European Federation of Associations of Health Product Manufacturers

EHPM Contribution in the context of the TRIS notification: **2023/0116/F**

Draft Order specifying the details relating to the content and the conditions for presenting the information provided for in I and II of Article L. 5232-5 of the Public Health Code

30/05/2023

Dear Madam/Sir,

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 TRIS notification number 2023/0116/F on the French *draft order specifying the details relating to the content and the conditions for presenting the information provided for in I and II of Article L. 5232-5 of the Public Health Code* (hereinafter "draft order").

The draft order details the content and conditions for informing consumers about the presence of endocrine disruptors (EDs) in products on the French market. It also includes nutrients in its scope and sets a dedicated framework for these ingredients.
Vitamin D3 (cholecalciferol) is the first nutrient to be listed in the French draft order notified in October 2021 and, according to the present draft order notified in March 2023, other nutrients should be included in the list of EDs in the future and a dedicated framework is set up for these ingredients.

EHPM is deeply concerned by the inclusion of nutrients in such a framework, as this is not in line with the European regulatory framework, with scientific evidence accepted by EFSA, and would create uncertainties to consumers regarding the safety of their food products.

In light of the above, we call on the exclusion of nutrients from the scope of the French draft order and from the list of substances with ED properties.

Essential nutrients should be excluded from the list of endocrine disruptors

Essential nutrients, either naturally present or authorised in certain foods for nutritional purposes, are recognised for their beneficial effects on health.
EFSA has established dietary levels below which only beneficial effects of nutrients are expected (tolerable upper intake level). Consequently, nutrients lawfully present or added to food products sold on the European market do not carry any risks and should not be in the scope of the present French order.
Thus, this ingredient should be excluded from the list of EDs.

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The inclusion of cholecalciferol in the list of EDs disregards scientific evidence

Cholecalciferol, the main form of vitamin D3, is the first nutrient to be listed in the French draft order notified on October 2021 (2021/680/F) establishing the list of substances with ED properties, to which EHPM and other stakeholders responded with detailed contributions.

We would like to reiterate again that according to the World Health Organisation (WHO), an ED is *"an exogenous substance or mixture that alters function(s) of the endocrine system* [i.e. the cells and organs involved in the production of hormones and their action on the so-called 'target' cells through receptors] *and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations"*[1].

Vitamin D3 is the precursor of a steroid hormone, calcitriol (or 1,25 dihydroxy-vitamin D3), which is secreted by certain kidney cells, but is also produced by a large number of tissues where its action is local. It is therefore not "foreign to the organism". Like all hormones, it acts on the metabolism of other hormones. Vitamin D3 is the most bioavailable form of vitamin D and, thus, is the form most widely used in foods. More specifically, vitamin D3 (cholecalciferol) is considered the most absorbable form of vitamin D instead of vitamin D2 (ergocalciferol)[2].

The inclusion of cholecalciferol in the list of EDs would generate unjustified mistrust and reluctance towards vitamin D3 supplementation for the reasons already explained above.
This would be hugely detrimental for EU citizens' public health considering that vitamin D, also known as the "sunshine vitamin", has greatly beneficial effects on health[3,4,5,6].

Moreover, we deem imperative to reiterate that cholecalciferol used in safe amounts in foods and food supplements as established by EFSA[7] should be out of the scope of the French order. EFSA has identified a safe upper limit of 100 µg/day which does not raise hormone disturbance, as it is

[1] International Programme on Chemical Safety. (2002). Global assessment on the state of the science of endocrine disruptors. World Health Organization. https://apps.who.int/iris/handle/10665/67357

[2] 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.

[3] Commission Regulation (EU) No 1228/2014 of 17 November 2014 authorising and refusing to authorise certain health claims made on foods and referring to the reduction of disease risk (Text with EEA relevance).

[4] https://connect.efsa.europa.eu/RM/sfc/servlet.shepherd/document/download/0691v00000gXddhAAC

[5]The intake of supplementary vitamins is recommended by the Belgian Authorities, for the entire population (Conseil supérieur de la santé, 2016). This recommendation applies in particular to adolescents (Hochberg *et al.*, 2002), pregnant and lactating women (Clarys *et al.*, 2014) and the elderly. It is even more explicitly intended for young children under 6 years of age (De Ronne & De Schepper 2013; Hochberg *et al.*, 2002) in the form of a supplement dosed at 10 µg (=400 IU/day).

