)	Other usage restrictions	Implementation deadline
1	874-874,4 MHz ^[8]	Non-specific short-range devices ^[1]	500 mW e.r.p. Adaptive Power Control (APC) required, alternatively other mitigation techniques which achieve at least an equivalent level of spectrum compatibility	Techniques to access spectrum and mitigate interference that provide an appropriate level of performance to comply with the essential requirements of Directive 2014/53/EU shall be used. If relevant techniques are described in harmonised standards or parts thereof the references of which have been published in the <i>Official Journal</i>	This set of usage conditions is only available for data networks All nomadic and mobile devices within the data network shall be controlled by a master network access point ^[4] , ^[5] , ^[6] , ^[7]	1 July 2022

				<p>of the European Union under Directive 2014/53/EU, performance at least equivalent to these techniques shall be ensured.</p> <p>Bandwidth: ≤ 200 kHz</p> <p>Duty cycle: ≤ 10 % for network access points ^[4]</p> <p>Duty cycle: 2,5 % otherwise</p>		
2	917,4-919,4 MHz ^[9]	Wideband data transmission devices ^[3]	25 mW e.r.p	<p>Techniques to access spectrum and mitigate interference that provide an appropriate level of performance to comply with the essential requirements of Directive 2014/53/EU shall be used. If relevant techniques are described in harmonised standards or parts thereof the references of which have been published in the <i>Official Journal of the European Union</i> under Directive 2014/53/EU, performance at least equivalent to these techniques shall be ensured.</p> <p>Bandwidth: > 600 kHz and ≤ 1 MHz</p> <p>Duty cycle: ≤ 10 % for network access points ^[4]</p> <p>Duty cycle: ≤ 2,8 % otherwise</p>	<p>This set of usage conditions is only available for wideband short-range devices in data networks</p> <p>All nomadic and mobile devices within the data network shall be controlled by a master network access point ^{[4], [5], [6]}</p>	1 July 2022

3	916,1-918,9 MHz ^[10]	Radio Identification devices ^[2] Frequency (RFID)	Interrogator transmissions at 4 W e.r.p. only permitted at the centre frequencies 916,3 MHz, 917,5 MHz, 918,7 MHz	Techniques to access spectrum and mitigate interference that provide an appropriate level of performance to comply with the essential requirements of Directive 2014/53/EU shall be used. If relevant techniques are described in harmonised standards or parts thereof the references of which have been published in the <i>Official Journal of the European Union</i> under Directive 2014/53/EU, performance at least equivalent to these techniques shall be ensured. Bandwidth: ≤ 400 kHz	^{[5], [6], [7]}	1 July 2022
4	917,3-918,9 MHz	Non-specific short-range devices ^[1]	500 mW e.r.p. Transmissions only permitted within the frequency ranges 917,3-917,7 MHz, 918,5-918,9 MHz Adaptive Power Control (APC) required, alternatively other mitigation techniques which achieve at least an equivalent level of spectrum compatibility	Techniques to access spectrum and mitigate interference that provide an appropriate level of performance to comply with the essential requirements of Directive 2014/53/EU shall be used. If relevant techniques are described in harmonised standards or parts thereof the references of which have been published in the <i>Official Journal of the European Union</i> under Directive 2014/53/EU, performance at least equivalent to these techniques shall be ensured.	This set of usage conditions is only available for data networks. All nomadic and mobile devices within the data network shall be controlled by a master network access point ^{[4], [5], [6], [7]} .	1 July 2022

				<p>Bandwidth: ≤ 200 kHz</p> <p>Duty cycle: ≤ 10 % for network access points ^[4]</p> <p>Duty cycle: ≤ 2,5 % otherwise</p>		
5	917,4-919,4 MHz ^[9]	Non-specific short-range devices ^[1]	25 mW e.r.p.	<p>Techniques to access spectrum and mitigate interference that provide an appropriate level of performance to comply with the essential requirements of Directive 2014/53/EU shall be used. If relevant techniques are described in harmonised standards or parts thereof the references of which have been published in the <i>Official Journal of the European Union</i> under Directive 2014/53/EU, performance at least equivalent to these techniques shall be ensured.</p> <p>Bandwidth: ≤ 600 kHz</p> <p>Duty cycle: ≤ 1 %,</p>	<p>This set of usage conditions is only available for short-range device in data networks. All nomadic and mobile devices within the data network shall be controlled by a master network access point ^[4], ^[5], ^[6]</p>	1 July 2022

^[1] The non-specific short-range device category covers all kinds of radio devices, regardless of the application or the purpose, which fulfil the technical conditions as specified for a given frequency band. Typical uses include telemetry, telecommand, alarms, data transmissions in general and other applications.

^[2] The radio frequency identification (RFID) device category covers tag/interrogator based radio communications systems, consisting of radio devices (tags) attached to animate or inanimate items and of transmitter/receiver units (interrogators) which activate the tags and receive data back. Typical uses include the tracking and identification of items, such as for electronic article surveillance (EAS), and collecting and transmitting data relating to the items to which tags are attached, which may be either battery-less, battery assisted or battery powered. The responses from a tag are validated by its interrogator and passed to its host system.

^[3] The wideband data transmission device category covers radio devices that use wideband modulation techniques to access the spectrum. Typical uses include wireless access systems such as radio local area networks (WAS/RLANs) or wideband short-range devices in data networks.

^[4] A network access point in a data network is a fixed terrestrial short range device that acts as a connection point for the other short range devices in the data network to service platforms located outside of that data network. The term data network refers to several short range devices, including the network access point, as network components and to the wireless connections between them.'

^[5] According to Article 3(1) the frequency bands shall be designated and made available on a non-exclusive and shared basis. The harmonised technical conditions shall make it possible for most short-range devices in most Member States to be operated subject to a general authorisation regime under national law. This is without prejudice to Articles 46 and 51 of Directive (EU) 2018/1972 and to Articles 3(2) and 7 of Directive 2014/53/EU. Member States may limit usage of this entry such that installation and operation are performed only by professional users and may consider individual authorisation, e.g. to administer geographical sharing and/or the application of mitigation techniques to ensure protection of radio services.

^[6] In Member States where parts or all of this frequency range are used for public order and public security purposes and defence and coordination is not possible, Member States may decide not to implement this entry partially or entirely, in accordance with Article 1(4) of Decision 676/2002/EC and Article 3(2) of this Decision.

^[7] National rules, such as local coordination, may also be needed in order to avoid interference to radio services operating in the adjacent bands, for example due to intermodulation or blocking.

^[8] This frequency range 874-874,4 MHz is the harmonised minimum core band.

^[9] This frequency range 917,4-919,4 MHz is the harmonised minimum core band.

^[10] RFID tags respond at a very low power level (-10 dBm e.r.p.) in a frequency range around the RFID interrogator channels and must comply with the essential requirements of Directive 2014/53/EU.

