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COMMISSION DELEGATED REGULATION (EU) 2019/625

of 4 March 2019

supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of certain animals and goods intended for human consumption

(Text with EEA relevance)

(OJ L 131, 17.5.2019, p. 18)

Corrected by:

<u>B</u>

►<u>C1</u> Corrigendum, OJ L 176, 5.6.2020, p. 15 (2019/625)

COMMISSION DELEGATED REGULATION (EU) 2019/625

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(Text with EEA relevance)

Article 1

Subject matter and scope

- 1. This Regulation supplements Regulation (EU) 2017/625 as regards the requirements for the entry in the Union of consignments of certain animals and goods intended for human consumption from third countries or regions thereof in order to ensure that they comply with the applicable requirements established by the rules referred to in Article 1(2)(a) of Regulation (EU) 2017/625 or with requirements recognised to be at least equivalent thereto.
- 2. The requirements referred to in paragraph 1 cover:
- (a) the identification of animals and goods subject to the following requirements for entry into the Union:
 - (i) the requirement that those animals and goods shall come from a third country or region thereof listed in accordance with Article 126(2)(a) of Regulation (EU) 2017/625;
 - (ii) the requirement that those animals and goods be dispatched from, and obtained or prepared in, establishments which comply with applicable requirements referred to in Article 126(1) of Regulation (EU) 2017/625, or with requirements recognised to be at least equivalent thereto, and which appear on lists drawn-up and updated in accordance with Article 127(3)(e)(ii) and (iii) of Regulation (EU) 2017/625;
 - (iii) the requirement that each consignment of animals and goods be accompanied by an official certificate, or official attestation or any other evidence of compliance with the rules referred to in Article 1(2)(a) of Regulation (EU) 2017/625, such a as private attestation, in accordance with Article 126(2)(c) of Regulation (EU) 2017/625;
- (b) requirements for the entry into the Union of certain animals and goods from a third country or region thereof, listed in accordance with Article 127(2) of Regulation (EU) 2017/625;
- (c) requirements that consignments of certain goods from third countries be dispatched from, and obtained or prepared in, establishments which comply with the applicable requirements referred to in Article 126(1) of Regulation (EU) 2017/625, or with requirements recognised to be at least equivalent thereto, and which appear on lists drawn-up and updated in accordance with Article 127(3)(e)(ii)and (iii) of Regulation (EU) 2017/625;

- (d) requirements for the entry into the Union for placing on the market of the specific following commodities in addition to the requirements laid down in accordance with Article 126 of Regulation (EU) 2017/625:
 - fresh meat, minced meat, meat preparations, meat products, mechanically separated meat and raw materials intended for the production of gelatine and collagen;
 - (ii) live bivalve molluses, echinoderms, tunicates and marine gastropods;
 - (iii) fishery products;
 - (iv) composite products;
- (e) additional requirements for the official certificates, official attestations and private attestations that shall accompany certain animals and goods for entry into the Union.
- 3. This Regulation shall not apply to:
- (a) Animals and goods not intended for human consumption, however when the destination of the animals and goods has not been decided at entry into the Union, this Regulation applies;
- (b) Animals and goods intended for human consumption only for transit through the Union without being placed on the market.

Definitions

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

- (1) 'equivalent' means equivalent as defined in Article 2(1)(e) of Regulation (EC) No 852/2004;
- (2) 'placing on the market' means placing on the market as defined in point (8) of Article 3 of Regulation (EC) No 178/2002;
- (3) 'establishment' means an establishment as defined in Article 2(1)(c) of Regulation (EC) No 852/2004;
- (4) 'private attestation' means an attestation signed by the importing food business operator;
- (5) 'fresh meat' means fresh meat as defined in point 1.10 of Annex I to Regulation (EC) No 853/2004;
- (6) 'minced meat' means minced meat as defined in point 1.13 of Annex I to Regulation (EC) No 853/2004;
- (7) 'meat preparations' means meat preparations as defined in point 1.15 of Annex I to Regulation (EC) No 853/2004;
- (8) 'meat products' means meat products as defined in point 7.1 of Annex I to Regulation (EC) No 853/2004;
- (9) 'mechanically separated meat' means mechanically separated meat as defined in point 1.14 of Annex I to Regulation (EC) No 853/2004;
- (10) 'gelatine' means gelatine as defined in point 7.7 of Annex I to Regulation (EC) No 853/2004;

