



Council for Responsible Nutrition

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VIA ELECTRONIC SUBMISSION

To : European Commission Feedback : https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13246-Border-controls-for-food-import-conditions-and-border-controls-of-trade-samples-and-certain-composite-products_en

Copy to:

International Affairs
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration

Office of the U.S. Trade Representative
Executive Office of the President

Office of Consumer Goods
International Trade Administration
U.S. Department of Commerce

Foreign Agricultural Service
U.S. Department of Agriculture

Re: EU Delegated Regulation 2019/625; Border controls for food – import conditions and border controls of trade samples and certain composite products.

Dear European Commission,

The Council for Responsible Nutrition (CRN)¹ appreciates the opportunity to provide input on the European Commission Delegated Regulation (EU) .../... “amending Delegated Regulation (EU) 2019/615 as regards combined nomenclature and harmonized system codes, import conditions of certain composite products, amending Delegated Regulation (EU) 2019/2122 as regards certain pet birds exempted from official controls at border control posts and amending Delegated Regulation (EU) 2021/630 as regards for composite products exempted from official controls at border control points [hereafter termed the ‘Delegated Regulation’].

¹The Council for Responsible Nutrition, founded in 1973, is a Washington, D.C.-based trade association representing 180 dietary supplement and functional food manufacturers, ingredient suppliers, and companies providing services to those manufacturers and suppliers. In addition to complying with a host of federal and state regulations governing dietary supplements and food in the areas of manufacturing, marketing, quality control and safety, our manufacturer and supplier members also agree to adhere to additional voluntary guidelines as well as to CRN’s Code of Ethics. See www.crnusa.org.

General Comments

Since founding in 1973, CRN and its members are committed to manufacturing and marketing products for public health and has consistently advocated for (1) a responsible and safe use of dietary/food supplements and functional foods based on totality of the scientific evidence and (2) regulations to be proportionate to the risk identified.

While CRN appreciate the work EC is taking to also protect public health, CRN and CRN Members have significant concerns regarding the Draft Delegated Regulation. The regulation as written could significantly restrict the importation of vitamin D3 into the Europe Union, which can create a public health crisis for the EU population and also have a major adverse financial and cost impact on businesses in the EU. The proposed regulation classifies vitamin D3 as a product of animal origin, and therefore, imposes that vitamin D3 be accompanied by an export health certificate. While vitamin D3 is sourced from lanolin from sheep's wool, it goes through lengthy chemical processes to produce purified vitamin D3. CRN proposes the Commission to take into account the low risk profile of vitamin D3 and exempt vitamin D3 from the requirements designated for animal-derived ingredients by clearly placing vitamin D3 under Article 48(h) of Regulation (EU) 2017/625.²

Commercial Vitamin D3 is Highly Processed Chemical Compound

Commercial manufacturer of vitamin D3 utilizes cholesterol obtained from the lanolin of sheep's wool; it goes through number of processes that ultimately purifies vitamin D3. Typically, cholesterol is extracted from the lanolin of sheep's wool and goes through eighteen steps before it is converted into 7-dehydrocholesterol. The crystalline 7-dehydrocholesterol is then dissolved in an organic solvent and irradiated with UV light, which transforms the compound into cholecalciferol. It is then purified and crystallized further before used in foods and dietary/food supplements.³ While the original source of vitamin D3 is the cholesterol from the lanolin of sheep's wool, by the time vitamin D3 is imported into the EU by food and dietary/food supplement manufacturers, there is no public health concern related to vitamin D3.

Potential Unintended Consequence of Restricting Vitamin D3 Import on Public Health

Vitamin D is an essential nutrient required for the body to regulate calcium and phosphate, which are needed to keep bones, teeth and muscles healthy. While the body can create vitamin D from direct sunlight on the skin, Europeans rely on vitamin D3 supplementation to meet the recommendations established by governments in many EU Member States. In a recently published scientific opinion, the EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA) concluded that vitamin D is one of the essential nutrients that are “below current dietary

² Regulations (EU) 2017/625 of the European Parliament and of the Commission of 15 March 2017. *Official Journal of the European Union*. 7.4.2017. <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0625&from=EN>

³ Agriculture Marketing Service. United States Department of Agriculture. (2011). Vitamin D3. <https://www.ams.usda.gov/sites/default/files/media/Vitamin%20D3%20TR.pdf>

recommendations in specific sub-groups of European populations.” According to the survey conducted in EU/EEA Member States, 13 countries reported that vitamin D intake was inadequate for general population, 6 countries reported for children, and 4 countries reported for elderly.⁴ Based on this finding, the demand for foods and dietary/food supplements containing vitamin D3 will continue to grow in the EU.

In addition, as acknowledged in the Draft Delegated Regulation, the EU is highly dependent on the importation of vitamin D3. It is estimated that 85% of global vitamin D3 is produced in China, followed by India. Unfortunately, China and India are not listed countries under Annex XIII Regulation (EU) 2021/405 as sources of products of ovine origin, and therefore, vitamin D3 synthesized from cholesterol in these countries cannot be imported into the EU unless it is accompanied by an export health certificate.

With the growing demand for vitamin D3 in European populations and import restrictions of vitamin D3 from China and India, we can predict that there could be potential shortages of vitamin D3 available in the EU Member States in the near future. This shortage can inadvertently impact the public health of the EU population, especially the vulnerable population of children and elderly, and impact feed for farm animals and pets. In addition to the serious public health impact on the EU population, this will impact global trade of products into the EU.

It is important to note that there is an exception of animal original certificates for Vitamin D in other western markets, such as in the U.S. (Guideline 1122⁵) where fully finished food products for human consumption containing Vitamin D3 are exempted. Thus, to ensure a fair open market and give Europeans access to any and all efficacious Vitamin D products to support their health and wellbeing during this unprecedented time, the European Commission should adopt similar policies.

A Tailor-Made Risk Management Decision is Needed

Based on the above-mentioned elements, CRN and CRN Members urge the Commission to consider a proportionate and science-based risk management approach for vitamin D3 by exempting vitamin D3 from (1) the need for border checks, (2) approved residue plan requirement, and (3) export health certificate or private attestation requirements when importing animal-derived vitamin D3 into the EU Member States.

⁴ EFSA Panel on Nutrition, Novel Foods and Food Allergens (NDA). (2021). Scientific Opinion advising on the development of harmonized mandatory front-of-pack nutrition labelling and the setting of nutrient profiles for restricting nutrition and health claims on foods.

<https://connect.efsa.europa.eu/RM/s/publicconsultation2/a011v00000E877g/pc0108>

⁵ USDA. Animal and Plant Health Inspection Service. (2021). Guidelines: Animal Products That Do Not Require An Import Permit.

<https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/import-live-animals/no-import-permit-req>

I would be happy to address any concerns you may have and will be available to discuss at your convenience.

Respectfully submitted,

A handwritten signature in black ink, consisting of a large, stylized 'J' followed by a horizontal line extending to the right.

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