COMMISSION IMPLEMENTING DECISION (EU) 2022/173**of 7 February 2022****on the harmonisation of the 900 MHz and 1 800 MHz frequency bands for terrestrial systems capable of providing electronic communications services in the Union and repealing Decision 2009/766/EC***(notified under document C(2022) 605)***(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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

Having regard to Directive (EU) 2018/1972 of the European Parliament and of the Council of 11 December 2018 establishing the European Electronic Communications Code ⁽¹⁾,

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) ⁽²⁾, and in particular Article 4(3) thereof

Whereas:

- (1) As announced in the Commission's Communication *Shaping Europe's Digital Future* of 19 February 2020, digital solutions are crucial to help Europe pursue its own way towards a digital transformation that works for the benefit of citizens and undertakings in compliance with the Union's values. To that end, it is essential that: people benefit from technology; a single market without borders is ensured in which undertakings of all sizes can compete on equal terms; and democratic values, respect for fundamental rights and a sustainable, climate-neutral and resource-efficient economy are pursued. In that context, radio spectrum is a key public resource that is used more and more for an extensive range of commercial and public services.
- (2) The way in which radio spectrum policy in the Union is pursued and implemented is to comply with and contribute to freedom of expression, including freedom of opinion and freedom to receive and disseminate information and ideas, irrespective of borders, as well as freedom and plurality of the media, in line with the Union's values under Article 2 of the Treaty of the European Union. Indeed, market access for several operators is necessary to ensure pluralism and freedom of information.
- (3) Commission Decision 2009/766/EC ⁽³⁾ harmonises the technical conditions for using the radio spectrum in the 880-915 MHz and 925-960 MHz frequency bands ('900 MHz frequency band') and in the 1 710-1 785 MHz and 1 805-1 880 MHz frequency bands ('1 800 MHz frequency band') for terrestrial systems capable of providing electronic communications services in the Union, including wireless broadband services. It ensures compliance with Article 1(1) of Council Directive 87/372/EEC ⁽⁴⁾ as regards the coexistence of terrestrial systems capable of providing electronic communications services with GSM systems in the 900 MHz band.

⁽¹⁾ OJ L 321, 17.12.2018, p. 36.

⁽²⁾ OJ L 108, 24.4.2002, p. 1.

⁽³⁾ Commission Decision 2009/766/EC of 16 October 2009 on the harmonisation of the 900 MHz and 1 800 MHz frequency bands for terrestrial systems capable of providing pan-European electronic communications services in the Community (OJ L 274, 20.10.2009, p. 32). This Decision has been amended by Commission Decisions 2011/251/EU and (EU) 2018/637. The latter amendment addresses harmonised technical conditions for the internet of Things.

⁽⁴⁾ Council Directive 87/372/EEC of 25 June 1987 on the frequency bands to be reserved for the coordinated introduction of public pan-European cellular digital land-based mobile communications in the Community (OJ L 196, 17.7.1987, p. 85). This Directive has been amended by Directive 2009/114/EC of the European Parliament and of the Council.

- (4) Article 6(3) of Decision No 243/2012/EU of the European Parliament and the Council ⁽⁵⁾ requires Member States to help providers of electronic communication services regularly upgrade their networks to the latest, most efficient technology, in order to create their own spectrum dividends in line with the principles of service and technological neutrality. Therefore, use of the 900 MHz and 1 800 MHz frequency bands with large block sizes of at least 5 MHz in support of next generation (5G) terrestrial wireless systems should be facilitated in pursuance of the objectives of the EU regulatory framework and in compliance with EU law.
- (5) The Commission's Communication 'Connectivity for a Competitive Digital Single Market – towards a European Gigabit Society' ⁽⁶⁾ sets out new connectivity objectives for the Union updated with the Commission Communication '2030 Digital Compass: the European way for the Digital Decade' ⁽⁷⁾. Those objectives are to be achieved through the widespread deployment and take-up of very high capacity networks. The Commission Communication '5G for Europe: an Action Plan' ⁽⁸⁾ identifies coordinated actions at Union level, including the identification and harmonisation of spectrum for 5G on the basis of the opinion of the Radio Spectrum Policy Group (RSPG), in order to ensure uninterrupted 5G coverage in all urban areas and major terrestrial transport paths by 2025.
- (6) In its two opinions of 16 November 2016 ⁽⁹⁾ and 30 January 2019 ⁽¹⁰⁾ on a strategic spectrum roadmap towards 5G for Europe, the RSPG identified the need to ensure that the technical and regulatory conditions for all bands already harmonised for mobile networks are fit for 5G use, including the 900 MHz and 1 800 MHz frequency bands, which are currently in use in the Union predominantly for the second (GSM), the third (UMTS) and the fourth (LTE) generation of mobile systems.
- (7) On 14 July 2017, in accordance with Article 4(2) of the Radio Spectrum Decision the Commission issued a mandate to the European Conference of Postal and Telecommunications Administrations (CEPT) to review the harmonised technical conditions for use of the 900 MHz and 1 800 MHz bands for terrestrial wireless broadband electronic communications services with the objective to also allow their use by the internet of Things (IoT).
- (8) In response to that mandate, on 13 March 2018, the CEPT adopted its CEPT Report 66, which identifies wireless IoT technologies in relation to mobile broadband (i.e. cellular) communications systems and harmonised technical conditions for their use in the 900 MHz and 1 800 MHz frequency bands. Those IoT technologies are Extended Coverage GSM IoT (EC-GSM-IoT), LTE Machine Type Communications (LTE-MTC), LTE evolved Machine Type Communications (LTE-eMTC), and Narrowband IoT (NB-IoT). CEPT Report 66 also concludes that EC-GSM-IoT is an integral part of the GSM system under Directive 87/372/EEC. Therefore, EC-GSM-IoT complies with the technical conditions applicable to a GSM system without any need to amend these conditions.
- (9) On 12 July 2018, the Commission issued under Article 4(2) of the Radio Spectrum Decision a mandate to the CEPT to review the harmonised technical conditions for certain EU-harmonised frequency bands, including the 900 MHz and 1 800 MHz frequency bands, and to develop least restrictive harmonised technical conditions suitable for next-generation (5G) terrestrial wireless systems.
- (10) In response to that mandate, on 5 July 2019, the CEPT adopted its CEPT Report 72 (Report A) which concludes that within the 900 MHz frequency band, GSM and narrowband terrestrial systems including cellular IoT systems will continue to be in commercial operation for the foreseeable future. This Report stipulates a need for a frequency separation of 200 kHz, when GSM and narrowband terrestrial systems, including cellular IoT systems, are in

⁽⁵⁾ Decision No 243/2012/EU of the European Parliament and of the Council of 14 March 2012 establishing a multiannual radio spectrum policy programme (OJ L 81, 21.3.2012, p. 7).

⁽⁶⁾ COM(2016) 587.

⁽⁷⁾ COM(2021) 118 final.

⁽⁸⁾ COM(2016) 588.

