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**COMMISSION NOTICE**  
**on the implementation of requirements for composite products**  
(C/2026/3013)

**Abbreviations used in the Document**

|            |                                                                                               |
|------------|-----------------------------------------------------------------------------------------------|
| BCP        | Border Control Post                                                                           |
| CN         | Combined Nomenclature (Customs tariff codes)                                                  |
| ComP       | Composite product                                                                             |
| DG SANTE   | Directorate General for Health and Food Safety                                                |
| EFSA       | European Food Safety Authority                                                                |
| EU / Union | European Union                                                                                |
| HACCP      | Hazard analysis and critical control points                                                   |
| OJ         | <i>Official Journal of the European Union</i>                                                 |
| POAO       | Products of animal origin                                                                     |
| PPOAO      | Processed products of animal origin                                                           |
| RCP        | Control plan for residues of pharmacologically active substances, pesticides and contaminants |
| TRACES     | Trade Control and Expert System                                                               |

**Terms used in the document**

|                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|----------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Non shelf-stable ComP            | Means composite products that need to be transported or stored under controlled temperatures.                                                                                                                                                                                                                                                                                                                                                                       |
| Shelf-stable ComP                | Means composite products that do not need to be transported or stored under controlled temperatures.                                                                                                                                                                                                                                                                                                                                                                |
| Mixed product                    | Mix of different products of animal origin.<br><i>In this document is used the term mixed product. It is the same than the terminology compound product.</i>                                                                                                                                                                                                                                                                                                        |
| EU-approved/listed establishment | Means an establishment handling products of animal origin for which Annex III to Regulation (EC) 853/2004 lays down requirements and which is approved by the competent authority in accordance with Article 4(2) of Regulation (EC) 853/2004. In the case of an establishment operating in third countries, it means an establishment appearing on the lists encoded in TRACES, in accordance with Article 13(1) and 20(1) of Delegated Regulation (EU) 2022/2292. |
| Processed honey                  | Means honey resulting from the processing of unprocessed honey, an action that substantially alters the initial product (see Article 2(1), points (m), and (o), of Regulation (EC) 852/2004).<br>Honey entering the Union from third countries must come from an EU-approved/listed establishment (appearing on a list encoded in TRACES, in accordance with Article 13(1) of Delegated Regulation (EU) 2022/2292).                                                 |

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## 1. Introduction

The European Food Safety Authority with its 2012 opinion <sup>(1)</sup> on public health risks represented by certain ComP, i.e. products containing food of both plant origin and animal origin, notably reviewed the factors that affect microbial survival and growth in ComP. It concluded that the main factors to be considered are water activity, pH, temperature and duration of storage, processing, and intensity and duration of other non-thermal physical processes applied. Therefore, the evaluation of the animal and public health risks arising from ComP requires information on their shelf-stability, composition, processing and further handling. This EFSA opinion provided the basis for reconsidering and adapting the corresponding requirements laid down in Delegated Regulation (EU) 2022/2292.

*To consider: Article 20(2) and Article 20(4) of Delegated Regulation (EU) 2022/2292 establish the rules that third countries must comply with to enter composite products into the Union based on (1) their shelf-stability characteristics and (2) the processed products of animal origin (PPOAO) contained therein, i.e. meat products or colostrum-based products. This differentiation is used as categorisation of ComP.*

This ComP categorisation is based on the risks they pose to animal and public health. Consequently, the percentage of PPOAO contained in the ComP is not anymore relevant for their categorisation.

Based on that, there are five categories of ComP:

- (a) non shelf-stable ComP;
- (b) shelf-stable ComP that contain any quantity of colostrum-based products or meat products;
- (c) shelf-stable ComP that contain PPOAO other than colostrum-based products or meat products, for which requirements are laid down in Annex III to Regulation (EC) No 853/2004;
- (d) shelf-stable ComP that only contain PPOAO or ComP that fall under the scope of Regulation (EC) No 1332/2008, Regulation (EC) No 1333/2008, Regulation (EC) No 1334/2008, or that only contain vitamin D3;
- (e) shelf-stable ComP that contain PPOAO other than colostrum-based products or meat products, for which NO requirements are laid down in Annex III to Regulation (EC) No 853/2004.

This Commission Notice document aims to assist all players in the food chain to better understand and to apply correctly and in a uniform way the requirements on ComP.

This guidance is not giving a comprehensive or exhaustive overview of the topic but only addresses frequently raised questions and specific issues.

## 2. ComP - legal context

### 2.1. Food Safety and Hygiene requirements for ComP

— **Regulation (EC) No 178/2002** (also referred as the General Food Law) <sup>(2)</sup>

*Institutes the general requirements of food law and provides that food shall not be placed on the market if it is unsafe.*

<sup>(1)</sup> EFSA Journal 2012;10(5):2662.

<sup>(2)</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1, ELI: <http://data.europa.eu/eli/reg/2002/178/2024-07-01>).

- **Regulation (EC) No 852/2004** <sup>(3)</sup> lays down general hygiene requirements to be respected by food business operators at all stages of production and distribution of ComP.

*ComP should be produced and placed on the market and enter the Union in accordance with the requirements laid down in Regulation (EC) No 178/2002 and the general hygiene requirements in Regulation (EC) No 852/2004.*

- **Regulation (EC) No 853/2004** <sup>(4)</sup> lays down specific hygiene rules for food of animal origin. It therefore applies to the production of the PPOAO included in the COMP. Point 7 of Annex I to that Regulation provides definitions of certain PPOAO which are an essential part of ComP. Article 1(2) states that Regulation (EC) No 853/2004 does not, however, apply to food containing both products of plant origin and PPOAO, i.e. to their assembling.

*The establishment assembling a ComP is not subject to approval by the competent authority. However, if the establishment also produces the PPOAO, i.e. it processes the unprocessed product of animal origin, and therefore it must be approved in accordance with Regulation (EC) No 853/2004 and comply with the relevant hygiene rules laid down in that Regulation.*

## 2.2. Animal health requirements for the entry into the Union of ComP

- **Commission Delegated Regulation (EU) 2020/692** <sup>(5)</sup> lays down animal health rules for the entry into the Union of, amongst other things, products of animal origin, such as meat, dairy and egg products, contained in ComP.

**As regards the origin of the ComP:** Article 162(1) provides that consignments of both shelf-stable and non-shelf stable composite products containing meat products or colostrum based products, or both, and non-shelf stable composite products containing dairy products or egg products, or both, shall only be permitted to enter the Union if the ComP comes from a third country or territory, or zone thereof listed in the relevant Annexes to Implementing Regulation (EU) 2021/404 for entry into the Union of the specific products of animal origin contained in the ComP (This is also reflected in Article 20(2) of Delegated Regulation (EU) 2022/2292).

**As regards the POAO contained in the above-referred ComP:** Article 162(2) establishes, first of all, that the POAO contained in that ComP must comply with the general animal health requirements for entry into the Union of POAO laid down in Part I of Delegated Regulation (EU) 2020/692 and the animal health requirements for entry into the Union of the specific POAO, as laid down in Titles 3 to 5 of Part IV of that Delegated Regulation (see its point (a)) and secondly, that those POAO have to be obtained (see its point (b)) either:

- (i) in the same listed third country or territory of origin, or zone thereof of the ComP production;
- (ii) in the Union; or
- (iii) in a third country or territory, or zone thereof listed for entry into the Union of those POAO without undergoing a specific risk-mitigating treatment, in accordance with Articles 148 and 156, if the third country or territory, or zone thereof where the ComP is produced is also listed for entry into the Union of those POAO without the obligation to apply a specific risk-mitigating treatment.

