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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

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Delegations will find attached document C(2021) 3163 final.

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COMMISSION DELEGATED REGULATION (EU) .../...

of 7.5.2021

supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Following the adoption of the new Organic Regulation (EU) 2018/848, which will enter into application on 1 January 2022, this Delegated Regulation supplements Regulation (EU) 2018/848 as regards the rules governing the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species. This Regulation aims at providing producers with legal certainty on the new rules for this type of plant reproductive material.

This delegated act contains, among others, provisions on the breeding and production methods, the description, minimum quality requirements and labelling and packaging of organic heterogeneous material.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The act was thoroughly discussed with Member States at the Group of Experts on Organic Production as well as with the main organisations representing the organic sector and plant reproductive material sectors, namely IFOAM and their sector specific affiliated groups, COPA-COGECA and Euroseeds. DG SANTE cooperated closely with other DGs in the field of their specific expertise when drafting these rules, in particular with DG AGRI.

Input received in the context of the above mentioned consultation activities has been taken into account in the preparation of this Delegated Regulation.

Following the general public consultation, the act was slightly amended to exempt the transfer of plant reproductive material of organic heterogeneous material intended for research on, and development of, such material.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

Regulation (EU) 2018/848 underlines in its recitals 36 and 37 that using plant reproductive material that does not fulfil the variety definition as regards uniformity nor is a variety mixture could have benefits in particular with regard to organic production, for example to reduce the spread of diseases, to improve resilience and to increase biodiversity and that such material therefore should be available for use in organic production. Article 13(3) of that Regulation empowers the Commission to adopt delegated acts supplementing that Regulation and setting out rules governing the production and marketing of plant reproductive material of organic heterogeneous material.

COMMISSION DELEGATED REGULATION (EU) .../...

of 7.5.2021

supplementing Regulation (EU) 2018/848 of the European Parliament and of the Council as regards the production and marketing of plant reproductive material of organic heterogeneous material of particular genera or species

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/848 of the European Parliament and of the Council of 30 May 2018 on organic production and labelling of organic products and repealing Council Regulation (EC) No 834/2007¹, and in particular Article 13(3) and Article 38(8)(a)(ii) thereof,

Whereas:

- (1) Regulation (EU) 2018/848 provides that operators are to be allowed to market plant reproductive material of organic heterogeneous material without complying with the requirements for registration and without complying with the certification categories of pre-basic, basic and certified material or with the quality, health and identity requirements for CAC, standard or commercial categories, set out in Directives 66/401/EEC², 66/402/EEC³, 68/193/EEC⁴, 98/56/EC⁵, 2002/53/EC⁶, 2002/54/EC⁷, 2002/55/EC⁸, 2002/56/EC⁹, 2002/57/EC¹⁰, 2008/72/EC¹¹ and

¹ OJ L 150, 14.6.2018, p. 1.

² Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed (OJ 125, 11.7.1966, p. 2298).

³ Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed (OJ 125, 11.7.1966, p. 2309).

⁴ Council Directive 68/193/EEC of 9 April 1968 on the marketing of material for the vegetative propagation of the vine (OJ L 93, 17.4.1968, p. 15).

⁵ Council Directive 98/56/EC of 20 July 1998 on the marketing of propagating material of ornamental plants (OJ L 226, 13.8.1998, p. 16).

⁶ Council Directive 2002/53/EC of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ L 193, 20.7.2002, p. 1).

⁷ Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed (OJ L 193, 20.7.2002, p. 12).

⁸ Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed (OJ L 193, 20.7.2002, p. 33).

⁹ Council Directive 2002/56/EC of 13 June 2002 on the marketing of seed potatoes (OJ L 193, 20.7.2002, p. 60).

¹⁰ Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants (OJ L 193, 20.7.2002, p. 74).

¹¹ Council Directive 2008/72/EC of 15 July 2008 on the marketing of vegetable propagating and planting material, other than seed (OJ L 205, 1.8.2008, p. 28).

2008/90/EC¹², or in acts adopted pursuant to those Directives. It also states that marketing should comply with harmonised requirements adopted by the Commission.

