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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Crisis preparedness in food, animals and plants
Food hygiene, feed and fraud

IMPORT OF COMPOSITE PRODUCTS INTO THE EU

QUESTIONS & ANSWERS

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CHANGES COMPARED TO VERSION OF 18 December 2024

Revised questions

- 1.9; 1.12; 1.24
- 2.5; 2.11; 2.16; 2.17;3.2; 3.10
- 4.1; 4.6

New questions

- 1.26
- 1.27
- 3.16

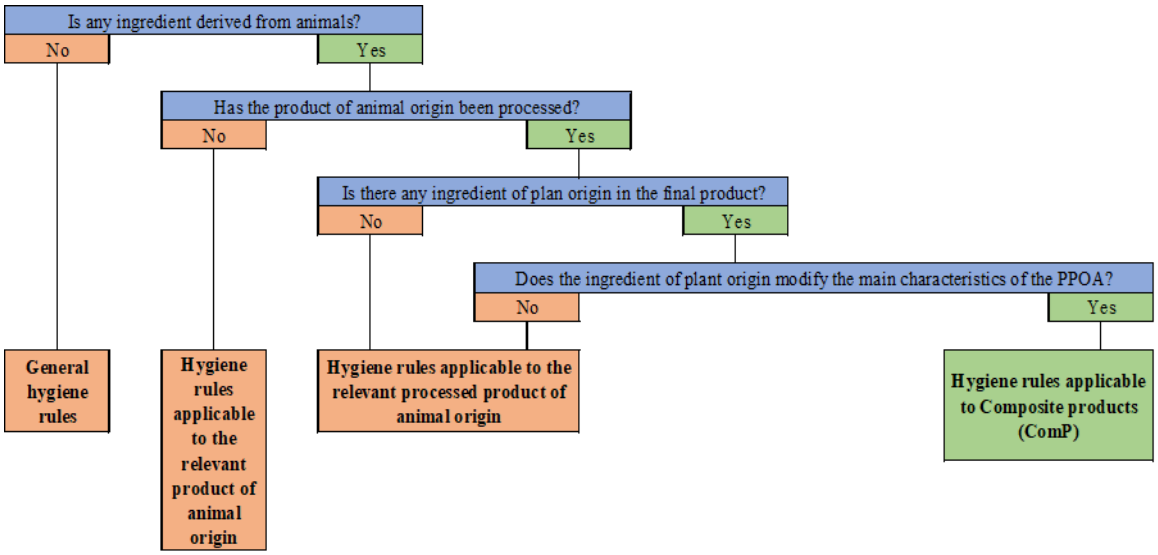
Removed questions

- 5.4

1. GENERAL

1.1. What is a composite product?

A composite product is a food containing both processed products of animal origin and products of plant origin. It is necessary to distinguish between composite products, processed products of animal origin (PPAO) and products, which could erroneously be considered as composite products. Though the decision should be made on the case by case basis, the following decision tree helps making a first assessment.



1.2. Are there differences in the categories of composite products intended to be exported to the EU after 21 April 2021?

Yes. Article 20.2 of Commission Delegated Regulation (EU) 2022/2292 establishes three categories of composite products:

(1) non shelf-stable composite products,

(2) shelf-stable composite products that contain any quantity of colostrum-based products or meat products, except gelatine, collagen and highly refined products, and

(3) shelf-stable composite products that do not contain colostrum-based products or meat products, except gelatine, collagen and highly refined products.

The requirements on the country of origin and the guarantees accompanying the composite products depend on their category. However, the requirements applicable to processed products of animal origin contained in the composite products are the same for the three categories.

1.3. What is the difference between a non shelf-stable and a shelf-stable composite product?

A non shelf-stable composite product needs to be transported or stored under controlled temperature. It is not the case for shelf-stable composite products which can be kept at ambient temperature.

1.4. What is not a composite product?

The addition of a product of plant origin during the processing defined in Article 2(1)(m) of Regulation (EC) No 852/2004 of a processed product of animal origin does not automatically mean that the resulting food falls within the definition of composite products. If such addition does not modify the main characteristics of this processed product of animal origin, the latter is not a composite product. The addition may have the sole purpose of adding special characteristics or being necessary for the manufacture of the product of animal origin (Article 2(1)(o) of Regulation (EC) No 852/2004).

For instance, a cheese to which herbs are added, or a yogurt to which fruit is added, remain a dairy product. Similarly, canned tuna to which vegetable oil is added remains a fishery product. These foodstuffs must be produced in approved establishments in accordance with Regulation (EC) No 853/2004.

1.5. What percentage of a processed product of animal origin makes a food subject to the rules applicable to composite products?

What makes foodstuff subject to the rules applicable to the composite products is the fact that it is made by both products of plant origin and processed products of animal origin. The percentage of processed product of animal origin included in the composite product is irrelevant.

1.6. What is the main change to the rules applicable to the import of composite products into the EU from 21 April 2021 onwards?

Import requirements are no longer based on the percentage of the processed products of animal origin in the composite product but rather on the animal health or public health risk linked to those ingredients of animal origin and on the need to transport or store composite products under controlled temperature conditions.

1.7. The composite product I manufacture contains very small amounts of processed products of animal origin, essentially present for technological reasons. Does it have to fulfil all of the relevant requirements for composite products?

Yes. The percentage of ingredients of animal origin in the composite product is irrelevant when determining which rules apply to a composite product.

1.8. Are confectionery products composite products?

Not necessarily. Only those confectionery products that contain both products of plant origin and processed products of animal origin are composite products.

1.9. Where can I find the legal requirements applicable to composite products?

The hygiene requirements for the production of composite products are set in Articles 3 to 6 of Regulation (EC) No 852/2004.

The requirements applicable to imports of composite products are set in Articles 5 to 8, and Articles 20 to 22 of Commission Delegated Regulation (EU) 2022/2292 and in Articles 162 and 163 of Commission Delegated Regulation (EU) 2020/692.
The models of the certificate and the private attestation which must accompany the composite products, according to their categories, are set out, respectively, in Chapter 50 of Annex III and in Annex V to Commission Implementing Regulation (EU) 2020/2235.
The relevant list of third countries from which composite products may enter the EU depends on the characteristics and composition of the composite products. The relevant lists (based on the processed products of animal origin contained in the composite products) can be found in Annexes to Commission Implementing Regulation (EU) 2021/405. In addition, Annex -I to Commission Implementing Regulation (EU) 2021/405 conditions as well the capacity of a country to export composite products, with regard to the monitoring of residues in products of animal origin when such processed products, end up in the composite products.

In the case of composite products presenting a lower risk, Commission Delegated Regulation (EU) 2021/630 grants an exemption from official controls of those composite products at border control posts; such controls should be performed at the place of destination, the point of release for free circulation, or the warehouses or premises of the operator responsible for the consignment of the composite product.

1.10. Why were the control requirements currently applicable to composite products (based on the percentage of processed products of animal origin) changed?

The rules for the composite products were adapted using a more "risk-based approach" relying on principles such as shelf-stability and the presence of colostrum-based products and meat products in the products (which poses an animal health risk). This approach takes into account the conclusions of a 2012 EFSA opinion on the risk represented by composite products[1].

[1] EFSA Journal 2012; 10(5):2662 Scientific Opinion on Public health risks represented by certain composite products containing food of animal origin

1.11. What is meant by "controlled temperatures"?

"Controlled temperatures" means that the products have been produced in a way that does not allow their transport and storage at ambient temperature.