<sup>(3)</sup> Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1, ELI: <http://data.europa.eu/eli/reg/2004/852/oj>).

<sup>(4)</sup> Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin (OJ L 139, 30.04.2004, p. 55 and re-published in OJ L 226, 25.6.2004, p. 22, ELI: <http://data.europa.eu/eli/reg/2004/853/oj>).

<sup>(5)</sup> Commission Delegated Regulation (EU) 2020/692 of 30 January 2020 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal origin (OJ L 174, 3.6.2020, p. 379, ELI: [http://data.europa.eu/eli/reg\\_del/2020/692/oj](http://data.europa.eu/eli/reg_del/2020/692/oj)).

*When those Articles refer to 'listed third country or territory of origin, or zone thereof', it means that those must be listed in the relevant Annexes to Implementing Regulation (EU) 2021/404 (cfr. Art. 2(1) of Delegated Regulation (EU) 2020/692).*

*Therefore, those ComP, referred above, may enter the Union provided any products of animal origin they contain, for which animal health rules apply, are eligible as such for the entry into the Union. Exceptions from that rule, in a form of specific requirements, have been laid down in Article 163(3) of Delegated Regulation (EU) 2020/692 for certain shelf-stable ComP containing dairy products, or egg products, or both (see Chapter 5 of this document).*

- **Commission Implementing Regulation (EU) 2021/404** <sup>(6)</sup> lays down the lists of third countries or territories, or zones thereof from which entry into the Union of POAO, falling within the scope of Delegated Regulation (EU) 2020/692, is permitted and provides specific conditions and animal health guarantees concerning listed diseases for individual third country or territory, or zone thereof.

### 2.3. Official controls on ComP

- **Regulation (EU) 2017/625 (Official Controls Regulation)** <sup>(7)</sup>.

*Official controls are performed within the Union at all stages of production, processing and distribution along the food chain. As a general rule, ComP entering the Union should be subject to official control at the border control post (BCP) of first arrival into the Union (Article 47(1) of the OCR). There are some exceptions from that rule explained in the following paragraphs.*

- **Commission Implementing Regulation (EU) 2021/632** <sup>(8)</sup>.

*Those animals and goods listed in the Annex to the above Regulation shall be subject to official controls at the BCP in accordance with Article 47(1) of Regulation (EU) 2017/625. This Implementing Regulation includes tables with the animals and goods' combined nomenclature (CN) codes in the first column (1), the description in the second column (2) and the qualification and explanation in the third column (3).*

*Animals and goods submitted to controls at the BCP are defined by the description provided in the third column (3). Where only certain specified animals and goods under any four-, six- or eight-digit code are required to be subject to official controls and no specific subdivision under this code exists in the CN, the code is marked 'Ex'.*

<sup>(6)</sup> Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council (OJ L 114, 31.3.2021, p. 1, ELI: [http://data.europa.eu/eli/reg\\_impl/2021/404/oj](http://data.europa.eu/eli/reg_impl/2021/404/oj)).

<sup>(7)</sup> Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/625/oj>).

<sup>(8)</sup> Commission Implementing Regulation (EU) 2021/632 of 13 April 2021 laying down rules for the application of Regulation (EU) 2017/625 of the European Parliament and of the Council as regards the lists of animals, products of animal origin, germinal products, animal by-products and derived products, composite products, and hay and straw subject to official controls at border control posts, and repealing Commission Implementing Regulation (EU) 2019/2007 and Commission Decision 2007/275/EC (OJ L 132, 19.4.2021, p. 24, ELI: [http://data.europa.eu/eli/reg\\_impl/2021/632/2022-08-18](http://data.europa.eu/eli/reg_impl/2021/632/2022-08-18)).

— **Commission Delegated Regulation (EU) 2021/630 <sup>(9)</sup>.**

*As a general rule, ComP entering the Union should be subject to official control at the BCP of first arrival into the Union. However, Delegated Regulation (EU) 2021/630 establishes conditions to be exempted from this requirement. The official controls are performed at the place of destination, at the point of release for free circulation in the Union or at the warehouses or the premises of the operator responsible for the consignment, instead of at the BCP.(See Chapter 10)*

— **Commission Delegated Regulation (EU) 2022/2292 <sup>(10)</sup>** establishes specific conditions applicable for the entry into the Union of ComP.

*This is the key regulation as it sets the requirements for ComP identified under their relevant combined nomenclature (CN) customs codes, in particular:*

- *Articles 5 to 8: ComP shall enter the Union only from a third country with an approved control plan for pharmacologically active substances, pesticides and contaminants and is therefore included in the list set out in Annex -I to Implementing Regulation (EU) 2021/405. In addition, by way of derogation, consignments of ComP may enter the Union from third countries that do not have an approved control plan for pharmacologically active substances, pesticides and contaminants but ensure that the food-producing animals and products of animal origin, including those used in ComP, originate in a EU Member State or a third country included in the list set out in Annex -I to Implementing Regulation (EU) 2021/405 as regards those food-producing animals or products of animal origin (see Article 2a of Implementing Regulation (EU) 2021/405, Article 20(3) of Delegated Regulation (EU) 2022/2292 and Section 5.2 of this document)*
- *Article 13: PPOAO (contained in the ComP) 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.*
- *Article 20(1) provides that ComP (with a certain CN code) shall enter the Union only if each PPOAO contained in the ComP was either produced in establishments that are located in third countries or regions thereof and authorised to enter the Union those PPOAO or in establishments located in EU Member States.*
- *Article 20(2) provides that, pending the establishment of the list referred to in paragraph 1, ComP may enter the Union if they originate from a third country authorised to enter the Union certain PPOAO.*
- *Article 20(3) sets up the requirement that the ComP come from a third country listed as having an approved control plan for pharmacologically active substances, pesticides and contaminants for the species or commodities from which the PPOAO contained in the ComP are derived.*
- *Articles 21 and 22 establish requirements that the ComP is accompanied by a document.*

— **Commission Implementing Regulation (EU) 2021/405 <sup>(11)</sup>.**

*This Regulation lays down the lists of third countries or regions thereof from which the entry into the Union of consignments of certain animals and goods intended for human consumption is permitted in accordance with Article 126 (2)(a) of Regulation (EU) 2017/625. PPOAO contained in the ComP must originate from either EU Member States or third countries or regions listed in Implementing Regulation (EU) 2021/405 for the entry of that product into the Union (see Article 3 of Delegated Regulation (EU) 2022/2292)*

<sup>(9)</sup> Commission Delegated Regulation (EU) 2021/630 of 16 February 2021 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards certain categories of goods exempted from official controls at border control posts and amending Commission Decision 2007/275/EC (OJ L 132, 19.4.2021, p. 17, ELI: [http://data.europa.eu/eli/reg\\_del/2021/630/oj](http://data.europa.eu/eli/reg_del/2021/630/oj)).

<sup>(10)</sup> Commission Delegated Regulation (EU) 2022/2292 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption. (OJ L 304, 24.11.2022, p. 1, ELI: [http://data.europa.eu/eli/reg\\_del/2022/2292/oj](http://data.europa.eu/eli/reg_del/2022/2292/oj)).

<sup>(11)</sup> Commission Implementing Regulation (EU) 2021/405 of 24 March 2021 laying down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council (OJ L 114, 31.3.2021, p. 118, ELI: [http://data.europa.eu/eli/reg\\_impl/2021/405/oj](http://data.europa.eu/eli/reg_impl/2021/405/oj)).

- **Commission Implementing Regulation (EU) 2020/2235** <sup>(12)</sup> lays down, amongst others, model animal health certificates, model official certificates and model animal health/official certificates for the entry into the Union of consignments of certain categories of products of animal origin intended for human consumption and model animal health certificate, model animal health/official certificate and model private attestation for the entry into or transit through the Union of certain categories of ComP.