- (2) In order to address the needs of operators and consumers of plant reproductive material of organic heterogeneous material concerning the identity, health and quality of such material, rules should be established concerning the description, minimum quality requirements for seed lots, including identity, analytical purity, germination rates and sanitary quality, packaging, and labelling of plant reproductive material of the organic heterogeneous material, and, where possible, the maintenance of such material by operators and the information to be kept by such operators.
- (3) In order to promote the adaptation of organic heterogeneous material to diverse agro-ecological conditions, the transfer of limited quantities of plant reproductive material of organic heterogeneous material for the purpose of research on, and development of, such material should be exempted from the requirements of this Regulation.
- (4) Specific criteria and conditions for the performance of official controls should also be set out to ensure the traceability at all stages of production, preparation and distribution, and compliance with Regulation (EU) 2018/848 concerning controls performed on operators marketing plant reproductive material of organic heterogeneous material.
- (5) Organic heterogeneous material is characterised by its high level of phenotypic and genetic diversity, and its dynamic nature to evolve and adapt to certain growing conditions. In contrast to seed mixtures that are rebuilt annually based on varieties, or synthetic varieties derived by intercrossing of a defined set of parental materials which are repeatedly cross-pollinated to reconstruct a stable population, or conservation and amateur varieties including landraces as defined in Commission Directive 2008/62/EC¹³ and Commission Directive 2009/145/EC¹⁴, organic heterogeneous material is intended to adapt to various biotic and abiotic stresses due to repeated natural and human selection and therefore is expected to change over time.
- (6) Rules should be established concerning the identification of seed lots of organic heterogeneous material, in order to take into account the particular characteristics of that material. The rules concerning minimum quality requirements such as health, analytical purity and germination should ensure the same standards as for the lowest category of seeds and other plant reproductive material (CAC, standard, commercial or certified category) as provided in Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 98/56/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC. Such rules are necessary in order to serve the interests of the users of that organic heterogeneous material, namely farmers and gardeners, who should be assured about its adequate quality and identity.

¹² Council Directive 2008/90/EC of 29 September 2008 on the marketing of fruit plant propagating material and fruit plants intended for fruit production (OJ L 267, 8.10.2008, p. 8).

¹³ Commission Directive 2008/62/EC of 20 June 2008 providing for certain derogations for acceptance of agricultural landraces and varieties which are naturally adapted to the local and regional conditions and threatened by genetic erosion and for marketing of seed and seed potatoes of those landraces and varieties (OJ L 162, 21.6.2008, p. 13).

¹⁴ Commission Directive 2009/145/EC of 26 November 2009 providing for certain derogations, for acceptance of vegetable landraces and varieties which have been traditionally grown in particular localities and regions and are threatened by genetic erosion and of vegetable varieties with no intrinsic value for commercial crop production but developed for growing under particular conditions and for marketing of seed of those landraces and varieties (OJ L 312, 27.11.2009, p. 44).

Experience has shown that plant reproductive material of organic heterogeneous material can fulfil those standards.

- (7) Operators should have the possibility to place on the market seed of organic heterogeneous material, which does not satisfy the conditions with respect to germination, to ensure greater flexibility for the marketing of that material. However, and in order to allow users to make informed choices, the supplier should indicate the germination rate of the seed concerned on the label or directly on the package of the plant reproductive material of organic heterogeneous material.
- (8) In accordance with Article 37 of Regulation (EU) 2018/848, organic production is subject to official controls and to other official activities carried out in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council¹⁵. Accordingly, Member States should designate relevant competent authorities for the official control of operators dealing with organic heterogeneous material, in order to ensure compliance with the rules on organic production. Organic heterogeneous material should be subject to risk-based official controls to guarantee the fulfilment of the requirements established in this Regulation. The controls of identity, analytical purity, germination rate, and plant health and their compliance with Regulation (EU) 2016/2031 should be conducted in accordance with official testing protocols carried out in laboratories, designated by the competent authorities, in accordance with the relevant international standards.
- (9) Operators should keep the necessary records to ensure the traceability, plant health controls and best possible management of the organic heterogeneous material, which is under their control.
- (10) Organic heterogeneous material is not stable and therefore the current methods for testing uniformity and stability used for variety registration are not appropriate. The identification and traceability of organic heterogeneous material should thus be guaranteed through the description of its production methods and its phenotypic and agronomic characteristics.
- (11) Rules should be set out for the maintenance of organic heterogeneous material to ensure identity and quality, if such maintenance is possible.
- (12) This Regulation should apply from 1 January 2022, as does Regulation (EU) 2018/848,

¹⁵ Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation establishes rules concerning the production and marketing of plant reproductive material of organic heterogeneous material within the meaning of Regulation (EU) 2018/848 which are seeds of agricultural and vegetable species, vegetable propagating material other than seeds, propagating material of ornamental plants, vine propagating material and fruit plant propagating material, within the meaning of Directives 66/401/EEC, 66/402/EEC, 68/193/EC, 98/56/EC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC, 2008/90/EC.

