

Voluntary Report – Voluntary - Public Distribution

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Report Name: Update on Changing EU Import Conditions for Composite Products

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Report Highlights:

U.S. exporters of composite products will face new documentary requirements for shipments to the European Union after January 15, 2022. The new requirements are broken down into three categories of composite products: non-shelf stable, shelf stable with meat, and shelf stable without meat. A new mandatory U.S. government-issued export certificate is needed for all non-shelf stable composite products and for shelf-stable composite products containing meat (except gelatin, collagen, and highly refined products derived from meat). The Food Safety and Inspection Service (FSIS) will issue the certificate for composite products that bear the USDA mark of inspection. The Agricultural Marketing Service, Dairy Program, will issue the composite products certificate for products that do not bear the USDA mark of inspection, regardless of whether dairy is an ingredient in the composite product. For shelf-stable composite products not containing meat, a private attestation from the importer will be required.

Acknowledgement

This report was prepared with contributions from multiple U.S. Government agencies, including the Foreign Agricultural Service (FAS), the Agricultural Marketing Service (AMS), the Food Safety and Inspection Service (FSIS), and the U.S. Food and Drug Administration (FDA).

Executive Summary

The EU defines composite products as “food containing both products of plant origin and products of processed animal origin” which can include any combination of meat, dairy, and egg components in the final product. Composite products include a wide variety of products, including cheesecakes, high protein food supplements, pizza, and some condiments. Following changes in several related pieces of [EU legislation](#), the import requirements on these products have changed. Previously, import requirements were based on the quantities of animal origin ingredients expressed as a percentage of the composite product. Now, the import requirements are based on the “risk” linked to the composite product regardless of the amount of animal ingredients in the final product. The EU defines “risk” based on the three categories of composite products (non-shelf stable, shelf stable with meat and shelf stable without meat). As a result, beginning on January 15, 2022: 1) Non-shelf stable composite products and shelf stable products containing meat will require a U.S. Government-issued certificate; and, 2) shelf stable products without meat will require a private attestation with the qualifications and title of the importer.

The New System in a Nutshell

The new regulations on the entry of composite products establish three categories of composite products: (1) non-shelf stable composite products, (2) shelf stable composite products that contain meat ingredients and (3) shelf stable composite products that do not contain meat ingredients.¹ Articles 12-14 of Commission Delegating Regulation (EU) [2019/625](#) lay out the different entry requirements for each of these three categories. The model certificates can be found in [Commission Implementing Regulation \(EU\) 2020/2235](#) (with further updates foreseen [in Commission Implementing Regulation \(EU\) 2022/36](#)) in Chapter 50 for composite products and Chapter 52 for Transiting Composite Products. For all three categories of composite products, all ingredients of animal origin must be sourced from [EU-approved establishments](#). The Regulation includes a list of HS codes of the products that fall within its scope.

The EU will require a U.S. Government-issued composite product certificate for all non-shelf stable products (category 1) and for shelf stable composite products with a meat ingredient (category 2). For shelf stable products not containing meat (category 3), a private attestation will be required confirming that the