*The model animal health/official certificate for the entry into the Union of non shelf-stable ComP intended for human consumption and shelf-stable ComP intended for human consumption containing any quantity of meat products (except gelatine or collagen, not derived from ruminant bones, and highly refined products) and any quantity of colostrum-based products, or both is set out in Chapter 50 of Annex III to that Implementing Regulation (model 'COMP').*

*The model private attestation to be used by the food business operator responsible for the entry into the Union of shelf-stable ComP that do not contain neither meat products (except gelatine or collagen, not derived from ruminant bones, and highly refined products), nor colostrum-based products (in accordance with Article 22 of Implementing Regulation (EU) 2022/2292) is set out in Annex V to Implementing Regulation (EU) 2020/2235. The model animal health certificate for the transit through the Union to a third country either by immediate transit or after storage in the Union of non shelf-stable ComP intended for human consumption, and shelf-stable ComP intended for human consumption and containing any quantity of meat products (other than gelatine or collagen or highly refined products), and any quantity of colostrum-based products is set out in Chapter 52 of Annex III to Implementing Regulation (EU) 2020/2235 (model 'TRANSIT-COMP').*

### 3. **When a food product containing both products of plant origin and animal origin falls under Regulation (EC) 853/2004**

#### 3.1. *Definition*

ComP are not defined in Regulation (EC) No 852/2004 or Regulation (EC) No 853/2004. They are, however, defined in Article 2, point (21), of Delegated Regulation (EU) 2022/2292 (adopted on the basis of and supplementing the Official Controls Regulation) as 'food containing both products of plant origin and processed products of animal origin'.

#### 3.2. *Examples of food products containing both products of plant origin and animal origin which DO NOT/DO fall under Regulation (EC) No 853/2004*

(A) The following are examples of food products containing both products of plant origin and animal origin which, as composite products in the sense of Article 1 (2) of Regulation (EC) No 853/2004, DO NOT fall under that Regulation:

- A pizza with salami and cheese;
- Biscuits with egg products and butter;
- A 'Caesar' salad with fried chicken and parmesan or a cooked egg and bacon burrito;
- The addition of 'nero di seppia' to a beer.

<sup>(12)</sup> Commission Implementing Regulation (EU) 2020/2235 of 16 December 2020 laying down rules for the application of Regulations (EU) 2016/429 and (EU) 2017/625 of the European Parliament and of the Council as regards model animal health certificates, model official certificates and model animal health/official certificates, for the entry into the Union and movements within the Union of consignments of certain categories of animals and goods, official certification regarding such certificates and repealing Regulation (EC) No 599/2004, Implementing Regulations (EU) No 636/2014 and (EU) 2019/628, Directive 98/68/EC and Decisions 2000/572/EC, 2003/779/EC and 2007/240/EC (OJ L 442, 30.12.2020, p. 1, ELI: [http://data.europa.eu/eli/reg\\_impl/2020/2235/oj](http://data.europa.eu/eli/reg_impl/2020/2235/oj)).

- (B) The following are examples of food products which contain both products of plant origin and animal origin and which DO fall under Regulation (EC) No 853/2004, because the product of animal origin is not processed in their production:
- Meat and fresh vegetable brochette;
  - Fish fillets with food of plant origin;
  - Sushi rolls made with fresh fishery products, rice, seaweed and vegetables;
  - Skewers with unprocessed beef, marinated in yogurt with fresh vegetables.
- (C) The following are examples of food products which contain both products of plant origin and animal origin, but which DO fall under Regulation (EC) No 853/2004 because their production consists essentially in the processing of the PPOAO:
- Cheeses to which herbs are added or yogurts to which fruit is added remain dairy products;
  - Cooked sausages to which garlic or soya is added remain meat products;
  - Salami with pistachios remains a meat product;
  - Canned tuna to which olive oil is added remains a fishery product;
  - Processed breaded chicken with bacon and cheese remains a PPOAO;
  - The addition of vitamins (no animal origin), carotenoids, etc, to fish oil does remains a fishery product.
- (D) The following are examples of food products containing both a product of plant origin and of animal origin, but where the plant and animal components of a food may be presented in the package separately and sold to the final consumers as one indivisible entity, leaving the consumer to assemble those food components (in such a case, the PPOAO is considered in isolation of the plant component and is required to comply with the rules applicable to that PPOAO):
- A coffee pod product including coffee and dairy in separate pods, one for coffee and another for dairy;
  - Instant noodles with one sachet containing herbs and the other sachet containing dairy, duly separated, are separately controlled on the basis of their dairy component and the ingredient of plant origin.
- (E) The following are examples of food products where several PPOAO are mixed or assembled but no product of plant origin is added (in such a case the processing of the various products of animal origin is subject to the Regulation (EC) No 853/2004):
- Surimi (without a plant origin ingredient) to which a very small amount of egg white is added for technological reasons;
  - Skewers prepared from two different types of meat;
  - Frozen fried Thai fish cake containing fish and eggs.

#### 4. Rules for the ComP-producing establishment

- *Establishment in EU:*

An establishment assembling ingredients to obtain a ComP, where all of the animal origin ingredients are already processed, is only to be registered by the competent authority in accordance with Regulation (EC) 852/2004 and does not need to be approved in accordance with Regulation (EU) 853/2004. It includes an establishment producing ComP by assembling only the ingredients (PPOAO and plant origin ingredients) and needs to apply a process necessary for this assembly, e.g., the production of biscuits.

However, an establishment that also process the unprocessed product of animal origin, for which requirements are laid down in Regulation (EC) No 853/2004, to be used as ingredient for the ComP, requires approval in accordance with Regulation (EC) No 853/2004. Then, the establishment must be classified in the relevant section according to the master list <sup>(13)</sup>. This applies also to operators further processing already PPOAO used as ingredients in the ComP in their establishment before the actual assembling of the ComP. This also includes establishments carrying out risk-mitigating treatments for animal health reasons.

— *Establishments in third countries:*

The same considerations apply to determining the scope of applicable hygiene rules for food products in respect of establishments located in a third country.

Establishments located in a third country and processing the unprocessed product of animal origin to be used as ingredient for the COMP should be listed to enter the Union this PPOAO (in accordance with Article 13(1) and Article 20(1) of Delegated Regulation (EU) 2022/2292). Then, the establishment must be classified in the relevant section according to the master list. This applies also to operators further processing already PPOAO used as ingredients in the ComP in their establishment before the actual assembling of the ComP. This also includes establishments carrying out risk-mitigating treatments for animal health reasons.

Establishments obtaining ComP, to enter the Union, by assembling the ingredients are not to be listed in accordance with Article 13(1) and Article 20(1) of Delegated Regulation (EU) 2022/2292.

— *Summary:*

| ComP                                                                                                          |                                                                                                                                                                  | ComP- establishment              |
|---------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| With PPOAO previously processed in an EU-approved/listed establishment                                        | Without further processing                                                                                                                                       | Registered                       |
|                                                                                                               | With a further processing of the PPOAO as part of the assembling of the final ComP such as cooking biscuits using an egg product.                                | Registered                       |
|                                                                                                               | With a further processing of the PPOAO, independent from the processing of the final ComP such as processing a dairy product into milk powder to make ice-cream. | EU-approved/listed establishment |
| With unprocessed products of animal origin that will be processed in the establishment manufacturing the ComP |                                                                                                                                                                  | EU-approved/listed establishment |

5. **Rules for the PPOAO contained in the ComP**

5.1. *Animal health requirements*

Animal health risks relevant for the PPOAO contained in the ComP need to be addressed. Such risks are notably higher when the ComP contains any meat products, dairy products, colostrum-based products or egg products.