If the choice is made to transport or store a shelf-stable composite product under controlled temperatures, for instance to preserve its quality or for technological reason, such as a transport in liquid form of milk chocolate under hot conditions, and as long as the temperature is not going below 0°C, the requirements for a shelf-stable composite product remain applicable. In such situation, it is important to explain why such controlled temperature is required to clearly distinguish those composite products from non shelf-stable ones. The private attestation could include such a declaration.

1.12. What if my composite product does not fall under the combined nomenclature (CN) codes listed in Article 20 of Commission Regulation (EU) 2022/2292?

The list of CN codes is updated as necessary. Composite products not listed under the CN codes referred to in Article 20 of Commission Regulation (EU) 2022/2292 are not covered by the requirements of that Regulation. Should a composite product not be covered by the CN codes listed in Article 20, the processed products of animal origin it contains must comply with Article 6 (4) of Regulation (EC) 853/2004.

1.13. I mix an unprocessed product of animal origin and technological ingredients derived from a processed product of animal origin (e.g. albumin binder), do I make a composite product?

No. The final product is not a composite product for two reasons: 1) it does not contain any product of plant origin, and 2) it contains an unprocessed product of animal origin.

1.14. Is it required to only include processed products of plant origin in a composite product?

No. A composite product contains both products of plant origin and processed products of animal origin, but there is no requirement to use only processed products of plant origin in the manufacture of the composite product.

1.15. Am I allowed to use unprocessed products of animal origin to manufacture a composite product?

You are allowed to start the manufacture of a composite product from an unprocessed product of animal origin as long as the processing of the product of animal origin is part of the manufacture of the final product. In that case, the establishment manufacturing the composite product must be approved in accordance with Regulation (EC) No 853/2004.

The same is applicable if you reprocess the processed product of animal origin used as ingredient in the composite product in your establishment before the actual manufacture of the composite product.

1.16. How can I differentiate processed products of animal origin with vegetable content from composite products containing processed products of animal origin?

The addition of a product of plant origin to a processed product of animal origin does not automatically mean that the resulting food falls within the meaning of Article 1(2) of Regulation (EC) No 853/2004 or within the definition of composite products. If such an addition does not modify the main characteristics of the processed product of animal origin, then the latter is not a composite product. E.g., cheeses to which herbs are added or yogurts to which fruit is added remain dairy products. They must be manufactured in accordance with Regulation (EC) No 853/2004.

This is a case-by-case decision considering the use of variety of products recipes. In case of doubt, the operator will have to provide details to border control post staff to allow conclusion whether the product is a composite product or not. The product may need to be subjected to a physical inspection to assist in the determination.

1.17. If I mix unprocessed products of animal origin and products of plant origin, do I make a composite product?

No. This is not a composite product as it contains an unprocessed product of animal origin.

1.18. I am adding a plant compound to a processed animal product. Is the final product always considered as a composite product?

Not necessarily. The addition of a product of plant origin during the processing (defined in Article 2(1)(m) of Regulation (EC) No 852/2004) of a product of animal origin does not automatically mean that the resulting food falls within the definition of a composite product. If such an addition does not modify the main characteristics of the processed product of animal origin, then the latter is not a composite product.

1.19. My product made with 100% plant origin ingredients requires the use of processing aids during its manufacture. Does it make it a composite product?

No, it is not a composite product, as according to the EU definition of processing aids, they are not supposed to remain in, and thus be part of, the product.

1.20. A coffee pod product includes both coffee and dairy in the same pod. Is it considered to be a composite product?

If they are in the same pod, it is a composite product and should respect the rules for composite products. Should the coffee pod be presented in two separate pods, one for coffee and another for the dairy products, the coffee pod is no longer considered as a composite product. The dairy component should then be considered as any other dairy product and respect the rules for that commodity.

1.21. If products not containing any component of animal origin are manufactured in the same factory (and with the same equipment) as composite products and may contain traces of components of animal origin, should those products be classified as composite products?

No, the cross contamination of a product does not make it a composite product. Good manufacturing practices should in any case apply and should avoid being confronted to such a contamination.

1.22. What are the rules applicable to composite products in transit?

As such composite products are not intended for the European market, and are not due to enter the EU, the requirements for the entry into the EU of composite products simply do not apply. For animal health reasons however, certain guarantees shall accompany certain composite products that are either non shelf-stable or that are shelf-stable and contain colostrum-based products or meat products (other than gelatine, collagen or highly refined products). For those, the model animal health certificate set out in Chapter 52 of Annex III to Commission Implementing Regulation (EU) 2020/2235 shall be used.

1.23. My shelf-stable composite product contains gelatine from fish. What are the requirements for my composite product to enter the European Union?

Assuming the product does not contain any colostrum-based products or meat products, the composite product should fulfil the requirements applicable to shelf-stable composite products that do not contain colostrum-based products or meat products other than gelatine, collagen or highly refined products. They are summarised on the European Commission's website. For more information, visit the *Special EU import conditions for composite products | Food Safety (europa.eu).*

To note in particular that the origin of the gelatine (fish origin) affects the requirement for the third country manufacturing the composite product. As fish gelatine is not a meat product, the country is not mandatorily required to be listed for meat products and can be listed either for meat products, fishery products, dairy products or egg products, including as regards residues, be they contained in the composite product or not.

1.24. My shelf-stable composite product contains gelatine/collagen from pig origin. What are the requirements for my composite product to enter the European Union?

Assuming the composite product does not contain any other meat products or colostrum-based products, the composite product in question is subject to the requirements applicable to shelf-stable composite products that do not contain other meat products than collagen, gelatine or highly refined products. For more information, visit the dedicated European Commission's website at *Special EU import conditions for composite products | Food Safety (europa.eu)*

The processed products of animal origin contained in the composite product must come from EU approved establishments located in countries authorised to export such processed products of animal origin to the EU.

1.25. The third country manufacturing the composite product has to be listed for the meat product contained in the composite product. In this case, it has to be listed for gelatine/collagen in the relevant annex to Commission Implementing Regulation (EU) 2021/405. Furthermore, the third country must have an EU approved plan for monitoring residues (in the species/commodities from which the processed products of animal origin are derived) and be listed in Annex -I to Commission Implementing Regulation (EU) 2021/405. There is however no such requirement as regards residues, for gelatine, collagen and highly refined products. Moreover, to enter into the EU, the composite product has to be accompanied by a private attestation.My establishment manufactures ice cream from dairy products and ingredients of plant origin. The milk powder used for the production of the ice cream is reprocessed in my establishment. Should my establishment be EU-approved?

Yes. A composite product establishment that also processes or reprocesses the ingredient of animal origin - here a dairy product - in the establishment before mixing it to produce the composite product - here the ice cream - must be EU-approved.

1.26. **My establishment manufactures ice cream from processed products of animal origin (milk powder or other processed milk derivates) and mixes them with ingredients from plant origin. Ice cream is classified as a composite product. If my ice cream is produced in an approved establishment, shall it bear the ID mark of the establishment where it was produced once placed on the EU market?**

Considering that ice cream is classified as a composite product, it is not subject to Regulation (EC) N° 853/2004 even if produced in an approved establishment, whether inside or outside the EU. Therefore, the application of an ID mark is not required.

1.27. My shelf-stable composite product contains gelatine/collagen from ruminant bones. What are the requirements for my composite product to enter the European Union?