- (11) 'collagen' means collagen as defined in point 7.8 of Annex I to Regulation (EC) No 853/2004;
- (12) 'bivalve molluscs' means bivalve molluscs as defined in point 2.1 of Annex I to Regulation (EC) No 853/2004;
- (13) 'fishery products' means fishery products as defined in point 3.1 of Annex I to Regulation (EC) No 853/2004;
- (14) 'composite product' means food containing both products of plant origin and processed products of animal origin;
- (15) 'reptiles' means animals belonging to the species Alligator mississippiensis, Crocodylus johnstoni, Crocodylus niloticus, Crocodylus porosus, Timon Lepidus, Python reticulatus, Python molurus bivittatus or Pelodiscus sinensis;
- (16) 'reptile meat' means the edible parts, either unprocessed or processed, derived from farmed reptiles, which are, when applicable, authorised in accordance with Regulation (EU) 2015/2283 and listed in Commission Implementing Regulation (EU) 2017/2470 (¹);
- (17) 'insects' means food consisting of, isolated from or produced from insects or their parts including any life stadia of insects intended for human consumption which are, when applicable, authorised in accordance with Regulation (EU) 2015/2283 and listed in Implementing Regulation (EU) 2017/2470;
- (18) 'sprouts' means sprouts as defined in point (a) of Article 2 of Commission Implementing Regulation (EU) No 208/2013 (²);
- (19) 'primary production' means primary production as defined in point (17) of Article 3 of Regulation (EC) No 178/2002;
- (20) 'slaughterhouse' means a slaughterhouse as defined in point 1.16 of Annex I to Regulation (EC) No 853/2004;
- (21) 'game-handling establishment' means a game-handling establishment as defined in point 1.18 of Annex I to Regulation (EC) No 853/2004;
- (22) 'cutting plant' means a cutting plant as defined in point 1.17 of Annex I to Regulation (EC) No 853/2004;
- (23) 'production area' means a production area as defined in point 2.5 of Annex I to Regulation (EC) No 853/2004;
- (24) 'factory vessel' means a factory vessel as defined in point 3.2 of Annex I to Regulation (EC) No 853/2004;
- (25) 'freezer vessel' means a freezer vessel as defined in point 3.3 of Annex I to Regulation (EC) No 853/2004;

⁽¹) 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 food (OJ L 351, 30.12.2017, p. 72).

⁽²⁾ Commission Implementing Regulation (EU) No 208/2013 of 11 March 2013 on traceability requirements for sprouts and seeds intended for the production of sprouts (OJ L 68, 12.3.2013, p. 16).

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- (26) 'reefer vessel' means a vessel equipped to store and transport palletized or loose cargo (bulk) goods in temperature controlled holds or chambers;
- (27) 'food business operator' means a food business operator as defined in point (3) of Article 3 of Regulation (EC) No 178/2002.

Article 3

Animals and goods which are required to come from third countries or regions thereof included in the list referred to in Article 126(2)(a) of Regulation (EU) 2017/625

Consignments of the following animals and goods intended for human consumption shall enter the Union only from a third country or region thereof included in the list for those animals and goods laid down in Articles 3 to 22 of Implementing Regulation (EU) 2019/626:

- (a) products of animal origin, including reptile meat and dead whole insects, parts of insects or processed insects, for which Combined Nomenclature codes ('CN codes') have been laid down in Chapters 2 to 5, 15 and 16, and Harmonised System codes ('HS codes') under headings 1702, 1806, 2102, 2103, 2105, 2106, 2202, 2301, 2822, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 3507, 3913, 4101, 4102, 4103, 4110 and 9602 of Part Two of Annex I to Regulation (EEC) No 2658/87, when these products are intended for human consumption;
- (b) live insects referred to by the CN code 0106 49 00 of Part Two of Annex I to Regulation (EEC) No 2658/87.