5.1.1. *Animal health requirements for PPOAO contained in all ComP*

A ComP can only enter the Union if the PPOAO contained therein comply with the rules for entry into the Union of those PPOAO, including the following animal health requirements laid down in Article 162 of Delegated Regulation (EU) 2020/692:

- (1) The PPOAO contained in the ComP comply with all of the relevant animal health requirements for entry into the Union of those POAO laid down in Delegated Regulation (EU) 2020/692; and

<sup>(13)</sup> [https://food.ec.europa.eu/system/files/2022-10/biosafety\\_fh\\_eu\\_food\\_establishments-techspecs\\_en.pdf](https://food.ec.europa.eu/system/files/2022-10/biosafety_fh_eu_food_establishments-techspecs_en.pdf).

- (2) The PPOAO have been obtained either:
- (a) in the same listed third country or territory of origin or zone thereof of the ComP; or
  - (b) in the Union; or
  - (c) in a third country or territory, or zone thereof, which is listed for entry into the Union of those products of animal origin without them undergoing a specific risk-mitigating treatment if the third country or territory, or zone thereof where the ComP is produced is also listed for entry into the Union of those products without the obligation to apply a specific risk-mitigating treatment.

*Point 2(a) above refers to the third country or territory, or zone thereof of the ComP production.*

*Point (2)(c) above can only be fulfilled by dairy products from third countries or territories, or zones thereof listed in Annex XVII (for dairy products not required to undergo specific risk-mitigating treatment against foot and mouth disease) or by meat products from third countries or territories, or zones thereof listed in Annex XV (for meat products with an assigned non-specific treatment 'A' meaning that none of the specific risk-mitigating treatments B, C or D is required) to Implementing Regulation (EU) 2021/404 for which there is no obligation to apply specific risk-mitigating treatments (see Article 162(2), point (b) (iii), of Delegated Regulation (EU) 2020/692).*

*Examples applicable to ComP intended for export to the Union and produced in third countries or territories, or zones thereof listed for the entry onto the Union of dairy products, meat products or egg products with or without an assigned specific risk-mitigating treatment in relevant Annexes to Implementing Regulation (EU) 2021/404:*

- *ComP from a third country or territory, or zone thereof listed in Annex XVIII for dairy products with an assigned specific risk-mitigating treatment CAN ONLY contain dairy products sourced in that same third country or territory, or zone thereof and CANNOT source dairy products in other third countries or territories, or zones thereof (see Article 162(2), point (b)(i) and (iii), of Delegated Regulation (EU) 2020/692).*
- *ComP from a third country or territory, or zone thereof listed in Annex XV for poultry meat products with an assigned specific risk-mitigating treatment 'D' CANNOT contain poultry meat products sourced from other third countries or territories, or zones thereof (see Article 162(2), point (b)(i) and (iii), of Delegated Regulation (EU) 2020/692).*
- *ComP from a third country or territory, or zone thereof listed in Annex XVII for dairy products without an assigned specific risk-mitigating treatment CAN contain dairy products sourced: in that same third country or territory, or zone thereof, in an EU Member State, or in another third country or territory, or zone thereof also listed in that Annex without an assigned specific risk-mitigating treatment (see Article 162(2), point (b), of Delegated Regulation (EU) 2020/692).*
- *ComP from a third country or territory, or zone thereof listed in Annex XV for poultry meat products with an assigned non-specific treatment 'A' (meaning that none of the specific risk-mitigating treatments B, C or D is required) CAN contain poultry meat products sourced: in that same third country or territory, or zone thereof, in an EU Member State, or in another third country or territory, or zone thereof also listed in that Annex with a non-specific treatment 'A' (see Article 162(2), point (b), of Delegated Regulation (EU) 2020/692).*

*Moreover, PPOAO obtained in the Union, intended for 're-entry' into the Union as ingredients of the ComP produced in third countries or territories, or zones thereof listed for entry into the Union of those PPOAO with an assigned specific risk-mitigating treatment, have to undergo in the third country, or territory, or zone thereof of that ComP production prior specific risk-mitigating treatment assigned to that third country, or territory, or zone thereof (see Article 121(1), subparagraph 2, point (b), and Art. 162(2), point (a), of Delegated Regulation 2020/692).*

*To consider, this specific risk-mitigating treatment must be carry out in an EU-approved/listed establishment (see Article 13 of Delegated Regulation (EU) 2022/2292) located in that third country, or territory, or zone thereof.*

*See point 5.1.2. of this document as regards Art. 163(3) of Delegated Regulation (EU) 2020/692 providing exceptions from the requirement described above under point 2(c) for the entry into the Union of certain shelf-stable ComP containing dairy products, egg products, or both.*

### 5.1.2. Animal health requirements for PPOAO contained in shelf-stable ComP

ComP that have been treated to become shelf-stable at ambient temperatures, containing dairy products, or egg products, or both, as PPOAO can enter the Union with a declaration instead of an animal health certificate provided that they comply with the respective conditions laid down in Article 163(1) of Delegated Regulation (EU) 2020/692 for dairy and egg products.

For dairy products contained in the shelf-stable ComP, a declaration instead of an animal health certificate may be used:

- (1) If the dairy products have not undergone a specific risk-mitigating treatment provided for in Annex XXVII to Delegated Regulation (EU) 2020/692, but they have been obtained, in accordance with Article 156 of that Delegated Regulation, either in the Union or in a third country or territory, or zone thereof, listed for entry into the Union of dairy products without undergoing a specific risk-mitigating treatment, (Annex XVII to Implementing Regulation (EU) 2021/404), and the ComP has been produced in a third country or territory, or zone thereof also listed for the entry into the Union without the requirement to apply a specific risk-mitigating treatment for those products.
- (2) If the dairy products have undergone a specific risk-mitigating treatment referred to in column A or B of Annex XXVII to Delegated Regulation (EU) 2020/692, relevant for the species of origin of the milk, and they have either been obtained in accordance with Article 156 of that Delegated Regulation, either in the Union, or in a third country or territory, or zone thereof, listed for entry into the Union of dairy products without undergoing a specific risk-mitigating treatment, or they have been obtained either in the Union, or in a third country or territory, or zone thereof, listed for entry into the Union of dairy products that have undergone a specific risk-mitigating treatment in accordance with Article 157 of that Delegated Regulation, the ComP has been produced in a third country listed for entry into the Union of dairy products if they have undergone a specific risk-mitigating treatment.

*In accordance with Article 121(1), subparagraph 2, point (b), of Delegated Regulation (EU) 2020/692, for dairy products originating from third countries listed in Annex XVIII to Implementing Regulation (EU) 2021/404 with an assigned specific risk-mitigating treatment, the assigned treatment has to be applied by that third country or territory, or zone thereof listed for entry into the Union of those particular categories of products of animal origin. Consequently, the above only applies to the third countries or territories, or zones thereof listed in Annex XVIII to Implementing Regulation (EU) 2021/404 with an assigned specific risk-mitigating treatment and not to those third countries or territories, or zones thereof listed in Annex XVII to that Implementing Regulation.*

- (3) If the dairy products have undergone a specific risk-mitigating 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, if the dairy products do not comply with all the requirements provided for in Article 163(1), point (a)(i) or (ii), of Delegated Regulation (EU) 2020/692 or they have been obtained either in the Union or in a third country or territory, or zone thereof which is not listed (in the relevant Annexes to Implementing Regulation (EU) 2021/404) for the entry into the Union of dairy products but is listed (in the relevant Annex to Implementing Regulation (EU) 2021/404) for the entry into the Union of other products of animal origin in accordance with that Delegated Regulation.