Assuming the composite product does not contain any other meat products or colostrum-based products, the composite product in question is subject to the requirements applicable to shelf-stable composite products that do not contain other meat products than collagen, gelatine or highly refined products. For more information, visit the dedicated European Commission's website at Special EU import conditions for composite products | Food Safety (europa.eu)

The processed products of animal origin contained in the composite product must come from EU approved establishments located in countries authorised to export such processed products of animal origin to the EU (including as regards residue monitoring obligations).

The third country manufacturing the composite product has to be listed for the meat product contained in the composite product. In this case, it has to be listed for gelatine/collagen in the relevant annex to Commission Implementing Regulation (EU) 2021/405. Furthermore, the third country must have an EU approved plan for monitoring residues (in the species/commodities from which the processed products of animal origin are derived) and be listed in Annex -I to Commission Implementing Regulation (EU) 2021/405. There is however no such requirement as regards residues, for gelatine, collagen and highly refined products.

In this case, the gelatine/collagen derives from ruminant bones, consequently, as the Union legislation on BSE requires official certification for such products of ruminant origin (Regulation (EC) No 999/2001, Annex IX, Chapter D, Section B), the official certificate in accordance with the model COMP set out in Chapter 50 of Annex III to Implementing Regulation (EU) 2020/2235 is to be provided.

2. REQUIREMENTS FOR PROCESSED PRODUCTS OF ANIMAL ORIGIN CONTAINED IN THE COMPOSITE PRODUCT

The general rules for the processed products of animal origin contained in the composite product can be summarised as follows:

The processed products of animal origin contained in the composite product should comply with the general rules on the hygiene of food established in Regulation (EC) No 852/2004 and, as relevant, with the specific rules on the hygiene of food of animal origin laid down in Regulation (EC) No 853/2004. In addition, relevant animal health requirements established in Commission Delegated Regulation (EU) 2020/692 apply and should be met.

The establishment manufacturing the processed product of animal origin contained in the composite product must be EU-approved if the products of animal origin are covered by the specific requirements laid down in Annex III to Regulation (EC) No 853/2004.

The third country of origin of the processed product of animal origin contained in the composite product must be listed in the relevant EU lists (laid down in Commission Implementing Regulations (EU) 2021/404 or (EU) 2021/405). Furthermore, the third country must be listed for residues in Annex -I to Commission Implementing Regulation (EU) 2021/405.
For animal health reasons, the processed products of animal origin must have been obtained either:

(1) in the same listed third country of the composite product manufacture; or
(2) in the EU; or
(3) in a third country which is listed for entry into the EU of those products without them undergoing a specific risk-mitigating treatment if the third country where the composite product is manufactured is also listed for entry into the EU under the same conditions.

2.1. Am I allowed to use processed products of animal origin from any source in the composite products I manufacture?

No. Article 1(2) of Regulation (EC) No 853/2004 applicable since 2006, clearly spells out that the processed products of animal origin used to prepare composite products are to be obtained and handled in accordance with the requirements of that Regulation. This implies that the processed products of animal origin are to be obtained from EU-approved establishments located either in the EU Member States or in third countries. These third countries must be listed in the relevant EU list and the establishments must be approved by the competent authority in the third country (as complying with EU hygiene rules) and duly listed in the Commission's Trade Control and Expert System (TRACES). Furthermore, the third country must be listed in the Annex -I to Commission Implementing Regulation (EU) 2021/405 (approved control plans for pharmacologically active substances, pesticides and contaminants).

2.2. Why am I asked to now use in my composite products, processed products of animal origin from EU-listed establishments?

This is an existing requirement since 2006. Whilst Regulation (EC) No 853/2004 excludes composite products from its scope, it makes it clear that such products can only be manufactured with ingredients of animal origin coming from EU-approved establishments.

2.3. If my country imports fishery products or processed fishery products from EU-listed establishments in third countries and these products are reprocessed to make composite products, does the establishment reprocessing those fishery products have to be EU-approved?

Yes, it is compulsory. The requirement is laid down in Article 5 of Commission Delegated Regulation (EU) 2022/2292. Approval as a processing establishment is required if the fish ingredient is processed or reprocessed in the establishment prior to its use in the manufacture of the composite product.

Such processing or reprocessing of the ingredient of animal origin to be used in the composite product should be distinguished from the processing necessary to the manufacture/assembly of the composite product.

2.4. When a composite product is made with a vegetable extract (plant origin) and a negligible amount of a fishery product (or another processed product of animal origin), are both establishments required to be EU-approved in order for the composite to be exported to the EU?

No, in this case, only the establishments manufacturing the products of animal origin must be EU-approved and listed in the Commission's Trade Control and Expert System (TRACES).

The establishments dispatching, obtaining or preparing consignments of goods detailed in Article 5 of Commission Regulation (EU) 2022/2292 are to 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.

2.5. If my establishment is located in a third country and sources meat products from EU-approved facilities for use in the manufacture of a composite product, is the composite product allowed for export to the EU?

If the composite product is non shelf-stable, the country where the establishment manufacturing the composite product is located has to be authorised to export to the EU all the processed products of animal origin contained in the composite product.

If the composite product is shelf-stable and contains meat products, the third country where the establishment manufacturing the composite product is located has to be authorised to export to the EU the meat products contained in the composite product.

The sourcing of the meat products included in the composite product is conditioned to the provisions of additional guarantees as regards the monitoring of residues in, and the animal health status of, the country of origin of such meat products.

For residues, the third country where the composite product is manufactured must be listed in Annex -I to Commission Implementing Regulation (EU) 2021/405 for each product of animal origin contained in the composite product. In case of sourcing of the processed products of animal origin from a third country already listed in Annex -I to Commission Implementing Regulation (EU) 2021/405, the third country where the composite product is manufactured must inform the Commission in writing of this intention, in order to be listed in that Decision indicating that it intends to source the processed product of animal origin in question.

Furthermore, such composite products may only enter the EU if the processed products of animal origin contained in the composite products comply with all the relevant animal health requirements for entry into the EU of products of animal origin laid down in Commission Delegated Regulation (EU) 2020/692 and they (the processed products of animal origin) have been obtained either:

a) in the same listed third country of the composite product manufacture; or
b) in the EU; or
c) in a third country which is listed for entry into the EU of those products without them undergoing a specific risk-mitigating treatment, if the third country where the composite product is manufactured is also listed for entry into the EU under the same conditions.

2.6. Is lactose to be considered as a processed product of animal origin?

Yes. This is a processed product of animal origin and must therefore be obtained in an EU-approved establishment and originate from a third country allowed to export dairy products to the EU. The raw milk from which the lactose is derived must have been subject to residue monitoring and the third country listed for milk in Annex -I to Commission Implementing Regulation (EU) 2021/405 (approved control plans for pharmacologically active substances, pesticides and contaminants).

2.7. Do all establishments producing processed products of animal origin contained in the composite product have to be EU-approved regardless of the percentage of ingredient of animal origin (even if the content is less than 1%)?

Yes. Each processed product of animal origin for which specific requirements were laid down in Annex III to Regulation (EC) No 853/2004 must come from an EU-approved establishment, independently of its percentage in the composite product. This has been required since 2006, when the EU food hygiene legislation (Regulation (EC) No 853/2004) became applicable.

2.8. For the manufacture of a composite product in my establishment, I would like to buy processed products of animal origin from a food-processing establishment in my country which has not yet been listed as EU-approved. Is this possible? If not how do I make it possible?

