VITAMIN D3: CHANGES TO IMPORT REQUIREMENTS WILL IMPACT EU SUPPLY AND PUBLIC HEALTH

Key concerns regarding the Draft Delegated Regulation amending Delegated Regulation (EU) 2019/625 as regards Combined Nomenclature and Harmonised System codes and import conditions of certain composite products [also amending Delegated Regulation (EU) 2019/2122 as regards certain samples and pet birds exempted from official controls at border control posts and amending Delegated Regulation (EU) 2021/630 as regards requirements for composite products exempted from official controls at border control posts]

Consultation link: 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

Deadline for responses: Tuesday 23rd November 2021

What is vitamin D3?

- Vitamin D helps to regulate the amount of calcium and phosphate in the body which, in turn, are needed to keep bones, teeth and muscles healthy. The body creates vitamin D from direct sunlight on the skin when outdoors, and a small amount of vitamin D can be obtained from certain foods such as oily fish and egg yolks.
- Owing to the lack of sunlight and the tendency for the population to be covered up or remain indoors, public health advice is to take vitamin D supplements during the Autumn and Winter, especially in the more northern countries of the EU. Daily supplementation all year round of vitamin D is recommended by governments in many EU Member States for infants and young children.
- Vitamin D3 is the more bioavailable form of vitamin D and, thus, is the form most widely used in foods. Vitamin D3 is included in a very wide range of mainstream fortified foods and it is used in specialist products such as infant formula, baby food, foods for special medical purposes and food supplements.
- The main raw material of vitamin D3 is NF grade cholesterol, which is synthesised through lengthy chemical processes from lanolin from sheep's wool. Cholesterol is not directly consumed by humans, but it undergoes further lengthy chemical processes in order to produce vitamin D3.
- The complex nature of the multiple chemical steps means that there is no risk of any undesirable elements that may be present in the original lanolin from sheep's wool to be present in the final pure crystalline vitamin D3.

What are the concerns with this draft Regulation?

- Up until now, vitamin D3 has been imported into the EU as an organic chemical, i.e. as a product of chemical synthesis (CN Code 2936).
- This proposed Regulation adds CN codes for vitamin D3 to Article 3 of Delegated Regulation (EU) 2019/625, thereby requiring it to be treated as a product of animal origin (POAO).
- The designation of vitamin D3 as a POAO means that all the requirements for POAO under the EU Animal Health Regulations will apply to this product and also to its starting material cholesterol.

This means that the originating country for cholesterol used to manufacture vitamin D3, and for vitamin D3 itself, must have listed third country status.

- The majority of cholesterol is manufactured in China, with other production occurring in India and Japan. There is no cholesterol production in the EU.
- It is estimated that 85% of global Vitamin D3 is produced in China, with the next main global producer being India[1]. While some vitamin D3 is produced in the EU, its production is reliant on cholesterol produced in China, India and Japan.
- China, India and Japan are not listed countries under Annex XIII Regulation (EU) 2021/405 as sources of products of ovine origin. Thus:
    - Cholesterol synthesised from lanolin from sheep's wool cannot be imported into the EU if it is intended to be used as a raw material for producing vitamin D3, meaning that manufacture of vitamin D3 cannot occur in the EU.
    - Vitamin D3 synthesised from cholesterol in third countries cannot be imported into the EU.
    - Products containing vitamin D3 cannot be imported into the EU.
- If imports of cholesterol and/or vitamin D3 are restricted, this risks a public health crisis in relation to adults, but more importantly in relation to infants and young children across the EU.
- Any prohibition on imports will also have impacts across other sectors, such as feed for farm animals and pets.
- Recital (3) of this draft Regulation acknowledges that the Union is highly dependent on the importation of vitamin D3 and that, due to the robust process by which it is obtained from lanolin, there is no public health concern related to its importation.
- However, the designation of vitamin D3 as a POAO imposes the need for its entry into the EU to be accompanied by an export health certificate, which appears disproportionate for a chemical substance for which there is no public health concern.
- Export Health Certificates or Private Attestations (in the case of shelf-stable composite products) would also be required for the import into the EU of products containing vitamin D3.
- The production of export health certificates has a major adverse financial and cost impact on businesses and could reduce the viability for many companies to import products containing vitamin D3 into the EU.

What is a potential solution to these concerns?

- It is understood that according to EU law, it appears to be no longer possible to treat vitamin D3 as an organic chemical, as it falls under the EU's definition of a POAO.
- Exemptions from the need for border control checks for vitamin D3 could be put in place under Article 48(h) of Regulation (EU) 2017/625:

[1] Global Vitamin D3 (Cholecalciferol) Market 2020 by Manufacturers, Regions, Type and Application, Forecast to 2026 (https://www.marketsandresearch.biz/report/44836/global-vitamin-d3-cholecalciferol-market-2020-by-manufacturers-regions-type-and-application-forecast-to-2026)

"Article 48

Animals and goods exempted from official controls at border control posts

The Commission shall adopt delegated acts in accordance with Article 144 to supplement this Regulation concerning rules establishing the cases where, and the conditions under which, the following categories of animals and goods are exempted from Article 47, and when such exemption is justified:

(a) goods sent as trade samples or as display items for exhibitions, which are not intended to be placed on the market;

(b) animals and goods intended for scientific purposes;

(c) goods on board means of transport operating internationally which are not unloaded and are intended for consumption by the crew and passengers;

(d) goods which form part of passenger's personal luggage and are intended for personal consumption or use;

(e) small consignments of goods sent to natural persons which are not intended to be placed on the market;

(f) pet animals as defined in point (11) of Article 4 of Regulation (EU) 2016/429;

(g) goods which have undergone specific treatment and do not exceed quantities to be established in those delegated acts;

(h) categories of animals or goods posing a low risk or no specific risk and for which controls at border control posts are therefore not necessary."

- As the majority of both cholesterol and vitamin D3 originate from non-listed countries, it should be specified within this Article 48(h) option that the requirements for an approved residue plan do not apply to either vitamin D3 or its starting material cholesterol. This will allow vitamin D3, and cholesterol intended for the manufacture of vitamin D3, to continue to be imported into the EU from China, India and Japan.
- Given the extent of processing involved, it should also be specified that neither Export Health Certificates nor Private Attestations (in the case of composite products) are required for the import into the EU of vitamin D3 or products containing vitamin D3.