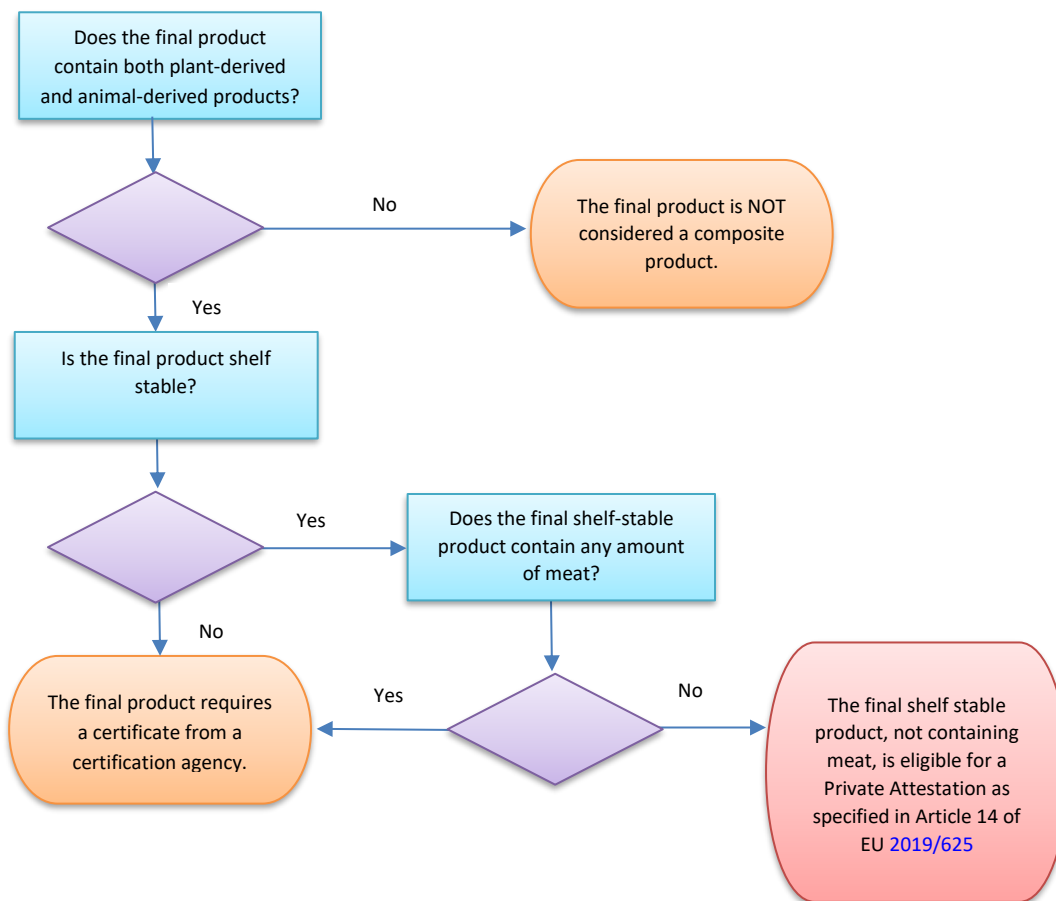
¹ Please note: collagen, gelatin, and highly-refined products derived from meat are not considered “meat products” for these categories.

consignments comply with the applicable requirements. Provided the public and animal health risk is considered minimal, a subset of category 3 products will be exempted from border checks. For these products, the importing food business operator will still have to provide the private attestation. [Commission Delegated Regulation \(EU\) 2021/630](#) lists the exempt products. Examples of products on this list are food supplements, cakes, pasta, and confectionery items.

Background: Does my composite product need a certificate from a certification agency?

The EU defines composite products as “food containing both products of plant origin and products of processed animal origin” which can include any combination of meat, dairy, egg components in the final product. Figure 1 below provides a flow chart to assist in determining if a food product is a composite product, and if the composite product requires a certificate issued by a regulatory agency.

Figure 1: Determination of a Composite Product



If a composite product is shelf stable and does NOT contain meat, the product is eligible to enter the EU market through use of the Private Attestation form provided in Annex V [of Commission Implementing Regulation \(EU\)](#)

[2020/2235](#). Importers of shelf-stable composite products NOT containing meat should complete the Private Attestation form in coordination with exporters.

A composite product certificate from a regulatory agency is required if:

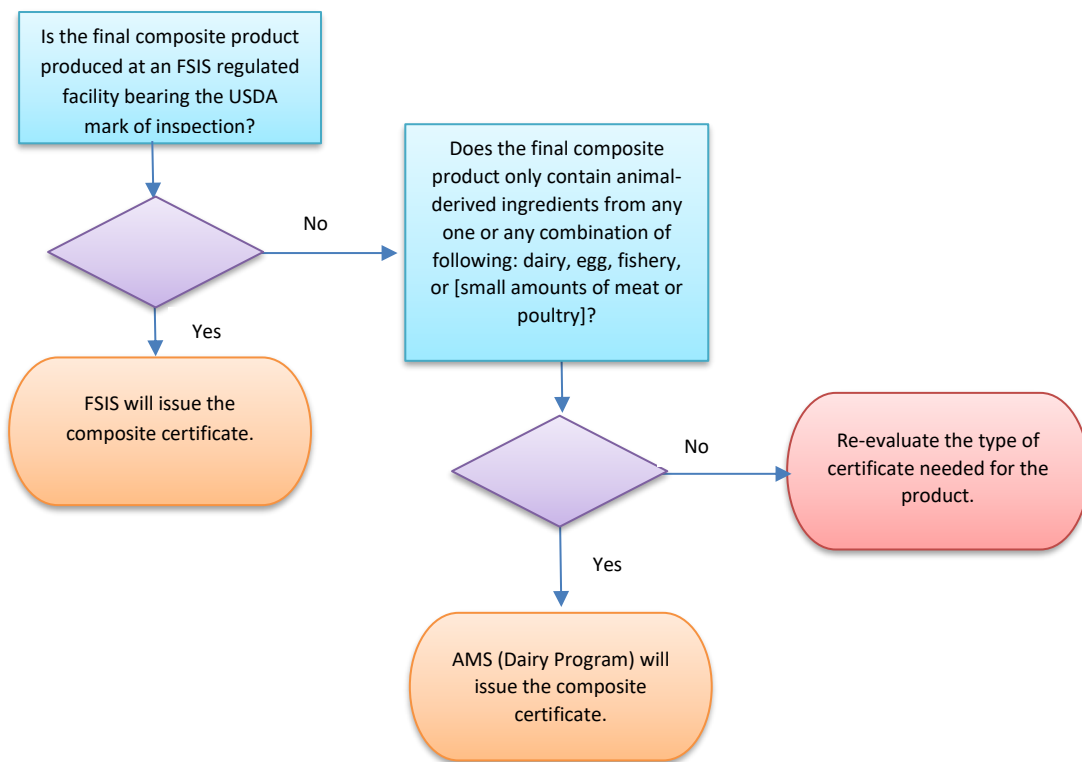
1. A shelf-stable composite product contains meat, or
2. The composite product is NOT shelf stable.

