food supplements europe

Food Supplements Europe Guidelines relating to the manufacturing and imports of food supplements containing products of animal origin, with a particular focus on Vitamin D3

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1. Introduction

Vitamin D3 (Cholecalciferol) is a nutritional substance that is authorised to be added to foods, food supplements and foods for special groups (infant formula, baby foods, foods for special medical purposes (FSMP) and total diet replacement products). It is also used in other sectors, such as feed, cosmetics and medicines.

Vitamin D3 is mostly produced by several chemical conversions from lanolin, which is the wax that covers the hairs of sheep's wool.

In 2021 the European Commission confirmed that from a legal perspective Vitamin D3 derived from lanolin is to be considered as a Product of Animal Origin (POAO) and consequently is to be covered under the relevant requirements of the European Official Controls legal framework established by Regulation (EU) 2017/625.

Until 31 December 2020 transitional measures derogating Vitamin D3 from import conditions applied. The Commission was no longer allowed by the European Parliament and the Council to prolong these derogations and therefore set in motion a number of legislative initiatives to ensure appropriate requirements apply for the imports of Vitamin D3 into the EU.

These guidelines are intended to help food business operators (FBO) to understand this new environment and the rules that are applying to their products. Since the rules differ depending on whether a product is a POAO or a Composite Product (CP), which are products containing both ingredients of animal and plant origin, these guidelines also provide clarity on how to assess if a product is a CP.

2. The applicable legal framework

The EU Official Controls Regulation (EU) 2017/625 renewed and revised the legal framework of official controls. This legislation covers the principles that apply to controls of goods that are imported into the EU by national enforcement authorities. In a nutshell, it includes rules to govern the performance of the controls, their financing, administrative cooperation between Member States, the establishment of a computerised information system to manage information and data in relation to official controls (TRACES) and, of relevance for the present guidelines, the conditions to be fulfilled with respect to animals and goods entering the EU from a third country.

This regulation is complemented by a number of Delegated and Implementing Regulations.

The legislation that is relevant to Vitamin D3 and foods containing Vitamin D3 is listed in Appendix I of these guidelines.

3. Establishing the status of a product

The applicable rules relating to imports, controls and certificates for Vitamin D3 (and its precursors) and products containing it differ depending on whether a food is considered a Product of Animal Origin (POAO), a Product of Plant Origin (POPO) or a Composite Product (CP).

The assessment of a product's status is essential and needs to be carried out on a case-by-case basis.

a. What is considered as 'food'?

> *'Food' is defined in the General Food Law Regulation (EC) No 178/2002 as 'any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. This includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. […]'.*

This definition applies for the purpose of the Official Controls Regulation (Regulation (EU) 2017/625, Article 3(12)).

Therefore not only finished foods intended for consumption by the final consumer, but also Vitamin D3 (and its precursors) and preparations containing Vitamin D3 intended to be used as ingredient in or in the production of foods are 'food' from a legal perspective.

The objective of these guidelines is to clarify the legal framework applying to Vitamin D3 intended for use in food. Vitamin D3 can also be produced or imported for use in products other than 'food', such as feed, medicinal products, cosmetics, etc. These guidelines do not cover the use of Vitamin D3 in products other than food. It is important to note that Vitamin D3 imported under the requirements applicable to feed cannot legally be used in food, while the inverse is possible.

b. What is considered a 'Product of Animal Origin'

> *A 'Product of Animal Origin' is defined in point 8.1 of Annex I to Regulation (EC) No 853/2004 as 'food of animal origin, including honey and blood […]'. This definition applies for the purpose of the Official Controls Regulation (Regulation (EU) 2017/625, Article 3(19)).*

This definition is very broad. In addition, a POAO always remains a POAO irrespective the number of processing steps applied. Depending on the nature of the food (e.g. meat, oil, gelatine, …) different requirements for imports and official controls are in place.

Examples of POAO of relevance to these guidelines include:

- Vitamin D3 as such, when of animal origin
- Food supplements that only contain POAO (e.g. gelatine capsules filled with fish oil)