It is not possible. The establishments dispatching, obtaining or preparing consignments of processed products of animal origin that you would intend to use in the manufacture of your composite product have to first be approved by the competent authority in your country to export to the European Union. This requirement is laid down in Regulation (EC) No 853/2004 and has been applicable since 2006.

In order to approve the establishment, the competent authority must inspect it to verify that the operator can produce the product of animal origin in compliance with EU rules. When the competent authority is satisfied that this is the case, it has to inform the Commission and the establishment can then be listed in the Commission's Trade Control and Expert System (TRACES).

2.9. My country wants to export a non shelf-stable composite product with processed products of animal origin obtained in an EU-approved establishment. What else do I need to export my composite product to the European Union?

Non shelf-stable composite products may enter the EU only if they come from a third country listed for entry into the EU of each of the processed products of animal origin contained in those composite products.

The third country from which the processed products of animal origin originate must also be listed in Annex -I to Commission Implementing Regulation (EU) 2021/405 for residues.

In addition, such composite products may enter the EU only if the processed products of animal origin contained in the composite products comply with all the relevant animal health requirements for entry into the EU of products of animal origin laid down in Commission Delegated Regulation (EU) 2020/692. Such processed products of animal origin must have been obtained either in the same third country of manufacture of the composite products, or in the EU or in a third country listed for entry into the EU of those processed products of animal origin without them undergoing a specific risk-mitigating treatment, if the third country where the composite product is manufactured is also listed for entry into the EU under the same conditions.

2.10. Are there animal health obligations applicable to dairy or egg products included in a composite product?

Yes, there are.

Non shelf-stable composite products may enter the EU only if they come from a third country listed for entry into the EU of each of the products of animal origin contained in those composite products. In addition, such composite products may enter the EU only if the processed products of animal origin contained in the composite products comply with all the relevant animal

health requirements for entry into the EU of products of animal origin laid down in Commission Delegated Regulation (EU) 2020/692. Such processed products of animal origin must have been obtained either in the same third country of manufacture of the composite products, or in the EU or in a third country listed for entry into the EU of those processed products of animal origin without them undergoing a specific risk-mitigating treatment, if the third country where the composite product is manufactured is also listed for entry into the EU under the same conditions.

Shelf-stable composite products containing only dairy or egg products may enter the EU provided they respect the following animal health rules:

(a) If the dairy products have not been subjected to a risk mitigating treatment referred to in Annex XXVII to Commission Delegated Regulation (EU) 2020/692 (originating from third countries listed in Annex XVII to Implementing Regulation (EU) 2021/404), the composite products must originate from a third country authorised for the entry into the Union of raw milk (listed in Annex XVII to Commission Implementing Regulation (EU) 2021/404).

(b) If the dairy products have undergone a risk-mitigating treatment referred to in column A or B of Annex XXVII to Commission Delegated Regulation (EU) 2020/692, relevant for the species of origin of the milk (originating from third countries listed in Annex XVIII to Implementing Regulation (EU) 2021/404), the composite products must originate from a third country authorised for entry into the Union of dairy products subject to treatment (listed in Annex XVIII to Implementing Regulation (EU) 2021/404).

(c) If the dairy products have undergone a treatment at least equivalent to those referred to in column B of Annex XXVII to Delegated Regulation (EU) 2020/692, regardless of the species of origin of the milk (originating from third countries listed in Annex XVIII to Implementing Regulation (EU) 2021/404), the composite products may originate from a third country not listed for entry into the Union of raw milk or dairy products but listed for either meat products, or egg products or fishery products in accordance with Regulation (EU) 2017/625.

(d) If the egg products have undergone a risk-mitigating treatment equivalent to those referred to in Annex XXVIII to Delegated Regulation (EU) 2020/692 (originating from third countries listed in Annex XIX to Implementing Regulation (EU) 2021/404), the composite products may originate from a third country not listed for entry into the Union egg products but listed for entry into the Union of either meat products, or dairy products or fishery products in accordance with Regulation (EU) 2017/625.

2.11. My country wants to export a shelf-stable composite product containing meat made with processed products of animal origin obtained in an EU-approved establishment. What else do I need to export my composite product to the European Union?

Shelf-stable composite products containing meat products may enter the EU only if they come from a third country listed for entry into the EU of the meat products contained in those composite products.

The meat products contained in the composite products must comply not only with the public health requirements but also with all the relevant animal health requirements for entry into the EU of products of animal origin laid down in Commission Delegated Regulation (EU) 2020/692. The third country from which the processed product of animal origin originates must also be listed in Annex -I to Commission Implementing Regulation (EU) 2021/405 with an approved control plan for pharmacologically active substances, pesticides and contaminants for the animal species in question, except for gelatine, collagen and highly refined products.

2.12. My composite product is made with a processed product of animal origin sourced from another third country eligible to export this animal product to the EU. Must my country have an approved residues monitoring plan?

Yes. The third country manufacturing the composite product must be listed in Annex -I to Commission Implementing Regulation (EU) 2021/405 for each of the animal species/commodities from which the processed products of animal origin contained in the composite product have been derived, except for gelatine, collagen or highly refined products.

2.13. Are animal derived food additives processed products of animal origin and can their use in my vegetable product make it a composite product?

Yes.

However, conditions established in Regulation (EC) 2022/2292 as regards third countries and residues control plan do not apply to those shelf-stable composite products where all the processed products of animal origin present in the final composite product fall within the scope of, and are used in that shelf-stable composite product in accordance with Regulations (EC) No 1332/2008, (EC) No 1333/2008, or (EC) No 1334/2008 of the European Parliament and of the Council.

2.14. There is no EU-approved establishment listed for the production of lanolin for food purposes. How can I source the vitamin D obtained from lanolin for use in my composite product then?

There is no list of EU-approved establishments for lanolin as there are no specific requirements established for lanolin in Annex III to Regulation (EC) No 853/2004. As a consequence, vitamin D obtained from lanolin can be sourced from any establishment in the EU or a third country listed for the import of “other products of animal origin” derived from small ruminants, including as regards residues.

2.15. Is the albumin that I use in my composite product and that is derived from de-fibrinated bovine blood considered as a meat product?

Yes.

2.16. What are the requirements for a product (e.g. breakfast cereal) containing just processed honey as processed product of animal origin?

As long as no specific requirements are laid down in Annex III to Regulation (EC) No 853/2004 for honey, Article 20(2)(c) of Commission Delegated Regulation (EU) 2022/2292 does not apply to composite products that contain only processed honey as processed product of animal origin.

The third country of production of the composite product containing processed honey must however be listed accordingly in Annex -I to Commission Implementing Regulation (EU) 2021/405.

According to Article 13 of Regulation (EU) 2022/2292 establishes that consignment of honey and apiculture products 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), points (e)(ii) and (iii), of Regulation (EU) 2017/625.

Furthermore, the food business operators importing those composite products shall ensure the compliance with the requirements established in Article 6(4) of Regulation (EC) No 853/2004.

2.17. What are the requirements for a foodstuff made of products of vegetable origin (e.g. breakfast cereal) and only containing honey as product of animal origin?

As natural honey is not a processed product of animal origin, the resulting product is not a composite product but a foodstuff containing natural honey. The requirements applicable to such product from public health perspective are thus laid down in Regulation (EC) No 852/2004. The natural honey contained in a breakfast cereal should be accompanied by a certificate in accordance with a model set out in Chapter 45 of Annex III to Commission Implementing Regulation (EU) 2020/2235 and should comply with the requirements established in Annex -I to Commission Implementing Regulation (EU) 2021/405 for residues.

