European Federation of Associations of Health Product Manufacturers

EHPM contribution to the feedback mechanism on the Draft delegated regulation on Border controls for food – import conditions and border controls of trade samples and certain composite products – Ares(2021)6601915

The European Federation of Associations of Health Product Manufacturers (hereinafter, EHPM), EU stakeholder registered on the EU Transparency Register (No. 65512466920-96), would like to submit its contribution in the context of the consultation on the proposed draft delegated act on *border controls for food – import conditions and border controls of trade samples and certain composite products*.

The EHPM welcomes the possibility to provide feedback on the draft delegated regulation with which the European Commission (EC) proposes to add the CN Code for vitamin D3 to Article 3 of Delegated Regulation (EU) 2019/625. This proposed measure would have a major impact on food business operators as well as on public health. EHPM prioritises safety, high-quality standards, clear information to consumers and transparency of the EU food safety system.

Vitamin D3 from sheep lanolin

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. Public health advice, as recently confirm by EFSA, is to take vitamin D supplements during the Autumn and Winter, especially in the more northern countries of the EU. For infants and young children, this is especially important, with daily supplementation being recommended by Authorities in many EU Member States for this age group.

Vitamin D3 is the most 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.
For this reason, food supplements of vitamin D3 are frequently suggested by doctors and nutrition advisors to meet the daily demand for vitamin D[1]. More specifically, vitamin D3 (cholecalciferol) is considered the most absorbable form of vitamin D instead of vitamin D2 (ergocalciferol).

Vitamin D3 is manufactured from cholesterol which is isolated from wool grease. The cholesterol is converted chemically to 7-dehydrocholesterol (7-DHC) which is irradiated with UV light to form pre-vitamin D3 and cisvitamin D3, the biologically active precursors to the vitamin D3 metabolites. The irradiation and heating processes are carefully controlled to avoid generating the many isomeric inactive forms of the vitamin from being generated.

[1] Dietary Supplement Fact Sheet: Vitamin D, (2011) U.S. National Institutes of Health, https://www.thebodypro.com/article/dietary-supplement-fact-sheet-vitamin-d

56 Rue des Colonies • B-1000 Brussels • Tel.: + 32 2 721 64 95
www.ehpm.org • info@ehpm.org

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. Therefore, there are no health concerns that fall within the scope of the official controls and the hygiene legislation.

In line with the above, 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), and we sincerely doubt that the designation of vitamin D3 as product of animal origin (POAO) in the framework of Reg. (EC) 853/2004 is justified. In fact, vitamin D3 is not a processed food but a product of an elaborate chemical synthesis from cholesterol, which in turn is produced by chemical synthesis from lanolin, the grease that lines the hairs of the wool of sheep.

Requirements for POAO's and implications for vitamin D3 supply in Europe

EHPM and its members welcome the EC's will to continue to allow the import of cholesterol and vitamin D3 derived from sheep lanolin, which does not raise any public health concerns, as also acknowledged by the EC in *recital 3* of the draft measure. However, we are afraid that the suggested classification as a POAO would pose several challenges such as the following:

- The measure will unintentionally put at risk the supply of vitamin D supplements in Europe by halting the import of crucial raw materials from third countries, mostly China and secondly India and Japan[2]. In fact, these Asian countries are not included on the list of third countries allowed to export *"other products of animal origin"* to the EU[3] nor on the list of countries with an EU approved plan for monitoring residues for this category[4].
- Vitamin D3 chemically synthesized from cholesterol is not included in the positive list of POAO's allowed to be exported from China to Europe[5]. In practice, this would create an immediate and tremendous supply shortfall in Europe impossible to overcome with evident consequences on public health.
- Vitamin D3 and its starting material, cholesterol, would be subject to all the requirements for POAO's under the EU Animal Health Regulations. In the case of shelf-stable composite products, export health certificates or private attestations would also be required for the import into the EU of products containing vitamin D3. The requirements for health certificate for a product of chemical synthesis is not proportionate in light of the history of safe use of vitamin D3 and will add excessive costly administrative burdens.

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

[3] Commission Implementing Regulation (EU) 2021/405

[4] Commission Decision 2011/163/EU

[5] Commission Decision 2002/994

56 Rue des Colonies • B-1000 Brussels • Tel.: + 32 2 721 64 95
www.ehpm.org • info@ehpm.org

European Federation of Associations of Health Product Manufacturers

Conclusions

In light of the above, EHPM calls on the EC to coherently intervene on all the relevant legal acts, foreseeing transitional measures if necessary, to allow the continuation of cholesterol and vitamin D3 imports with no disruption from critical supplying third countries.
Furthermore, we call on the EC to consider exceptions from border control check for shelf-stable finished products containing vitamin D3 and not to impose additional administrative burdens upon manufactures.

We hope that the European Commission will be able to consider our comments, and we remain available for any further information that may be necessary.

About the EHPM:
EHPM was created in 1975 and represents and supports approximately 1,600 health-product manufacturers, distributors and suppliers in 14 European Countries, the majority of which are Small and Medium Size Enterprises (SMEs).
As the EU trade association for the food supplement sector, EHPM proactively and constructively engages with the EU Institutions to contribute to the development of a fair European regulatory framework for the sector.
Through our member associations EHPM aims to provide consumers with safe, science-based, high-quality products as well as accurate and helpful information about their nutritional value and use.

56 Rue des Colonies • B-1000 Brussels • Tel.: + 32 2 721 64 95
www.ehpm.org • info@ehpm.org