This Regulation shall not apply to any transfer of limited quantities of plant reproductive material of organic heterogeneous material intended for research on, and development of, organic heterogeneous material.

Article 2

Definitions

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

- (1) ‘organic heterogeneous material’ means a plant grouping within the meaning of Article 3(18) of Regulation (EU) 2018/848, which is produced according to the requirements of Article 3(1) of that Regulation;
- (2) ‘parental material’ means any plant material the crossing or propagation of which resulted in organic heterogeneous material;
- (3) ‘small packages’ means packages containing seed up to the maximum quantities provided for in Annex II.

Article 3

Production and marketing within the Union of plant reproductive material of organic heterogeneous material

Plant reproductive material of organic heterogeneous material shall only be produced or marketed within the Union, if all of the following requirements are fulfilled:

- (1) it complies with the requirements on:
 - (a) identity, as referred to in Article 5;
 - (b) sanitary and analytical purity and germination, as referred to in Article 6;
 - (c) packaging and labelling, as referred to in Article 7;
- (2) its description includes the elements referred to in Article 4;
- (3) it is subject to the official controls pursuant to Article 9;
- (4) it is produced or marketed by operators who comply with the requirements concerning information in Article 8; and
- (5) it is maintained in accordance with Article 10.

Article 4

Description of organic heterogeneous material

1. The description of organic heterogeneous material shall include all of the following elements:
 - (a) a description of its characteristics, including:
 - (i) the phenotypic characterisation of the key characters which are common to the material, together with the description of the heterogeneity of the material by characterising the phenotypic diversity observable between individual reproductive units;
 - (ii) documentation of its relevant characteristics, including agronomic aspects such as regards yield, yield stability, suitability for low input systems, performance, resistance to abiotic stress, disease resistance, quality parameters, taste or colour;
 - (iii) any available results from tests concerning the characteristics referred to in point (ii);
 - (b) a description of the type of technique used for the breeding or production method of the organic heterogeneous material;
 - (c) a description of the parental material used to breed or produce the organic heterogeneous material and own production control programme used by the operator concerned with a reference to the practices as referred to in paragraph (2)(a) and, if applicable, in paragraph 2(c);
 - (d) a description of the on-farm management and selection practices with a reference to paragraph 2(b) and, if applicable, of the parental material with a reference to paragraph 2(c);
 - (e) a reference to the country of breeding or production, with information on the year of production and description of the pedo-climatic conditions;
2. The material referred to in paragraph 1 may be generated by one of the following techniques:
 - (a) crossing of several different types of parental material, using crossing protocols to produce diverse organic heterogeneous material by bulking of the progeny, repeatedly re-sowing and exposing the stock to natural and/or human selection, provided that this material shows a high level of genetic diversity which is in accordance with Article 3(18) of Regulation 2018/848;
 - (b) on-farm-management practices, including selection, establishing or maintaining material, which is characterized by a high level of genetic diversity in accordance with Article 3(18) of Regulation 2018/848;
 - (c) any other technique used for breeding or production of organic heterogeneous material, taking into account particular features of propagation.

Article 5

Requirements concerning the identity of seed lots of plant reproductive material of organic heterogeneous material

Plant reproductive material of organic heterogeneous material shall be identifiable on the basis of all of the following elements:

- (1) the parental material and the production scheme used in the crossing for creation of the organic heterogeneous material, as provided for in Article 4(2)(a) or, if applicable, in Article 4(2)(c), or the history of the material and the on-farm management practices, including whether the selection has occurred naturally and/or through human intervention, in the cases of Articles 4(2)(b) and 4(2)(c);
- (2) the country of breeding or production;
- (3) characterisation of the common key characters and of the phenotypic heterogeneity of the material.

