food supplements europe

FSE comments on notification TRIS 2021/680/FR

Food Supplements Europe represents companies that are involved in the manufacturing and placing on the market of food supplement and food supplement ingredients.

We herewith offer our comments on the proposed Draft Order laying down the list of substances with endocrine disrupting properties referred to in I and II of Article L. 5232-5 of the Public Health Code and the categories of products presenting a particular risk of exposure referred to in Article L. 5232-5 of the Public Health Code.

The main concern is that this proposed law lists cholecalciferol in Table A of Annex I as a substance with verified and presumed endocrine disrupting properties (endocrine disruptor). This is not justified and we would call upon the European Commission to request France to:

- Remove cholecalciferol from the annex to the law;
- Exclude products placed on the market as food from the scope of the law;
- Postpone the entry into force until after the TRIS process has been completed.

Justification:

- Cholecalciferol is also known as Vitamin D3. It is an essential nutrient that is naturally present in foods and frequently added to food supplements and fortified foods. Vitamin D3 is a nutrient of significant public health importance, because the intake is insufficient in many EU Member States, as recently confirmed by the European Food Safety Authority (EFSA).[1] Vitamin D3 is a prohormone with multiple health benefits recognised by EFSA.[2,3] The inclusion of Vitamin D3 in the list of endocrine disruptors is therefore inappropriate and is likely to undermine public health recommendations aimed at increasing the intake of Vitamin D3 in the population. The obligation by the law to provide information on the presence of endocrine disruptors present in foodstuffs is likely to confuse and deter consumers from consuming products that contribute to vitamin D3 intake in the diet.
- We understand that cholecalciferol (Vitamin D3) is included in this list because it was assessed as biocide and as such included in the ED List 1.[4] Vitamin D3 is not listed by the European Chemicals Agency (ECHA) as endocrine disruptor.[5] In fact, the Swedish assessment report confirms that despite its endocrine properties as rodenticide, Vitamin D3 does not present a risk to human health (p.37).[6] The classification as endocrine disruptor follows the criteria of the biocides legislation (Regulations 528/2021 and

[1] https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0l1v00000E877g/pc0108
[2] https://www.efsa.europa.eu/en/efsajournal/pub/1227
[3] https://www.efsa.europa.eu/en/efsajournal/pub/1468
[4] https://edlists.org/the-ed-lists
[5] https://echa.europa.eu/ed-assessment
[6] https://echa.europa.eu/documents/10162/a11bcbe5-9261-77a9-9589-3118dccf834d

2017/2100) which do not apply to food.[7,8] In food, at the quantities used, Vitamin D3 has an endocrine activity as a prohormone, which is a desired effect and this definitely does not disrupt human endocrinology. In contrast, the use of cholecalciferol as rodenticide is based on effects that occur at very high doses (0,3mg/kg bw/d) which, if applied to a 70 kg human adult, is over 200 times higher than the safe upper level of 100 µg/day as established by EFSA and is therefore not of relevance for intake via food.[9]

- Inclusion of a substance in the Annex of the proposed law triggers the obligation to provide information to consumers on finished products containing the substance. This could be considered appropriate for biocides. Products placed on the market as food however are already governed by legislation ensuring that only safe foods can be placed on the market and detailed labelling requirements are in place. The use and presence of Vitamin D3 in food does not raise safety concerns and in some foods it is even a mandatory ingredient (e.g. infant formulas by Regulation 2016/127).[10] In Finland, Vitamin D3 supplementation is a public health recommendation.[11] It is therefore not appropriate to cover food under this national law, given that specific requirements for food have been harmonised at EU level.
- The law is proposed to enter into force on 1 January 2022. The 3-months standstill period however runs until 26 January 2022. The entry into force should therefore be delayed to ensure that comments submitted in the TRIS process can fully be taken into consideration.

Food Supplements Europe

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[7] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02012R0528-20210610&qid=1637849520541

[8] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R2100&qid=1637850755713

[9] https://www.efsa.europa.eu/en/efsajournal/pub/2813

[10] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02016R0127-20210715&qid=1637854418415

[11] https://www.ruokavirasto.fi/en/themes/healthy-diet/nutrients/vitamin-d/

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