Article 4

Additional requirements for entry into the Union of certain animals and goods from a third country or region thereof

In addition to the requirements laid down in Article 127(3) of Regulation (EU) 2017/625, the Commission shall only decide on the inclusion of third countries or regions thereof in the list referred to in Article 126(2)(a) of that Regulation if the following requirements are recognised by the Commission as being at least equivalent to the relevant requirements in the Union for animals and goods referred to in Article 3:

- (a) the legislation of the third country on:
 - (i) the production of food of animal origin;
 - (ii) the use of veterinary medicinal products, including rules on their prohibition or authorisation, their distribution, their placing on the market and the rules covering administration and inspection;
 - (iii) the preparation and use of feed, including the procedures for using additives and the preparation and use of medicated feedingstuffs, as well as the hygiene quality of the raw materials used for preparing feedingstuffs and of the final product;

- (b) the hygiene conditions of production, manufacture, handling, storage and dispatch currently applied to products of animal origin destined for the Union;
- (c) any experience of marketing of the products of animal origin from the third country and the results of any official controls on entry in the Union;
- (d) when available, the results of controls carried out by the Commission in the third country related to other animals and goods for which the third country is already listed in accordance with Article 127(2) of Regulation (EU) 2017/625, in particular the results of the assessment of the competent authorities in the third country audited, and the action that the competent authorities have taken in the light of any recommendations addressed to them following such audits by the Commission;
- (e) the existence, implementation and communication of a zoonoses control programme approved by the Commission when applicable;
- (f) the existence, implementation and communication of a residues control programme approved by the Commission when applicable, in accordance with Directive 96/23/EC.

Requirements for entry into the Union of certain goods from a third country in relation to establishments

- 1. Consignments of the following goods shall only enter the Union where those consignments are dispatched from, and obtained or prepared in, establishments that appear on lists drawn up and kept up-to-date in accordance with Article 127(3)(e)(ii) and (iii) of Regulation (EU) 2017/625:
- (a) products of animal origin for which requirements are laid down in Annex III to Regulation (EC) No 853/2004, and for which CN codes have been laid down in Chapters 2 to 5, 15 and 16, and HS codes under headings 2102, 2103, 2105, 2106, 2202, 2301, 2822, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 3507, 3913, 4101, 4102, 4103 and 4110 of Part Two of Annex I to Regulation (EEC) No 2658/87;
- (b) sprouts referred to by the following HS codes: 0704 90, 0706 90, 0708 10, 0708 20, 0708 90 or 1214 90 of Part Two of Annex I to Regulation (EEC) No 2658/87.
- 2. Establishments referred to in paragraph 1 of this Article may be placed on the lists referred to in Article 127(3)(e) of Regulation (EU) 2017/625 only if, in addition to the guarantees laid down in Article 127 (3)(e)(ii) and (iv) of Regulation (EU) 2017/625, the third country gives the following guarantees:
- (a) such establishments, together with any establishments handling raw material of animal origin used in the manufacture of the products of animal origin concerned, comply with applicable requirements referred to in Article 126(1) of Regulation (EU) 2017/625, in particular those of Regulation (EC) No 853/2004, or with requirements recognised to be at least equivalent thereto;

- (b) the establishment, where appropriate, only handles raw materials of animal origin that come from third countries with an approved residues monitoring plan for that product category in accordance with Directive 96/23/EC or from Member States;
- (c) it has real powers to stop the establishments from exporting to the Union in the event that the establishments fail to meet the relevant Union requirements or requirements recognised to be at least equivalent thereto.
- 3. The Commission shall provide the Member States with any new and updated lists that it receives from the competent authorities of the third country in accordance with Article 127(3)(e)(iii) of Regulation (EU) 2017/625 and shall publish such lists on its website.
- 4. Member States shall allow the entry into the Union of the consignments referred to in paragraph 1 provided that the official certificates which are required to accompany such consignments pursuant to the applicable Union rules are issued by the competent authorities of the third country starting with the date of publication by the Commission of the lists referred to in paragraph 1.

