

ဥရောပသမဂ္ဂသို့တင်ပို့မည့်ပေါင်းစပ်ထုတ်ကုန်များ (Composite Products)

အတွက်ကျန်းမာရေးဆိုင်ရာလိုအပ်ချက်များစတင်အသက်ဝင်မည့်ကိစ္စ

၁။ ဥရောပသမဂ္ဂသို့ပေါင်းစပ်ထုတ်ကုန်များ (Composite Products) တင်ပို့ခြင်းအတွက်အများပြည်သူကျန်းမာရေးဆိုင်ရာလိုအပ်ချက်များသည် ၂၁-၄-၂၀၂၁ မှ စတင်၍သက်ရောက်မှုရှိမည်ဖြစ်ကြောင်း၊ အဆိုပါ ထုတ်ကုန်များဥရောပသမဂ္ဂအတွင်းသို့ ဝင်ရောက်ခြင်းနှင့်သက်ဆိုင်သော အများပြည်သူဆိုင်ရာကျန်းမာရေးလိုအပ်ချက်များ၏ အကျဉ်းချုပ်ဖော်ပြချက်၊ ပေါင်းစပ်ထုတ်ကုန်များ (Composite Products) ဥရောပသမဂ္ဂသို့ဝင်ရောက်ခြင်းဆိုင်ရာဆုံးဖြတ်မှုပုံစံ (Decision Tree) တို့ကို ပူးတွဲလျက် ဥရောပကော်မရှင်၏ ကျန်းမာရေးနှင့်အစားအသောက် ဘေးကင်းလုံခြုံမှုဌာနမှ ဥရောပသမဂ္ဂသို့ အသားထွက်ကုန်များ၊ ရေထွက်ကုန်များ၊ နို့ထွက်ပစ္စည်းများ(သို့မဟုတ်) ဥများတင်ပို့ခွင့်ရှိသည့် အီးယူပြင်ပနိုင်ငံများအားလုံး၏သံရုံးများသို့၁၁.၂.၂၀၁၉ နေ့စွဲပါစာဖြင့်ပေးပို့လာပါသည်။