⁽⁹⁾ Document RSPG16-032 final of 9 November 2016, *Strategic roadmap towards 5G for Europe: opinion on spectrum-related aspects for next-generation wireless systems (5G) (RSPG 1st opinion on 5G)*.

⁽¹⁰⁾ Document RSPG19-007 final of 30 January 2019, *Strategic spectrum roadmap towards 5G for Europe: opinion on 5G implementation challenges (RSPG 3rd opinion on 5G)*.

operation in the 900 MHz and 1 800 MHz frequency bands. Furthermore, this Report provides also information on the feasibility of using the 900 MHz and 1 800 MHz frequency bands for 5G, including any limitations of the GSM Directive for the 900 MHz band.

- (11) In response to that mandate, on 2 July 2021, the CEPT adopted its CEPT Report 80 (Report B), which proposes a harmonised band plan and the least restrictive harmonised technical conditions for the coexistence of narrowband and broadband terrestrial systems capable of providing electronic communications services using the 900 MHz and 1 800 MHz frequency bands, based on the concept of a block edge mask. Those conditions are essential for ensuring technology neutrality in the 900 MHz and 1 800 MHz frequency bands.
- (12) CEPT Report 80 defines one block edge mask for narrowband and broadband terrestrial systems using non-active antenna systems, and another block edge mask for broadband terrestrial systems using active antenna systems. GSM and EC-GSM-IoT are not covered by those block edge masks and are technically characterised by references to ETSI standards. On that basis, CEPT Report 80 provides the least restrictive technical conditions for the coexistence of different narrowband and broadband terrestrial systems⁽¹¹⁾ capable of providing electronic communications services within the 900 MHz and 1 800 MHz frequency bands. It also provides the conditions for coexistence of those systems with the GSM system in the 900 MHz frequency band, pursuant to the Council Directive 87/372/EEC.
- (13) The block edge masks cover narrowband terrestrial systems with a channel bandwidth of 200 kHz, but excluding GSM and EC-GSM-IoT. They also cover broadband terrestrial systems with a channel bandwidth larger than 200 kHz. The differentiation between narrowband and broadband terrestrial systems is necessary for the implementation of a frequency separation in certain scenarios at national level. In this regard, CEPT Report 80 sets out a frequency separation between the nominal channel edges of adjacent narrowband and broadband terrestrial systems capable of providing electronic communications services as well as between the nominal channel edges of different adjacent narrowband terrestrial systems capable of providing electronic communications services and also GSM and EC-GSM-IoT. The implementation of frequency separation should be managed at the national level. Different approaches could be implemented, depending on the spectrum edges of adjacent terrestrial systems as well as relevant national policies. CEPT Report 80 includes a toolbox for implementing frequency separation.
- (14) CEPT Report 80 provides the least restrictive technical conditions for the coexistence of narrowband and broadband terrestrial systems capable of providing electronic communications services with systems in adjacent frequency bands, in particular Railway Mobile Radio (RMR) systems. In this regard, a frequency separation of 200 kHz between the nominal channel edges of a terrestrial system capable of providing electronic communications services and an RMR system, which is adjacent in frequency, may be applied in certain scenarios. Coexistence between GSM systems and RMR should be managed at national level in accordance with the existing regulatory framework.
- (15) The harmonised technical conditions set out in CEPT Report 80 constitute the technical basis for this Decision. They should replace the harmonised technical conditions of Decision 2009/766/EC, which are based on references to ETSI standards, while ensuring compatibility with those conditions and their amendment. This should promote legal certainty and technical convergence across the Union in support of economies of scale of equipment and interoperable services in the single market.
- (16) Existing rights of use of spectrum in the 900 MHz and 1 800 MHz frequency bands, which are subject to Decision 2009/766/EC, vary across the Member States in terms of assigned block sizes, frequency arrangements or durations of those rights. Therefore, due to different national situations and policy objectives, there is a need to maintain flexibility for the national implementation of the harmonised technical conditions pursuant to this Decision. National flexibility should be time-limited in accordance with Article 53 of Directive (EU) 2018/1972 of the

⁽¹¹⁾ Including UMTS, in line with Article 1(1) of Council Directive 87/372/EEC.

European Parliament and of the Council ⁽¹²⁾, to allow the coordinated transition of existing individual rights of use of spectrum to those harmonised technical conditions. Any new or prolonged rights of use of spectrum granted after adoption of this Decision should comply with those harmonised technical conditions. This would foster a Union-wide ecosystem of equipment and services and stimulate 5G deployment in both frequency bands, as well as ensure the continued provision of GSM services in accordance with the GSM Directive.

- (17) This Decision should therefore supersede Commission Decision 2009/766/EC. In the interest of legal clarity, Commission Decision 2009/766/EC should be repealed. Its Annex and its relevant provision allowing use of spectrum in the 900 MHz and 1 800 MHz frequency bands for other systems not listed in the Annex should remain applicable for a transitional period.
- (18) Cross-border coordination agreements among Member States as well as between Member States and non-EU countries may be necessary to avoid harmful interference and to improve spectrum efficiency and non-fragmentation in spectrum use, in compliance with Article 28 of Directive (EU) 2018/1972.
- (19) The notion of ‘designating and making available’ the 900 MHz and 1 800 MHz frequency bands in the context of this Decision refers to the following steps: (i) the adaptation of the national legal framework on frequency allocation to include the intended use of these bands under the harmonised technical conditions set in this Decision, (ii) the initiation of all necessary measures in order to ensure coexistence with existing use in these bands to the extent necessary, (iii) the initiation of the appropriate measures, supported by the launch of a stakeholder consultation process where appropriate, in order to allow the use of these bands in accordance with the applicable legal framework at Union level, including the harmonised technical conditions of this Decision.
- (20) The measures provided for in this Decision are in accordance with the opinion of the Radio Spectrum Committee,

HAS ADOPTED THIS DECISION:

Article 1

This Decision establishes the harmonised technical conditions for the availability and efficient use of the 900 MHz band, in accordance with Directive 87/372/EEC, and of the 1 800 MHz band, for terrestrial systems capable of providing electronic communications services.

Article 2

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

- (a) ‘GSM system’ means an electronic communications network as specified by ETSI standards, in particular EN 301 502, EN 301 511, and EN 301 908-18, also including Extended Coverage GSM IoT (EC-GSM-IoT);
- (b) ‘900 MHz band’ means the 880-915 MHz and 925-960 MHz bands;
- (c) ‘1 800 MHz band’ means the 1 710-1 785 MHz and 1 805-1 880 MHz bands.

Article 3

1. The terrestrial systems capable of providing electronic communications services that can coexist with GSM systems in the 900 MHz band within the meaning of Article 1(1) of Directive 87/372/EEC shall comply with the parameters set out in the Annex within 30 months from the adoption of this Decision.

⁽¹²⁾ Directive (EU) 2018/1972 of the European Parliament and of the Council of 11 December 2018 establishing the European Electronic Communications Code (OJ L 321, 17.12.2018, p. 36).

