

**Voluntary Report** – Voluntary - Public Distribution

**Date:** August 09, 2023

**Report Number:** E42023-0030

**Report Name:** De Facto Suspension of Vanilla Extract Exports to the EU

**Country:** European Union

**Post:** Brussels USEU

**Report Category:** FAIRS Subject Report, MISC-Commodity, Sanitary/Phytosanitary/Food Safety

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**Report Highlights:**

U.S. exporters of vanilla extract are advised not to ship product to the European Union until further notice. The European Union introduced a requirement for an official certificate providing guarantees from the U.S. Government about the compliance of U.S. vanilla extract with the EU's maximum residue levels of ethylene oxide. There is no current U.S. Government process for providing the standardized certificate which the EU is now requiring as a condition for entry of vanilla extract from the United States. The EU will not accept third party certificates from other testing facilities, including those in the EU.

## Summary

Vanilla extract with Combined Nomenclature code 1302 19 05 originating from the United States was added to the list of products to which special entry conditions apply in [Commission Implementing Regulation \(EU\) 2023/174 of 26 January 2023](#) (see Row 22 in [Annex II](#) of the regulation). These shipments now require an official certificate stating that the products have been sampled and analyzed for this compound and the results show compliance with Regulation (EC) No 396/2005 on maximum residue levels of ethylene oxide.

The Food and Drug Administration (FDA) is the relevant U.S. Government (USG) competent authority, but FDA does not verify compliance with EU requirements and cannot provide the certification required for these products. The EU will not accept third party certificates from other testing facilities, including those in the EU. U.S. exporters of vanilla extract are therefore advised not to ship product to the European Union until further notice.

## Background

The Rapid Alert System for Food and Feed (RASFF) is a notification system operated by the European Commission to exchange information on identified hazards between Member States. Data from this system on the presence of ethylene oxide in vanilla extract from the United States were considered by the European Union as presenting a human health risk that requires special import conditions, including certification provided by the U.S. Government regarding the compliance of this product with the [Regulation \(EC\) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin](#).

## Special Conditions Governing on the Entry into the Union of Certain Food from Certain Third Countries

- **Legal References**

Vanilla extract with Combined Nomenclature code 1302 19 05 originating from the United States was added to the list of products to which special entry conditions apply in [Commission Implementing Regulation \(EU\) 2023/174 of 26 January 2023](#) (see Row 22 in [Annex II](#) of the regulation).

This regulation updated the annexes of 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. These updates take place on a biannual basis. The most recent June 2023 revision ([Commission Implementing Regulation \(EU\) 2023/1110 of 6 June 2023](#)) of the lists in the Annexes of Implementing Regulation (EU) 2019/1793 retained the listing for vanilla extract in Annex II of the regulation (row 20 in Annex II), keeping the

special entry conditions until the EU makes an explicit decision to change the import conditions for vanilla extract from the United States.

The most recent consolidated version of Regulation (EU) 2019/1793, which is the easiest version for readers to understand the full scope of the entry conditions laid down in the applicable articles, can be found here: [Consolidated text: 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.](#)

In this version of the legislation, the entry for U.S. vanilla extract can be found in row 22:

Row	Country of origin	Food and feed (intended use)	CN code	TARIC sub-division	Hazard	Frequency of identity and physical checks (%)
22	United States (US)	Vanilla extract ( <i>Food</i> )	1302 1905		Pesticide residues <sup>(10)</sup>	20

*(10) Residues of Ethylene Oxide (sum of ethylene oxide and 2-chloro-ethanol, expressed as ethylene oxide). In case of food additives, the applicable MRL is 0,1 mg/kg (LOQ). Prohibition of use of Ethylene Oxide provided for in Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).*

- **Special Entry Conditions applicable to Products Listed in Annex II of Regulation (EU) 2019/1793: What does it mean for the U.S. Government?**

Annex II of [Regulation \(EU\) 2019/1793](#) lists vanilla extract (CN 1302 19 05) from the United States for ethylene oxide, specifying a testing rate of 20 percent for this hazard upon import into the EU. While for products listed in Annex I, the testing rate at import is the only applicable requirement, for products listed in Annex II, additional entry conditions apply. Most importantly, according to Article 11 of the regulation, each consignment of a product listed in Annex II must be accompanied by an official certificate.

*Article 11*

**Official certificate**

1. Each consignment of food and feed listed in Annex II shall be accompanied by an official certificate in accordance with the model set out in Annex IV ('official certificate').
2. The official certificate shall comply with the following requirements:

(a) the official certificate shall be issued by the competent authority of the third country of origin or of the third country where the consignment is consigned from if that country is different from the country of origin;

...

As the hazard of concern for U.S. vanilla extract is ethylene oxide, the official certificate must state that the products have been sampled and analyzed for this compound and the results show compliance with Regulation (EC) No 396/2005 on maximum residue levels of ethylene oxide.

- **Special Entry Conditions applicable to Products Listed in Annex II of Regulation (EU) 2019/1793: What does it mean for the U.S. Exporters?**

If no certificate is included, the shipment is denied entry. The Food and Drug Administration (FDA) is the relevant U.S. Government (USG) competent authority, but FDA does not verify compliance with EU requirements and cannot provide the certification required for these products. U.S. exporters of vanilla extract are therefore advised not to ship product to the European Union until further notice. The EU will not accept third party certificates from other testing facilities, including those in the EU.

- **Special Entry Conditions applicable to Products Listed in Annex II of Regulation (EU) 2019/1793: What does it mean for importers?**

Food business operators in the EU responsible for the imported consignments of vanilla extract must give prior notification to the competent authorities of the Border Control Post before the arrival of the consignment. For this purpose, they must complete Part I of the standardized Common Health Entry Document (CHED) and transmit it to the competent authority at the BCP.

**Attachments:**

No Attachments.