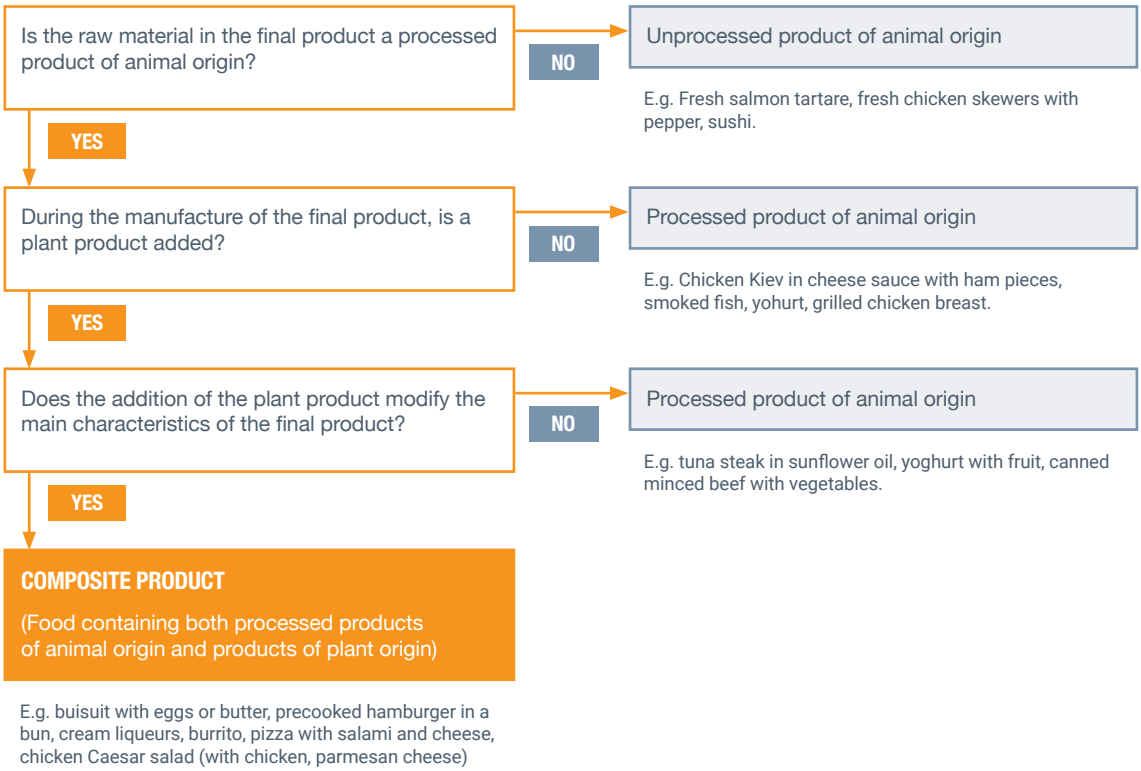
c. What is considered a 'Composite Product'?

> *'Composite Products' are defined in Article 47(1)b of Regulation (EU) 2017/625 as 'foodstuffs containing both products of plant origin and processed products of animal origin'. The same definition is included in Regulation (EU) 2022/2292, Article 2(21).*

While POAO is legally defined, POPO are not. A product of plant origin can therefore be interpreted in its normal linguistic sense as any product that originates from a plant source.

To decide on whether a product is a CP, a number of aspects need to be assessed. These are summarised in Figure 1.

Figure 1: Decision tree to establish the status of a food as POAO or CP



Source: European Commission 'Import of Composite Products into the EU: Questions and Answers'. https://food.ec.europa.eu/system/files/2022-07/ia_ic_composite-prods_qandas.pdf

It is important to note that a product can only be considered a CP if the POAO contained in it has been processed

> *'Processing' is defined in Article 2(1)(m) of Regulation (EC) No 852/2004 as 'any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes'.*

> *'Processed products' are defined as 'foodstuffs resulting from the processing of unprocessed products. These products may contain ingredients that are necessary for their manufacture or to give them specific characteristics' (Article 2(1)(o) of Regulation (EC) No 852/2004).*

Processed products are also covered by point 7 of Annex I to Regulation (EC) No 853/2004.

If unprocessed POAO are present (e.g. fresh meat, fish, natural honey) the product can never be a CP. The manufacturing of a CP may start from an unprocessed POAO as long as the processing of the POAO is part of the manufacture of the final product. In that case, the establishment manufacturing the CP must be approved in accordance with Article 4 of Regulation (EC) No 853/2004.

To note that Regulation (EC) No 853/2004 explicitly states that unless expressly indicated to the contrary, it does not apply to CP. However, processed POAO used to prepare such food shall be obtained and handled in accordance with the requirements of that Regulation (Article 1(2)).

In addition, FBO importing CP shall also ensure that the processed POAO contained in such food satisfy the requirements of paragraphs 1 to 3 of Article 6 of that Regulation and must be able to demonstrate that they have done so (for example, through appropriate documentation or certification) (Article 6(4)).

How to establish the status of a food as a composite product?

Whether a food is to be considered a POAO, POPO or CP needs to be carefully assessed on a case-by-case basis. In case of doubt, the FBO will have to provide details to Border Control Post (BCP) staff to support the conclusion whether the product is a CP or not. The product may need to be subjected to a physical inspection to assist in the determination.

The Commission has developed a Q&A that aims to clarify these differences and help to decide on the status of a food. It contains a decision tree, examples and answers to a number of questions. The guidance document does not particularly consider food supplements as examples. [1]

The main decision tree is presented in figure 1 above.

From this decision tree it is clear that the addition of a POPO to a processed POAO does not automatically mean that the resulting food falls within the definition of CP. Three elements of importance are highlighted:

- **The nature of the POPO and its function in the food**

  The guidance specifies that, in order to be considered a CP, the addition of a POPO to a POAO should **modify the main characteristics of the final product**.

  If the POPO only adds special characteristics or is necessary for the manufacture of the POAO this would not automatically result in the product being a CP.