Moreover, Article 13 of Regulation (EU) 2022/2292 establishes that consignment of honey and apiculture products 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), points (e)(ii) and (iii), of Regulation (EU) 2017/625.

2.18. What are the appropriate heat treatment requirements for imports of composite products containing dried egg yolk that is a common ingredient in some composite products, for example, mayonnaise?

The risk mitigating treatments for the inactivation of highly pathogenic avian influenza (HPAI) virus in egg products are laid down in Annex XXVIII to Commission Delegated Regulation (EU) 2020/692. That Annex does not provide such treatment for dried egg yolk. Therefore, the egg products containing dried egg yolk can only be prepared from eggs obtained from animals kept in establishments in which and within a 10 km radius of which, during the period of 30 days prior to the date of collection of the eggs, no outbreak of HPAI was confirmed. See options under point II.3.D.1 of the model certificate COMP and in point II.1.C.1 of certificate TRANSIT-COMP set out respectively in Chapters 50 and 52 of Annex III to Commission Implementing Regulation (EU) 2020/2235.

2.19. My composite product contains Vitamin D3 as the only processed product of animal origin. What are the requirements to export such composite product into the Union?

The food business operator importing this composite product shall ensure the compliance with the requirements established in Article 6(4) of Regulation (EC) No 853/2004 as regards the vitamin D3 contained in the composite product.

The requirements established by Commission Delegated Regulation (EU) 2022/2292 for the third country of origin of the composite product, for the obligation of having a control plans for pharmacologically active substances, pesticides and contaminants and for the guarantees accompanying the composite products do not apply.

3. REQUIREMENTS APPLICABLE TO THE COUNTRY OF ORIGIN OF THE COMPOSITE PRODUCTS

The general rules and requirements applicable to the countries of origin of the composite products can be summarised as follows:

Non shelf-stable composite products shall originate from third 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;

Shelf-stable composite products that **contain any quantity of colostrum-based products or any quantity of meat products, ,** shall originate from third countries authorised for the entry into the European Union of the colostrum-based products or the meat products contained in the composite product (including as regards the monitoring of residues in meat products[2]);

Shelf-stable composite products **that do not contain colostrum-based products or meat products,** shall originate from third countries authorised for entry into the European Union of either meat products or dairy products or fishery products or egg products, including as regards the monitoring of residues in such products[2].

For shelf-stable composite products where all the processed products of animal origin present in the final composite product fall within the scope of, and are used in the shelf -stable composite product in accordance with Regulations (EC) No 1332/2008, (EC) No 1333/2008, or (EC) No 1334/2008, of the European Parliament and of the Council, or where the only processed product of animal origin is vitamin D3, the requirements established by Commission Delegated Regulation (EU) 2022/2292 for the third country of origin of the composite products do not apply.

Furthermore, as regards the monitoring of residues, the third country manufacturing the composite product has to be listed in Annex -I to Commission Implementing Regulation (EU) 2021/405 for each product of animal origin contained in the composite product, with the exception of gelatine, collagen and highly refined products listed in point 1 of Section XVI of Annex III to Regulation (EC) No 853/2004. In case of sourcing of a processed product of animal origin from another third country, already listed in Annex -I to Commission Implementing Regulation (EU) 2021/405, the third country where the composite product is manufactured must inform the Commission in writing of this intention, in order to be listed in Annex -I of that Regulation. Only after being listed, a third country can export the composite product into the Union.

For shelf-stable composite products where all the processed products of animal origin present in the final composite product fall within the scope of, and are used in the shelf-stable composite product in accordance with Regulations (EC) No 1332/2008, (EC) No 1333/2008, or (EC) No 1334/2008, of the European Parliament and of the Council, or where the only processed product of animal origin is vitamin D3, the requirements established by Commission Delegated Regulation (EU) 2022/2292 for the third country of origin of the composite products, for the

[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

obligation to have a control plans for pharmacologically active substances, pesticides and contaminants and for the guarantees accompanying that composite products do not apply.

Finally, some animal health rules are applicable for certain composite products and certain ingredients:

Composite products containing meat products, other than gelatine, collagen or highly refined products, or colostrum-based products and composite products containing dairy products or egg products which have not been processed to become shelf-stable will only be permitted to enter the EU if they come from a third country, which is listed for entry into the EU of the specific product of animal origin contained in those composite products. In addition, such composite products will only be permitted to enter the EU if the processed products of animal origin contained in the composite products comply with all of the relevant animal health requirements for entry into the EU of products of animal origin laid down in Commission Delegated Regulation (EU) 2020/692 and they (the processed products of animal origin) have been obtained either:

(1) in the *same* listed third country of the composite product manufacture; or

(2) in the EU; or

(3) in a third country which is listed for entry into the EU of those products without them undergoing a specific risk-mitigating treatment if the third country or territory or zone thereof where the composite product is manufactured is *also* listed for entry into the EU under the same conditions.

Shelf-stable composite products containing only dairy or egg products may enter the EU provided they respect the following animal health rules:

(a) If the dairy products have not been subjected to a risk mitigating treatment referred to in Annex XXVII to Commission Delegated Regulation (EU) 2020/692 (originating from third countries listed in Annex XVII to Implementing Regulation (EU) 2021/404), the composite products must originate from a third country authorised for the entry into the Union of raw milk (listed in Annex XVII to Commission Implementing Regulation (EU) 2021/404).

(b) If the dairy products have undergone a risk-mitigating treatment referred to in column A or B of Annex XXVII to Commission Delegated Regulation (EU) 2020/692, relevant for the species of origin of the milk (originating from third countries listed in Annex XVIII to Implementing Regulation (EU) 2021/404), the composite products must originate from a third country authorised for entry into the Union of dairy products subject to treatment (listed in Annex XVIII to Implementing Regulation (EU) 2021/404).

(c) If the dairy products have undergone a treatment at least equivalent to those referred to in column B of Annex XXVII to Delegated Regulation (EU) 2020/692, regardless of the species of origin of the milk (originating from third countries listed in Annex XVIII to

Implementing Regulation (EU) 2021/404), the composite products may originate from a third country not listed for entry into the Union of raw milk or dairy products but listed for either meat products, or egg products or fishery products in accordance with Regulation (EU) 2017/625.

(d) If the egg products have undergone a risk-mitigating treatment equivalent to those referred to in Annex XXVIII to Delegated Regulation (EU) 2020/692 (originating from third countries listed in Annex XIX to Implementing Regulation (EU) 2021/404), the composite products may originate from a third country not listed for entry into the Union egg products but listed for entry into the Union of either meat products, or dairy products or fishery products in accordance with Regulation (EU) 2017/625.

3.1. My country wants to export a shelf-stable composite product not containing meat made with processed products of animal origin obtained from an EU-approved establishment. What else do I need to export my composite product to the European Union?

Such composite products can only use processed products of animal origin sourced from the EU Member States or from third countries authorised (for animal health purposes) for the entry into the European Union of either meat products or dairy products or fishery products or egg products, including for the respective control of residues. Furthermore, the third country *manufacturing* the composite product must also be listed in Annex -I to Commission Implementing Regulation (EU) 2021/405 for the species/commodity of animal origin present in your composite product, with the exception of collagen, gelatine and highly refined products listed in point 1 of Section XVI of Annex III to Regulation (EC) No 853/2004.