Establishments not subject to the requirements of Article 5(1)

The requirements laid down in Article 5 shall not apply to establishments that only carry out the following activities:

- (a) primary production;
- (b) transport operations;
- (c) storage of products of animal origin not requiring temperaturecontrolled storage conditions;.
- (d) production of highly refined chondroitin sulphate, hyaluronic acid, other hydrolysed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids referred to in Section XVI of Annex III to Regulation (EC) No 853/2004 and referred to by the CN codes under the heading of 2833, ex 3913, 2930, ex 2932, 3507 or 3503 of Part Two of Annex I to Regulation (EEC) No 2658/87.

Article 7

Requirements for consignments of fresh meat, minced meat, meat preparations, meat products, mechanically separated meat and raw materials intended for the production of gelatine and collagen

Consignments of the following products of animal origin shall only enter the Union if they have been manufactured from raw materials obtained in slaughterhouses, game-handling establishments, cutting plants and establishments handling fishery products, appearing on lists of establishments drawn up and kept up-to-date in accordance with Article 127(3)(e) of Regulation (EU) 2017/625:

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- (a) fresh meat;
- (b) minced meat;
- (c) meat preparations;
- (d). meat products and mechanically separated meat;
- (e) raw materials intended for the production of gelatine and collagen referred to respectively in point 4(a) of Chapter I of Section XIV and in point 4(a) of Chapter I of section XV of Annex III to Regulation (EC) No 853/2004.

Article 8

Requirements for consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods

- 1. Notwithstanding Article 6, consignments of live bivalve molluscs, echinoderms, tunicates and marine gastropods for which CN codes have been laid down in heading 0307 of Part Two of Annex I to Regulation (EEC) No 2658/87 shall enter the Union only from production areas in third countries that appear on lists drawn up by the competent authorities of the third country in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and published by the Commission.
- 2. The following products may enter the Union from production areas which have not been classified by the competent authorities in the third country in accordance with Article 18(6) of Regulation (EU) 2017/625:
- (a) Pectinidae, except where data from official monitoring programmes as established by Article 57 of Implementing Regulation (EU) 2019/627 enable the competent authorities to classify fishing grounds as set out in point (2) of Chapter IX of Section VII of Annex III to Regulation (EC) No 853/2004;
- (b) marine gastropods that are not filter feeders and *Holothuroidea* that are not filter feeders.

Article 9

Listing of production areas

1. Before the lists referred to in Article 8(1) are drawn up by the competent authorities of the third country, particular account shall be taken of the guarantees that the competent authorities of the third country can give concerning compliance with the requirements of Article 52 of Implementing Regulation (EU) 2019/627 on the classification and control of production areas.

The Commission shall carry out an on-the-spot control visit before such lists are drawn up.

2. Once lists referred to in Article 8(1) are drawn up, and when the competent authorities of the third country offer sufficient guarantees on the management and controls of production areas under their responsibility, the on-the-spot Commission control visit need not to be carried out prior to the addition of a new production area to an existing list established in accordance with Article 5.

Special requirements for fishery products

Consignments of fishery products for which CN codes have been laid down in headings 0301, 0302, 0303, 0304, 0305, 0306, 0307, 0308, 1504, 1516, 1603, 1604, 1605 or 2106 of Part Two of Annex I to Regulation (EEC) No 2658/87, shall enter the Union for placing on the market only if they have been obtained or prepared, at any stage of their production, in an on-land establishment, a factory or freezer vessel or stored in a cold-store or a reefer vessel that appears on a list drawn up and updated in accordance with Article 127(3)(e) of Regulation (EU) 2017/625 and published by the Commission.

