USDA United States Department of Agriculture
Foreign Agricultural Service

GAIN Global Agricultural Information Network

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Report Name: Procedure for EU TRACES Registration of Honey and Other Apiculture Products Establishments - New EU Market Access Rules from 29 November 2024

Country: European Union

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Report Category: Sanitary/Phytosanitary/Food Safety, Honey, FAIRS Subject Report

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Report Highlights:

This report provides an overview of the processes required for U.S. apiculture product establishments to meet new EU import requirements and become registered in EU TRACES. Beginning November 29, 2024, all apiculture products entering the EU must come from EU-approved establishments. Composite products containing apiculture ingredients must also source those ingredients from EU-approved establishments. FDA and AMS have co-created a pathway for future compliance.

Contents

DISCLAMER:

This report was prepared by the staff of FAS/Washington and FAS/Brussels for U.S. exporters of domestic food and agricultural products. While every possible care has been taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies was not available. It is highly recommended that U.S. exporters verify the current certification requirements from AMS and FDA and verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped.

FINAL IMPORT APPROVAL OF ANY PRODUCTS IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Executive Summary

In accordance with EU regulation 2023/2652, starting November 29, 2024, all apiculture products entering the EU must come from EU approved establishments listed in the EU Trade Control and Expert System (TRACES). "Establishment" is defined as the unit in the business where the apiculture product is produced, and if the business has multiple such production units each must be approved and registered. These requirements do NOT apply to primary producers (i.e., beekeepers, etc.), and businesses involved only in transporting and storing apiculture products.

All composite products using apiculture ingredients must also source those ingredients from establishments in TRACES, but the process for compliance is different. A pathway for U.S. establishments to come into compliance for export to the EU has now been established.

To be registered in TRACES, establishments will first need to pass a three-part, on-site assessment done by the Agricultural Marketing Service (AMS). After successfully completing the AMS assessment, honey and other apiculture establishments must apply for inclusion on the "EU Honey Export List" (list name subject to change) via the FDA Export Listing Module (ELM). After verification of information, FDA will submit the updated list to TRACES on a quarterly basis. The FDA apiculture product module is not yet live, but updates will soon be available.

Section I. New EU Import Requirements

We wish to inform industry regarding implementation of Regulation (EU) 2023/2652 (https://eur-lex.europa.eu/eli/reg_del/2023/2652/oj), changing EU entry requirements for honey and other apiculture products. As of November 29, 2024, all apiculture products must come from EU-approved establishments.

This registration requirement applies to all apiculture products, which include honey, beeswax, royal jelly, propolis or pollen, intended for human consumption. The legislation specifically references the following product HS headings: 0409, 0410, 1212, 1521, and 1702.

The United States recently has clarified with the European Commission that this requirement also applies to composite products with honey and other apiculture products as ingredients.

(*Note: Regulation (EU) 2023/2652 contains also several other amendments to Regulation (EU) 2022/2292 on the EU's entry requirements for food of animal origin but this report addresses only apiculture products. The consolidated version of Regulation (EU) 2022/2292 on the EU's entry requirements for foods of animal origin is available from https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02022R2292-20231218&qid=1732533625115.)*

According to the regulation, consignments of honey and other apiculture products intended for human consumption may only enter the EU if dispatched from, obtained and/or prepared in EU approved establishments. These requirements do NOT apply to primary producers and businesses involved only in transporting and storing honey and therefore, these establishments do not have to be listed (Regulation 2022/2292, Art. 14). Specifically, the requirement is for apiculture product establishments that export to the EU or supply honey or other apiculture products to food manufacturers that export products that contain honey or other apiculture products into the EU to be registered on the list of Honey and Other Apiculture Products Establishments (HON) in EU's Trade Control and Expert System (TRACES).

TRACES is the European Commission's digital certification and management platform for all sanitary and phytosanitary requirements, supporting the importation of animals, animal products, food and feed of non-animal origin and plants into the European Union.

Section II. Registration of U.S. Apiculture Product Establishments

This section addresses the procedure for the EU approval of U.S. honey and apiculture establishment listing.

Establishments intending to export apiculture products to the EU or that supply these products to food manufacturers as ingredients in composite products exported to the EU must be registered in EU TRACES.

To be registered in TRACES as an approved establishment, packers must first successfully complete an on-site assessment by the Agricultural Marketing Service (AMS). After successful completion of the on-site assessment, packers must submit a request to the Food and Drug Administration (FDA) for listing in TRACES. AMS is an agency within the U.S. Department of Agriculture and FDA is an agency within the U.S. Department of Health and Human Services.