3.2. My country is only authorised to export honey to the EU. Am I allowed to export shelf-stable composite products to the EU?

No. Only third countries listed by the EU for the export of meat products or fishery products or dairy products or egg products are allowed to export shelf-stable composite products that do not contain meat to the EU.

However, if the shelf-stable composite product contains processed honey as the only processed product of animal origin, the third country could export such shelf-stable composite products to the Union provided that the third country of origin of that COMP is listed in Annex -I to Implementing Regulation (EU) 2021/405 as having a control plans for pharmacologically active substances, pesticides and contaminants. Food business operators importing composite products should ensure that the processed product of animal origin, processed honey in this case, contained in such composite products satisfies the requirements of Article 6(4) of Regulation (EC) 853/2004.

3.3. My country is authorised to export fishery products to the EU. Am I allowed to export any shelf-stable composite products that do not contain meat products or colostrum-based products to the EU?

Shelf-stable composite products that do not contain meat products nor colostrum-based products, must originate from third countries authorised for entry into the EU of either meat products or dairy products or fishery products or egg products, having an approved control plan for pharmacologically active substances, pesticides and contaminants and being listed in Annex -I to Commission Implementing Regulation (EU) 2021/405 for the corresponding products. It is to be noted that when a third country is authorised only for wild catch as regards fishery products and thus without any control plan for pharmacologically active substances, pesticides and contaminants being approved, and as a result is not listed in the Annex – I to Regulation (EU) 2021/405, this third country is not eligible to export such composite products to the EU.

3.4. My country is authorised to export fishery products to the EU. Am I allowed to export shelf-stable composite products containing meat to the EU?

No. Shelf-stable composite products containing meat products, must originate from third countries authorised for the entry into the European Union for the meat products contained in the composite product (including for the control of residues when applicable).

3.5. My country is authorised to export meat products to the EU. Am I allowed to export non-shelf stable composite products containing dairy to the EU?

No. Non shelf-stable composite products must originate from countries authorised for entry into the European Union, in the relevant legislation on animal health, public health and residues, for each processed product of animal origin contained in the composite product.

3.6. As long as the processed products of animal origin contained in my composite product come from EU-approved establishments, can I export any composite product to the EU?

No. Additional conditions apply.

If the composite product is non shelf-stable, its (third) country of manufacture must be listed for each processed product of animal origin contained in the composite products. For instance, for a frozen pizza, the salami, the anchovies and the cheese must come from a third country listed for meat products and fishery products and dairy products.

If the composite product is shelf-stable and does not contain meat products, the third country of manufacture must be listed for the export to the EU of either meat products or fishery products or dairy products or egg products (including as regards the control of residues for the products in question). Furthermore, the third country where the establishment manufacturing the

composite product is located has also to be listed in Annex -I to Commission Implementing Regulation (EU) 2021/405 for each of the animal species/commodities from which the processed products of animal origin contained in the composite product have been derived, except for gelatine, collagen or highly refined products.

3.7. When a third country manufactures ice cream using dairy products from EU-approved establishments, will it be able to export such ice cream from 21 April 2021 onwards?

Yes. If that third country is listed among the third countries authorised to export dairy products to the EU (for animal/public health and for residues), then it can export ice cream.If a third country is authorised to export dairy products, fishery products or egg products to the EU, is this country eligible to export shelf stable composite products to the EU, regardless of the processed product of animal origin for which this country is authorised, and provided that the processed product of animal origin contained in the final composite product come from the EU listed establishment?

Yes, under the condition that the shelf-stable composite product intended to be exported to the EU do not contain colostrum-based products or meat products. The export of shelf-stable composite products that contain colostrum-based products or meat products is allowed only if the third country manufacturing the composite products is authorised for entry into the EU of colostrum-based products or meat products contained in the composite products.

Attention, however, should the third country manufacturing the shelf-stable composite product in question be only listed for the export of fishery products from wild catch, without having in place a control plan for pharmacologically active substances, pesticides and contaminants for aquaculture, the import into the Union of that composite product from this country would be authorised only if the processed product of animal origin contained in the composite product is a fishery product from wild catch.

3.8. My country wants to export a composite product. What are the requirements on residues?

The third country where the composite products are manufactured must be listed in Annex -I to Commission Implementing Regulation (EU) 2021/405 for each of the animal species (e.g. bovine, ovine, porcine etc.) or raw commodity (e.g. milk, eggs etc.) from which the processed products of animal origin contained in these composite products are derived, with the exception of collagen, gelatine and highly refined products listed in point 1 of Section XVI of Annex III to Regulation (EC) No 853/2004. Thus, if the composite product contains dairy products, egg products and processed bovine meat, the third country should be listed in the above Annex -I to Commission Implementing Regulation (EU) 2021/405 with an approved control plan for pharmacologically active substances, pesticides and contaminants for bovine animals, milk and eggs. The third country manufacturing the composite product needs to be listed in that Annex -I to Regulation (EU) 2021/405 even if the processed product of animal origin is sourced from another approved

third country or from an EU Member State. In that case the third country manufacturing the composite product will be listed in the that Annex -I with an 'O' or a 'Δ' or a 'P' for the commodity/species contained in the composite product. To be so listed, the third country must inform the Commission in writing of its intention to source the processed products of animal origin as described above.

For composite products to be allowed to enter the EU, they must come from a third country authorised to export certain products of animal of origin to the EU. The higher the risk posed by the composite product, the more requirements for its country of origin. The authorisation of a third country to export to the EU a given product of animal origin encompasses both animal and public health requirements, including the monitoring of residues, as clearly stated in Article 20 of Regulation (EU) No 2022/2292. As a consequence, being listed only for residues is not sufficient for your country to export composite products.

3.9. My third country is on a list of third countries authorised to export fishery products to the EU and has an approved control plan for pharmacologically active substances, pesticides and contaminants for fishery products (of aquaculture origin), but not for dairy/egg products. If my third country sources dairy or egg products contained in shelf-stable composite products from an EU Member State or from an EU listed establishments in another listed third country, is my third country eligible to export such composite products to the EU?

Yes, provided that your country is listed in Annex -I to Commission Implementing Regulation (EU) 2021/405 for each of the processed products of animal origin contained in these composite products. Such listing implies that your country has a control plan for pharmacologically active substances, pesticides and contaminants for those products or that it intends to source them from an EU Member State or a third country which is listed in this Annex -I for those commodities. In the case it intends to source the processed products, the third country manufacturing the composite product must inform the Commission in writing of its intention in order to also be listed in Annex -I to Commission Implementing Regulation (EU) 2021/405 with an 'O' or a 'Δ' or a 'P'.

3.10. Is the EU planning to list establishments manufacturing composite products in third countries?

No. Establishments in a third country which are manufacturing composite products should be *registered* by the responsible competent authority. They do not need to be *approved* by the competent authority and listed in Commission's Trade Control and Expert System (TRACES). However, the establishments processing the products of animal origin contained in the composite product must be EU-approved and listed in TRACES. In the event that an establishment in a third country manufacturing composite products was also processing products of animal origin it would need to be EU-approved and listed in TRACES.

3.11. If all of the processed products of animal origin contained in the shelf-stable composite products manufactured in my country are sourced from an EU Member State or from an EU-approved establishment located in a listed third country, must my country also be listed in the Annex -I to Implementing Regulation (EU) 2021/405?