Article 11

- 1. A vessel may be included on the lists of establishments referred to in Article 127(3)(e)(ii) of Regulation (EU) 2017/625 provided that the competent authorities of the third country the flag of which the vessel is flying and the competent authorities of another third country to which the competent authorities of the third country the flag of which the vessel is flying have delegated responsibility for the inspection of the vessel concerned, provide the Commission with a joint communication stating that all four of the following requirements are met:
- (a) both third countries appear on the list of third countries or regions thereof, drawn up in accordance with Article 127(3) of Regulation (EU) 2017/625, from which entry into the Union of fishery products is permitted;
- (b) all fishery products from the vessel concerned that are destined for placing on the market in the Union are landed directly in the third country to which the third country the flag of which the vessel is flying has delegated responsibility for the inspection of the vessels concerned;
- (c) the delegated competent authorities have inspected the vessel and have declared that it complies with the applicable Union requirements:
- (d) the delegated competent authorities have declared that they will regularly inspect the vessel to ensure that it continues to comply with the applicable Union requirements.
- 2. A vessel may be included on the lists of establishments referred to in Article 127(3) of Regulation (EU) 2017/625 on the basis of a joint communication from the competent authorities of the third country the flag of which the vessel is flying and from the competent authorities of a Member State, to which the competent authorities of the third country the flag of which the vessel is flying have delegated responsibility for the inspection of the vessel concerned, if all three of the following requirements are met:
- (a) all fishery products from the vessel concerned that are destined for placing on the market in the Union are landed directly in that Member State;
- (b) the competent authorities of that Member State have inspected the vessel and have declared that it complies with the applicable Union requirements;

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- (c) the competent authorities of that Member State have declared that they will regularly inspect the vessel to ensure that it continues to comply with the applicable Union requirements.
- 3. When consignments of fishery products enter the Union directly from a reefer, factory or a freezer vessel flying the flag of a third country, the official certificate referred to in Article 13(3) of Commission Implementing Regulation (EU) 2019/628 (1) may be signed by the captain.

Article 12

Requirements for consignments of composite products

- 1. Consignments of composite products referred to by the HS codes under headings 1601, 1602, 1603, 1604, 1605, 1901, 1902, 1905, 2004, 2005, 2103, 2104, 2105, 2106 of Part Two of Annex I to Regulation (EEC) No 2658/87 shall enter the Union for placing on the market only if each processed product of animal origin contained in the composite products was either produced in establishments that are located in third countries or regions thereof and authorised to export those processed products of animal origin to the Union in accordance with Article 5 or in establishments located in Member States.
- 2. Pending the establishment by the Commission of a specific list of third countries or regions thereof authorised to export composite products to the Union, consignments of composite products from third countries or regions thereof may enter into the Union, subject to compliance with the following rules:
- (a) composite products referred to in paragraph 1 that need to be transported or stored under controlled temperatures shall originate from third countries or regions thereof authorised to export each processed product of animal origin contained in the final product to the Union, pursuant to Commission Decision 2007/777/EC, Commission Regulation (EU) No 605/2010, Commission Decision 2006/766/EC, Commission Regulation (EC) No 798/2008 and Decision 2011/163/EU;
- (b) composite products referred to in paragraph 1 that do not need to be transported or stored under controlled temperatures containing any quantity of processed meat shall originate from third countries or regions thereof authorised to export to the Union the meat products contained in the composite product pursuant to Commission Decision 2007/777/EC and Commission Decision 2011/163/EU;

⁽¹) Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (see page 101 of this Official Journal).

(c) composite products referred to in paragraph 1 that do not need to be transported or stored under controlled temperatures and which contain processed products of animal origin other than processed meat, for which requirements are laid down in Annex III to Regulation (EC) No 853/2004 shall originate from third countries or regions thereof authorised to export meat products, dairy products, colostrum-based products, fishery products or egg products to the Union on the basis of the Union animal and public health requirements and which are listed at least for one of these products of animal origin pursuant to Commission Decision 2007/777/EC, Commission Regulation (EU) No 605/2010, Commission Decision 2006/766/EC and Commission Regulation (EC) No 798/2008, and in the annex to Commission Decision 2011/163/EU on the basis of a residues control plan approved in accordance with Directive 96/23/EC.