The procedures for each are described below:

A. Agricultural Marketing Service (AMS) Verification Process

On-Site Assessment

To satisfy EU Establishment requirements, packers must successfully complete an on-site assessment. The on-site assessment will consist of a Hazard Analysis and Critical Control Point (HACCP) Verification Survey, Plant Survey, and Food Defense System Survey by the AMS Specialty Crops Inspection Division (SCI).

To schedule an on-site assessment, producers must contact SCI. Requests for cost estimates, service, or additional questions can be sent to sciinspectionoperations@usda.gov.

After successful registration in TRACES, certification of honey and other apiculture exports may still be required prior to shipping to the EU. To arrange for additional product certification or other related inspection services, please contact SCI at sciinspectionoperations@usda.gov.

B. Food and Drug Administration (FDA) Electronic Portal and EU TRACES Registration Process

1. Application Requirement:
    - After successful completion of an Agricultural Marketing Service (AMS) on-site assessment, industry must apply for inclusion on the "EU Honey Export List" (this name may change when the system goes live) via the Export Listing Module (ELM). Please visit FDA's Online Applications for Export Lists for a link to this electronic system and step-by-step instructions when it goes live.
    - As part of the application process, applicants will be required to upload their AMS provided letter (and other written documentation) that indicates their findings, including compliance with Commission Delegated Regulation (EU) 2022/2292 and the requirements of Regulations (EC) No 853/2004, Article 6.
    - FDA will verify the applicant is an FDA-regulated manufacturer of honey or other apiculture product (and other establishments as applicable) as well as are in good regulatory standing with FDA for the products intended for export.

2. FDA Approval in ELM:
    - Approval of your application in the FDA's Export Listing Module (ELM) signifies that FDA has approved your establishment for inclusion on the export list.
    - This approval pertains solely to FDA's review and evaluation process.
3. Submission to TRACES:
    - Once FDA approves your application, your establishment will be included in the next quarterly update of the export list.
    - At that point, FDA will submit the updated list to TRACES (Trade Control and Expert System), managed by the European Commission.
4. TRACES Review and Decision:
    - While FDA facilitates the transmission of the export list, final review, and decision-making regarding acceptance of establishments remain under TRACES' authority.
    - The EU reserves the right to delay or reject applications, even after FDA has approved them.

Important Considerations

Please be aware that while FDA conducts a thorough and timely review of export listing applications, we have no control over the EU's review process or decisions once the list is submitted to TRACES. The timeline for inclusion in TRACES is subject to their procedures and requirements.

Contact Information

For general inquiries about export certification for CFSAN-regulated food products, please contact the CFSAN Export Certification Team at CFSANExportCertification@fda.hhs.gov or 240-402-2307. Additional information can be found at FDA's webpage for Food Export Lists.

C. EU TRACES Listing

Once the registration is finalized in EU TRACES and the receiving entity in the EU, DG SANTE, has completed the review and upload process, it will be publicly available on the TRACES website. The EU TRACES list of Honey and Apiculture approved facilities can be found here: https://webgate.ec.europa.eu/tracesnt/directory/listing/establishment/publication/index#!/search?classificationSectionId=HONEY_AND_OTHER_APICULTURE&classificationSectionChapter=food

Section III. U.S. Composite Products Containing Apiculture Products as Ingredients

This section addresses the official documentation for the import into the EU of composite products including an apiculture product ingredient. FAS received clarification from the European Commission that food manufacturers using apiculture products *as ingredients* will also be subject to the new rule.

The EU defines composite product as products foodstuffs intended for human consumption that contain *processed* products of animal origin and ingredients of plant origin. Three categories of composite product are distinguished: (1) non-shelf stable composite products, (2) shelf stable composite products that contain meat products and (3) shelf stable composite products that do not contain meat products. (Note: Shelf-stable products are products that do not need to be transported or stored under controlled temperatures).

The EU requires composite product certificates for all non-shelf stable products and for shelf stable composite products with a meat ingredient. For shelf stable products not containing meat, such as sauces with honey, no certificates signed by the U.S. Government are required. For these products, the representative of the importer must declare that the goods meet the relevant EU requirements, using the "Private Attestation" model form in Annex V of Commission Implementing Regulation (EU) 2020/2235. [1](see in the annex).

The importer will have to provide the EU establishment approval number of the honey ingredient establishment on the private attestation. Importers have been able to use an FDA registration number on this attestation, but it is our understanding that the EU approval number will be required as of November 29, 2024.

More information on the import conditions for composite products is available on the European Commission's website. This website also includes a compilation of Questions & Answers intended to clarify a multitude of practical questions that have been raised on the new rules.

For (1) non-shelf stable composite products and (2) shelf stable composite products that contain meat products, a composite product certificate is required. This certificate is not updated yet by the EU. However, the information on the honey ingredient establishment will still have to be provided. An additional GAIN report will be published when the information becomes available.