Yes. The requirement to monitor the residues of pharmacologically active substances, pesticides and contaminants stays. Should your country not have an approved control plan for pharmacologically active substances, pesticides and contaminants for each ingredient of animal origin contained in the composite product (with the exception of collagen, gelatine and highly refined products listed in point 1 of Section XVI of Annex III to Regulation (EC) No 853/2004), it remains possible to source such ingredients from EU Member States and other listed third countries (listed for both animal health AND residues for the species/commodities in question). The ingredients must come from EU-approved establishments in those third countries. To be so listed, your country must inform the Commission in writing of its intention to source the processed products of animal origin as described above. In such a case, your country will not be able to export the composite product until it is listed in Annex -I to Commission Implementing Regulation (EU) 2021/405 with an 'O' or a 'Δ' or a 'P' for the commodity/species contained in the composite product.

3.12. What is the procedure for my country to be listed in Annex -I to Commission Implementing Regulation (EU) 2021/405 to allow the sourcing of processed products of animal origin from a different country?

Your country must send a letter to the European Commission asking for such listing.

3.13. Will the EU establish a specific list of third countries authorised to export composite products to the EU?

Yes, but the procedure will require time. Pending establishment of the list, the requirements will be based on the nature (shelf stability, meat content and colostrum-based content) of the composite product and the existing lists of countries authorised for the import into the EU of the processed products of animal origin contained in the composite products.

3.14. If my country is not listed in Annex -I to Commission Implementing Regulation (EU) 2021/405 for any commodity, can my country export composite products containing processed products of animal origin from other third countries already listed in such Regulation?

No.

3.15. My country is listed with a "O" for milk in Annex -I to Implementing Regulation (EU) 2021/405. Can my country export to the Union a non shelf-stable composite product containing a dairy product?

No. According to Article 20.2 (a), the third country exporting a non shelf-stable composite product to the Union must be authorised to enter the Union

each processed product of animal origin contained in the composite product. Therefore, in this case, the country of origin must be listed for dairy products in Implementing Regulation (EU) 2021/404 and/or Implementing Regulation (EU) 2021/405 and in the Annex -I to Implementing Regulation (EU) 2021/405 with an “X” for milk (approved control plans for pharmacologically active substances, pesticides and contaminants).

4. GUARANTEES ACCOMPANYING THE COMPOSITE PRODUCTS AT IMPORT INTO THE EU

4.1. Must a shelf-stable composite product not containing meat products always be accompanied by a private attestation? Could such an attestation be made available only regularly?

A private attestation must accompany every consignment of shelf-stable composite products imported into the EU that do not contain colostrum-based products or meat products, with the exception, for the latter of gelatine, collagen, not derived from ruminant bones, or highly refined products.

If the shelf-stable composite product contains a processed product of animal origin for which there are not specific requirements in Annex III to Regulation (EC) 853/2204, this composite product shall meet the requirement established in Article 6(4) of Regulation (EC) 853/2004.

4.2. Who has to sign the documents accompanying the composite products?

For those composite products for which an animal health/official certificate is required, the animal health requirements must be signed by an official veterinarian and the public health requirements must be signed by a certifying officer.

The private attestation must be signed by the representative of the importing food business operator.

4.3. Who checks the private attestation accompanying shelf-stable composite products not containing meat products? Where does this check happen?

The checks on shelf-stable composite products containing neither meat products nor colostrum-based products are carried out on entry into the EU at an EU border control post, unless the composite product is listed in Regulation (EU) 2021/630 as presenting a lower risk. For the latter, the EU Member States' competent authorities may carry out the controls/checks at the place of destination, the point of release for free circulation, or the warehouses or premises of the operator responsible for the consignment of the product in accordance with their national control plans.

4.4. What is the penalty in the absence of a private attestation accompanying the composite product?

In case of non-compliance with EU rules when entering the Union, the EU Member States' competent authorities must place the consignment under official detention in accordance with Article 66 of Regulation (EU) 2017/625.

4.5. Implementing Regulation (EU) 2020/2235 sets down a model animal health/official certificate for the entry into the EU of composite products. In the case of non shelf-stable products containing fresh meat (or meat preparations) but not *processed* animal products, how should such products be certified?

A product containing fresh meat is not a composite product. The certificate for composite products is therefore not to be used in such cases. In the above example, the model certificates relevant for fresh meat or meat preparations must accompany the consignment.

4.6. I want to export to the EU a shelf-stable composite product that contains gelatine. What health certificate should accompany the product?

Shelf-stable composite products that contain colostrum-based products or meat products, other than gelatine or collagen, not derived from ruminant bones, or highly refined products, must be accompanied by an animal health/official certificate to provide guarantees notably with regard to animal health risks.

However, in the case where the shelf-stable composite product contains only gelatine, not derived from ruminant bones, as meat products ingredient, a private attestation as set out in Annex V to Commission Implementing Regulation (EU) 2020/2235, will suffice. This is also valid for collagen and highly refined products of meat origin.

4.7. My country wants to export to the EU a non shelf-stable composite product that contains gelatine (or collagen or highly refined product) <u>and</u> other meat products. Which certificate is required?

Non shelf-stable composite products must be accompanied always by an animal health/official certificate in accordance with the model set out in Chapter 50 of Annex III to Commission Implementing Regulation (EU) 2020/2235. This certificate must be signed by the competent authorities of the third country where the composite product is manufactured. It specifies the guarantees on public health, animal health and residues with which the competent authority certifies compliance.

4.8. My country is exporting to the EU a composite product that is listed in Regulation (EU) 2021/630. Which guarantees must accompany it?

Whilst those composite products listed in Regulation (EU) 2021/630 are exempted from official controls at border control posts, they must however comply with all import conditions and requirements set out in EU legislation and must be accompanied by a private attestation. Checks on the products and the accompanying private attestations may be carried out by the EU Member States' competent authorities at the point of destination, point of release for free circulation, warehouses or operators premises.

4.9. Does the private attestation need to be uploaded in TRACES?

It does not need to, but it can be uploaded in TRACES instead of a paper presentation at the border control post where border controls are required.

4.10. Does the private attestation need to be provided at the border control post on paper?

Yes, for composite products controlled at a border control post, except if the document is uploaded in Commission's Trade Control and Expert System (TRACES). However, there is no requirement to provide an original document to the border control post. As this is not an official certificate or an official attestation in the meaning of Articles 89 and 91 of Regulation (EU) No 2017/625, the scanned copy of the private attestation can be uploaded in TRACES with part 1 of the Common Health Entry Document (CHED).

For composite products exempted from official controls at the border control post, the private attestation shall accompany the products at the time of the placing on the market.

4.11. Can the private attestation be e-signed?

No. A scanned version of the signed document can be uploaded in Commission's Trade Control and Expert System (TRACES). But it cannot be electronically signed in TRACES as certain certificates could.

4.12. Is it necessary to indicate in the private attestation the code of the farm producing the milk, even if this farm is in the EU?

No. Only the processing establishments are to be mentioned.

4.13. Regarding composite products that require a private attestation, is it necessary to supplement the private attestation with an official certificate for the dairy ingredients contained in the composite products?

No. The private attestation provides the necessary guarantees.

