

Docket No. XRIN 0694-XC120

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF COMMERCE

INDUSTRY AND SECURITY BUREAU

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON THE

**NOTICE OF REQUEST FOR PUBLIC COMMENTS ON SECTION 232 NATIONAL
SECURITY INVESTIGATION OF IMPORTS OF PHARMACEUTICALS AND
PHARMACEUTICAL INGREDIENTS**

May 7, 2025

Prefatory remarks

The American Herbal Products Association (AHPA) is the national trade association and voice of the herbal products and dietary supplements industries. AHPA members include companies doing business as growers, importers, processors, manufacturers, and marketers of herbs, herbal products, and other dietary supplements. AHPA serves its members by promoting the responsible commerce of such products, including conventional human foods, dietary supplements, health and beauty products, animal products, and other products.

On April 2, 2025, the White House issued an executive order establishing a system of reciprocal tariffs on goods entering the United States.¹ At section 3(b) of this order, the administration exempted a range of goods from the reciprocal tariff regime. Many of the categories of commodities exempted were subject to separate duties imposed pursuant to section 232 of the Trade Expansion Act of 1962 (Section 232). Other excluded commodities were listed in Annex II to the order (Annex II), which identified them by their commodity codes under the United States Harmonized Tariff Schedule (HTS). Of relevance to these comments, a significant number of commodity codes identified in this list were classified under Chapter 29 of the HTS, “organic chemicals,” including a large number of commodities, such as vitamins and amino acids, used in pharmaceutical formulation, fortification of conventional food and animal feed, and formulation of dietary supplements.

On April 16, 2025, the Department of Commerce published a Federal Register notice² (the April 16 Notice), announcing that on April 1, 2025, it had initiated an investigation under Section 232 to determine the effects on national security of imports of pharmaceuticals, pharmaceutical ingredients, and their derivative products, and seeking comments relevant to the same (the Section 232 investigation). This notice did not specify any particular commodities, including by their HTS codes, that are the subjects of the investigation.

¹ Regulating Imports with a Reciprocal Tariff to Rectify Trade Practices that Contribute to Large and Persistent Annual United States Goods Trade Deficits, Exec. Order No. 14,257 (April 2, 2025), 90 Fed. Reg. 15,041 (April 7, 2025).

² Notice of Request for Public Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients, 90 Fed. Reg. 15,951 (April 16, 2025).

In a meeting with the United States Trade Representative, AHPA received confirmation that commodities included in Annex II that were not already subject to Section 232 duties were selected with the intention that they would be subject to a Section 232 investigation and, following such an investigation, the potential imposition of import controls.

Commodity categories listed in Annex II under Chapter 29 of the HTS include vitamins, amino acids, and other substances used in the creation of products manufactured and sold by AHPA members such as dietary supplements and personal care products. AHPA members would be adversely impacted by the imposition of import controls on such commodities following this Section 232 investigation. AHPA and its members therefore have an interest in any actions taken pursuant to the outcomes of this investigation.

AHPA's comments herein are limited to substances mentioned in Annex II as they are used in dietary supplements. For the purposes of these comments, these commodities are referred to as "Annex II dietary ingredients." AHPA accompanies these comments with a nonexhaustive list of commodity codes covering substances in this category. AHPA expresses no opinion on other commodity categories or subsequent uses not addressed.

Domestic capacity for Annex II dietary ingredients production is limited

The April 16 Notice requests specific comment regarding the feasibility of increasing domestic capacity for pharmaceuticals and pharmaceutical ingredients to reduce import reliance. In the context of Annex II dietary ingredients, such capacity is limited at best.

Given their use across the conventional food, pharmaceutical, animal feed, personal care product, and dietary supplement markets, vitamins and amino acids, produced at sufficient scale to stabilize sole or significant domestic sourcing, would require a truly massive industrial buildout with associated infrastructure and support. The development of production capacity for construction of such capacity requires specialized construction and capital outlays measured across several years. For example, choline, a vital amino acid, is produced using industrial scale chemical synthesis or similarly scaled bioproduction using controlled fermentation facilities. Such industrial sites function similarly to those used in petroleum refining, but due to the purity requirements of outputs such facilities may require far greater controls and standards.

Negative incentives also make the development of such production generally unappealing; the production of purified vitamins or specialized amino acid commodities tends to be highly energy intensive and, depending on the commodity, may also entail the production of significant waste byproducts.

