

The import of Lanolin-origin Vitamin D3 into Europe could be banned

Solution: Phytosterol Vitamin D3 40miu/g Crystal

The import of Lanolin origin Vitamin D3 from outside of Europe could be banned

On 11th June 2021, the European Commission updated the Q&A section of its [Import of Composite Products into the EU](#) document, with specific comment regarding Lanolin-origin Vitamin D3:

2.14. There are no EU-approved establishment listed for the production of lanolin for food purposes. How can I source the vitamin D obtained from lanolin for use in my composite product then?

There is no list of EU-approved establishments for lanolin as there are no specific requirements established for lanolin in Annex III to Regulation (EC) No 853/2004. As a consequence, the vitamin D obtained from lanolin can be sourced from any establishment in the EU or a third country listed for the import of "other products of animal origin" derived from small ruminants, including as regards residues.

The significance of this statement is that classification of Vitamin D3 from Lanolin as a Product of Animal Origin (POAO) means that Lanolin Vitamin D3 from China and India would not be acceptable. Details below:

The Department for Environment, Food and Rural Affairs (DEFRA) confirmed that the correct Legislative route to consider for Lanolin-origin Vitamin D3 is following Article 25(a) of [Commission Implementing Regulation \(EU\) 2021/405](#), which lays down the lists of third countries, territories and zones thereof from which entry into the European Union of animals, germinal products and products of animal origin (POAO) is permitted. *China and India (the primary sources of Lanolin-origin Vitamin D3 in the market) are not on the list.*

The Solution

Phytosterol Vitamin D3 40miu/g Crystal is Cholecalciferol (98-101%) from 100% plant-origin. It is produced through conversion of Phytosterol to Cholesterol and subsequent conversion to Vitamin D3 via Cholesterol. From a regulatory perspective it is no different to Animal-origin Vitamin D3 (Lanolin / other) as the Cholecalciferol is formed.

Conversion to Vitamin D3 and regulatory compliance

The key Regulatory point is we are producing Vitamin D3 40miu/g Crystal that meets USP and EP monographs for Cholecalciferol, using a starting point of Cholesterol USP / EP. This is no different to the synthetic pathway used to produce Vitamin D3 from animal-origins including Lanolin. No Vitamin D3 legislation stipulates the source of Cholesterol. The resulting Vitamin D3 is not a POAO and thus overcomes the European Commission's decision here.

Issue 1, June 28, 2021