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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) 4298 final.

Encl.: C(2021) 4298 final



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

of 13.7.2021

amending Delegated Regulation (EU) 2020/692 as regards the animal health requirements for the entry into the Union of products of animal origin contained in composite products

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Commission Delegated Regulation (EU) 2020/692¹ lays down animal health requirements for the entry into the Union of animals, germinal products and products of animal origin. Its Articles 162 and 163 lay down specific requirements for the entry into the Union of products of animal origin contained in composite products.

In accordance with those provisions, shelf-stable composite products not containing meat products are to be accompanied by a declaration prepared and signed by an operator. The processed products of animal origin must however be subject to a strict risk-mitigating treatment that ensures their safety from the animal health point of view.

Nevertheless, it appears disproportionate to require such strict risk-mitigating treatments to dairy products that originate from countries that are already authorised for the entry into the Union of raw milk or dairy products. Therefore, this Delegated Regulation intends to amend Delegated Regulation (EU) 2020/692 to allow the entry into the Union of shelf-stable composite products containing dairy products that originate from third countries listed for the entry into the Union of:

- raw milk and dairy products not subject to a risk-mitigating treatment, without undergoing any specific risk-mitigating treatment;
- dairy products subject to a risk-mitigating treatment, if they have undergone a risk-mitigating treatment in accordance with Article 157 of Delegated Regulation (EU) 2020/692.

This will grant safe trade of those products avoiding, at the same time, unnecessary burdens.

In addition, this Delegated Regulation clarifies other aspects related to the animal health requirements for the entry into the Union of products of animal origin contained in composite products, including gelatine and collagen and colostrum-based products.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission circulated the contents of this draft Delegated Regulation to members of the Expert Group on Animal Health (E00930).

3. LEGAL ELEMENTS OF THE DELEGATED ACT

This Delegated Regulation is to be adopted within the framework of Regulation (EU) 2016/429 of the European Parliament and of the Council², and in particular pursuant to Articles 234(2), 237(4) and 239(2) thereof.

¹ Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

² Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law') (OJ L 84, 31.3.2016, p. 1).

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

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amending Delegated Regulation (EU) 2020/692 as regards the animal health requirements for the entry into the Union of products of animal origin contained in composite products

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health ('Animal Health Law')³, and in particular Articles 234(2), 237(4) and 239(2) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) 2020/692⁴ supplements the animal health rules laid down in Regulation (EU) 2016/429, as regards the entry into the Union, and the movement and handling after entry into the Union, of consignments of certain animals, germinal products and products of animal origin. In particular, Articles 162 and 163 of Delegated Regulation (EU) 2020/692 lay down specific requirements for the entry into the Union of products of animal origin contained in composite products. Articles 162 and 163 of Delegated Regulation (EU) 2020/692 do not provide specific requirements for colostrum-based products contained in composite products. This Regulation should therefore clarify the requirements that apply for the entry into the Union of those products when contained in composite products in accordance with the rules applicable to the entry into the Union of colostrum-based products provided for in Article 153 of Delegated Regulation (EU) 2020/692.
- (2) Gelatine and collagen fall within the definition of 'meat products' provided for in Article 2, point (44), of Delegated Regulation (EU) 2020/692 and therefore only consignments of gelatine and collagen complying with the requirements for entry into the Union of meat products are permitted to enter the Union. However, gelatine and collagen contained in shelf-stable composite products pose a very low animal health risk due to the treatments they undergo during their processing. For this reason, composite products containing only these kind of meat products should be added to the list of composite products covered by the derogation provided for in Article 163 of Delegated Regulation (EU) 2020/692 and therefore not be required to be accompanied by an animal health certificate, but only be required to be accompanied by a declaration instead.

³ OJ L 84, 31.3.2016, p. 1.

⁴ Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379).