Article 6

Requirements concerning the sanitary quality, analytical purity and germination of plant reproductive material of organic heterogeneous material

1. Plant reproductive material of organic heterogeneous material shall comply with the provisions of Regulation (EU) 2016/2031, Commission Implementing Regulation (EU) 2019/2072¹⁶ and the other relevant acts adopted pursuant to Regulation (EU) 2016/2031 concerning the presence, and the measures against, Union quarantine pests, protected zone quarantine pests and Union regulated non-quarantine pests.
2. For the production and marketing of plant reproductive material of organic heterogeneous material of fodder plant species listed in Article 2(1)(A) of Directive 66/401/EEC, the following provisions shall apply:
 - (a) point 1 and the last column of the table in point 5 of Annex I to Directive 66/401/EEC, and
 - (b) Section I, points 2 and 3 and Section III of Annex II to Directive 66/401/EEC.
3. For the production and marketing of plant reproductive material of organic heterogeneous material of cereal species listed in Article 2(1)(A) of Directive 66/402/EEC, the following provisions shall apply:
 - (a) point 1 and the last column of the table in point 6 of Annex I to Directive 66/402/EEC;
 - (b) the third, sixth, tenth, thirteenth, sixteenth, twentieth and twenty-first row of the table in point 2(A) and point 2(B) of Annex II to that Directive,
 - (c) the last column in the table in point 3 of Annex II to that Directive;
 - (d) the third and the sixth row in the table in point 4 of Annex II to that Directive.
4. For the production and marketing of plant reproductive material of organic heterogeneous material of vine within the meaning of Directive 68/193/EEC, the following provisions shall apply:
 - (a) Sections 2, 3, 4, 6 and 7 and point 6 of Section 8 of Annex I to Directive 68/193/EEC;
 - (b) Annex II to Directive 68/193/EEC, with the exception of point 1(1).

¹⁶ Commission Implementing Regulation (EU) 2019/2072 of 28 November 2019 establishing uniform conditions for the implementation of Regulation (EU) 2016/2031 of the European Parliament and the Council, as regards protective measures against pests of plants, and repealing Commission Regulation (EC) No 690/2008 and amending Commission Implementing Regulation (EU) 2018/2019 (OJ L 319, 10.12.2019, p. 1).

5. For the production and marketing of plant reproductive material of organic heterogeneous material of ornamental plants within the meaning of Directive 98/56/EC, Article 3 of Directive 93/49/EEC¹⁷ shall apply.
6. For the production and marketing of plant reproductive material of organic heterogeneous material of beet within the meaning of Directive 2002/54/EC, points A(1), B(2) and B(3) of Annex I to that Directive shall apply.
7. For the production and marketing of plant reproductive material of organic heterogeneous material of vegetable species listed in Article 2(1)(b) of Directive 2002/55/EC, points 2 and 3 of Annex II to that Directive shall apply.
8. For the production and marketing of plant reproductive material of organic heterogeneous material of seed potatoes within the meaning Directive 2002/56/EC, the provisions for the lowest category of seed potatoes in point 3 of Annex I and in Annex II shall apply.
9. For the production and marketing of plant reproductive material of organic heterogeneous material of oil and fibre plants as listed in Article 2(1)(b) of Directive 2002/57/EC, the following provisions shall apply:
 - (a) point 1 and the last column of the table in point 4 of Annex I to Directive 2002/57/EC;
 - (b) the table in point I(4)(A) of Annex II, except the requirements for basic seed of *Brassica* ssp. and *Sinapis alba*, and the last column of the table in point I(5) of Annex II to Directive 2002/57/EC.
10. For the production and marketing of organic heterogeneous vegetable propagating and planting material, other than seed within the meaning of Directive 2008/72/EC, Articles 3 and 5 of Commission Directive 93/61/EEC¹⁸, shall apply.
11. For the production and marketing of plant reproductive material of organic heterogeneous fruit plant propagating material and fruit plants intended for fruit production within the meaning of Directive 2008/90/EC, the following provisions shall apply:
 - (a) Article 23, except point (1)(b), Articles 24, 26, 27 and 27a of Commission Implementing Directive 2014/98/EU¹⁹;
 - (b) Annexes I, II and Annex III and the requirements concerning CAC material in Annex IV to Implementing Directive 2014/98/EU.
12. Paragraphs 2 to 11 shall only apply with regard to the analytical purity and germination requirements for seed and the quality and health requirements for other propagating material, but not with regard to varietal identity and varietal purity and

¹⁷ Commission Directive 93/49/EEC of 23 June 1993 setting out the schedule indicating the conditions to be met by ornamental plant propagating material and ornamental plants pursuant to Council Directive 91/682/EEC (OJ L 250, 7.10.1993, p. 9).

¹⁸ Commission Directive 93/61/EEC of 2 July 1993 setting out the schedules indicating the conditions to be met by vegetable propagating and planting material, other than seed pursuant to Council Directive 92/33/EEC (OJ L 250, 7.10.1993, p. 19).