*To consider: An establishment carrying out the application of the specific risk-mitigating treatment must be an EU-approved/listed establishment (see Article 13 of Delegated Regulation (EU) 2022/2292 and Article 4(2) of Regulation (EC) 853/2004).*

For egg products contained in ComP that have been treated to become shelf-stable at ambient temperature a declaration instead of an animal health certificate may be used if the egg products have undergone a specific risk-mitigating treatment equivalent to those set out in Annex XXVIII to Delegated Regulation (EU) 2020/692.

Nevertheless, in accordance with Article 163(3) of Delegated Regulation (EU) 2020/692, shelf-stable ComP containing dairy products referred in point 3 above, or egg products, or both can enter the Union, accompanied by a declaration instead of an animal health certificate, even if they were produced in a third country or territory, or zone thereof which is not specifically listed for the entry into the Union of those products of animal origin (dairy products or egg products) but is listed either for meat products, dairy products or egg products in accordance with Delegated Regulation (EU) 2020/692, or for fishery products in accordance with Article 127 of Regulation (EU) 2017/625.

## 5.2. Hygiene requirements

The hygiene requirements for production and placing on the market of ComP are mainly established in Articles 3 to 6 of Regulation (EC) No 853/2004. Amongst others, the following obligations need to be respected by food business operators (including as relevant in EU-approved/listed establishment in third countries):

- The food business operator monitors the food safety of both products and processes under their responsibility;
- General hygiene provisions for primary production and general hygiene requirements after primary production are respected;
- Compliance with microbiological criteria for foodstuffs in accordance with Commission Regulation (EC) No 2073/2005 <sup>(14)</sup>;
- Procedures based on the Hazard Analysis and Critical Control Points principles (HACCP) are implemented;
- The establishment from which the PPOAO used for producing the ComP have been dispatched, obtained or prepared, must be an EU-approved/listed establishment (See Section 4 of this document).

## 5.3. Residue control requirements

In accordance with Articles 6 to 8 and 20(3) of Delegated Regulation (EU) 2022/2292, the third country of origin of the ComP must be listed in Annex -I to Implementing Regulation (EU) 2021/405, for the species or commodities from which the PPOAO contained in the ComP (with the exception, amongst others, of collagen, gelatine, highly refined products of animal origin and fish from wild catch - see Article 5 of Delegated Regulation (EC) 2022/2292) are derived.

This requirement should be met in addition to the other public and animal health requirements, e.g., listing of the third country, EU-approved/listed establishment, application of specific risk-mitigating treatments for animal health reasons when needed, etc.

Considering the above, as regards residues, for each PPOAO contained in the ComP, the third country of origin of the ComP must either:

- have an approved residue control plan for residues of pharmacologically active substances, pesticides and contaminants (RCP) for each animal species or commodity from which the PPOAO contained in the ComP is derived. Such third countries are marked in Annex -I to Implementing Regulation (EU) 2021/405 with an 'X' (see Article 2a(1) of Implementing Regulation (EU) 2021/405), or

<sup>(14)</sup> Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/2073/oj>).

- use only raw material of animal origin from either an EU Member State or from another third country authorised for entry into the Union of such raw material (and listed in Annex -I to Implementing Regulation (EU) 2021/405 with an 'X' for the species or commodities from which the PPOAO contained in the ComP, destined to export to the Union, is derived). In this case the third country of origin of the ComP is included in the list with a 'Δ' (see Article 2a(2) of Implementing Regulation (EU) 2021/405), or
- use PPOAO, derived from bovine, ovine/caprine, porcine or equine animals, rabbits or poultry, from either an EU Member State or from a third country which has an RCP for the species covered by the request (i.e., listed for residues in Annex -I to Implementing Regulation (EU) 2021/405 with an 'X' for the animal species). To be able to export the ComP, the country of origin of the ComP does not need to have an approved RCP for that animal species from which the PPOAO is derived but could make a request for the species/contained in the ComP and will be marked with an 'O' in the table of Annex -I (see Article 2a(3) of Implementing Regulation (EU) 2021/405), or
- have been marked with an 'X' in Annex -I to Implementing Regulation (EU) 2021/405 for either 'aquaculture' or 'milk' or 'eggs'. In this case, the third country of origin of the ComP may enter to the Union ComP containing PPOAO derived from the remaining of these categories (aquaculture, milk, eggs) provided that they make a request and are additionally marked with an 'O', in the table of Annex -I, for the remaining of these categories not marked with an 'X' (see Article 2a(4) of Implementing Regulation (EU) 2021/405), or
- have been marked with an 'X' in Annex -I to Implementing Regulation (EU) 2021/405 for either 'bovine', 'ovine/caprine', 'porcine', 'equine', 'poultry', 'aquaculture', 'milk', 'eggs', 'rabbit', 'wild game' or 'farmed game'. In this case, the third country of origin of the ComP may enter to the Union ComP containing processed products derived from bivalve molluscs originating either in an EU Member State or in a third country or region thereof authorised for the entry into the Union of consignments of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods (listed in Annex VIII to Implementing Regulation (EU) 2021/405), and could request to be additionally marked with a 'P' for bivalve molluscs in the column aquaculture in Annex -I (see Article 2a(5) of Implementing Regulation (EU) 2021/405).

### 5.3.1. Examples of application of Annex -I to Implementing Regulation (EU) 2021/405

#### Example 1:

*The third country of origin of the ComP is listed, as regards requirements on residues, in Annex -I to Implementing Regulation (EU) 2021/405 with an 'X' for 'bovine'.*

*This third country is listed, as regards animal and public health requirements, in the relevant Annexes to Implementing Regulations (EU) 2021/404 and (EU) 2021/405 for the entry into the Union of bovine meat products.*

*This implies that this third country could export to the Union ComP containing bovine meat products.*

*In addition, for this third country, it could be also possible to export to the Union shelf-stable ComP containing PPOAO other than meat product, such as fishery products, dairy or egg products (see Article 20(2), point (c), of Delegated Regulation (EU) 2022/2292), as long as the third country is also listed in Annex -I to Implementing Regulation (EU) 2021/405 for those species or commodities (see Article 20(3) of Delegated Regulation (EU) 2022/2292).*

## Example 2:

*In the case of ComP containing processed honey, the third country of origin of the ComP must be listed in Annex -I to Implementing Regulation (EU) 2021/405 with an 'X' for honey (see Article 2a(1) of Implementing Regulation (EU) 2021/405), or the third country of origin of the ComP must be listed in that Annex with an 'Δ' for 'honey', showing that the honey comes from an EU Member State or a listed third country (see Article 2a(2) of Implementing Regulation (EU) 2021/405).*

## Example 3:

*When a third country is listed in Annex -I to Implementing Regulation (EU) 2021/405 with an 'X' for a specific commodity, as for example 'camel milk only', the ComP originating from that third country can contain only camel milk (and not milk from any other species) originating from that third country (see Article 2a(1) of Implementing Regulation (EU) 2021/405). In the case that the third country is listed in Annex -I to Implementing Regulation (EU) 2021/405 with a 'Δ' for 'milk', the third country is authorised to use camel milk from other listed third countries (see Article 2a(2) of Implementing Regulation (EU) 2021/405).*

## Example 4:

*The third country of origin of a ComP uses for its production raw fish from aquaculture from France. That third country could request to be listed in Annex -I to Implementing Regulation (EU) 2021/405 with a 'Δ' for 'aquaculture' and following such listing could export to the Union ComP containing processed fish from aquaculture (see Article 2a(2) of Implementing Regulation (EU) 2021/405).*