  Examples given in the Q&A are cheese with herbs, yogurt with fruit, canned tuna in vegetable oil, etc. These remain POAO and should not be considered as CP. The reason is that the addition of these substances does not change the nature of the product and the safety. The control requirements imposed by hygiene legislation should continue to apply. E.g. such products must be produced in approved establishments in accordance with Regulation (EC) No 853/2004.

- **The quantity of the POPO**

  The legislation only specifies that what makes foodstuff subject to the rules applicable to CP is the fact that it is made by both POPO and processed POAO.

  The guidance states that the percentage of processed POAO included in the CP is therefore not a relevant factor.

1 https://food.ec.europa.eu/system/files/2022-07/ia_ic_composite-prods_qandas.pdf

- **The risk of the product**

  Under the previous legislation a threshold of 50% of processed POAO was applicable for products to be considered as CP. This has been removed and the import requirements are now based on the animal health or public health risk linked to those ingredients of animal origin and on the need to transport or store CP under controlled temperature conditions. The risk is therefore another factor to be considered.

  Regulation (EU) 2022/887 amending Regulation (EU) 2019/625 on requirements for entry into EU of Vitamin D3 (since replaced by Regulation (EU) 2022/2292) clearly states that due to the robust process by which Vitamin D3 is obtained from lanolin, there is no public health concern related to the importation of such product (Recitals 3,11 and 20). This limited public health concern mentioned was the reason for more flexible import conditions introduced in Regulation (EU) 2019/625 for Vitamin D3 and products containing it, as regards the list of countries from which it can be imported and the absence of need for Private Attestations and BCP control for shelf stable CP containing Vitamin D3 as only POAO. These requirements have been included in Regulation (EU) 2021/630 and carried over in Regulation (EU) 2022/2292 repealing and replacing Regulation (EU) 2019/625 from 15 December 2022.

When applied to food supplements, the following aspects must be taken into consideration

- Processed POAO such as Vitamin D3 can be sold as mixtures with ingredients such as vegetable oil (liquid preparations) or starch (dry preparations) for use as a food ingredient. The vegetable oil and the starch typically are the main ingredients (constituting over 99% of the mixture). Such mixtures can be considered as a CP. Also finished food supplements in which these ingredients are used can be considered as CP, provided all the POAO present are processed.
- Food supplements can contain ingredients of plant origin, such as botanicals, vitamins of plant origin, etc. These ingredients are characterising ingredients of the food supplement. Article 6(3)(a) of Directive 2002/46/EC explicitly requires to indicate in the labelling 'the names of the categories of nutrients or substances that characterise the product or an indication of the nature of those nutrients or substances'. This is additional to the mention of these ingredients in the list of ingredients or in the nutrition table by virtue of Regulation (EU) No 1169/2011.[2] When a food supplement contains both processed POAO and POPO as characterising ingredients, such products can be considered as CP.
- Food supplements can contain ingredients of plant origin, such as maltodextrin, starch or food additives of plant origin such as pullulan that are an integral part of the food supplement and essential for its characteristic format. Without the use of these POPO a tablet or capsule would not have its particular characteristics after manufacturing. Food supplements containing both processed POAO and POPO that are indispensable for the manufacturing of the specific format of a food supplement can be considered as CP.

2 Note: The notion of 'characterising ingredient' in this sense is not linked to the concept or 'primary ingredient', which is defined in Regulation (EU) No 1169/2011 as 'an ingredient or ingredients of a food that represent more than 50 % of that food or which are usually associated with the name of the food by the consumer and for which in most cases a quantitative indication is required'.

4. Manufacturing and import requirements

This Chapter describes the legal requirements for the manufacturing and import into the EU of Vitamin D3 and products containing Vitamin D3 of animal origin.

To identify the rules applicable to the manufacturing or imports of Vitamin D3 (and its precursors) and food supplements or preparations containing Vitamin D3, three aspects need to be assessed:

- That the Vitamin D3 is produced or imported under the requirements applying to food;
- Whether the product is a POAO or a CP;
- What the CN or HS code is under which the product is imported.

A distinction is to be made between products that are POAO and those that are CP.

A general overview is presented in Figure 2.