¹⁹ Commission Implementing Directive 2014/98/EU of 15 October 2014 implementing Council Directive 2008/90/EC as regards specific requirements for the genus and species of fruit plants referred to in Annex I thereto, specific requirements to be met by suppliers and detailed rules concerning official inspections (OJ L 298, 16.10.2014, p. 22).

field inspection requirements for varietal identity and varietal purity of the plant reproductive material of organic heterogeneous material.

13. By way of derogation from the provisions of paragraphs 1 to 12, operators may place on the market seed of organic heterogeneous material, which does not satisfy the conditions with respect to germination, provided that the supplier indicates the germination rate of the seed concerned on the label or directly on the package.

Article 7

Requirements concerning packaging and labelling of plant reproductive material of organic heterogeneous material

1. Plant reproductive material of organic heterogeneous material not contained in small packages shall be contained in packages or containers, which are closed in such a manner that they cannot be opened without leaving evidence of tampering on the package or container.
2. The operator shall affix on packages or containers of seeds or plant reproductive material of organic heterogeneous material a label in at least one of the official languages of the Union.
That label shall:
 - (a) be legible, printed or written on one side, unused and easily visible;
 - (b) include the information set out in Annex I to this Regulation;
 - (c) be yellow with a green diagonal cross.
3. Instead of a label, the information set out in Annex I may be directly printed or written on the package or the container. In that case, point 2(c) shall not be applicable.
4. In the case of small, transparent packages, the label may be placed inside the package provided it is clearly legible.
5. By way of derogation from paragraphs 1 to 4, seed of organic heterogeneous material contained in closed and labelled packages and containers may be sold to final users in unmarked and unsealed packages up to the maximum quantities provided for in Annex II, provided that, on request, the purchaser is informed in writing at the time of delivery about the species, the denomination of the material and the reference number of the lot.

Article 8

Requirements concerning information to be kept by operators

1. Any operator producing or marketing plant reproductive material of organic heterogeneous material shall:
 - (a) keep a copy of the notification submitted in accordance with Article 13(2) of Regulation (EU) 2018/848, a copy of the declaration submitted under Article 39(1)(d) thereof and, where applicable, a copy of the certificate received in accordance with Article 35 thereof;
 - (b) ensure the traceability of the organic heterogeneous material in the production scheme as provided for in Article (4)(2)(a) or, if applicable, in Article (4)(2)(c)

by keeping information allowing to identify the operators which have supplied parental material of organic heterogeneous material.

The operator shall keep those documents for five years.

2. The operator producing plant reproductive material of organic heterogeneous material intended for marketing shall also record and keep the following information:
 - (a) name of the species and denomination used for each notified organic heterogeneous material; type of technique used for the production of organic heterogeneous material as referred to in Article 4;
 - (b) characterisation of the notified organic heterogeneous material as provided for in Article 4;
 - (c) location of breeding of organic heterogeneous material and location of production of organic plant reproductive material of the organic heterogeneous material as provided for in Article 5;
 - (d) surface area for the production of organic heterogeneous material and quantity produced.
3. The responsible official bodies in accordance with Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 98/56/EC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC shall have access to the information referred to in paragraphs 1 and 2 of this Article.

Article 9

Official controls

The competent authorities of the Member States or the delegated bodies, where the competent authorities have delegated control tasks in accordance with Chapter III of Title II of Regulation (EU) 2017/625, shall carry out risk-based official controls in relation to the production and marketing of plant reproductive material of organic heterogeneous material to check compliance with the requirements of Articles 4, 5, 6, 7, 8 and 10 of this Regulation.

The testing of germination and analytical purity shall be carried out in accordance with the applicable methods of the International Seed Testing Association.

Article 10

Maintenance of organic heterogeneous material

Where maintenance is possible, the operator who has notified the organic heterogeneous material to the competent authorities pursuant to Article 13 of Regulation (EU) 2018/848, shall preserve the main characteristics of the material at the time of its notification, by maintaining it as long as it remains on the market. That maintenance shall be undertaken according to accepted practices adapted to the maintenance of such heterogeneous material. The operator responsible for the maintenance shall keep records of duration and content of maintenance.

At all times, the competent authorities shall have access to all records kept by the operator responsible for the material, in order to check its maintenance. The operator shall keep those records for five years after the moment the plant reproductive material of organic heterogeneous material is not marketed anymore.

Article 11

Entry into force and application

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

It shall apply from 1 January 2022.

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

Done at Brussels, 7.5.2021

For the Commission

The President

Ursula VON DER LEYEN