2. Member States shall designate and make available, within 30 months from the adoption of this Decision, on a non-exclusive basis, the 1 800 MHz frequency band for:

- (a) GSM systems; and
- (b) terrestrial systems capable of providing electronic communications services, in compliance with the parameters set out in the Annex.

Article 4

Member States shall facilitate cross-border coordination agreements to enable operation of GSM systems and the terrestrial systems referred to in Article 3(1) and 3(2)(b), taking into account existing regulatory procedures and rights as well as relevant international agreements, in compliance with EU law.

Article 5

Member States shall ensure that terrestrial systems referred to in Article 3(1) and 3(2)(b) give appropriate protection to systems in adjacent bands.

Article 6

Member States shall keep the use of the 900 MHz and 1 800 MHz bands under permanent review to ensure the efficient use thereof, and in particular report as soon as necessary to the Commission any need for a revision of this Decision, in compliance with EU law.

Article 7

Decision 2009/766/EC is hereby repealed. Its Article 5 and its Annex shall remain applicable for 30 months from the adoption of this Decision.

Article 8

This Decision is addressed to the Member States.

Done at Brussels, 7 February 2022.

For the Commission
Thierry BRETON
Member of the Commission

ANNEX

'ANNEX

PARAMETERS REFERRED TO IN ARTICLE 3

1. Definitions

Active antenna systems (AAS) means a base station and an antenna system where the amplitude and/or phase between antenna elements is continually adjusted, resulting in an antenna pattern that varies in response to short-term changes in the radio environment. This excludes long-term beam shaping such as fixed electrical down tilt. In AAS base stations the antenna system is integrated as part of the base station system or product.

Non-active antenna systems (non-AAS) means a base station and an antenna system that provides one or more antenna connectors, which are connected to one or more separately designed passive antenna elements to radiate radio waves. The amplitude and phase of the signals to the antenna elements is not continually adjusted in response to short-term changes in the radio environment.

Equivalent isotropically radiated power (EIRP) is the product of the power supplied to the antenna and the antenna gain in a given direction relative to an isotropic antenna (absolute or isotropic gain).

Total radiated power (TRP) is a measure of how much power a composite antenna radiates. It equals the total conducted power input into the antenna array system less any losses in the antenna array system. TRP means the integral of the power transmitted in different directions over the entire radiation sphere, as shown in the formula:

$$TRP \stackrel{\text{def}}{=} \frac{1}{4\pi} \int_0^{2\pi} \int_0^{\pi} P(\theta, \varphi) \sin(\theta) d\theta d\varphi$$

where $P(\vartheta, \varphi)$ is the power radiated by an antenna array system in direction (ϑ, φ) given by the formula:

$$P(\theta, \varphi) = P_{Tx} g(\theta, \varphi)$$

where P_{Tx} denotes the conducted power (measured in Watts), which is input to the array system, and $g(\vartheta, \varphi)$ denotes the array systems directional gain along the (ϑ, φ) direction.

Narrowband system is a terrestrial system capable of providing electronic communications services operating in a 200 kHz channel ⁽¹⁾, excluding any GSM system.

Broadband system is a terrestrial system capable of providing electronic communications services operating in a channel larger than 200 kHz ⁽²⁾.

2. Frequency arrangement

Within the 900 MHz band, the frequency arrangement shall be as follows:

- (1) The duplex mode of operation is Frequency Division Duplex (FDD). The duplex spacing shall be 45 MHz, with terminal station transmission ("900 MHz FDD uplink") located in the lower part of the band starting at 880 MHz and finishing at 915 MHz ("900 MHz lower band") and base station transmission ("900 MHz FDD downlink") located in the upper part of the band starting at 925 MHz and finishing at 960 MHz ("900 MHz upper band").
- (2) The assigned block size shall generally provide the opportunity to access at least 5 MHz of contiguous spectrum. If smaller block sizes are assigned, they shall be in multiples of 200 kHz.

⁽¹⁾ An example of such a system is NB-IoT.

⁽²⁾ Examples of such systems are: LTE, including LTE Machine Type Communications and LTE evolved Machine Type Communications; UMTS; WiMAX; 5G New Radio.

- (3) The 900 MHz lower band, or portions thereof, can be used for uplink-only operation ^(?) without paired spectrum within the 900 MHz upper band.
- (4) The 900 MHz upper band, or portions thereof, can be used for downlink-only operation ⁽⁴⁾ without paired spectrum within the 900 MHz lower band.
- (5) Base station and terminal station transmission shall comply with the technical conditions specified in Sections 4, 5 and 6, respectively.

Within the 1 800 MHz band, the frequency arrangement shall be as follows:

- (6) The duplex mode of operation is Frequency Division Duplex (FDD). The duplex spacing shall be 95 MHz, with terminal station transmission ("1 800 MHz FDD uplink") located in the lower part of the band starting at 1 710 MHz and finishing at 1 785 MHz ("1 800 MHz lower band") and base station transmission ("1 800 MHz FDD downlink") located in the upper part of the band starting at 1 805 MHz and finishing at 1 880 MHz ("1 800 MHz upper band").
- (7) The assigned block size shall generally provide the opportunity to access at least 5 MHz of contiguous spectrum. If smaller block sizes are assigned, they shall be in multiples of 200 kHz.
- (8) The 1 800 MHz lower band, or portions thereof, can be used for uplink-only operation³ without paired spectrum within the 1 800 MHz upper band.
- (9) The 1 800 MHz upper band, or portions thereof, can be used for downlink-only operation⁴ without paired spectrum within the 1 800 MHz lower band.
- (10) Base station and terminal station transmission shall comply with the technical conditions specified in Sections 4, 5 and 6, respectively.

3. Frequency separation

Frequency separations are required to ensure coexistence in the absence of bilateral or multilateral frequency coordination agreements between neighbouring systems, without precluding less stringent technical parameters if agreed among the operators of such systems.

In the absence of frequency coordination, a frequency separation of 200 kHz shall be applied between the nominal channel edges of adjacent systems as follows:

- (1) a narrowband system and a broadband system, both complying with the block edge mask ^(?);
- (2) two different types of narrowband systems, both complying with the block edge mask;
- (3) a GSM system, and either a narrowband system or a broadband system, both complying with the block edge mask.

In the case of a narrowband system operating in the guard-band mode ⁽⁶⁾ of a relevant broadband system, a frequency separation of 200 kHz or more shall be applied between the channel edge of that narrowband system and the edge of the operator's block, taking into account existing guard bands between operators' block edges or the edge of the operating band (adjacent in frequency to other services). That narrowband system shall operate only in channel bandwidths of the relevant broadband system of 10 MHz or higher.

^(?) Such as supplemental uplink.

⁽⁴⁾ Such as supplemental downlink.

⁽³⁾ Refer to Section 4 of this Annex.