Exporters of composite products to the EU should check with their importers and other in-country resources to ensure all requirements are met. Exporters are encouraged to contact Member State FAS offices in case exporters encounters problems at the border.

There is additional information on exporting honey to the EU in a recently released AGRINFO Guidance: Exporting Honey to the European Union - An Introduction to Evolving EU Regulations (https://agrinfo.eu/documents/82/Exporting_Honey_to_EU_2024.pdf)

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[1] M11

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2744 of 20 November 2023:
https://publications.europa.eu/resource/cellar/9540f4ab-9b38-11ee-b164-01aa75ed71a1.0006.03/DOC_1

Annex:

ANNEX V: MODEL PRIVATE ATTESTATION BY THE OPERATOR ENTERING SHELF-STABLE COMPOSITE PRODUCTS INTO THE UNION IN ACCORDANCE WITH ARTICLE 22 OF COMMISSION DELEGATED REGULATION (EU) 2022/2292

COUNTRY					
Part I: Description of consignment	**I.1** **Consignor/Exporter** Name Address Country ISO country code		**I.2** **Attestation**	**I.2a** **IMSOC reference** **QR CODE**	
	I.5 **Consignee/Importer** (7) Name Address Country ISO country code		**I.6** **Operator responsible for the consignment** Name Address Country ISO country code		
	I.7 **Country of origin** ISO country code		**I.9** **Country of destination** ISO country code		
	I.8 **Region of origin** Code		**I.10** **Region of destination** Code		
	I.11 **Place of dispatch** Name Address Registration/Approval No Country ISO country code		**I.12** **Place of destination** Name Address Country ISO country code		
	I.13 **Place of loading**		**I.14** **Date and time of departure**		
	I.15 **Means of transport** □ Aircraft □ Vessel □ Railway □ Road vehicle Identification		**I.16** **Entry Border Control Post** **I.17** **Accompanying documents** Type Code Country ISO country code Commercial document reference		
	I.18 **Transport conditions**	□ Ambient □ Chilled			
	I.19 **Container number/Seal number** Container No Seal No				
	I.20 **Certified as or for** □ Products for human consumption				
			I.22 □ **For internal market**		
	I.24 **Total number of packages**			**I.26** **Total net weight/gross weight (kg)**	
	I.27 **Description of consignment**				
	CN code		Type of packaging	Net weight	
		Nature of commodity	Number of packages	Batch No	
	□ Final consumer	Manufacturing plant	Date of production		

Part II: Attestation

II. Health information	**II.a Attestation**	**II.b IMSOC reference**

I, the undersigned, ……

(*name, address, and full details of the importer*)

as representative of the food business operators entering goods into the Union of the consignment of composite products described in Part I declare that the composite products accompanied by this attestation:

1. comply with the applicable requirements referred to in Article 126(2) of Regulation (EU) 2017/625 of the European Parliament and of the Council;
2. do not need to be stored or transported under controlled temperature, unless the shelf-stable composite product needs to be transported chilled for organoleptic quality reasons;
3. contain no colostrum-based products and no processed meat other than gelatine [3], collagen [3] or highly refined products [3] referred to in Section XVI of Annex III to Regulation (EC) No 853/2004 of the European Parliament and of the Council;
4. contain the following list of ingredients of plant origin and of processed products of animal origin [1]: ……..……;
5. contain processed products of animal origin, for which requirements are laid down in Annex III to Regulation (EC) No 853/2004 originating from the following approved establishment(s) [2]: ……..……;
6. contain processed products of animal origin which originate, with the exception of gelatine, collagen, and the highly refined products listed in Section XVI, point 1, of Annex III to Regulation (EC) No 853/2004, from third countries or regions thereof authorised for the entry into the Union of each processed product of animal origin as listed in Annex –I to Commission Implementing Regulation 2021/405 or from a Member State;
7. originate from third countries or regions thereof authorised for the entry into the Union of meat products, dairy products, fishery products or egg products on the basis of the Union animal and public health requirements and which are listed at least for one of these products of animal origin pursuant to Implementing Regulation (EU) 2021/405 or Commission Implementing Regulation (EU) 2021/404 and included in the list laid down in Annex –I to Implementing Regulation 2021/405 for the species/commodity from which the processed products of animal origin contained in the composite products, 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;
8. have been produced in an establishment which fulfils hygiene standards, recognised to be equivalent to those required by Regulation (EC) No 852/2004 of the European Parliament and of the Council;