For the above reasons, while import controls might eventually (after several years) elicit some limited latent capacity for these commodities, restrictive cost and externality factors would pose fundamental structural barriers to domestic production driven by import controls alone.

Import controls on Annex II dietary ingredients will do harm to national security

Due to the above concerns, actions to protect domestic access to Annex II dietary ingredients through import controls or duties would have the likely effect of short- and long-term limits on access to the commodities themselves. For example, vitamins and their role in the fortification of the U.S. food, drug, and health products supply are major components of the American general public health apparatus, underwriting and supporting the breadth of general choices available to consumers in foods and personal care products as well as supporting the health of many millions of consumers through their use in pharmaceutical and dietary supplement products.

As the demand for these commodities is relatively inelastic, import controls would result in an increase in cost for these commodities regardless of and throughout the latency of production shifts. More seriously, should a reduction in all-sources availability occur, unpredictable shortages may occur in substances vital to both the public health and healthy commerce. For example, substances used in animal feed supplementation are required to stabilize the domestic production and supply of basic meat and poultry products. Since the time for the development of even limited domestic capacity for these substances is measured across multiple years, these public shortages, and the health and market effects they produce, would be highly visible.

In consideration of the above, AHPA asks the Department of Commerce to refrain from any recommendation that would result in the imposition of import controls on Annex II dietary ingredients, whether through specialized Section 232 authority or through the imposition of the general reciprocal tariffs from which these commodities are currently exempt.

Domestic production of Annex II dietary ingredients is better driven by positive trade measures

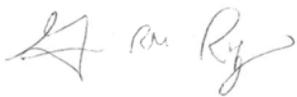
AHPA appreciates the strong public interest of securing a stable and safe supply of vital nutrient substances. However, under these circumstances restrictions on importation are unlikely to be productive as a major or sole mechanism to drive diversification of supply or domestic production. Instead, beyond the setting of the current investigation, AHPA encourages the examination of additional measures to protect and develop positive policies to encourage diverse and domestic sources for Annex II dietary ingredients.

Such measures may include preferential treatment for the importation of such commodities from countries with established capacity that are not current sources or the use of domestic positive financial incentives to support domestic infrastructure and investment necessary to the long-term development of a stable and safe supply for these commodities.

Summary

AHPA greatly appreciates the opportunity to present comments on this national security investigation. AHPA staff and counsel will make themselves available at any mutually convenient time to further address any of the topics addressed herein. Please feel free to contact us if clarification or additional discussion is needed on the issues raised in these comments.

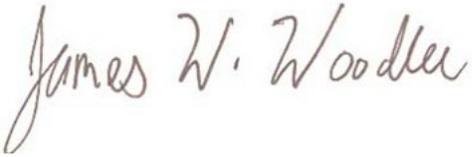
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Annex II Dietary Ingredients

Vitamins

29362100	Vitamins A and their derivatives, unmixed, natural or synthesized
29362200	Vitamin B1 (Thiamine) and its derivatives, unmixed, natural or synthesized
29362300	Vitamin B2 (Riboflavin) and its derivatives, unmixed, natural or synthesized
29362401	Vitamin B5 (D- or DL-Pantothenic acid) and its derivatives, unmixed, natural or synthesized
29362500	Vitamin B6 (Pyridoxine and related compounds with Vitamin B6 activity) and its derivatives, unmixed, natural or synthesized
29362600	Vitamin B12 (Cyanocobalamin and related compounds with Vitamin B12 activity) and its derivatives, unmixed, natural or synthesized
29362700	Vitamin C (Ascorbic acid) and its derivatives, unmixed, natural or synthesized
29362800	Vitamin E (Tocopherols and related compounds with Vitamin E activity) and its derivatives, unmixed, natural or synthesized
29362910	Folic acid and its derivatives, unmixed
29362916	Niacin and niacinamide
29362920	Aromatic or modified aromatic vitamins and their derivatives, nesoi
29362950	Other vitamins and their derivatives, nesoi
29369001	Vitamins or provitamins (including natural concentrates) and intermixtures of the foregoing, whether or not in any solvent

Other substances

29072990	Other polyphenols, nesoi
29146200	Coenzyme Q10 (ubidecarenone (INN)
29159010	Fatty acids of animal or vegetable origin, nesoi
29393000	Caffeine and its salts
29397900	Vegetable alkaloids, natural or reproduced by synthesis, their salts and other derivatives, nesoi
29398000	Other alkaloids, natural or reproduced by synthesis and their salts, ethers, esters & other derivatives, nesoi