⁽⁶⁾ I.e. on the side of a frequency block used for the broadband system.

Depending on the national circumstances as regards the deployment of terrestrial systems capable of providing electronic communications services and railway mobile radio ⁽⁷⁾ systems, a frequency separation of 200 kHz may be applied between the nominal channel edges of those systems at the frequency border of 925 MHz in the following cases:

- (a) a railway mobile radio system operating in a 200 kHz channel, which is adjacent in frequency to a broadband system;
- (b) a railway mobile radio system operating in a channel larger than 200 kHz, which is adjacent in frequency to a narrowband system;
- (c) a railway mobile radio system operating in a 200 kHz channel, which is adjacent in frequency to a narrowband system of a different type.

The implementation of the frequency separation of 200 kHz shall be managed at national level ⁽⁸⁾, with the objective of ensuring efficient spectrum use.

4. Technical conditions for base stations – block edge mask

The technical parameters for base stations, called block edge mask (BEM) set out in this section, are essential to ensuring coexistence between neighbouring electronic communications networks in the absence of bilateral or multilateral agreements between operators of such neighbouring networks. BEMs relate to technical conditions attached to the rights of use of radio spectrum and the avoidance of interference between radio spectrum users who benefit from such rights.

Operators of electronic communications networks in the 900 MHz or 1 800 MHz frequency bands may agree, on a bilateral or multilateral basis, less stringent technical parameters provided that they continue to comply with the technical conditions applicable for the protection of other services, applications or networks and with their obligations resulting from cross-border coordination.

A BEM is an emission mask that defines power levels as a function of frequency relative to the edge of a block of spectrum assigned (or licensed) to an operator. It consists of several elements, as defined in Table 1.

The baseline power limit ensures that the spectrum of other operators within either the 900 MHz or the 1 800 MHz frequency band is protected. The additional baseline power limit is an out-of-band limit, which ensures that spectrum for services and applications outside either the 900 MHz or the 1 800 MHz frequency band is protected. The transitional region power limit enables a roll-off of power levels from the in-block to the baseline power limit and ensures co-existence with other operators in adjacent blocks.

The BEMs set out in this Annex do not apply to GSM systems.

Table 1

Definition of BEM elements

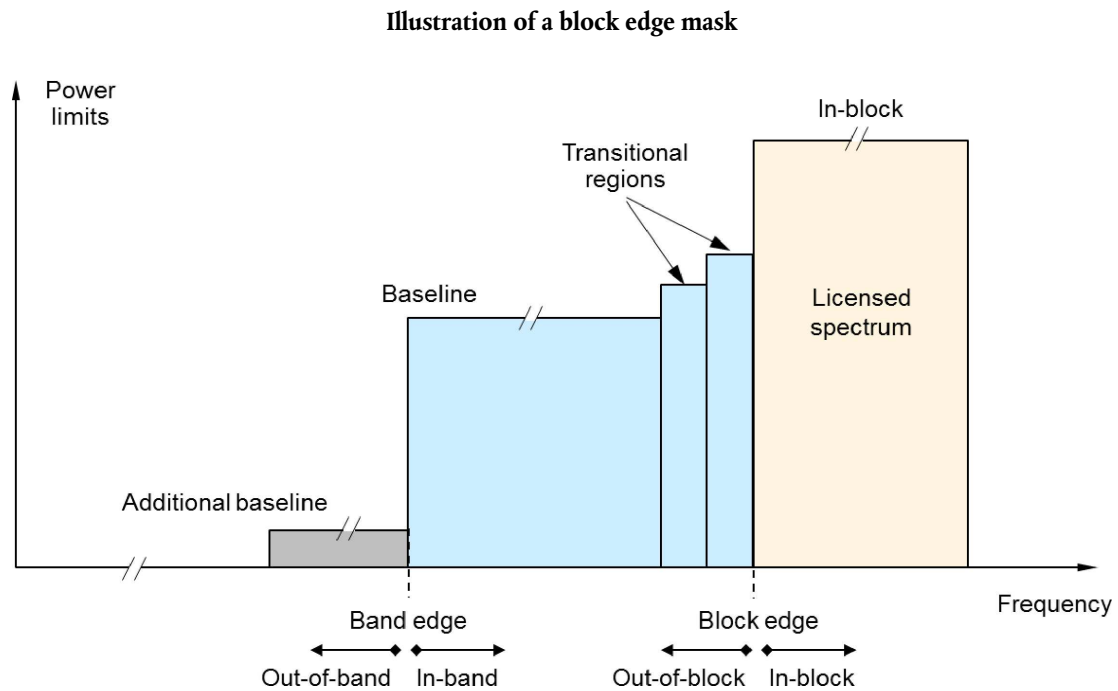
BEM element	Definition
In-block	Assigned spectrum block for which the BEM is derived.
Baseline	Spectrum within either the 900 MHz or 1 800 MHz frequency band used for terrestrial systems capable of providing electronic communications services, not including the operator's block under consideration and corresponding transitional regions.
Transitional region	Spectrum adjacent to an operator's block.
Additional baseline	Spectrum within bands adjacent to either the 900 MHz or the 1 800 MHz frequency band, where specific power limits apply for the protection of other services.

⁽⁷⁾ Railway mobile radio comprises the Global System for Mobile Communications-Rail (GSM-R) and its successors, including the Future Railway Mobile Communication System (FRMCS). Harmonised spectrum for railway mobile radio systems is subject to Commission Decision (EU) 2021/1730.

⁽⁸⁾ CEPT Report 80 contains a toolbox for implementing a frequency separation between different terrestrial systems capable of providing electronic communications services.

Figure 1 shows a general BEM applicable to either the 900 MHz or the 1 800 MHz frequency band.

Figure 1



Power limits are provided separately for non-AAS and AAS. For non-AAS, the power limits apply to the mean EIRP; for AAS, they apply to the mean TRP. The mean EIRP or mean TRP are measured by averaging over a time interval and over a frequency bandwidth. In the time domain, the mean EIRP or mean TRP is averaged over the active portions of signal bursts and corresponds to a single power control setting. In the frequency domain, the mean EIRP or mean TRP is measured over a frequency bandwidth as given in Tables 3, 4 and 5 below. In general, and unless stated otherwise, the BEM power limits correspond to the aggregate power radiated by the relevant device including all transmit antennas, except in the case of baseline, transition and additional baseline power limits for non-AAS base stations, which are specified per antenna.

The technical conditions for non-AAS base stations apply to terrestrial systems capable of providing electronic communications services using both the 900 MHz and 1 800 MHz frequency bands. The technical conditions for AAS base stations apply to terrestrial systems capable of providing electronic communications services using the 1 800 MHz frequency band. AAS base stations shall not be used in the 900 MHz frequency band.

Equipment operating in either the 900 MHz or 1 800 MHz frequency band may also make use of technical parameters other than those set out below, provided that appropriate mitigation techniques are applied. These mitigation techniques must comply with Directive 2014/53/EU of the European Parliament and of the Council (*) and offer at least an equivalent level of protection to that provided by the essential requirements of that Directive.