Figure 2: Summary of manufacturing and import requirements

	Vitamin D and its precursors (CN Code Chapter 29 (ex 2936))	Food supplements containing Vitamin D (imported under HS Code 2106)		
		Product of Animal Origin	Shelf stable Composite Product *	
			Containing processed POAO	Containing Vitamin D as only POAO
Imports into the EU	**Permitted** • R 2022/2292 Art 3 (CN Chapter 29)	**Permitted** • R 2022/2292 Art 3 (HS 2106)	**Permitted** • R 2022/2292 Art 3 (HS 2106)	**Permitted** • R 2022/2292 Art 3 (HS 2106)
Countries of origin	**All countries in R 2021/405, Annex XII** • R 2022/2292 Art 3 • R 2021/405 Art 22(a) **Import from China (Only for use in or as food supplement)** • D 2002/994 Art 2(2)	**Countries in R 2021/405 Annexes (as appropriate)** • R 2022/2292 Art 3 • R 2022/405, Annexes **Import from China permitted (only when containing substances listed in the annex to D 2002/994)** • D 2002/994 Art 2(2); Annex	**Countries in R 2021/405 or R 2021/404 Annexes (as appropriate)** • R 2022/2292 Art 20(b) and (c) **Import from China permitted (only when containing substances listed in the annex to D 2002/994)** • D 2002/994 Art 2(2); Annex	**No need to come from an approved country** • R 2022/2292 Art 20(4) **Import from China permitted** • D 2002/994 Art 2(2); Annex
Approved residue monitoring plan	**No need to come from a country with an approved residue monitoring plan** • R 2022/2292 Art 5(2)	**Countries in Annex –I of R 2021/405** • R 2022/2292 Art 3 • R 2021/405 Annex –I	**Countries in Annex –I of R 2021/405** for each POAO contained (except for gelatine, collagen or highly refined products such as Vitamin D) (unless originating from a EU Member State) • R 2022/2292 Art 20(3) • R 2022/405 Annex –I	**No need to come from a country with an approved residue monitoring plan** • R 2022/2292 Art 20(4)
Manufacturing requirements	**EU:** Approved establishments • R 853/2004 Art 4(2), Annex III Section XVI **Import:** Approved establishments, No need to be listed establishments • R 2022/2292 Art 13(1)(a) (CN Chapter 29 not listed)	**EU:** Approved establishments • R 853/2004 Art 4 **Import:** Listed establishments • R 2017/625 Art 127 • R 2022/2022 Art 13(1)(a) (HS 2106) (No listing for Vitamin D and the gelatine capsule part of the product) • R 2022/2292 Art 13(1)(a) and Art 14	**EU:** No approved establishments • R 853/2004 Art 1(2) **Import:** All POAO must comply with applicable requirements • R 2022/2292 Art 20(1) and 22 All POAO must come from listed establishements (except Vitamin D and gelatine capsules) • R 2022/2292 Art 13(1)(a) and Art 14	**EU:** No approved establishments • R 853/2004 Art 1(2) **Import:** Vitamin D must comply with the applicable requirements • R 853/2004 Art 6(4) • R 2022/2292 Art 20 and 22
Identification Mark - Certificates	**EU:** Identification mark required • R 853/2004 Art 5 **Import:** Identification mark required • R 853/2004 Art 6(1)(c)(i) Health certificate required • R 2022/2292 Art 21(1)(b) (CN Chapter 29) • R 2022/2235 Art 24 (Annex III, Chapter 46)	**EU:** Identification mark required • R 853/2004 Art 5 **Import:** Health certificate required • R 2022/2292 Art 21(1)(b) (HS 2106) • R 2022/2235 as appropriate (Gelatine capsules not derived from ruminant bones: No health certificate) • R 2022/2292 Art 21(3)	**EU:** No identification mark • R 853/2004 Art 1(2) **Import:** Private attestation • R 2022/2292 Art 22(1) (HS 2106) • 2020/2235 Art 33 (Annex V) (Non-shelf stable products: health certificate) • R 2022/2292 Art 21(1) (HS 2106) • R 2020/2235 Art 28 (Annex III, Chapter 50) (Gelatine capsules not derived from ruminant bones: No health certificate) • R 2022/2292 Art 21(3)	**EU:** No identification mark • R 853/2004 Art 1(2) **Import:** No private attestation • R 2022/2292 Art 21-22 in conjunction
Controls at Border Control Post (BCP)	**Control at BCP** • R 2021/632 Annex Chapter 29 (CN ex 2936) • R 853/2004 Art 6(3)(a)	**Control at BCP** • R 2021/632 Annex Chapter 21 (CN ex 2106) • R 853/2004 Art 6(3)(a)	**No control at BCP** for shelf stable food supplements packaged for final consumer (HS ex 2106) • R 2021/630 Annex	**No control at BCP** • R 2021/630 Art 3(1)(b); Annex

* The rules applying to non-shelf stable CP are different, but are not described, as this is considered not relevant for food supplements.

4.1. Vitamin D3 and its precursors (CN 2936) intended for use as or in food

Vitamin D3 produced from sheep's wool lanolin is considered a POAO. Vitamin D3 is produced via a number of chemical conversions from lanolin. The intermediates of these chemical conversions are collectively termed Vitamin D3 precursors. These precursors are also considered POAO and must comply with the same requirements as Vitamin D3.

- **New hygiene requirements have been included in Annex III of Regulation (EC) No 853/2004 (Section XVI: Highly Refined Products) by Regulation (EU) 2022/2258.**

  Under point 2, it is now specified that the raw materials used for the manufacturing of the highly refined products such as fat derivatives, including vitamin D3 must be derived from:

  (a) animals, including feathers thereof, which have been slaughtered in a slaughterhouse and the meat of which have been found fit for human consumption following ante-mortem and post-mortem inspection, or

  (b) fishery products complying with Section VIII, or

  (c) Rendered fats and greaves complying with Section XII, or wool, if these products are submitted to one of the following processes:

  (1) transesterification or hydrolysis at a temperature of at least 200 °C, under corresponding appropriate pressure, for at least 20 minutes (glycerol, fatty acids and esters);

  (2) saponification with NaOH.12M:

  – in a batch process at 95 °C for three hours; or

  – in a continuous process at 140 °C 2 bars (2 000 hPa) for eight minutes; or

  (3) hydrogenation at 160 °C at 12 bars (12 000 hPa) for 20 minutes

It is to be noted that treatments that differ from the above requirements e.g. applied to the production of Vitamin D3 for use in other regulated categories, such as medicinal products, are not acceptable as alternative methods.