၂။ ပူးတွဲပါအကြောင်းကြားစာတွင် ဥရောပသမဂ္ဂမှ ၂၀၁၇ ခုနှစ်တွင် ချမှတ်ခဲ့သော တရားဝင်ထိန်းချုပ်မှုဆိုင်ရာ မူဘောင်အသစ် Regulation (EU) 2017/625 သည် ၁၄-၁၂-၂၀၁၉ နေ့မှစတင်၍ သက်ရောက်မှုရှိမည်ဖြစ်ကြောင်း၊ ဥရောပသမဂ္ဂအတွင်းသို့ ဝင်ရောက်မည့်တိရိစ္ဆာန်ထွက်ကုန်စည်များနှင့် လူသားများစားသုံးရန်အတွက် ရည်ရွယ်သောကုန်စည်များနှင့် သက်ဆိုင်သည့် ကျန်းမာရေးဆိုင်ရာလိုအပ်ချက်များနှင့်စပ်လျဉ်း၍ ကော်မရှင်၏လုပ်ထုံးလုပ်နည်း (၃) ခုဖြင့်ဖြည့်စွက်ဆောင်ရွက်သွားမည်ဖြစ်ကြောင်း၊ အထူးသဖြင့် အပင်ထွက်ပစ္စည်းများနှင့် တိရိစ္ဆာန်ထွက်ပစ္စည်းများကို ပေါင်းစပ်၍ လူသားများစားသုံးရန်အတွက် ရည်ရွယ်၍ ထုတ်လုပ်ထားသည့် စားသောက်ကုန်များ (Foodstuffs containing both products of plant origin and processed products of animal origin) ကို ပေါင်းစပ်ထုတ်ကုန်များ (Composite Product) အဖြစ်သတ်မှတ်ထားသည်ကို ရရှိပြုစေလိုကြောင်း၊ ဥရောပသမဂ္ဂ၏ လုပ်ထုံးလုပ်နည်း Regulation (EU) 2016/429 ကိုအခြေခံ၍ပေါင်းစပ်ထုတ်ကုန်များ (Composite Products) အီးယူအတွင်းသို့ဝင်ရောက်ခြင်းဆိုင်ရာ တိရိစ္ဆာန်ကျန်းမာရေးနှင့် စပ်လျဉ်းသည့် လုပ်ထုံးလုပ်နည်းမှာပြင်ဆင်ဆောင်ရွက်နေဆဲဖြစ်ပြီး၊ အတည်ပြုချမှတ်ပြီးပါက အဆိုပါ တိရိစ္ဆာန်ကျန်းမာရေးဆိုင်ရာ လိုအပ်ချက်များကို ဤအကြောင်းကြားစာတွင် ဖော်ပြထားသည့် အများပြည်သူကျန်းမာရေးဆိုင်ရာ လိုအပ်ချက်များတွင် ထပ်မံထည့်သွင်းစဉ်းစားဆောင်ရွက်သွားမည်ဖြစ်ကြောင်း၊ ယင်းအချက်များကို အချိန်မီအကြောင်းကြားပေးသွားမည်ဖြစ်ပါကြောင်း၊ ဥရောပကော်မရှင်၏ လုပ်ထုံးလုပ်နည်း Commission Delegated Regulation (EU) 2019/625 ၏ ပုဒ်မ(၁၂) အရ ခွဲခြားထားသည့် ပေါင်းစပ်ထုတ်ကုန် (Composite Products) အမျိုးအစား(၃)မျိုးအား ဥရောပသမဂ္ဂသို့ တင်ပို့ခြင်းအတွက် ကျန်းမာရေးဆိုင်ရာလိုအပ်ချက်များသည် ၂၁-၄-၂၀၂၁ရက်နေ့မှစတင်၍ သက်ရောက်မှုရှိမည်ဖြစ်ကြောင်း၊ ယင်းအတွက်လိုအပ်သည့် ကူးပြောင်းမှုများလွယ်ကူချောမွေ့စွာ ဆောင်ရွက်နိုင်ရေးနှင့် သက်ဆိုင်ရာတာဝန်ရှိသူများနှင့် စားသောက်ကုန်ထုတ်လုပ်ငန်းများ အဆင်သင့်ပြင်ဆင်နိုင်ရေးတို့

အတွက် အသိပေးအကြောင်းကြားပေး စေလိုပါကြောင်းစသည်ဖြင့် အဓိကဖော်ပြထားသည်ကို တွေ့ရှိရ ပါသည်။

၃။ သို့ဖြစ်ပါ၍ ဥရောပသမဂ္ဂသို့ တင်ပို့မည့်ပေါင်းစပ်ထုတ်ကုန်များ (Composite Products) အတွက် ကျန်းမာရေးဆိုင်ရာ လိုအပ်ချက်များအား ပူးတွဲဖော်ပြထားပါသည်။

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) 2016/429¹ ("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 residues², for each processed product of animal origin contained in the composite product;

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 products³ contained in the composite product (including for the control of residues²);
- (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 products³ or dairy products/colostrum-based products⁴ or fishery products⁵ or egg products⁶, including for the respective control of residues².

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) 2016/429¹ ("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.

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.