(*) 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).

Table 2

In-block power limits for non-AAS and AAS base stations

BEM element	Non-AAS EIRP limit	AAS TRP limit (only for the 1 800 MHz frequency band)
In-block	Not obligatory. If an upper limit is set by a Member State, a value between 63 dBm/(5 MHz) and 67 dBm/(5 MHz) per antenna may be applied for a broadband system, and a value between 60 dBm/(200 kHz) and 69 dBm/(200 kHz) per antenna may be applied for a narrowband system.	Not obligatory. If an upper limit is set by a Member State, a value of 58 dBm/(5 MHz) per cell (*) may be applied.

(*) In a multi-sector base station, the radiated power limit applies to each of the individual sectors.

Explanatory note to Table 2

For locations where a coordination procedure with adjacent services applies, Member States can set an upper limit to the radiated power.

Table 3

Baseline power limits for non-AAS and AAS base stations

BEM element	Frequency range	Non-AAS maximum mean EIRP limit per antenna	AAS maximum mean TRP limit per cell (only for the 1 800 MHz frequency band) (*)
Baseline	FDD downlink blocks	+ 3 dBm/MHz	- 6 dBm/MHz

(*) In a multi-sector base station, the radiated power limit applies to each of the individual sectors.

Table 4

Transitional region power limits for non-AAS and AAS base stations

BEM element	Frequency range	Non-AAS maximum mean EIRP limit per antenna (*)	AAS maximum mean TRP limit per cell (only for the 1 800 MHz frequency band) (**)
Transitional region	0 to 0,2 MHz offset from block edge	32,4 dBm/(0,2 MHz)	17,4 dBm/(0,2 MHz)
	0,2 to 1 MHz offset from block edge	13,8 dBm/(0,8 MHz)	4,7 dBm/(0,8 MHz)
	1 to 5 MHz offset from block edge	5 dBm/MHz	- 4 dBm/MHz
	5 to 10 MHz offset from block edge	12 dBm/(5 MHz)	3 dBm/(5 MHz)

(*) The non-AAS EIRP limits could be relaxed at national level, either if agreed among all affected operators of terrestrial systems capable of providing electronic communications services or in accordance with national implementation already in place.

(**) In a multi-sector base station, the radiated power limit applies to each of the individual sectors.

Table 5

Additional baseline power limits for non-AAS base stations

BEM element	Applicable frequency range	Non-AAS maximum mean EIRP limit per antenna (*) (**)
Additional baseline	0 to 0,2 MHz offset from block edge	32,4 dBm/(0,2 MHz)
	0,2 to 1 MHz offset from block edge	13,8 dBm/(0,8 MHz)
	1 to 5 MHz offset from block edge	5 dBm/MHz
	5 to 10 MHz offset from block edge	12 dBm/(5 MHz)
	> 10 MHz offset from block edge (***)	3 dBm/MHz

(*) Provided that adjacent services, applications and networks remain protected above 960 MHz, below 1 805 MHz and above 1 880 MHz, higher EIRP limits may be applied for non-AAS base stations on a case-by-case basis at national level. Namely, (a) EIRP limits of up to 6 dB higher are allowed in the range of 0 to 0,2 MHz from the band edge to support in-block conducted power of a narrowband system higher than 49 dBm/(200 kHz) (i.e. up to 55 dBm/(200 kHz)), (b) EIRP limits of up to 11 dB higher are allowed in the range of 0 to 10 MHz from the band edge to support higher antenna gain than 18 dBi (i.e. up to 29 dBi).

(**) Provided that adjacent services, applications and networks remain protected below 925 MHz, higher EIRP limits may be applied to non-AAS base stations on a case-by-case basis at national level.

(***) The spurious value in Section 5 applies for a frequency spacing of more than 10 MHz from the band edge.

Explanatory note to Table 5

Table 5 applies only to the out-of-band domain in line with Figure 1 and Table 1. This implies that the applicable frequency range entirely falls within the out-of-band domain.

For AAS base stations, the out-of-block limits given in Tables 3 and 4 also apply to the out-of-band domain in the range of 0 to 10 MHz from the band edge, as appropriate, considering the position of the assigned spectrum block.

5. Other conditions

The spurious emission domain for base stations in the 900 MHz and 1 800 MHz frequency bands starts at a frequency spacing of 10 MHz from the respective band edge ⁽¹⁰⁾.

Terrestrial systems capable of providing electronic communications services using AAS shall not be granted more protection from systems in adjacent bands than terrestrial systems capable of providing electronic communications services using non-AAS.

6. Technical conditions for terminal stations

AAS terminal stations shall not be used in the 900 MHz or 1 800 MHz frequency bands.

Table 6

In-block power limit for terminal stations

BEM element	Maximum mean power limit (*)
In-block	25 dBm' (**)

(*) The power limit recommended above for mobile terminal stations is specified as TRP. The in-block radiated power limit for fixed/nomadic terminal stations may be agreed on a national basis provided that protection of other services, networks and applications is not compromised and cross-border obligations are fulfilled.

(**) It is recognised that this value includes a possible tolerance of up to +2 dB, to take account of operation under extreme environmental conditions and production spread. This value does not include test tolerance.

⁽¹⁰⁾ Relevant limits are provided in ERC Recommendation 74-01.

COMMISSION IMPLEMENTING DECISION (EU) 2022/174**of 8 February 2022****determining, for a limited period of time, that the regulatory framework applicable to central counterparties in the United Kingdom of Great Britain and Northern Ireland is equivalent, in accordance with Regulation (EU) No 648/2012 of the European Parliament and of the Council****(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 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories ⁽¹⁾ and in particular Article 25(6) thereof,

Whereas:

- (1) On 29 March 2017, the United Kingdom of Great Britain and Northern Ireland (the 'United Kingdom') submitted the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. On 17 October 2019, the Union and the United Kingdom reached an agreement on the Withdrawal Agreement ⁽²⁾, with a revised Protocol on Ireland and Northern Ireland and a revised Political Declaration ⁽³⁾. Pursuant to that agreement and following its ratification by the House of Commons in the United Kingdom, its adoption by the European Parliament and its conclusion by the Council, the United Kingdom became a third country on 1 February 2020 and Union law ceased to apply to and in the United Kingdom on 31 December 2020.
- (2) Central clearing increases market transparency, mitigates credit risk and reduces the risk of contagion in the event of the default of one or more participants in a central counterparty ('CCP'). The provision of such services is therefore critical for safeguarding financial stability. Moreover, financial instruments cleared by CCPs are also essential for financial intermediaries and their clients, for example, to hedge interest rate risks, with implications for the functioning of the real economy of the Union.
- (3) As of 31 December 2020, according to the Bank for International Settlements the outstanding notional amount of OTC derivatives was about EUR 477 trillion worldwide, of which interest rate derivatives represent about 80 % and foreign exchange derivatives almost 17 %. More than 30 % of all OTC derivatives are denominated in euro and other Union currencies. The market for central clearing of OTC derivatives is highly concentrated, in particular the market for central clearing of euro-denominated OTC interest rate derivatives, of which more than 90 % are cleared in one single CCP established in the United Kingdom ('UK CCP').
- (4) In the context where such a significant volume of financial transactions denominated in Union currencies is cleared through UK CCPs, the withdrawal of the United Kingdom from the internal market and from the associated Union framework of regulation, supervision and enforcement in the financial sector created major challenges for Union and Member States' authorities in safeguarding financial stability.