9. for the fishery products from wild catch or fishery products derived from live bivalve molluscs/live echinoderms/live tunicates/live marine gastropods from wild catch monitoring arrangements are in place to control compliance with Union legislation on contaminants, in accordance with Commission Regulation (EU) 2023/915 on maximum levels for certain contaminants in food and on pesticide residues and in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council on maximum residue levels of pesticides in or on food and feed of plant and animal origin;
10. contain dairy products [3], which:
    - [3] [4] *either* have not undergone a specific risk-mitigating treatment provided for in Annex XXVII to Commission Delegated Regulation (EU) 2020/692;
    - [3] [5] *or* have undergone a specific risk-mitigating treatment provided for in column A or B of the table set out in Annex XXVII to Delegated Regulation (EU) 2020/692;
    - [3] [6] *or* have undergone a specific risk-mitigating treatment at least equivalent to one of the treatments provided for in column B of the table set out in Annex XXVII to Delegated Regulation (EU) 2020/692;
11. contain egg products, which have undergone a specific risk-mitigating treatment at least equivalent to one of the treatments provided for in the table set out in Annex XXVIII to Delegated Regulation (EU) 2020/692 [3].

Notes

In accordance with the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community, and in particular Article 5(4) of the Protocol on Ireland/Northern Ireland in conjunction with Annex 2 to that Protocol, references to the Union in this attestation include the United Kingdom in respect of Northern Ireland.

Part I:

Box reference I.6.:	Optional in the case of products exempted from official controls at border control posts.
Box reference I.13.:	Optional in the case of products exempted from official controls at border control posts.
Box reference I.15.:	Optional in the case of products exempted from official controls at border control posts.
Box reference I.16.:	Optional in the case of products exempted from official controls at border control posts.
Box reference I.18.:	Indicate chilled when the shelf-stable composite product is being transported under controlled temperature for organoleptic quality reasons.
Box reference I.19.:	Optional in the case of products exempted from official controls at border control posts.

	Box reference I.27.:	If the private attestation covers several composite products, the description of goods in Box I.27 must be presented clearly and separately for each composite product (one line by product). Description of consignment: "Type of packaging": Indicate the type of packaging according to the definition given in Recommendation No 21[A] of UN/CEFACT (United Nations Centre for Trade Facilitation and Electronic Business). "Net weight": Indicate the mass of each composite product covered by the private attestation. Those data are needed to calculate the total net weight in Box I.26. "Manufacturing plant": Indicate registration number or address of the plant where the final composite product is produced.

	Date	Qualification and title of the importer
	Stamp	Signature

(1) Please list the ingredients in descending order of weight. Grouping certain ingredients by dairy products, fishery products, egg products, products of non-animal origin as relevant is allowed.

(2) Please introduce the approval number of the establishment(s) having produced the processed products of animal origin contained in the composite product and the third country or territory, or zone thereof, or the Member State, where the approved establishment is located, as provided for in Article 4(2) of Regulation (EC) No 853/2004, and indicated by the food business operator entering goods into the Union.

(3) Delete if not applicable.

(4) Only if:

(a) the third country or territory, or zone thereof of origin of the composite product (ISO country code inserted in Box I.7 of Part I of the attestation) is listed for the entry into the Union of milk and dairy products not subject to a risk-mitigating treatment in Annex XVII to Implementing Regulation (EU) 2021/404; and

(b) the approved establishment of origin of the raw milk or the dairy product (indicated in point 5 of Part II of the attestation) is located:

(i) in a third country or territory, or zone thereof listed for the entry into the Union of milk and dairy products not subject to a risk-mitigating treatment in Annex XVII to Implementing Regulation (EU) 2021/404; or

(ii) in the Union.

(5) Only if:

(a) the third country or territory, or zone thereof of origin of the composite product (ISO country code inserted in Box I.7 of Part I of the attestation) is listed for the entry into the Union of dairy products subject to a risk-mitigating treatment in Annex XVIII to Implementing Regulation (EU) 2021/404; and

(b) the approved establishment of origin of the raw milk or the dairy product (indicated in point 5 of Part II of the attestation) is located:

(i) in a third country or territory, or zone thereof listed for the entry into the Union of milk and/or dairy products in Annex XVII or XVIII to Implementing Regulation (EU) 2021/404; or

(ii) in the Union.

(6) If:

(a) the third country or territory, or zone thereof of origin of the composite product (ISO country code inserted in Box I.7 of Part I of the attestation) is not listed for the entry into the Union of milk and/or dairy products in Annex XVII or XVIII to Implementing Regulation (EU) 2021/404; and

(b) the approved establishment of origin of the dairy product (indicated in point 5 of Part II of the attestation) is located:

(i) in a third country or territory, or zone thereof listed for the entry into the Union of milk and/or dairy products in Annex XVII or XVIII to Implementing Regulation (EU) 2021/404; or

(ii) in the Union.

(7) Importer: Representative of the food business operator entering goods into the Union as laid down in Article 22(1) of Delegated Regulation (EU) 2022/2292.'.

[A] Last version: www.unece.org/uncefact/codelistrecs.html

Attachments:

No Attachments.