*It should be noted that the third country must comply with the other animal and public health requirements, e.g.: have EU-approved/listed establishment for entry into the Union of that commodity, fish in this case.*

## Example 5:

*The third country of origin of a ComP containing egg products while not having a RCP for eggs but having an RCP for aquaculture and thus marked in Annex -I to Implementing Regulation (EU) 2021/405 with an 'X' for 'aquaculture', could request to be also marked in that Annex with an 'O' for 'eggs' and then be able to export those ComP to the Union (see Article 2a(4) of Implementing Regulation (EU) 2021/405).*

*Attention should be paid to the footnotes which limit the production of ComP depending on the RCP for which the third country is listed. For example, if a third country is marked in Annex -I to Implementing Regulation (EU) 2021/405 with an 'X' for 'aquaculture' with a footnote 'for crustaceans only', that third country can only produce ComP containing crustaceans.*

## Example 6:

*If the third country of origin of a ComP containing processed bivalve molluscs wants to export to the Union those products and is listed in Annex -I to Implementing Regulation (EU) 2021/405 with an 'X' for 'poultry', it could request to be additionally marked with a 'P' for 'aquaculture' in order to be able to enter that ComP into the Union (see Article 2a(5) of Implementing Regulation (EU) 2021/405).*

#### 5.4. *Other requirements for ComP*

Production and entry into the Union of food containing PPOAO and products of plant origin are also subject to other requirements that need to be complied with. Additional rules apply, in particular and, where appropriate, requirements concerning contaminants, requirements on maximum residue levels for pesticides, requirements on the use of food additives, materials and articles in contact with foodstuffs, requirements on food irradiation, novel foods, radioactivity, requirements on genetically modified organisms (GMOs) and phytosanitary requirements.

Implementing Regulation (EU) 2019/1793<sup>(15)</sup> does not cover products of animal origin and ComP. Therefore, ComP should not be checked in relation to Implementing Regulation (EU) 2019/1793. However, knowing that certain products from certain third countries are listed in Implementing Regulation (EU) 2019/1793, the competent authorities of the EU Member States responsible for official controls of ComP may include that information in their risk assessment and check these products to ensure the compliance with the requirements in areas laid down in Article 1(2) of the OCR.

#### 6. **What about the ID mark?**

In accordance with Article 5(1), point (b), of Regulation (EC) No 853/2004, when Article 48 of Implementing Regulation (EU) 2019/627 does not provide for the application of a health mark, an identification mark is required when placing on the market a product of animal origin handled in an establishment subject to approval in accordance with Article 4(2) of that Regulation.

ComP do not need to bear an identification mark.

An EU-approved/listed establishment obtaining also ComP may, however, use the identification mark required for the products of animal origin contained in the ComP for that ComP as well (according to point B.7 of Section I of Annex II to Regulation (EC) No 853/2004)

#### 7. **Rules for the third country of origin of the ComP**

According to Article 20(1) of Delegated Regulation (EU) 2022/2292, where a ComP is produced in establishments located in a third country, it may, in principle, enter the Union only if the PPOAO are authorised to enter the Union.

Animal health legislation on entry into the Union of products of animal origin lays down rules for entry into the Union of certain products of animal origin from individually listed third countries based on their animal health status. In general, third countries with a favourable animal health status can source ingredients for production of products of animal origin covered by that legislation amongst each other but only the third country of their production can certify animal health requirements. Those rules are risk-based and depend on the shelf-stability characteristics of the ComP and their possible content of meat products and colostrum-based products. Three different categories of ComP can be distinguished in that Article:

- (1) Non shelf-stable ComP must originate from a third country or region thereof authorised for entry into the Union of each of the PPOAO contained in the ComP, and is thus listed in Implementing Regulation (EU) 2021/405 for all of the PPOAO contained in the ComP (Article 20(2), point (a), of Delegated Regulation (EU) 2022/2292).

‘Controlled temperatures’ means that the products have been produced in a way that does not allow their transport and storage at ambient temperature without affecting their preservation or safety.

<sup>(15)</sup> Commission Implementing Regulation (EU) 2019/1793 of 22 October 2019 on the temporary increase of official controls and emergency measures governing the entry into the Union of certain goods from certain third countries implementing Regulations (EU) 2017/625 and (EC) No 178/2002 of the European Parliament and of the Council and repealing Commission Regulations (EC) No 669/2009, (EU) No 884/2014, (EU) 2015/175, (EU) 2017/186 and (EU) 2018/1660. (OJ L 277, 29.10.2019, p. 89, ELI: [http://data.europa.eu/eli/reg\\_impl/2019/1793/oj](http://data.europa.eu/eli/reg_impl/2019/1793/oj)).

Shelf-stable ComP transported or stored under controlled temperatures not for food safety but for quality or technological reasons, and as long as the temperature is not going below 0 °C, should be understood as ComP that have been produced as shelf-stable and the requirements for a shelf-stable ComP should remain applicable. In such a situation, it is important to explain why such controlled temperatures are applied? to be able to clearly distinguish *those* ComP from non-shelf-stable ComP. Therefore, such an explanation should be attached to or written in the private attestation in order to distinguish the shelf-stable ComP from non-shelf-stable ComP.

- (2) Shelf-stable ComP containing any quantity of colostrum-based products or meat products shall originate from third countries or regions thereof authorised to export to the Union the colostrum-based products or meat products contained in the ComP and is thus listed in Implementing Regulation (EU) 2021/405 for the colostrum-based products or meat products contained in the ComP (Article 20(2), point (b), of Delegated Regulation (EU) 2022/2292).
- (3) Shelf-stable ComP that contain PPOAO *other* than colostrum-based products or meat products, for which requirements are laid down in Annex III to Regulation (EC) No 853/2004, shall originate from third countries or regions thereof that are authorised to export to the Union *at least* meat products, fishery products, dairy products, or egg products and thus are listed in Implementing Regulation (EU) 2021/405 either for meat products, fishery products, dairy products or egg products, even if those PPOAO are not contained in the ComP (Article 20(2), point (c), of Delegated Regulation (EU) 2022/2292).

If there are no specific requirements laid down in Annex III to Regulation (EC) No 853/2004 for the PPOAO contained in the shelf-stable ComP, then the rules on the origin of the ComP (Article 20(2), point (c)) do not apply. This is the case for example for shelf-stable ComP containing processed honey or processed insects:

- in the case of a third country of origin of a shelf-stable ComP containing only processed honey as the sole PPOAO ingredient, the requirements on the origin of the ComP established in Article 20(2) of Delegated Regulation (EU) 2022/2292 do not apply but besides other applicable requirements, the third country of origin of that ComP should be listed in Annex -I to Implementing Regulation (EU) 2021/405 with an 'X' or a 'Δ';
- in the case of a third country of origin of a shelf-stable ComP containing only processed insects as the sole PPOAO ingredient, considering that RCP is not required for insects, the requirements laid down in Article 20(2) of Delegated Regulation (EU) 2022/2292 do not apply.

In addition, there is also a fourth category, those are shelf-stable ComP containing only PPOAO or ComP falling under the scope of Regulation (EC) No 1332/2008 <sup>(16)</sup>, Regulation (EC) No 1333/2008 <sup>(17)</sup>, Regulation (EC) No 1334/2008 <sup>(18)</sup>, or containing only vitamin D3, for which the requirements on the origin of ComP established in Article 20(2) of Delegated Regulation 2022/2292 (EU) do not apply (Article 20(4) of Delegated Regulation (EU) 2022/2292); and a fifth category, those are Shelf-stable ComP that contain PPOAO *other* than colostrum-based products or meat products, for which NO requirements are laid down in Annex III to Regulation (EC) No 853/2004, Article 6(4) of Regulation (EC) 853/2004 applies to them.