Because specific requirements are now included in this legislation, this means that:

- **When produced in the EU**

  – Vitamin D3 and its precursors **must be produced in an Approved Establishment** (Article 4(1)). These products must be produced in a way that ensures that the treatment of the raw materials used eliminates any animal or public health risk. These treatments are specified in Annex III, Section XVI of Regulation (EC) No 853/2004 as described above.

  – Vitamin D3 preparations that are not CP, **must carry an Identification Mark** (Regulation (EC) No 853/2004, Article 5(1)).

- **When produced outside the EU:**
  - Vitamin D3 and its precursors (under CN Chapter 29) must be imported from a **third country or region thereof included in the list** for those animals and goods laid down in Regulation (EU) 2021/405 (Regulation (EU) 2022/2292, Article 3).

    These are the countries or regions thereof, listed in Annex XII (Regulation (EU) 2021/405, Article 22(a)).
  - Import of POAO, **originating from China** are only permitted for products that are included in the Annex to Decision 2002/994/EC (Article 2(2)).

    Part I of this Annex includes substances to be used as or in food supplements as regulated under Directive 2002/46/EC. This covers Vitamin D3 intended for use in food supplements and food supplements containing Vitamin D3 as only POAO. Gelatine and substances to be used as food additives are also listed. Amending legislation to allow the imports also of the precursors and substances to be used in other categories of foods is underway.
  - The products **must come from an establishment, approved** by the local responsible competent authority (Regulation 853/2004, Article 6, point 1(c)(ii)) and Regulation 2017/625, Article 148). The establishments are not required to be listed in EU legislation and TRACES by virtue of Regulation 2022/2292, Article 13(1)a).

    Authorities from third countries therefore do not need to submit a list of establishments to the EU, but a list of establishments complying with the EU requirements for Vitamin D3 must be available and presented e.g. during an audit.
  - Vitamin D3 preparations that are not CP, **must carry an Identification Mark** (Regulation (EC) No 853/2004, Article 6(1)(c)(i).
  - Consignments of Vitamin D3 and its precursors (under CN Chapter 29) must be accompanied by a **Health Certificate** (Regulation 2022/2292, Article 21(1)(b).

    The relevant Health Certificate, to be signed by a certifying officer, is that presented in Annex III, Chapter 46 of Regulation (EU) 2020/2235 (Art 24).
  - Consignments of Vitamin D3 and its precursors (Under CN 2936) must be **presented for controls at BCP** (Regulation (EU) 2021/632 Annex Chapter 29).

4.2. Vitamin D3 preparations used in or as food supplements (HS 2106)

4.2.1. Products of Animal Origin

Food supplements and food supplement ingredients that only contain POAO (e.g. gelatine capsules filled with fish oil and/or Vitamin D3 of animal origin) are allowed to be produced and imported in the EU under the following conditions:

- **When produced in the EU:**
  - POAO for which hygiene requirements are laid down in the Annexes of Regulation (EC) No 853/2004 must be produced in an **Approved Establishment** (Article 4).
  - POAO for which hygiene requirements are laid down in the Annexes of Regulation (EC) No 853/2004 must carry an **Identification Mark** (Article 5).
- **When produced outside the EU:**
  - POAO (under HS 2106) must be imported from a **third country or region thereof included in the list** for those animals and goods laid down in Regulation (EU) 2021/405 (Regulation (EU) 2022/2292, Article 3).

    These are the countries or regions thereof, listed in the respective Annexes of Regulation (EU) 2021/405 covering the POAO contained in the product.

    As regards Vitamin D3, these are the countries or regions thereof, listed in Annex XII (Regulation (EU) 2021/405, Article 22(a)).

    Depending on the types of POAO present in the product, these need to come from EU-approved establishments listed in TRACES.
  - Import of products of animal origin **originating from China** are only permitted for products that are included in the Annex to Decision 2002/994/EC (Article 2(2)).

    Part I of this Annex includes substances to be used as or in food supplements as regulated under Directive 2002/46/EC.
  - Consignments of POAO under HS 2106 must be dispatched from, and obtained or prepared in, **EU-approved establishments** that appear on lists drawn up and kept up-to-date in accordance with Article 127(3)(e)(ii) and (iii) of Regulation (EU) 2017/625 (Regulation 2022/2292, Article 13(1)(a)).

    No listing is required for the establishments from which Vitamin D (and gelatine capsules) originate (Regulation 2022/2292, Article 13(1)a and Article 14).

- Consignments of POAO (under HS 2106) must be accompanied by a **Health Certificate** (Regulation 2022/2292, Article 21(1)b).