[6] The clinical trial of Sabico *et al.* (2021) concluded that 5000IU daily supplementation of Vitamin D for 2 weeks is safe and tolerable for patients with mild to moderate Covid-19. It was found that "a 2-week oral supplementation of 5000 IU vitamin D3 was superior to 1000 IU in resolving cough and gustatory sensory loss among COVID-19 patients with sub-optimal vitamin D presenting with mild to moderate symptoms". The findings are in line with a vast area of clinical evidence on the beneficial effects of vitamin D supplementation against COVID-19.

[7] https://www.efsa.europa.eu/it/efsajournal/pub/2813

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approximately 225 times lower than the very high doses of cholecalciferol used as a rodenticide (0,3 mg/kg bw/day) mentioned in the ECHA report[8] at the base of the French initiative.

The toxicity level identified in the ECHA report focuses on the safety assessment of cholecalciferol as a rodenticide and falls under the biocide legislation (Regulations 528/2021 and 2017/2100) which does not apply to foods and food supplements.
It must also be noted that cholecalciferol is also used in medicinal products at much higher doses than in foods and food supplements. As a matter of fact, many medicinal products are authorised in Europe at dosages between 25.000 IU (equivalent to 625 µg) and 300.000 IU (equivalent to 7.500 µg).

In addition, the French Food Safety Agency – Anses – issued an opinion[9] in October 2022 in which it recommended not to include vitamin D3 in the list of endocrine disruptors applying to food products.

Finally, we would like to recall that, in the framework DG SANTE's ongoing work on setting harmonised maximum levels in food supplements and fortified foods, EFSA reviewed its previous opinions on tolerable upper intake levels (ULs) for eight micronutrients including vitamin D and has established dietary levels below which only beneficial effects of vitamin D are expected. In EFSA's draft scientific opinion on the Tolerable Upper Intake Level for vitamin D released on April 2023, and despite an extensive review of the literature, the endocrine disrupting hazard is never associated with vitamin D.

The foreseen framework would mislead consumers

In practice, the present draft order foresees that, when a nutrient is listed as an ED, food business operators (FBOs) shall inform consumers that the specific nutrient is an ED and, at the same time, that it has beneficial effects.
EHPM is concerned that the two contradictory information will confuse consumers or even generate suspicion on the reliability of the information given.

Furthermore, the confusion the proposed framework creates in consumers' mind is in breach of Regulation 1169/2011 on food information to consumers which states "Food information shall be accurate, clear and easy to understand for the consumer". The risk of confusion arising from the proposed French scheme has been recognised by the French Food Safety Agency – Anses – itself in its opinion of October 2022 on vitamin D3. The Agency states that "*identifying cholecalciferol as an ED on labels (or equivalent information provisions) of food products containing it is likely to provide erroneous information on the risk*".

Barrier to trade and unnecessary burden on FBOs

EHPM believes that the provisions foreseen in the French draft order will create unjustified barriers. In fact, EHPM is concerned that the foreseen framework and inclusion of vitamin D3 (cholecalciferol) in the list of substances with ED properties will threaten the competitiveness of FBOs of the food supplement sector, mostly small and medium enterprises, that must fulfil regulations implemented differently in each Member State, the provision of information on products having to comply to a specific national regulation (and costs associated with) and the transport of goods with different specifications. This will, in practice, disrupt the proper functioning of the Single Market, one of the EU founding principles.

[8] https://echa.europa.eu/documents/10162/a11bcbe5-9261-77a9-9589-3118dccf834d
[9] https://www.anses.fr/en/system/files/NUT2022AST0099EN.pdf

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Conclusions

In light of the above, we call on the Commission to oppose the French draft order and to ask the French Authorities to amend the draft order in a way that vitamin D3 (cholecalciferol) and other nutrients are excluded from the proposed list of substances with ED properties.

About EHPM
The European Federation of Associations of Health Product Manufacturers (EHPM) was created in 1975. With its 14 National Associations and 11 Member Companies, EHPM represents product manufacturers, distributors, the majority of whom are small and medium-sized enterprises (SMEs), in 17 European countries.
EHPM proactively cooperates with the European Institutions and stakeholders to strengthen the overarching strategy for a healthier Europe enshrined in the Farm to Fork and the European Green Deal.

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