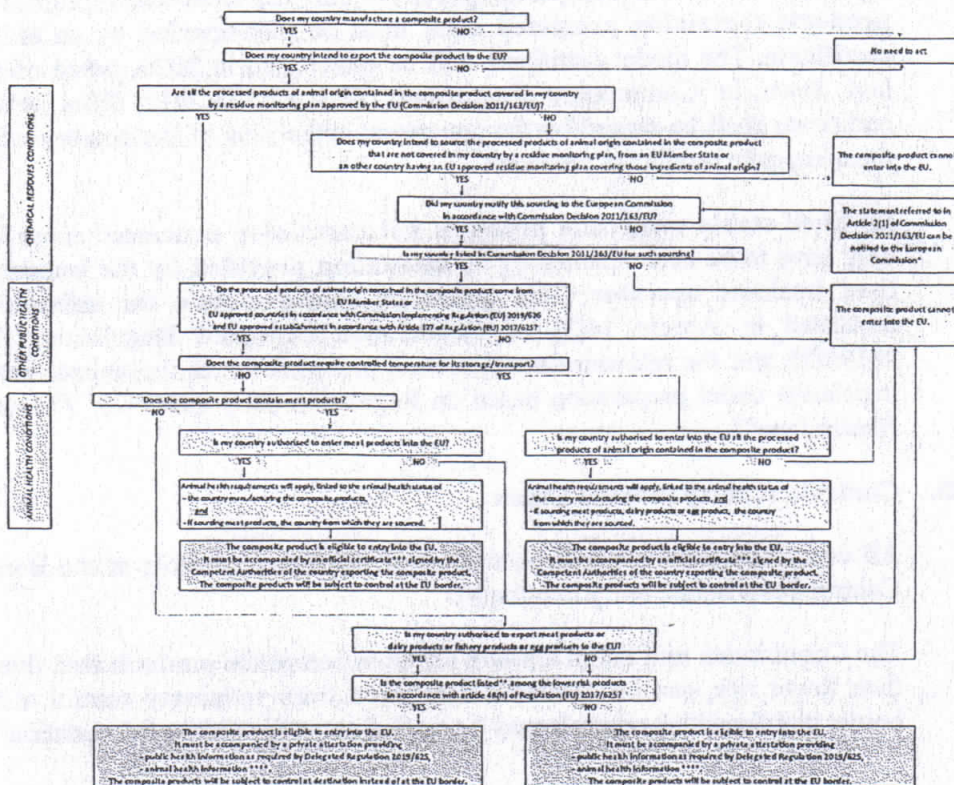
⁵ Please, note that this legal act will be repealed as from 14 December 2019 and will be replaced by Regulation (EU) 2019/626 Commission Decision 2006/766/EC of 6 November 2006 establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine 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

Decision tree for the entry into the European Union of composite products
Applicable as of 21 April 2011

Document date:
12 April 2011 (Vet/ah/6/2011)



ANIMAL HEALTH CONSIDERATIONS
 OTHER PUBLIC HEALTH CONSIDERATIONS
 RESIDUE CONSIDERATIONS

* If a third country manufacturing a composite product is not listed for a specific type of animal origin mentioned in the composite product in Commission Decision 2011/143/EU and wishes to source this ingredient from a Member State or from a third country which has an EU approved residue monitoring plan covering this ingredient, it needs to be authorized with a decision in Commission Decision 2011/143/EU. If so, the following statement should be added to the European Commission in that regard.
 The competent authority of that country ensures that animal products for human consumption sourced in the European Union from that particular animal product type are covered by an EU approved residue monitoring plan covering those ingredients of animal origin. I shall only source from establishments approved in accordance with Article 177 of Regulation (EC) No 853/2004 and hereby declare product, as per the questionnaire sent, are the result of a control program in each third country or only from Member States of the European Union or EU/EEA countries listed for the respective raw material in the Annex to Commission Decision 2011/143/EU. I will not use a notified plant name as provided for in Article 2(7) of the Decision.

** As far as it is established before 21 April 2011 by a Commission Delegated Regulation.

*** The official certificate is also used for adaptation to 2002.

**** The animal health requirements are also used for adaptation to 2002.

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

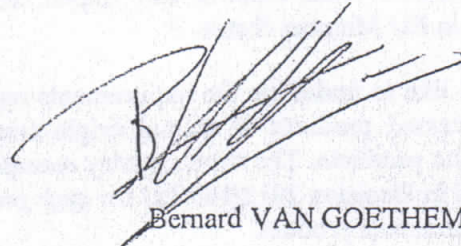
While an official certificate will be required for composite products of categories (1) and (2), a private attestation will accompany composite products of category (3). The content of the certificate will be established in 2020. The elements to present in the attestation are described in Commission 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
M. Hudson, S. Jülicher, P. Colombo, E. Synowiec