- (3) In accordance with Article 163 of Delegated Regulation (EU) 2020/692 shelf-stable composite products not containing meat products are to be accompanied by a declaration prepared and signed by an operator. The processed products of animal origin must however be subject to a strict risk-mitigating treatment that ensures their safety from the animal health point of view. Nevertheless, it would appear disproportionate to require such strict risk-mitigating treatments to dairy products that originate from countries that are authorised for the entry into the Union of raw milk or dairy products. For those third countries, the requirements should be proportionate to the risk posed by the country of origin and the guarantees provided by the competent authorities should be considered. Therefore, Delegated Regulation (EU) 2020/692 should be amended to allow the entry into the Union of shelf-stable composite products containing dairy products that originate from third countries listed for the entry into the Union of raw milk and dairy products not subject to a risk-mitigating treatment, without undergoing any specific risk-mitigating treatment. In addition, Delegated Regulation (EU) 2020/692 should also be amended to allow the entry into the Union of shelf-stable composite products containing dairy products that originate from third countries listed for the entry into the Union of dairy products subject to a risk-mitigating treatment, if they have undergone a risk-mitigating treatment in accordance with Article 157 of Delegated Regulation (EU) 2020/692.
- (4) Dairy products that have undergone strict risk-mitigating treatments and egg products contained in shelf-stable composite products only represent a limited risk, both from an animal and public health point of view. Therefore, those goods should be permitted to enter the Union if they come from a third country, territory or zone thereof which is not listed for the entry into the Union of the particular species and category of products of animal origin, but is listed for the entry into the Union of either meat products, dairy products or egg products.
- (5) To avoid undue administrative burden for the entry into the Union of consignments of composite products posing a low animal health risk, it should be permitted that the operator responsible for the entry into the Union of the consignments signs the declaration referred to in Article 163 of Delegated Regulation (EU) 2020/692.
- (6) The rules provided in Delegated Regulation (EU) 2020/692 supplement those laid down in Regulation (EU) 2016/429. As those rules are interrelated, they are laid down together in one single act. In the interest of clarity and for their effective application, it is appropriate for the rules amending Delegated Regulation (EU) 2020/692 to be also laid down in a single delegated act providing a comprehensive set of requirements for the entry into the Union of products of animal origin.
- (7) Delegated Regulation (EU) 2020/692 should therefore be amended accordingly.
- (8) As Delegated Regulation (EU) 2020/692 applies from 21 April 2021, in the interest of legal certainty, this Regulation should enter into force as a matter of urgency,

HAS ADOPTED THIS REGULATION:

Article 1

Delegated Regulation (EU) 2020/692 is amended as follows:

1. Article 162 is amended as follows:
 - (a) the title is replaced by the following:

‘Article 162

Composite products containing meat products, dairy products, colostrum-based products and/or egg products'

(b) paragraph 1 is replaced by the following:

1. Consignments of the following composite products shall only be permitted to enter the Union if the composite products of the consignments come from a third country or territory or zone thereof listed for entry into the Union of the specific products of animal origin contained in those composite products:
 - (a) composite products containing meat products;
 - (b) non-shelf stable composite products containing dairy products, and/or egg products
 - (c) composite products containing colostrum-based products.';

2. Article 163 is replaced by the following:

Article 163

Specific requirements for shelf-stable composite products

1. By way of derogation from Article 3, point (c)(i), consignments of composite products that do not contain meat products, except gelatine and collagen, or colostrum-based products, and that have been treated to become shelf-stable at ambient temperature, shall be permitted to enter the Union accompanied by a declaration, as provided for in paragraph 2, if they contain:
 - (a) dairy products that comply with one of the following conditions:
 - (i) they have not undergone a risk-mitigating treatment provided for in Annex XXVII, provided that the dairy products have been obtained either:
 - in the Union; or
 - in a third country or territory or zone thereof listed for the entry into the Union of dairy products without undergoing a specific risk-mitigating treatment, in accordance with Article 156, and the third country or territory or zone thereof where the composite product is produced, if different, is also listed for entry into the Union of those products without the obligation to apply a specific risk-mitigating treatment;
 - (ii) they have undergone a risk-mitigating treatment provided for in column A or B of Annex XXVII, relevant for the species of origin of the milk, provided that they have been obtained in a third country or territory or zone thereof listed for entry into the Union of dairy products that have undergone a specific risk-mitigating treatment, in accordance with Article 157, and the third country or territory or zone thereof where the composite product is produced, if different, is also listed for entry into the Union of those products if they have undergone a specific risk-mitigating treatment;
 - (iii) they have undergone a risk-mitigating treatment at least equivalent to those referred to in column B of Annex XXVII, regardless of the species of origin of the milk, if the dairy products do not comply

with all the requirements provided for in points (i) or (ii) or they have been obtained in a third country, territory or zone thereof which is not authorised for the entry into the Union of dairy products but is authorised for the entry into the Union of other products of animal origin in accordance with this Regulation;

- (b) egg products that have undergone a risk-mitigating treatment equivalent to those provided for in Annex XXVIII.
2. The declaration referred to in paragraph 1:
- (a) shall only accompany consignments of composite products in cases when the final destination of the composite products is in the Union;
 - (b) shall be issued by the operator responsible of the entry into the Union of the composite products, attesting that the composite products in the consignment comply with the requirements provided for in paragraph 1.
3. By way of derogation from of Article 3, point (a)(i), dairy products referred to in paragraph 1, point (a)(iii), of this Article, and egg products contained in composite products that have been treated to become shelf-stable at ambient temperature shall be permitted to enter the Union if they come from a third country, territory or zone thereof which is not specifically listed for the entry into the Union of those products of animal origin but listed for the entry into the Union of either:
- (a) meat products, dairy products or egg products;
 - or
 - (b) fishery products in accordance with Regulation (EU) 2017/625.

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Article 2

References to former Article 163(a) of Delegated Regulation (EU) 2020/692 shall be construed as references to Article 163(1) of that Delegated Regulation.

Article 3

This Regulation shall enter into force on the 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, 13.7.2021

For the Commission
The President
Ursula VON DER LEYEN