



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Crisis management in food, animals and plants
The Director

Brussels,
SANTE.DDG2.G.4/PC/acg(2019)4905160

Subject: Public health requirements applicable to the entry into the European Union of composite products as of 21 April 2021

Your Excellency,

In 2017, the European Union adopted a new framework for official controls (Regulation (EU) 2017/625¹) that will be applicable as from 14 December 2019.

With regard to public health requirements applicable to the entry into the European Union of consignments of certain animals and goods intended for human consumption, this was supplemented by three acts on:

- requirements for the entry into the European Union of consignments of certain animals and goods intended for human consumption²,
- list of third countries authorised for the entry into the EU of certain animals and goods intended for human consumption³ and,
- model official certificates for certain animals and goods⁴.

¹ 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. 1–142

² 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 OJ L 131, 17.5.2019, p. 18–30

³ Commission Implementing Regulation (EU) 2019/626 of 5 March 2019 concerning lists of third countries or regions thereof authorised for the entry into the European Union of certain animals and goods intended for human consumption, amending Implementing Regulation (EU) 2016/759 as regards these lists OJ L 131, 17.5.2019, p. 31–50

⁴ 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 OJ L 131, 17.5.2019, p. 101–194

Embassies of all non-EU countries authorised to export
meat products, fishery products, dairy products or egg products
to the European Union

Though the public health requirements remain essentially similar to those presently applicable to the entry of foodstuffs into the EU, I wish to draw your attention to the specific case of foodstuffs containing both products of plant origin and processed products of animal origin, also known as “composite products”.

With regard to animal health, a Commission Delegated Regulation establishing notably the animal health requirements for the entry into the Union of composite products, based on Regulation (EU) 2016/429⁵, is in preparation. Once adopted, these requirements will also have to be taken into consideration in addition to the public health requirements, which are the subject of this letter. I will write in due time to clarify those.

Categories of composite products

The way in which composite products are categorised will change. Entry requirements will no longer be based on *percentage* of ingredients of animal origin but rather on the animal health or public health *risk* linked to the composite product itself.

Article 12 of Commission Delegated Regulation (EU) 2019/625² establishes three categories of composite products: (1) non shelf stable composite products, (2) shelf stable composite products that contain meat products, and (3) shelf stable composite products that do not contain meat products. The requirements for entry into the Union of the three categories of composite products will be applicable as from 21 April 2021.

Processed products of animal origin contained in the composite products

For the processed products of animal origin contained in the composite products, the public health requirements remain the same as at present. All the processed products of animal origin contained in the composite products must either be produced in establishments located in third countries authorised for the entry into the European Union of those processed products of animal origin – and consequently listed in the Commission's Trade Control and Expert System (TRACES)⁶ – or in establishments located in EU Member States.

I would like to underline the requirements regarding residues of chemical substances in the processed products of animal origin contained in each of the three categories of composite products. The third country *manufacturing* a composite product will have to be listed in Decision 2011/163/EU for each processed product of animal origin contained in the composite product.

This means that, from 21 April 2021 onwards, the third country manufacturing the composite product must either have an approved residue monitoring plan for each of the ingredients of animal origin in question (in which case the country is listed in the Annex to the above Decision) *or* it must source the animal ingredients either from an EU Member State or a third country which is listed in the above Decision for those commodities (in which case the country manufacturing the composite is listed in the Annex to the above Decision with a footnote⁷).

⁵ 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. 1–208

⁶ Available here: https://webgate.ec.europa.eu/sanco/traces/output/non_eu_listsPerActivity_en.htm

⁷ "Third countries using only raw material either from Member States or from other third countries approved for imports of such raw material to the Union, in accordance with Article 2."

Should a country manufacturing a composite product wish to source ingredients of animal origin from another country or an EU Member State it would have to inform the Commission of its intention to source ingredients in accordance with Article 2(1) of Commission Decision 2011/163/EU. Such a statement should be addressed to Mrs P. Colombo, Director for Health and Food Audits and Analysis and emailed to SANTE-TCRESIDUEPLANS@ec.europa.eu so that the country can be listed in Commission Decision 2011/163/EU with a footnote accordingly, which is planned to be amended twice a year.

Country manufacturing composite products

The requirements for countries manufacturing the composite products vary according to the category of composite product they intend to enter the European Union.

Certification of composite products

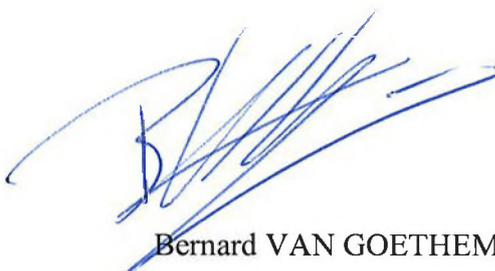
While an official certificate will be required for composite products of categories (1) and (2), a private attestation will accompany composite products of category (3). The content of the certificate will be established in 2020. The elements to present in the attestation are described in Commission Delegated Regulation (EU) 2019/625² for public health aspects, and will be supplemented in 2020 by animal health requirements.

The attached annex offers more details and a decision tree for an easy decision-making.

The Commission services are available should any clarification be needed.

I would appreciate if you could relay this message and its annexes to whom it may concern so that the transition can happen as smoothly as possible and your country's authorities as well as your food business operators be ready by 21 April 2021.

Yours sincerely,



Bernard VAN GOETHEM

Enclosure: Summary of application rules and decision tree to determine relevant applicable rules for the entry of composite products into the European Union

Contact: Mr Paolo Caricato, paolo.caricato@ec.europa.eu

Copy to: EU Delegation in the countries authorised to export meat products, fishery products, dairy products or egg products to the EU
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