Which agency provides a certificate for my composite product?

The Food Safety and Inspection Service (FSIS) will issue certificates for composite products that are manufactured in a facility regulated by FSIS and bear the USDA mark of inspection.

The Agricultural Marketing Service (AMS) Dairy Program will issue certificates for composite products that do not bear the USDA mark of inspection (regardless of whether dairy is an ingredient in the composite product).

Figure 2: Determination of Certification Agency



What information do I need to include for a composite product certificate produced at an FSIS-regulated facility?

- All animal-derived ingredients must be sourced from EU listed/approved facilities and the EU approval number must be provided when applying for a certificate.
- All dairy ingredients must be accompanied with a Certificate of Conformance as described in the AMS Dairy Program's Export Verification Program (EVP) for the EU.
- The composite product certificate is available at [FSIS Export Library \(EU Requirements\)](#).

What information do I need to include for a composite product certificate from AMS (Dairy Program)?

This section is applicable for the Chapter 50 Composite Product certificate for products intended for consumption within the EU.

Composite product manufacturer

Composite product manufacturers are not required to be on an EU approved list; however, composite product manufacturers are required to be registered with the competent authority. If a composite product manufacturer is on an EU list, provide the EU-listed number to identify the facility. If a composite product manufacturer is not on an EU list, provide the FDA Establishment Identifier (FEI) number to identify the facility.

Animal-derived ingredients

Each animal-derived ingredient in a composite product is required to be sourced from an EU-listed facility. Please check the EU's "[IMSOC TRACES Establishment Lists](#)" website to ensure U.S. facilities are properly listed. Additionally, if a foreign-sourced animal-derived ingredient is used, check the appropriate country's list to be certain the facility is EU listed. All sources of animal-derived products must be EU-listed and the EU number must be provided, regardless of the country of origin. If multiple facilities provided animal-derived ingredients, all facilities must be identified with their EU number. Special note for any foreign-sourced animal-derived ingredients: In addition to providing the facility EU number, exporters must also identify the country of origin, facility name, city, region (state), date the number was obtained from the EU facility list website, and a copy of the EU facility list identifying the ingredient supplier(s).

- Dairy ingredients must be identified with the EU-approved establishment number for each ingredient. Additionally, a Certificate of Conformance as described in the AMS Dairy Program's [Export Verification Program](#) must be provided.
- Egg ingredients must be identified with the EU-approved establishment number for each ingredient. Special note on composite products containing egg: Composite product manufacturers utilizing egg products as an ingredient must participate in the AMS [Processed Egg and Egg Products Verification Program](#) to be eligible for an EU Composite Product Certificate.
- Fishery product ingredients must be identified with the EU-approved establishment number for each ingredient.
- Meat or poultry ingredients must be identified with the EU-approved establishment number for each ingredient, along with the species, treatment, and country of origin of the product. Additionally, to ensure the meat or poultry ingredient(s) meet specific EU requirements, a copy of the EU Health Mark for the meat or poultry ingredient(s) and their applicable production codes must be provided. This information will support that the meat or poultry ingredient(s) participate in the applicable EU EVPs such as the Non-Hormone Treated Cattle (NHTC) Program: Beef and Veal, the Pork for the European

Union (PFEU) Program, or the Poultry Export Verification (PEV). Details on these programs are provided in the [FSIS Import & Export Library for the European Union](#) in the “Other Requirements” section. Special note for foreign-source meat ingredients: If a foreign-sourced meat product is utilized as an ingredient in a composite product, first confirm via the [FSIS Import & Export Library](#) that the supplier is eligible to import the meat product into the U.S. Second, referencing the “[IMSOC TRACES Establishment Lists](#),” obtain the EU-approved facility identification number and other required information to request a certificate.

