ANNEX I

SUMMARY OF THE PUBLIC HEALTH REQUIREMENTS FOR ENTRY INTO THE EUROPEAN UNION APPLICABLE TO COMPOSITE PRODUCTS AS OF 21 APRIL 2021

Composite products are foodstuffs containing both products of plant origin and processed products of animal origin.

1. REQUIREMENTS FOR THE 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 be produced either

- in establishments located in third countries authorised for the entry into the European Union of those processed products of animal origin, or
- in establishments located in EU Member States.

With regard to the control of residues, the third country manufacturing a composite product must be listed in Commission Decision 2011/163/EU for each processed product of animal origin contained in this composite product.

For example, if the composite product contains dairy products and egg products, the non-EU country manufacturing the composite product must have an approved residue monitoring plan for dairy products and egg products (and be listed in the above Decision) or must source the dairy products and egg products either from an EU Member State or a third country which is listed in the above Decision for both those commodities. In that case the third country manufacturing the composite product shall be listed in Decision 2011/163/EU with a footnote indicating such sourcing.

This possibility to source processed products of animal origin – and thus the entry into the Union of the composite products containing such processed products of animal origin sourced from another country – will also be subject to further animal health requirements that are under preparation and may be further limited depending on the animal health situation of the country manufacturing the composite product. *For example*, it could be limited to shelf stable composite products only, or for non shelf stable composite products, to countries benefiting from light risk mitigation requirements with regard to animal health. The draft Regulation fixing such animal health requirements is under discussion and is planned for adoption by the end of 2019.

In the event that a country wishes, for the manufacture of a composite product intended for entry into the EU, to source processed products of animal origin from either an EU Member State or a third country already listed in Commission

Decision 2011/163/EU for those (processed) animal products, it must inform the Commission in writing of its intention to do so and provide the statement below:

"*The competent authority of [third country] ensures that animal products for human consumption exported to the European Union, in particular products produced from raw material imported into [third country], shall only come from establishments approved in accordance to Article 12 of Regulation (EC) No 854/2004 and having reliable procedures in place to guarantee that raw material of animal origin used in such food originates only from Member States of the European Union or third countries listed for the respective raw material in the Annex to Commission Decision 2011/163/EU without a restrictive footnote as provided for in Article 2(2) of the Decision.*"

This should be addressed to Mrs P. Colombo, Director for Health and Food Audits and Analysis and emailed to SANTE-TCRESIDUEPLANS@ec.europa.eu.

2. PUBLIC HEALTH REQUIREMENTS APPLICABLE TO THE DIFFERENT CATEGORIES OF COMPOSITE PRODUCTS FOR THEIR ENTRY INTO THE UNION

The main change of the requirements for entry into the Union for composite products is that they are no longer based on *quantities* of processed products of animal origin (expressed *in percentage* of ingredients of the composite product), but rather on the *risk* linked to the composite product itself, be that from animal health or public health point of view.

The Commission Delegated Regulation establishing, amongst other issues, the animal health requirements for entry into the European Union of composite products based on Regulation (EU) 2016/429[1] ("Animal Health Law") is under discussion and is planned for adoption by the end of 2019.

Composite products are thus now categorised in three categories:

(1) non-shelf-stable composite products (which need to be transported or stored under controlled temperatures);

(2) shelf-stable composite products (which do not need to be transported or stored under controlled temperatures) that contain meat products as ingredient;

(3) shelf-stable (which do not need to be transported or stored under controlled temperatures) that do not contain meat products as ingredient.

2.1. Requirements for countries from which the composite products originate

(1) **Non-shelf-stable** composite products shall originate from countries authorised for entry into the European Union, in the relevant legislation on animal health, public health and residues[2], for each processed product of animal origin contained in the composite product;

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[1] 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

[2] Commission Decision No 2011/163/EU of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC OJ L 70, 17.3.2011, p. 40

(2) **Shelf-stable** composite products that **contain processed meat** shall originate from countries authorised for the entry into the European Union for the meat products[3] contained in the composite product (including for the control of residues[2]);

(3) **Shelf-stable** composite product **that do not contain processed meat** shall originate from countries authorised for the entry into the European Union of meat products[3] **or** dairy products/colostrum-based products[4] **or** fishery products[5] **or** egg products[6], including for the respective control of residues[2].

2.2. Requirements for certification and attestation guarantees accompanying the composite products

(1) Non-shelf-stable composite products and (2) shelf-stable composite products containing processed meat must be accompanied by an **official certificate.** The model certificate will be established in 2020, based on that laid down in Commission Regulation (EU) No 28/2012. This official certificate shall be signed by the competent authorities of the country where the composite product is produced.

(3) Shelf-stable composite products not containing processed meat will only have to be accompanied by an **attestation provided by the importing food business operator**. This attestation should include the information requested in Article 14(3) of Commission Delegated Regulation (EU) 2019/625 and the relevant documentation provided for in the animal health legislation under preparation based on Regulation (EU) 2016/429[1] *("Animal Health Law")*.

2.3. Controls at entry into the Union

All composite products will be subject to veterinary controls at the Border Control Posts before entry into the EU.

The Commission will list in a future act those composite products that, due to their lower risk, can be granted a derogation from veterinary control at the border and for which controls may be carried out at the point of destination.

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[3] *Please, note that this legal act will be repealed as from 21 April 2021 and will be replaced by legal acts based on Regulation (EU) 2016/429 ("Animal Health Law")*
Commission Decision 2007/777/EC of 29 November 2007 laying down the animal and public health conditions and model certificates for imports of certain meat products and treated stomachs, bladders and intestines for human consumption from third countries and repealing Decision 2005/432/EC OJ L 312, 30.11.2007, p. 49;

[4] *Please, note that this legal act will be repealed as from 21 April 2021 and will be replaced by legal acts based on Regulation (EU) 2016/429 ("Animal Health Law")*
Commission Regulation (EU) No 605/2010 of 2 July 2010 laying down animal and public health and veterinary certification conditions for the introduction into the European Union of raw milk and dairy products intended for human consumption OJ L 175, 10.7.2010, p. 1.

[5] *Please, note that this legal act will be repealed as from 14 December 2019 and will be replaced by Regulation (EU) 2019/626*
Commission Decision 2006/766/EC of 6 November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted OJ L 320, 18.11.2006, p. 53.

[6] *Please, note that this legal act will be repealed as from 21 April 2021 and will be replaced by legal acts based on Regulation (EU) 2016/429 ("Animal Health Law")*
Commission Regulation (EC) No 798/2008 of 8 August 2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through the Community and the veterinary certification requirements OJ L 226, 23.8.2008, p. 1