Article 13

Official certificates

- 1. Each consignment of the following products shall enter the Union only where the consignment is accompanied by an official certificate:
- (a) products of animal origin for which CN codes have been laid down in Chapters 2 to 5, 15 and 16, and HS codes under headings 1506, 1521, 1601, 1602, 1603, 1604, 1605, 2102, 2103, 2105, 2106, 2202, 2301, 2932, 3001, 3002, 3501, 3502, 3503, 3504, 3507, 3913, 4101, 4102, 4103, 4110 and 9602 of Part Two of Annex I to Regulation (EEC) No 2658/87, when these products are intended for human consumption;
- (b) live insects referred to by the CN code 0106 49 00 of Part Two of Annex I to Regulation (EEC) No 2658/87;

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(c) sprouts and seeds intended for the production of sprouts and referred to by the following HS codes: 0704 90, 0706 90, 0708 10, 0708 20, 0708 90, 0713 10, 0713 33, 0713 34, 0713 35, 0713 39, 0713 40, 0713 50, 0713 60, 0713 90, 0910 99, 1201 10, 1201 90, 1207 50, 1207 99, 1209 10, 1209 21, 1209 91 or 1214 90 of Part Two of Annex I to Regulation (EEC) No 2658/87.

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- 2. The official certificates referred to in paragraph 1 shall certify that the products comply with:
- (a) the requirements laid down in Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 or provisions recognised to be equivalent to those requirements;
- (b) any specific requirements for entry into the Union set out in this Regulation.
- 3. The official certificates referred to in paragraph 1 may include details required in accordance with other Union legislation on public and animal health matters.
- 4. The official certificate for sprouts and seeds intended for the production of sprouts referred to in paragraph 1(c), shall accompany the consignment until it reaches its destination as indicated in the official certificate. In the case of splitting of the consignment, a copy of the official certificate shall accompany each part of the consignment.

Private attestation

- 1. A private attestation, prepared and signed by the importing food business operator, shall accompany the consignments of composite products as referred to in Article 12(2)(c) confirming that the consignments comply with the applicable requirements referred to in Article 126(1) of Regulation (EU) 2017/625.
- 2. By way of derogation to paragraph 1, for the products exempted from official controls at border control posts, in accordance with Article 48(h) of Regulation (EU) 2017/625, the private attestation shall accompany the products at the time of the placing on the market.
- 3. The private attestation referred to in paragraph 1 shall ensure the traceability of the consignment and shall include:
- (a) information regarding the consignor and consignee of the imported goods;
- (b) the list of products of plant origin and processed products of animal origin contained in the composite products, indicated in descending order of weight, as recorded at the time of their use in the manufacture of the composite product;
- (c) the approval number of the establishment(s) manufacturing the processed products of animal origin contained in the composite product, as provided for in Article 4(2) of Regulation (EC) No 853/2004 and indicated by the importing food business operator.
- 4. The private attestation referred to in paragraph 1 shall attest that:
- (a) the third country or region thereof producing the composite product is listed at least for one of the following category of product of animal origin:
 - (i) meat products;
 - (ii) dairy products or colostrum-based products;
 - (iii) fishery products;
 - (iv) egg products;
- (b) the establishment producing the composite products fulfils hygiene standards, recognised to be equivalent to those required by Regulation (EC) No 852/2004;
- (c) the composite product does not need to be stored or transported under controlled temperature;
- (d) the processed products of animal origin contained in the composite product originate from third countries or regions thereof authorised to export each processed product of animal origin to the Union, or from the Union, and are sourced from listed establishment(s);
- (e) the processed products of animal origin used in the composite product have undergone at least the treatment provided for those products pursuant to Commission Decision 2007/777/EC and Commission Regulation (EU) No 605/2010 with a brief description of any processes undergone and temperatures applied to the product.

Entry into force

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

It shall apply from 14 December 2019. However, the requirements laid down in Article 12, and Article (14)(1) and (2) shall apply from 21 April 2021.

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