<sup>(16)</sup> Regulation (EC) No 1332/2008 of the European Parliament and of the Council of 16 December 2008 on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 (OJ L 354, 31.12.2008, p. 7, ELI: <http://data.europa.eu/eli/reg/2008/1332/oj>).

<sup>(17)</sup> Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16, ELI: <http://data.europa.eu/eli/reg/2008/1333/oj>).

<sup>(18)</sup> Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC (OJ L 354, 31.12.2008, p. 34, ELI: <http://data.europa.eu/eli/reg/2008/1334/oj>).

## 8. Documents accompanying the ComP

In accordance with Articles 21 and 22 of Delegated Regulation (EU) 2022/2292 ComP can only enter the Union if they are accompanied by documents demonstrating that they comply with the EU rules. There are three different types of documents to accompany ComP entering the Union. The use of one or the other will depend on the categorisation of the ComP.

The animal health/official certificate (corresponding to the model 'COMP' set out in Chapter 50 of Annex III to Implementing Regulation (EU) 2020/2235) is signed by the competent authority of the country of origin of the ComP. This document certifies compliance with the requirements of the relevant European Union's legislation for those ComP presenting the highest risk. It must thus accompany any consignment of non-shelf-stable ComP or any consignment of shelf-stable ComP containing any quantity of colostrum-based products or meat products (with the exclusion of shelf-stable ComP that do not contain meat products other than gelatine or collagen not derived from ruminant bones or highly refined products of animal origin) (Article 21(1), point (f), of Delegated Regulation 2022/2292).

*To consider: for those mixed products containing more than one PPOAO but not containing plant origin ingredient the animal health certificate or animal health/official certificate is required for each PPOAO.*

The private attestation (corresponding to the model set out in Annex V to Implementing Regulation (EU) 2020/2235) is to accompany shelf-stable ComP containing those PPOAO for which specific requirements are laid down in Annex III to Regulation (EC) No 853/2004 (see Article 20(2), point (c), of Delegated Regulation (EU) 2022/2292) other than colostrum-based products or meat products (Article 22(1), points (a) and (b), of Delegated Regulation (EU) 2022/2292). It does not have to be signed by the competent authority. It is signed by the importer as the representative of the food business operator entering the goods into the Union. Such private attestation may also fulfil the purpose of a declaration in the sense of Article 163(1) and (2), point (a), of Delegated Regulation (EU) 2020/692 for ComP that have been treated to become shelf-stable, that declaration is covered by the relevant attestations of the model private attestation.

The animal health certificate (corresponding to the model 'TRANSIT-COMP' set out in Chapter 52 of Annex III to Commission Implementing Regulation (EU) No 2020/2235) shall accompany non shelf-stable ComP intended for human consumption, and shelf-stable ComP intended for human consumption containing any quantity of meat products (other than gelatine or collagen or highly refined products), and any quantity of colostrum-based products during transit through the Union to a third country either by immediate transit or after storage in the Union (in accordance with Article 237(1), point (a), of Regulation (EU) 2016/429).

There are cases where additional documents are needed in accordance with *other* legal requirements:

- Consignments of ComP containing gelatine or collagen derived from ruminant bones can only enter the Union with a certification of the origin of the gelatine, therefore these consignments shall be always accompanied by an official certificate corresponding to the model 'COMP' set out in Chapter 50 of Annex III to Implementing Regulation (EU) 2020/2235. It is to be provided, as the Union legislation on BSE requires official certification for such products of ruminant origin (Annex IX, Chapter D, Section B, point 1, to Regulation (EC) No 999/2001).
- For shelf-stable ComP containing PPOAO for which no requirements are laid down in Annex III to Regulation (EC) 853/2004, the food business operator shall ensure that the PPOAO meets the requirements established in Article 6(4) of Regulation (EC) 853/2004 and shall provide an appropriate documentation to support that (i.e., trade documents, commercial documents, invoices, etc.) (Article 6(4) of Regulation (EC) No 853/2004).

## 9. Particular Cases

For shelf-stable ComP that only contain PPOAO or ComP that fall under the scope of Regulation (EC) No 1332/2008 (food enzymes), Regulation (EC) No 1333/2008 (food additives), Regulation (EC) No 1334/2008 (flavourings and certain food ingredients with flavouring properties), or that only contain vitamin D3, the following rules do not apply:

- rules on the country of origin of the ComP, established in Article 20(2) of Commission Delegated Regulation (EU) 2022/2292 (Article 20(4) of Delegated Regulation (EU) 2022/2292),
- rules on the country of origin of the ComP established in Article 20(3) of Commission Delegated Regulation (EU) 2022/2292 (Article 20(4) of Delegated Regulation (EU) 2022/2292),
- rules on documents accompanying the ComP (an animal health/official certificate or a private attestation) established in Articles 21 and 22 of Delegated Regulation (EU) 2022/2292 (in accordance with Article 21(1), point (f), and with Article 22(1), point (a)).

*To consider: chips with bacon flavour, when derived from POAO, are a ComP; however, as the only PPOAO contained in the ComP (the bacon flavour) falls under Regulation (EC) No 1334/2008, rules on the origin of the ComP do not apply, and they are exempted from having to be accompanied by an animal health/official certificate or a private attestation.*

*Food business operators responsible for importing such ComP into the Union shall ensure that the PPOAO contained in the ComP satisfy the requirements for products of animal origin referred in Article 6(1) to (4) of Regulation (EC) No 853/2004 and the operators must be able to demonstrate that through appropriate documentation (i.e., trade documents, commercial documents, invoices, etc.)*

## 10. Official controls at EU border control posts (BCPs)

As any product entering the Union, ComP are identified for custom control reasons by their CN code, as provided for in Council Regulation (EEC) No 2658/87 <sup>(19)</sup>. Article 20(1) of Delegated Regulation (EU) 2022/2292 lists the CN codes of ComP to which the requirements laid down in that Article apply. If a CN code is missing from that Article, a request to add it could be sent to the Commission. It is important to highlight that the CN codes mentioned in Article 20(1) of Delegated Regulation (EU) 2022/2292 are not *exclusively* used for ComP.

Article 47(1) of Regulation (EU) 2017/625 provides that, among others, products of animal origin and ComP entering the Union must be subject to official controls at the border control post (BCP) of first arrival into the Union. The list of products of animal origin and ComP which must be presented for official controls at the BCP is set out in Commission Implementing Regulation (EU) 2021/632.

Commission Delegated Regulation (EU) 2021/630 (adopted on the basis of Article 48, point (h), and Article 77(1), point (k), of Regulation (EU) 2017/625) *exempts* certain ComP, that present a lower risk, from official controls at the BCP provided that they meet certain requirements laid down in that Delegated Regulation such as being identified as intended for human consumption, being securely packaged or sealed, *inter alia*, including being listed in the Annex to that Delegated Regulation. However, those ComP presenting a lower risk and listed in the Annex to Delegated Regulation (EU) 2021/630, which must comply with animal and public health requirements applicable to them, may be controlled either at the place of destination, or at the point of release for free circulation or at the warehouses or premises of the operator responsible for the consignment. The competent authorities shall perform the official controls for these ComP regularly, on a risk basis and with an appropriate frequency in accordance with Article 44 of Regulation (EU) 2017/625.

<sup>(19)</sup> Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff (OJ L 256, 7.9.1987, p. 1, ELI: <http://data.europa.eu/eli/reg/1987/2658/oj>).