  The relevant Health Certificate is the Certificate presented in the Annex III of Regulation (EU) 2020/2235, covering the POAO contained in the product.

  As regards Vitamin D3, this is the certificate, to be signed by a certifying officer, presented in Regulation (EU) 2020/2235, Annex III, Chapter 46 (Article 24).

  A certificate is only required for the POAO contained in the food supplement and not for the gelatine capsule under HS 3913, 3926 or 9602, when not derived from ruminant bones (Regulation 2022/2292, Article 21(3). If the gelatine is derived from ruminant bones, however, the certificate is in principle the one listed in Regulation 2020/2235, Annex III, Chapter 41 (Article 19).

  Appendix 2 lists a number of further aspects of imports of gelatine capsules and food supplements placed on the market as gelatine capsules.

- Consignments of POAO (Under HS 2106) must be presented for **controls at BCP** (Regulation (EU) 2021/632 Annex Chapter 21).

4.2.2. Composite Products (CP)

Note: The below describes the requirements for food supplements and food supplement ingredients that are **shelf stable CP**. The rules applying to non-shelf stable CP are different, but are not described, as this is considered not relevant for food supplements. Non-shelf stable CP must always be accompanied by an animal health/official certificate in accordance with the model set out in Chapter 50 of Annex III to Regulation (EU) 2020/2235 (Article 28).

Shelf stable CP are CP that do not need to be transported or stored under controlled temperatures. 'Controlled temperature' means that the products have been produced in a way that does not allow their transport and storage at ambient temperature. A product that must be kept refrigerated (e.g. below 7°C) would be considered as non-shelf stable in this context.

If storage at a temperature in the normal range of ambient temperatures is mentioned on the label (e.g. store below 25°C) for stability or shelf-life reasons, this should not be considered as 'controlled temperature'. Likewise, if the FBO would choose to transport or store the product at a lower temperature (above 0°C) to preserve its quality for technological reasons, such products would still be considered shelf stable. It is nevertheless important to explain in the Private Attestation why such controlled temperature is required to clearly distinguish such products from non-shelf stable ones.

Whether a food ingredient or food can be considered a CP or not needs to be assessed on a case-by-case basis as described in Chapter 3 of the present guidelines. The below applies to preparations and food supplements containing Vitamin D3 of animal origin that are shelf stable CP and classified under HS 2106.

Food supplements and food supplement ingredients that contain both processed POAO and POPO (e.g. gelatine capsules filled with herbal ingredients and Vitamin D3) are allowed to be produced and imported in the EU under the following conditions:

- **When produced in the EU:**
  - CP do **not need to be produced in an Approved Establishment**, as CP are excluded from the scope of Regulation (EC) No 853/2004 (Article 1(2)).

    The establishment manufacturing CP should however still be **registered with the local competent authority**.

    The establishments processing the POAO contained in the CP must be approved and listed in TRACES where this is legally required for the POAO concerned. This is also the case for establishments manufacturing both CP and POAO.

    The processed POAO contained in the CP must comply with the requirements applicable to them (Regulation (EC) No 853/2004, Article 6(4)).
  - CP **do not need to carry an Identification Mark** as CP are excluded from the scope of Regulation (EC) No 853/2004 (Article 1(2)).
- **When produced outside the EU:**
  - The processed POAO contained in the CP must comply with the requirements applicable to them (Regulation (EC) No 853/2004, Article 6(4)).
  - Establishments in a third country which are manufacturing CP should be **registered by the local responsible competent authority**. They do not need to be approved by the competent authority and listed in TRACES (Regulation 853/2004, Article 6(4).

    However, the establishments processing the POAO contained in the CP must be EU-approved and listed in TRACES where this is legally required for the POAO concerned (Regulation 853/2004, Article 6(4)). This is also the case for establishments manufacturing both CP and POAO.
  - CP that do not need to be transported or stored under controlled temperatures (i.e. shelf stable products) and which contain processed POAO for which requirements are laid down in Annex III to Regulation (EC) No 853/2004 and other than colostrum-based products or processed meat, **must originate from third countries** or regions thereof that are authorised to export meat products, dairy products, fishery products or egg products to the EU on the basis of EU animal and public health requirements and are listed at least for one of these products of animal origin (Regulation 2022/2292, Article 20(2)(c)).

    These lists are included in the Annexes of Regulation (EU) 2021/405 or Regulation (EU) 2021/404 as appropriate.
  - CP **can only originate from a third country** or region thereof included in the list laid down in the Annex to Decision 2011/163/EU as having an **approved residues monitoring plan** in accordance with Directive 96/23/EC for the species/commodity from which the processed POAO contained in the CP, with the exception of collagen, gelatine and the highly refined products listed in Section XVI, point 1, of Annex III to Regulation (EC) No 853/2004, are derived (Regulation 2022/2292, Article 20(3)).
  - Shelf stable CP not containing colostrum-based products or processed meat other than gelatine, collagen or highly refined products referred to in Section XVI of Annex III to Regulation (EC) No 853/2004 must be accompanied by a **Private Attestation** (Regulation 2022/2292, Article 22(1)(b)).
  - The model of private attestation which must accompany the CP is set out in Annex V to Regulation (EU) 2020/2235 (Art 33).