⁽¹⁾ OJ L 201, 27.7.2012, p. 1.

⁽²⁾ Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (OJ C 384I, 12.11.2019, p. 1).

⁽³⁾ Political declaration setting out the framework for the future relationship between the European Union and the United Kingdom (OJ C 384I, 12.11.2019, p. 178).

- (5) In order to address the possible risks to financial stability that could arise as a consequence of an abrupt disruption in the provision of clearing of derivatives by UK CCPs to Union clearing members and clients, the Commission adopted Implementing Decision (EU) 2020/1308 ⁽⁴⁾ on 21 September 2020. That Decision determines that the regulatory framework applicable to UK CCPs is considered to be equivalent to the requirements laid down in Regulation (EU) No 648/2012. That Decision applies only for a limited period and is to expire on 30 June 2022.
- (6) The impact of the withdrawal of the United Kingdom from the Union has been the subject of several communications from the Commission to the European Parliament, the Council and the European Central Bank, including a Communication on fostering openness, strength and resilience ⁽⁵⁾. In that Communication, there was a clear expectation that Union clearing members would reduce their exposures and reliance on UK CCPs that are systemically important for the Union, in particular OTC derivative exposures that are denominated in euro and other Union currencies.
- (7) Following that Communication, in early 2021, the Commission established a Working Group on the opportunities and challenges related to transferring the clearing of derivatives from the United Kingdom to the Union. The Working Group focused on how to reduce the Union's excessive reliance on clearing services provided by the CCPs established in the United Kingdom, identifying possible impediments to reducing exposures in UK CCPs, finding ways to overcome such impediments and incentives to move clearing services to CCPs established in the Union.
- (8) The discussions of the Working Group concluded that some transactions cleared in UK CCPs simply cannot be cleared elsewhere at this point in time and that a combination of different measures will be needed to develop the Union's own clearing capacity and reduce Union market participants' excessive exposures to systemically important UK CCPs in the years to come. In light of those discussions, the expiry date of Implementing Decision (EU) 2020/1308 is too soon in order to develop the Union's clearing capacity to an adequate level. As the rationale for adopting that Decision has not changed, that is to avoid potential risks to financial stability in the event of an abrupt disruption in access of Union clearing members to UK CCPs, it is therefore necessary to adopt this Decision, which prolongs, for a limited period of time, the recognition that the regulatory framework applicable to central counterparties in the United Kingdom is equivalent to the framework established by Regulation (EU) No 648/2012.
- (9) In accordance with Article 25(6) of Regulation (EU) No 648/2012, three conditions are to be fulfilled in order to determine that the legal and supervisory arrangements of a third country regarding CCPs authorised therein are equivalent to those laid down in that Regulation.

⁽⁴⁾ Commission Implementing Decision (EU) 2020/1308 of 21 September 2020 determining, for a limited period of time, that the regulatory framework applicable to central counterparties in the United Kingdom of Great Britain and Northern Ireland is equivalent, in accordance with Regulation (EU) No 648/2012 of the European Parliament and of the Council (OJ L 306, 21.9.2020, p. 1)

⁽⁵⁾ Communication from the Commission to the European Parliament, the Council and the European Central Bank of 4 May 2017, 'Responding to challenges for critical financial market infrastructures and further developing the Capital Markets Union' (COM(2017) 225 final), Communication from the Commission to the European Parliament, the European Council, the Council, The European Central Bank, the European Economic and Social Committee, the Committee of the Regions and the European Investment Bank of 19 July 2018, 'Preparing for the withdrawal of the United Kingdom from the European Union on 30 March 2019' (COM(2018) 556 final) and Communication from the Commission to the European Parliament, the European Council, the Council, The European Central Bank, the European Economic and Social Committee, the Committee of the Regions and the European Investment Bank of 13 November 2018, 'Preparing for the withdrawal of the United Kingdom from the European Union on 30 March 2019: a Contingency Action Plan' (COM(2018) 880 final), Communication from the Commission to the European Parliament, the Council, The European Central Bank, the European Economic and Social Committee, the Committee of the Regions of 19 January 2021, 'The European economic and financial system: fostering openness, strength and resilience' (COM(2021) 32 final).

- (10) First, the legal and supervisory arrangements of a third country are to ensure that CCPs in that third country comply with legally binding requirements, which are equivalent to the requirements laid down in Title IV of Regulation (EU) No 648/2012. The United Kingdom incorporated the relevant provisions of Regulation (EU) No 648/2012 into its domestic law with effect from the date of the United Kingdom's withdrawal from the Union ⁽⁶⁾ and therefore United Kingdom domestic law can be considered equivalent to the requirements laid out in Title IV of Regulation (EU) No 648/2012.
- (11) Second, the legal and supervisory arrangements of the third country are to ensure that CCPs established in that third country are subject to effective supervision and enforcement on an ongoing basis. Until 31 December 2020, UK CCPs were under the supervision of the Bank of England, as determined by United Kingdom domestic law in accordance with Regulation (EU) No 648/2012 ⁽⁷⁾. As part of the incorporation of Regulation (EU) No 648/2012 into United Kingdom domestic law, the Bank of England remains responsible for the supervision of CCPs after that date and no significant changes to that supervision are foreseen.
- (12) Third, the legal framework of the third country must provide for an effective equivalent system for the recognition of CCPs authorised under that third country's legal regime. The United Kingdom has incorporated the key elements of the equivalence system in Article 25 of Regulation (EU) No 648/2012 into United Kingdom domestic law. However, the United Kingdom has introduced a Temporary Recognition Regime, which suspends key amendments to Regulation (EU) No 648/2012 for a period of at least 3 years. That Temporary Recognition Regime also gives the Bank of England wide discretionary powers to withdraw the 'temporary deemed recognition', which creates legal uncertainty for CCPs recognised under this regime. Notwithstanding that uncertainty, the third condition can be considered as fulfilled at this point in time.
- (13) As the three conditions are considered to be fulfilled, the legal and supervisory arrangements of the United Kingdom, which are applicable to UK CCPs that were already established and authorised on 31 December 2020, should be considered to be equivalent to the requirements laid down in Regulation (EU) No 648/2012.
- (14) This Decision is based on the information currently available to the Commission on the legal and supervisory arrangements applicable to UK CCPs. Those arrangements should be considered equivalent only insofar as the requirements applicable to CCPs in United Kingdom domestic law are maintained, applied and enforced. The recognition of equivalence can only be maintained if any future changes to the United Kingdom regulatory and supervisory framework do not negatively affect equivalence in terms of regulation or supervision, leading to an un-level playing field between UK CCPs and CCPs established in the Union ('Union CCPs') or to risks to financial stability of the Union. As the Commission may decide to amend, suspend, review or revoke this Decision at any time, notably if developments occur which affect the equivalence determination, an effective exchange of information and coordination of supervisory activities between the European Securities Markets Authority (ESMA) and the Bank of England is a prerequisite for maintaining the recognition of equivalence up until the expiry date of this Decision.
- (15) The exchange of information between the ESMA and the Bank of England requires the conclusion of comprehensive and effective cooperation arrangements in accordance with Article 25(7) of Regulation (EU) No 648/2012. Those cooperation arrangements are to ensure the pro-active sharing of all relevant information with the authorities referred to in Article 25(3) of Regulation (EU) No 648/2012, including the ECB and the other members of the European System of Central Banks, for the purpose of consulting those authorities about the recognised status of UK CCPs or where that information is necessary for those authorities to carry out their supervisory tasks.