Food business operators have the responsibility to guarantee the compliance of all consignments entering the Union and to provide the relevant documented evidence in case of control by the competent authorities in the EU Member States. Commission Implementing Regulation (EU) 2020/2235 includes the model animal health/official certificate (Chapter 50 of Annex III to that Implementing Regulation) and the model private attestation (Annex V to that Implementing Regulation) for the entry into the Union of ComP.

#### 11. Summary of the requirements applicable to ComP intended for entry into the Union <sup>(20)</sup>

| Requirements                                                                                                                                                                                                                                             | Category of ComP                                                                                                                                                                          |                                                                                                                               |                                                                                                                                                                                                                               |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                          | Non shelf-stable                                                                                                                                                                          | Shelf-stable                                                                                                                  |                                                                                                                                                                                                                               |
|                                                                                                                                                                                                                                                          |                                                                                                                                                                                           | Containing colostrum-based products or meat products (except gelatine, collagen or highly refined products derived from meat) | Not containing colostrum-based products or meat products (except gelatine, collagen or highly refined products derived from meat) for which requirements are laid down in Annex III to Regulation (EC) No 853/2004            |
| Ingredients of animal origin (see Article 4 of Regulation (EU) 853/2004 and Article 13 of Delegated Regulation (EU) 2022/2292)                                                                                                                           | All PPOAO contained in the ComP must come from EU-approved/listed establishments located in third countries authorised for entry into the Union of such PPOAO.                            |                                                                                                                               |                                                                                                                                                                                                                               |
| The third country of ComP production is listed in Commission Implementing Regulation (EU) 2021/405 as relevant (*). (Article 20(2) of Delegated Regulation (EU) 2022/2292)                                                                               | For each PPOAO contained in the ComP.                                                                                                                                                     | For the colostrum-based product and/or meat product contained in the ComP.                                                    | Either for meat products, fishery products, dairy products (and colostrum-based) or egg products, be they contained in the ComP or not. For gelatine or/and collagen or/and HRP derived from meat when contained in the ComP. |
| The third country of ComP production has an EU approved RCP (for the species/commodities from which the PPOAO are derived) and/or is listed in Annex -I to Implementing Regulation (EU) 2021/405. (Article 20(3) of Delegated Regulation (EU) 2022/2292) | For each PPOAO contained in the ComP (**), except for example gelatine, collagen, highly refined products and fish from wild catch (see Article 5 of Delegated Regulation (EU) 2022/2292) |                                                                                                                               |                                                                                                                                                                                                                               |

<sup>(20)</sup> This table is not applicable to shelf-stable ComP:

- containing PPOAO for which there are not requirements laid down in Annex III to Regulation (EC) 853/2004;
- containing only PPOAO or ComP that fall within the scope of Regulation (EC) No 1332/2008 of the European Parliament and of the Council, Regulation (EC) No 1333/2008 of the European Parliament and of the Council, Regulation (EC) No 1334/2008 of the European Parliament and of the Council, or that only contain vitamin D3 (Art. 20 (4) of Regulation (EU) 2022/2292).

| Requirements                                                                                                          | Category of ComP                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                    |
|-----------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                       | Non shelf-stable                                                                                                                                                                                                                                                                                                                                                                                                                                          | Shelf-stable                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                                                                                                    |
|                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Containing colostrum-based products or meat products (except gelatine, collagen or highly refined products derived from meat)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Not containing colostrum-based products or meat products (except gelatine, collagen or highly refined products derived from meat) for which requirements are laid down in Annex III to Regulation (EC) No 853/2004 |
| Animal health aspects (in particular, Articles 229(1), 234(1) and (2), 237(1) and 239(2) of Regulation (EU) 2016/429) | The PPOAO contained in the composite products comply with the relevant requirements for entry into the EU laid down in Commission Delegated Regulation (EU) 2020/692. They have been produced either in the EU, in the third country of COMP production, or in another third country listed without an obligation to undergo any specific risk-mitigating treatment provided the third country of COMP production is also listed without such obligation. | <p>Shall be permitted to enter the Union accompanied by a declaration if they contain:</p> <ul style="list-style-type: none"> <li>— dairy products not required to undergo an animal health specific risk-mitigating treatment originating from an EU Member State and/or third countries listed in Annex XVII to Implementing Regulation (EU) 2021/404, if the third country of ComP production is listed in that Annex;</li> <li>— dairy products required to undergo an animal health specific risk-mitigating treatment originating from third countries listed in Annex XVIII to Implementing Regulation (EU) 2021/404 (subjected to an assigned to them treatment applied in that third country), if the third country of ComP production is listed in that Annex;</li> <li>— dairy products not complying with abovementioned requirements provided they have undergone specific risk-mitigating treatment (at least equivalent to those referred to in column B of the table in Annex XXVII to Delegated Regulation 2020/692). The third country of ComP production is listed either for meat products, dairy products, egg products or for fishery products (in accordance with Article 163(3) of Delegated Regulation (EU) 2020/692)</li> <li>— egg products contained in the ComP have undergone a risk mitigation treatment(s) at least equivalent to those set out in Annex XXVIII to Delegated Regulation (EU) 2020/692. The third country of COMP production is listed either for meat products, dairy products, egg products or for fishery products (in accordance with Article 163(3) of Delegated Regulation (EU) 2020/692).</li> </ul> |                                                                                                                                                                                                                    |

| Requirements                                                                                                                                                                                         | Category of ComP                                                                  |                                                                                                                                                                                                                                                                                                                              |                                                                                                                                                                                                                    |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                      | Non shelf-stable                                                                  | Shelf-stable                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                    |
|                                                                                                                                                                                                      |                                                                                   | Containing colostrum-based products or meat products (except gelatine, collagen or highly refined products derived from meat)                                                                                                                                                                                                | Not containing colostrum-based products or meat products (except gelatine, collagen or highly refined products derived from meat) for which requirements are laid down in Annex III to Regulation (EC) No 853/2004 |
| Animal health/official certificate corresponding to model 'COMP' set out in Chapter 50 of Annex III to Implementing Regulation (EU) No 2020/2235 (Article 21 of Delegated Regulation (EU) 2022/2292) | Required and signed by the competent authority of the country of ComP production. | Not applicable, except for gelatine or collagen derived from ruminant bones.                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                    |
| Private attestation corresponding to the model set out in Annex V to Implementing Regulation (EU) No 2020/2235 (Article 22 of Delegated Regulation (EU) 2022/2292)                                   | Not applicable.                                                                   | Issued and signed by the representative of the food business operator entering goods into the Union (in case of exemption from the control at the EU border, it must accompany the products at the time of the placing on the market)<br>Not applicable to ComP containing gelatine or collagen derived from ruminant bones. |                                                                                                                                                                                                                    |
| Control in EU border control posts                                                                                                                                                                   | Yes.                                                                              | Yes, except when the COMP presents a lower risk as listed in Annex to Delegated Regulation (EU) 2021/630 and is then exempted from the control at the border.                                                                                                                                                                |                                                                                                                                                                                                                    |

(\*) Should the third country of ComP production (third country A) wish to source PPOAO from outside its territory, its competent authority shall ensure that such PPOAO come from either EU-approved establishments located in an EU Member States or EU-approved/listed establishments located in other third countries listed in Annex -I to Implementing Regulation (EU) 2021/405 for the relevant species/commodities from which the PPOAO are derived. Third country A must be accordingly listed in Annex -I to Implementing Regulation (EU) 2021/405.

(\*\*) Annex IX (for fishery products) to Implementing Regulation (EU) 2021/405 or in Annexes XVII (for dairy products not required to undergone specific risk-mitigating treatment against foot and mouth disease), XVIII (for dairy products required to undergone specific risk-mitigating treatment against foot and mouth disease), XV (meat products) or XIX (for egg products) to Implementing Regulation (EU) 2021/404.