



FLAVOR AND EXTRACT MANUFACTURERS ASSOCIATION OF THE UNITED STATES

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7 May 2025

Via Electronic Submission

Department of Commerce
Bureau of Industry and Security
Office of Strategic Industries and Economic Security

Response to the Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients. [Docket No. 250414-0065] XRIN 0694-XC120. 90 Fed. Reg. 15951 (16 April 2025).

Dear Sir or Madam:

On behalf of the Flavor and Extract Manufacturers Association of the United States (FEMA), we appreciate the opportunity to submit comments in response to the Department of Commerce Bureau of Industry and Security [Docket No. 250414-0065], Notice of Request for Public Comments on the Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients. 90 Fed. Reg. 15951. 16 April 2025

The Flavor and Extract Manufacturers Association of the United States (FEMA)

Founded in 1909, FEMA is the national association of the U.S. flavor industry. FEMA's diverse membership includes flavor ingredient suppliers, flavor manufacturers, and flavor users of all sizes. A number of FEMA member companies are family-owned businesses. FEMA is committed to ensuring the safe and responsible use of flavoring substances.

FEMA members manufacture and market more than 95 percent of all flavors sold in the United States and create flavors for use in a wide variety of food, beverage, and pharmaceutical products. Our country's production of foods, beverages, and pharmaceuticals depends upon FEMA members as important links in supply chains. Food and beverage manufacturing is the largest U.S. manufacturing sector and employs nearly 2 million people. It is also the largest user of flavors. Thousands of food processing operations around the United States rely upon the high-quality ingredients and flavor products that FEMA members provide, which are sourced globally. Every American is positively impacted by our successful food supply chains that include flavors and extracts as key components.

The Role of Flavors in Pharmaceutical Products

Above and beyond their role in assuring reliable food security and economic stability of the nation's food system, flavors and extracts are utilized every day to ensure successful U.S. production and application of pharmaceutical products. From ensuring that daily low-dose preventative treatments are more acceptable for consumption, to helping

mask otherwise astringent characteristics of pharmaceuticals, to helping our children take important medicine that ensures their health and wellbeing, these are the vital roles that flavors play within our society. Analgesics, cough syrups, and other medications, routinely offered in various of flavors, increase acceptance of consumers of all ages and help build and preserve a healthier U.S. population.

The Section 232 Investigation

In order to ensure uninterrupted supply chains for U.S. consumers, FEMA has recommendations related to the 232 investigation under consideration here, and how that policy interacts with Annex II of the Executive Order issued April 2, 2025, entitled “Regulating Imports with a Reciprocal Tariff to Rectify Trade Practices that Contribute to Persistent Annual Goods Trade Deficits.” Because the two initiatives are linked, it is important to outline priorities and policy imperatives impacting both. Our goals are to ensure strong and robust U.S. production and processing of foods, beverages, and pharmaceuticals, as well as continued access to materials and ingredients needed for domestic production.

FEMA firmly believes that in addition to preserving the list of exempted ingredients included in Annex II, it is vital that plant-based and naturally harvested products used for similar purposes also be included in Annex II and protected from supply chain disruption. For example, vanilla plants, whose beans are used to produce vanilla extract, the most popular flavor in the world, are not grown in commercial quantities in the U.S. Protecting the vanilla bean supply is of vital importance to U.S. food security as production is highly dependent upon specific climate and land characteristics. Coffee and tea are almost exclusively grown outside of the U.S. and are important sources of flavor materials. Similarly, many spices are unable to be grown in the U.S. and are used to produce essential oils and natural flavoring substances. Preserving the trade in these products and avoiding geographic-based duties and tariffs that target vanilla production and other critical ingredients should be a top priority for protecting U.S. consumers and staving off future inflationary pressures. In addition to vanilla, unique essential oils and extracts, including those of certain citrus sources and mint derivatives, should also be protected/exempted from tariffs to provide certainty and reliability for U.S. consumers. In summary, Annex II should be expanded to include plant-based products and at a minimum, every effort should be made to avoid country-based tariffs that will harm access to critical ingredients for the U.S. food supply.

FEMA firmly believes that in addition to the expansion described above, those pharmaceutical ingredients listed under Annex II should not be subjected to new tariffs under the 232 investigation that has been initiated. Supply chains, sourcing, and availability of such products are quite limited, and there are no domestic prospects for productions either in the development or conceptual stages. Industry in the U.S. would likely suffer if those ingredients were suddenly subject to price spikes or restricted in availability altogether. FEMA recognizes that the purpose of a Section 232 investigation is to help protect national security and believes that subjecting exempted ingredient products found in Annex II to Section 232 tariffs would have the opposite effect on national security that the statutory authority intends.

Our industry would welcome further dialogue and is available to provide specific product examples and HTSUS codes that U.S. consumers depend upon in the domestic pharmaceutical and food security supply chains. Given the rapid nature of this process and the combined overlay of this comment period along with the recent Executive Order and associated annexes, FEMA provides this information to help preserve and bolster U.S.-based processing and manufacturing.

Sincerely,

A handwritten signature in blue ink, appearing to read 'AP' followed by a stylized flourish.

Anthony Pavel
General Counsel