Cold Storage Facilities

If a composite product is shipped from a cold storage facility, the cold storage facility must be on an EU-approved facility list. Thus, if a composite product is shipped from a cold storage facility, provide the EU approved cold storage facility number.

What information do I need to include for a composite product transit certificate?

This section is applicable for the Chapter 52 Composite Product Transit Certificate for products transiting through the EU to another country.

For FSIS regulated composite products, the transit composite product certificate is available at [FSIS Export Library \(EU Requirements\)](#).

Composite product manufacturer

Composite product manufacturers are not required to be on an EU-approved list; however, composite product manufacturers are required to be registered by their competent authority. If a composite product manufacturer is on an EU list, provide the EU listed number to identify the facility. If a composite product manufacturer is not on an EU list, provide the FDA Establishment Identifier (FEI) number to identify the facility.

Animal-derived ingredients

U.S.-sourced animal-derived ingredients included in composite products transiting through the EU are NOT required to be sourced from an EU listed facility. However, if a facility is not on an EU list, a U.S. regulatory agency identification number must be provided for the facility.

- Dairy ingredients must be identified with each ingredient’s facility number. This may be an EU-approved establishment number, an Interstate Milk Shipments number, USDA plant number, or FEI number. Along with the manufacturing facility number, the manufacturing date or date range for those dairy ingredients must also be provided. Additionally, a Certificate of Conformance as described in the AMS Dairy Program’s [Export Verification Program](#) must be provided.
- Egg ingredients must be identified with each ingredient’s facility number. This may be an EU-approved establishment number or USDA plant number. Special note on Chapter 52 Composite Product Transit certificates containing egg products: Because the composite product is not destined for the EU, composite product manufacturers utilizing egg products as an ingredient are not required to participate

in the AMS [Processed Egg and Egg Products Verification Program](#) to be eligible for an EU Composite Product Certificate.

- Fishery product ingredients do NOT require information to be included on the Chapter 52 transit certificate.
- Meat or poultry ingredients must be identified with either each ingredient supplier's EU-listed number or the [FSIS establishment number](#). Additionally, meat or poultry ingredients from the U.S. must be on the "[Official Listing for Eligible Suppliers for the USDA Export Verification Program for Products Transiting the EU.](#)" Special note on Chapter 52 Composite Product Transit certificates: Because the composite product is not destined for the EU, foreign-sourced meat/poultry ingredients are not required to be on EU lists. However, the supplying establishment must be on the relevant [FSIS Eligible Foreign Establishments list](#). Finally, the species, treatment, and country of origin of the product must be identified.

Certification Agency Contact Information:

USDA, AMS, Dairy Program

Dairy Grading Branch, Export Team

Phone: 202-720-3171

Fax: 844-804-4701

E-mail: DairyExportsQuestions@usda.gov

Food Safety and Inspection Service (FSIS)

Office of Policy and Program Development (OPPD)

Import/Export Program Development Staff (IEPDS)

Phone (202) 720-0082

E-mail: importexport@usda.gov

Other Agency Contact information:

For questions about the AMS Dairy Program Certificate of Conformance for dairy ingredients:

USDA, AMS, Dairy Program

Dairy Grading Branch, Audit Services

Phone: 559-509-2599

Fax: 844-804-4701

E-mail: DairyAuditServices@usda.gov

For questions about the AMS [Processed Egg and Egg Products Verification Program](#):

USDA, AMS, Livestock and Poultry

Quality Assessment Division, Auditing

Phone Number: 501-766-4782

Fax Number: 202-690-2746

E-mail: EV.Export@usda.gov

- Import Conditions for Composite Products:

https://ec.europa.eu/food/safety/international_affairs/trade/special-eu-import-conditions-composite-products_en

- Compilation of Questions & Answers

https://ec.europa.eu/food/sites/food/files/safety/docs/ia_ic_composite-prods_qandas.pdf

Attachments:

No Attachments.