⁽⁶⁾ After the end of the transition period, several pieces of United Kingdom legislation provide the regulatory and supervisory framework covering clearing services in the United Kingdom. This includes, but is not limited to, the European Union (Withdrawal) Act 2018, The Over the Counter Derivatives, Central Counterparties and Trade Repositories (Amendment, etc., and Transitional Provision) (EU Exit) Regulations 2020, the Financial Services (Consequential Amendments) Regulations 2020 and the Financial Services Contracts (Transitional and Saving Provision) (EU Exit) Regulations 2019.

⁽⁷⁾ Part 5 of The Financial Services and Markets Act 2000 (Over the Counter Derivatives, Central Counterparties and Trade Repositories) Regulations 2013.

- (16) The cooperation arrangements established pursuant to Article 25(7) of Regulation (EU) No 648/2012 are to ensure that the ESMA has immediate and ongoing access to all information, including information allowing for the assessment of any material risks posed by UK CCPs to the Union or its Member States, either directly or indirectly. The cooperation arrangements are to specify the mechanisms and procedures for the prompt exchange of information related to the clearing activities of UK CCPs with respect to financial instruments denominated in Union currencies, trading venues, clearing participants as well as subsidiaries of Union credit institutions and investment firms; to interoperability arrangements with other CCPs; to own resources; to default funds composition and calibration, to margins, liquid resources and collateral portfolios including haircut calibrations and to stress tests. They are also to specify the mechanisms and procedures for the prompt notification of any change affecting UK CCPs or the United Kingdom legal and supervisory arrangements applicable to UK CCPs and for the prompt notification of the ESMA of any developments with regard to UK CCPs that could affect monetary policy in the Union. The Bank of England is also to cooperate closely with Union authorities in accordance with Article 25(7). In particular, it is important that there are effective cooperation arrangements between the ESMA and the responsible United Kingdom authorities regarding the coordination of their supervisory activities, including, in particular, procedures to deal with any emergency situations related to the recognised UK CCPs which have or may have an adverse effect on market liquidity or the stability of the financial system of the Union.
- (17) The United Kingdom authorities are expected to inform the Union about all changes to the United Kingdom's regulatory or supervisory framework affecting the provision of clearing services in the United Kingdom. The Commission, in cooperation with the ESMA, will monitor any changes introduced in the legal and supervisory arrangements affecting the provision of clearing services in the United Kingdom, market developments as well as the effectiveness of supervisory cooperation, including prompt information exchange between the ESMA and the Bank of England. The Commission may undertake a review at any time where relevant developments make it necessary to re-assess the equivalence granted by this Decision, including where the United Kingdom authorities do not effectively cooperate, do not allow for an effective assessment of the risk that UK CCPs pose to the Union or its Member States or the actions taken by UK CCPs or the Bank of England promote undue and unfair competition.
- (18) The current over-reliance of Union clearing members on services provided by UK CCPs still presents risks for the financial stability of the Union and for the transmission and conduct of the Union's monetary policy, especially in the event of stress. This was confirmed by the assessment of the ESMA in December 2021. ⁽⁸⁾ That assessment identified three clearing services provided by UK CCPs as being of substantial systemic importance to the Union or to one or more Member States. While that assessment concluded that, at this point in time, the costs of derecognising those clearing services would outweigh the benefits, it nonetheless identified important risks and vulnerabilities in connection with a continued recognition of those clearing services, in particular, in times of stress in the market.
- (19) Consequently, and as stressed in the Communication on 'fostering openness, strength and resilience' ⁽⁹⁾, exposures to UK CCPs that are systemically important for the Union, in particular OTC derivative exposures that are denominated in euro and other Union currencies, should continue to be reduced.
- (20) The duration of this Decision should therefore give enough time for the development of the clearing capacity of Union CCPs, exploring ways to enhance liquidity in those CCPs and to expand the range of clearing solutions on offer from Union infrastructures, including via the adoption of regulatory measures facilitating that process, in order to allow for a significant reduction of Union clearing members' exposures to UK CCPs. This Decision should also give sufficient time for the review of the Union's supervisory framework for CCPs. Accordingly, it is appropriate that this Decision expires 3 years after its date of application.

⁽⁸⁾ ESMA, Assessment Report under Article 25(2c) of EMIR, <https://www.esma.europa.eu/press-news/esma-news/esma-publishes-results-its-assessment-systemically-important-uk-central>.

⁽⁹⁾ Communication from the Commission to the European Parliament, the Council, The European Central Bank, the European Economic and Social Committee, the Committee of the Regions of 19 January 2021, 'The European economic and financial system: fostering openness, strength and resilience' (COM(2021) 32 final).

- (21) This Decision should enter into force as a matter of urgency in order to ensure legal certainty for clearing members and trading venues established in the Union ahead of the expiry of Implementing Decision (EU) 2020/1308. In order to avoid any disruption in the recognition of UK CCPs by the ESMA, it should apply from the day following that on which Implementing Decision (EU) 2020/1308 expires.
- (22) The measures provided for in this Decision are in accordance with the opinion of the European Securities Committee,

HAS ADOPTED THIS DECISION:

Article 1

For the purposes of Article 25 of Regulation (EU) No 648/2012, the legal and supervisory arrangements of the United Kingdom of Great Britain and Northern Ireland applicable to central counterparties already established and authorised in the United Kingdom of Great Britain and Northern Ireland on 31 December 2020 shall be considered to be equivalent to the requirements laid down in Regulation (EU) No 648/2012.

Article 2

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 1 July 2022.

It shall expire on 30 June 2025.

Done at Brussels, 8 February 2022.

For the Commission
The President
Ursula VON DER LEYEN

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

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