Private Attestation

The Private Attestation must be signed by the representative of the importing FBO (Regulation 2022/2292, Article 22(1)). This person needs to be legally established in the EU. A private attestation cannot be e-signed. It should be presented in paper form.

For CP that have to undergo official controls at a BCP, there is no requirement to provide an original document to the BCP. As a Private Attestation is not an official certificate or an official attestation in the meaning of Articles 89 and 91 of Regulation (EU) No 2017/625, the scanned copy of the private attestation can be uploaded in TRACES with part 1 of the Common Health Entry Document (CHED).

When several CP are present in the same package, one Private Attestation for each CP must be provided. Nevertheless, it could be possible to enter various CP with different CN codes in the same Private Attestation if they all refer to the same information provided by the Private Attestation and, in particular, that they all meet the same guarantees. If the Private Attestation covers several CP, the description of goods in box I.27 and the statements in points 4 (list of ingredients) and 5 (list of approved establishments) must be presented clearly and separately for each CP.

For CP exempted from official controls at BCP, the private attestation must accompany the products at the time of the placing on the market. It must be retained until the end of the shelf-life of the CP.

The original private attestation should be retained by the first importer indicated in the Private Attestation. When the batch of a shelf stable composite product is divided and distributed in the different EU Member States, copies may accompany the different lots without translation of the original document into the languages of the different EU Member States of destination. The importer must in any case ensure the traceability inside the EU.

To protect intellectual property, it is possible to group the information on the percentage of ingredients contained in the CP in the private attestation. The percentage of all dairy ingredients could be grouped, or the percentage of all plant ingredients could be grouped. Only ingredients belonging to the same category can be grouped.

A private attestation is also sufficient for shelf stable CP not containing any other processed meat than gelatine, collagen or highly refined products derived from meat.

Regulation (EU) 2022/2292 does not apply to goods intended for human consumption for the purpose of samples for product analysis and quality testing without being placed on the market. A Private Attestation is not required in such cases.

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

– Depending on the the CN or HS code and on their inclusion, or not, in the Annex to Regulation (EU) 2021/632, to be read in conjunction with Regulation (EU) 2021/630 which provides for certain exemptions, certain shelf stable CP must be **presented for controls at BCP** (Regulation (EU) 2021/632 Annex Chapter 21).

  However, **shelf stable food supplements packaged for the final consumer**, containing processed POAO (including glucosamine, chondroitin or chitosan) are exempted from controls at BCP provided they meet the following requirements (Regulation 2019/630, Article 3(1) and Annex):

  - they comply with the requirements for entry into the EU as specified above (Regulation (EU) 2022/2292, Article 20(2));
  - any dairy and egg products contained complies with the treatments as described in Article 163(1) of Regulation (EU) 2020/692;
  - they are identified as intended for human consumption;
  - they are securely packaged or sealed.

  For such products that are exempted from official controls at BCP, such controls are performed at the place of destination, the point of release for free circulation, or the warehouses or premises of the FBO responsible for the consignment of the CP (Regulation 2021/630, Article 4(2)).

– The Private Attestation must be available and accompany the products at the time of the placing on the market (Regulation 2022/2292, Article 22(2)).

- **When Vitamin D3 is the only processed POAO contained in the shelf stable CP, the rules for imports are simplified:** [3]

  a. The CP does **not need to originate from third countries** or regions thereof that are authorised to export meat products, dairy products, fishery products or egg products to the EU on the basis of EU animal and public health requirements and are listed at least for one of these products of animal origin (Regulation 2022/2292, Article 20(4).

  b. The CP does **not need to be imported from a third country** or region thereof included in the list laid down in the Annex to Decision 2011/163/EU as having an **approved residues monitoring plan** in accordance with Directive 96/23/EC for the species/commodity from which the processed POAO contained in the CP are derived) (Regulation 2022/2292, Article 20(4)).

  c. The CPs does **not need to come from an EU-approved establishment** listed in TRACES but the establishment must be registered by the responsible competent authority.

  d. The CP does **not need to be accompanied by a Private Attestation** (Regulation 2022/2292, Articles 20 and 22 in conjunction).

  e. The CP does **not need to be presented to controls at BCP** (Regulation (EU) 2021/630, Article 3(1)(b)).

3 This will also apply if apart from vitamin D3 a food supplement contains food additives / enzymes / flavourings as only POAO.