4.14. Are composite products containing gelatine required to have an official certificate?

Not necessarily. If the composite product is shelf-stable and does not contain any other meat products than gelatine, collagen or highly refined products derived from meat, a certificate is not required. The private attestation provides the necessary guarantees. However, if the gelatine or the collagen comes from ruminant bones, a certification in accordance with the TSE provisions Regulation (EC) 999/2001 should accompany the private attestation. This certificate could be found in Chapter 41 and Chapter 42 of Regulation (EU) 2020/2235.

4.15. With a view to protect intellectual property, is it possible to group the information on the percentage of ingredients contained in the composite products when described in the private attestation?

Yes. For instance, the percentage of all dairy ingredients could be grouped, or the percentage of all plant ingredients could be grouped. Only ingredients belonging to the same category can be grouped.

4.16. Is the private attestation required for each product or each consignment?

The approach is similar as to that applicable to certificates. The necessary information has to accompany the products as prescribed by the legislation. A private attestation must accompany each batch.

4.17. If a composite product is manufactured from composite products itself, do they need to be listed on the private attestation?

If the final product is a composite product in accordance with Article 20 of Regulation (EU) 2022/2292, it has indeed to be accompanied by a private attestation, providing the details on the origin of the processed products of animal origin contained in the composite product used as ingredients to manufacture the final composite product.

4.18. My composite product is shelf stable and does not contain meat. It is listed among the products presenting a lower risk. Do I need to provide a certificate to prove that animal health risks have been addressed through proper mitigating treatments?

No. The private attestation provides the necessary guarantees notably on those treatments.

4.19. What are the obligations for import/export from third countries to the EU of composite food trade samples and display items, trade samples imported for taste testing, lab samples containing processed products of animal origin? Will they require a private attestation for each consignment?

Regulation (EU) 2022/2292 shall not apply to goods intended for human consumption for the purpose of samples for product analysis and quality testing without being placed on the market. In those cases, the private attestation is not required.

4.20. Is it correct that only a private attestation is required for the re-export to the EU of chocolate confectioneries (shelf stable, no meat) classified under the codes 1806, initially produced in the European Union and subsequently exported to that third country for storage purposes?

Yes.

4.21. Is it correct to request an official certificate for a composite product that contains rendered animal fat?

Yes, as rendered animal fat is a meat product.

4.22. Is the private attestation or a certificate required for a composite product in transit? For example, for a composite product from a third country, stored in a warehouse under customs control in the EU, and then reexported to a third country without distribution/sale in any EU Member State?

No.

As the composite product never enters the EU market, it is not subject to the rules applicable for the import into the EU of composite products, and *a fortiori* is not required to be accompanied by such guarantees.

For animal health reasons however, certain guarantees shall accompany certain composite products that are either non shelf-stable or that are shelf-stable and contain colostrum-based products or meat products (other than gelatine, collagen or highly refined products). For those, the certificate in accordance with the model TRANSIT-COMP set out in Chapter 52 of Annex III to Commission Implementing Regulation 2020/2235 shall be used.

4.23. For composite products exempted from checks at border control posts, until when should the private attestations be retained?

The private attestation must be retained until the end of the shelf-life of the composite product.

4.24. Does the representative of the importing food business operator who signs the private attestation need to be legally established in the EU?

Yes. He needs to.

4.25. Is a private attestation needed for confectionery products containing beef/pork gelatine?

Yes, if the confectionary product is a shelf-stable composite product containing only gelatine as meat products, the private attestation is needed. If the gelatine comes from ruminant bones, a certification in accordance with Regulation (EC) 999/2001 on TSE should accompany the private attestation. This certificate could be found in Chapter 41 of Regulation (EU) 2020/2235.

4.26. Is a private attestation needed for composite products that are exempted from border control under Commission Delegated Regulation (EU) 2021/630 and are sent directly to consumers?

Composite products exempted from controls at border control posts under Regulation (EU) 2021/630 should be accompanied by a private attestation when placed on the market.

Small consignments of composite products sent to natural persons which are not intended to be placed on the market and which meet the requirements of Article 10 of Regulation (EU) 2019/2122 are not required to be accompanied by a private attestation.

4.27. We mix various composite products prior to export in the same packaging. Should we fill out different attestations for each composite product?

Yes. If you have several composite products in the same package, you have to provide one private attestation for each composite product.

Nevertheless, it could be possible to enter various composite products with various CN codes in the same private attestation if they all refer to the same information provided by the private attestation and, in particular, that they all meet the same guarantees. If the private attestation covers several composite products, the description of goods in box I.27 and the statements in points 4 (list of ingredients) and 5 (list of approved establishments) must be presented clearly and separately for each composite product.

4.28. When the batch of a shelf-stable composite product is divided and distributed in the different EU Member States, should the private attestation accompany the different lots? Should the private attestation be translated in the different languages of the EU Member States of destination?

The original private attestation should be retained by the first importer indicated in the private attestation. Copies of the private attestation may accompany the different lots without translation of the original document into the languages of the different EU Member States of destination. The importer must in any case ensure the traceability inside the Union.

4.29. Are vehicle licence plate and vessel details requested to be completed in the private attestation?

Yes.

According to the model attestation set out in Annex V to Commission Implementing Regulation (EU) 2020/2235, box I.15 must be completed with the reference to the means of transport (i.e. aircraft, railway, vessel or road vehicle), and box I.19 must be completed with container numbers. Therefore, we confirm that, for example, in the case of maritime transport other than ferry, the name of the vessel and the container number are both required in the private attestation, as well as in part 1 of the Common Health Entry Document (CHED).

4.30. How am I supposed to fill in the box 1.11 in the certificate accompanying a non-shelf stable composite product while establishments manufacturing composite products are not required to be EU-approved?

In the case where an establishment does not need to be EU-approved/listed, the registration number is only optional and the corresponding area can be left empty in the certificate.

4.31. What is expected to be included in Part I, box I.27 "Description of consignment" of the certificate that must accompany composite products due to enter, or transit through, the EU, as relevant?

The box I.27 should include the CN code, the type of packaging, the number of packages, the net weight, the batch number (if any), the final consumer (box to tick if the product is already packaged for final consumers), the approval number of the producer, when applicable, or the address and the approval number of the intermediate cold store(s) before exporting, if any. All the rest is optional.

In addition, the information must be distributed in several lines if the certificate covers various products (one line by product).

5. CONTROLS AT THE BORDER

5.1. Which composite products are subject to official controls at the entry into the EU?

All composite products which are listed in the Annex to Commission Implementing Regulation (EU) 2021/632 shall be subject to official controls at border control posts. The composite products that present a lower risk and are listed in Commission Delegated Regulation (EU) 2021/630, are controlled at the place of destination, the point of release for free circulation, the warehouses or the premises of the operator responsible for the consignment.

5.2. Could the list of composite products eligible to a derogation from the control at the EU border be modified?

Yes. The Commission can adapt the list of exempted composite products in Commission Delegated Regulation (EU) 2021/630.

5.3. Are all composite products eligible to be accompanied by a private attestation exempted from the checks at the border?

No. Only those composite products listed in Commission Delegated Regulation (EU) 2021/630 are exempted from the checks at the EU borders. Controls may be carried out at the place of destination, the point of release for free circulation in the Union or the warehouses or the premises of the operator responsible for the consignment.

5.4. Question removed.

5.5. What will be the frequency of checks at borders for shelf-stable composite products not containing meat?

Documentary checks are compulsory for all composite products. Identity and physical checks are performed on frequency established in Commission Implementing Regulation (EU) 2019/2129.

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