5. Appendix I: Legal references

- **Directive 2002/46/EC** of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (Text with EEA relevance)Text with EEA relevance

  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02002L0046-20220930&qid=1663401088610

- **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

  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02002R0178-20220701&qid=1663394512492

- **Commission Decision of 20 December 2002** concerning certain protective measures with regard to the products of animal origin imported from China **(2002/994/EC)**

  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02002D0994-20150703&qid=1663491627489

- **Regulation (EC) No 852/2004** of the European parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs

  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02004R0852-20210324&qid=1663398943408

- **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

  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02004R0853-20211028&qid=1663395293533

- **Commission Decision of 16 March 2011** on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC

  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02011D0163-20220811&qid=1663573935912

- **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)

  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02017R0625-20220128&qid=1663394369458

- **Commission Delegated Regulation (EU) 2019/2122** of 10 October 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council as regards certain categories of animals and goods exempted from official controls at border control posts, specific controls on passengers' personal luggage and on small consignments of goods sent to natural persons which are not intended to be placed on the market and amending Commission Regulation (EU) No 142/2011

  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02019R2122-20220627&qid=1663739974273

- **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

  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02020R0692-20220120&qid=1663603093881

- **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

  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02020R2235-20220716&qid=1663570666531

- **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 of the Council

  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02021R0404-20221027&qid=1672848984808

- **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

  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02021R0405-20220812&qid=1663491294159

- **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

  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02021R0630-20220627&qid=1663570142695

- **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

  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02021R0632-20220818&qid=1663590477087

- **Commission Delegated Regulation (EU) 2022/2292** of 6 September 2022 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

  https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02022R2292-20221124&qid=1672839517314

6. Appendix 2: Specificities relating to gelatine

a. Gelatine

Gelatine is considered a POAO, but since it is highly processed, specific exemptions apply.

Gelatine, collagen and certain highly refined products can be imported without submitting a residue monitoring plan and, consequently, it is not necessary that countries are listed in the Annex -I to Regulation (EU) 2021/405 to be allowed to export these products to the EU or to use these products as ingredients in CP for export to the EU.

Listing in accordance with Articles 18, 19 or 20 of Regulation (EU) 2021/405 however remains mandatory. These articles and respective annexes cover the lists of third countries or regions thereof from which imported gelatine and raw materials for the production of gelatine, depending on the animal source, can originate.

Gelatine must also originate from approved establishments (Regulation (EC) 853/2004, Article 4(2)) and be accompanied by a heath certificate (Regulation (EU) 2020/2235, Article 19). The lists of approved establishments are consultable on the website of the European Commission. [4]

b. Gelatine capsules

Empty gelatine capsules are considered as gelatine and should therefore comply with the import conditions for gelatine, such as the requirement to originate from third countries or regions thereof authorised to export gelatine to the EU and the guarantees to be provided on the manufacturing of raw materials in accordance with Article 15 of Regulation (EU) 2022/2292.

However, as the public health risk from establishments manufacturing gelatine capsules is negligible, gelatine capsules using HS codes under headings 3913, 3926 or 9602 are exempted from the requirements for entry into the EU in relation to establishments and certification, except, as regards certification, when the gelatine capsules contain gelatine derived from ruminant bones in accordance with Regulation (EC) No 999/2001 (Regulation 2022/2292, Article 21(3)).

No official certificate is necessary for the entry into the EU of gelatine capsules covered by HS headings 3913, 3926 or 9602, nor for gelatine capsules as part of POAO or as part of CP, where those capsules are not derived from ruminant bones (Regulation (EU) 2022/2292, Article 21(3).

In the case of empty gelatine capsules containing gelatine derived of ruminant bones, in the absence of a specific health certificate model for gelatine capsules, the model official certificate for gelatine (Chapter 41 of Annex III to Commission Implementing Regulation (EU) 2020/2235) is to be used.

4 https://webgate.ec.europa.eu/tracesnt/directory/publication/establishment/index#!/search?sort=country.translation

c. Food supplements under the form of gelatine capsules

Food supplements using gelatine capsules can either be POAO or CP. As no health certificate is required for empty gelatine capsules under CN 3913, 3926 or 9602, if they are not derived from ruminant bones (Regulation 2022/2292, Article 21(3)), for consistency, no certificate or private attestation is required for the same gelatine capsules filled only with POPO or with other POAO (fish oil for example).

- In the case where the food supplement is a shelf stable CP containing only gelatine as processed POAO, a private attestation as set out in Annex V to Regulation (EU) 2020/2235, is sufficient. This is also valid for collagen and highly refined products of meat origin contained in the product. A certificate for the gelatine part is required in case the gelatine is derived of ruminant bones (Regulation 2022/2292 Article 21(3)).
- In the case where the food supplement is a shelf stable CP containing not only gelatine but also other processed POAO, the respective certificates are required for any colostrum-based products or processed meat other than gelatine, collagen or highly refined products contained in the capsule. A certificate for the gelatine part is still required in case the gelatine is derived of ruminant bones (Regulation 2022/2292 Article 21(3)).
- In the case where the food supplement under HS 2016 is not a CP but a gelatin capsule filled with one or more other POAO, the respective certificates are required for the product itself and for any colostrum-based products or processed meat, other than gelatine, collagen or highly refined products contained in the capsule. A certificate for the gelatine part is still required in case the gelatine is derived of ruminant bones (Regulation 2022/2292, Article 21(3)). Animal health requirements must be signed by an official veterinarian and the public health requirements must be signed by a certifying officer.

In all cases however, the gelatine used to produce the gelatine capsule must comply with the import conditions as described under point A above.

food supplements europe

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