Nutrients are essential to life.

They are not endocrine disruptors.

Synadiet position on TRIS Notification 2023/116/F

May 2023

A Draft French 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 was notified through the TRIS procedure on March 17th of 2023. It details the content and conditions for informing consumers about the presence of endocrine disruptors in products on the French market.

This draft order includes nutrients in its scope and sets a dedicated framework for these ingredients. It considers that, even though they carry health benefits, these ingredients could be considered as endocrine disruptors. Vitamin D3 (cholecalciferol) is the first nutrient to be listed in the French draft decree notified on October 2021 establishing the list of substances with endocrine disrupting properties. According to the present draft decree, other nutrients should be included in the list of endocrine disruptors in the future.

As representative of the French food supplements sector, we are very concerned about the inclusion of nutrients in a scheme dedicated to endocrine disruptors. Nutrients and other substances authorized in food supplements are recognized for their beneficial effects on health. By including them in the present scheme, French authorities seem to disregard scientific evidence, to ignore European Food law, to create a new barrier to trade and to create uncertainties for consumers regarding the safety of their food products.

Therefore, we ask for all nutrients and for other substances authorized in food supplements as an active ingredient with health benefits to be excluded from the scope of the present French scheme.

The inclusion of cholecalciferol in the list of endocrine disruptors disregards scientific evidence

The inclusion of vitamin D3 in the list of endocrine disruptors lacks scientific grounds. First of all, the French Food Safety Agency – Anses – issued an opinion[1] on October 2022 in which it recommended not to include vitamin D3 in the list of endocrine disruptors applying to food products. Moreover, EFSA has established dietary levels below which only beneficial effects of vitamin D are expected (tolerable upper intake level)[2]. 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 hazardous is never identified for vitamin D.

Furthermore, an endocrine disruptor is, according to the WHO, *"an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations".*

At doses permitted in food and food supplements, cholecalciferol (vitamin D) does not alter the functions of the endocrine system but, on the contrary, participates in it and generates beneficial effects on the body. It cannot, therefore, be considered as an endocrine disruptor.

These beneficial effects of vitamin D and other nutrients are recognized by the French authorities themselves in the present draft order : *"For certain substances, due to their nutrient character (vitamins, minerals) and their health benefits up to a certain dose (higher safety limits), such as cholecalciferol (vitamin D3), the information on the presence of substances with endocrine disrupting properties will be adapted"* This acknowledgment is in complete opposition with the alleged endocrine disrupting properties of the substances.

[1] ANSES. (2022). Scientific and technical support note on the application to cholecalciferol (vit D3) of the provisions relating to substances with endocrine-disrupting properties under Act no. 2020-105 of 10 February 2020, known as the "AGEC Act" (Request no. 2022-AST-0099). Maisons-Alfort: ANSES, 18 p.
[2] EFSA NDA Panel, 2012b. Scientific Opinion on the Tolerable Upper Intake Level of vitamin D. Efsa Journal, 10:2813. doi: https://doi.org/10.2903/j.efsa.2012.2813

A framework generating a misinformation of consumers

The present draft order proposes, when a nutrient is listed as an endocrine disruptor, to appease consumers by informing them, together with the information that the nutrient is an endocrine disruptor, that it has beneficial effects. The proposed statement to be used by food business operators when communicating on the presence of the substance in their products is the following : *"contains the substance [insert the name of the substance as given in Table Abis mentioned above]: this substance has health benefits when used according to the precautions and dosage specified on the package leaflet or product labelling. If in doubt, seek the advice of a health professional".*

This statement raises two questions :

- How could beneficial substances be considered as endocrine disruptors? Or how could an endocrine disruptor be beneficial for health?

This first question demonstrates the complete opposition of the two concepts and the improperness for nutrients used in foods to be listed as endocrine disruptors.

- What will consumers understand when faced with these two contradictory indications?

The identification of the substance as endocrine disruptor will generate their fear and the proposed statement will, at best, confuse them, at worst generate suspicion on the reliability of the information given.

A draft order in breach of EU Food law

By nature, Food products put on the market in the EU must be safe (article 14 of regulation 178/2002). In this regard, EFSA has established dietary levels below which only beneficial effects of nutrients are expected (tolerable upper intake level). By questioning the safety of nutrients, the French scheme disregards this founding principles of EU food law. 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.

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 recognized by the French Food Safety Agency – Anses – itself in its opinion of October 2022 on vitamin D3[3]. The Agency states that *"identifying cholecalciferol as an endocrine disruptor on labels (or equivalent information provisions) of food products containing it is likely to provide erroneous information on the risk".*

Finally, in creating a new requirement for companies selling products in France, the French Order creates a new barrier to trade within the single market. It imposes a requirement that, not only, does not derive from EU law but is in opposition with it.

Conclusion

In view of the importance of vitamin D and other nutrients and substances for public health, and the safety of the substances authorized in food products, it is particularly incomprehensible to include them in a framework dedicated to endocrine disruptors.

Such inclusion would indeed be likely to turn the population away from foodstuffs containing them and would thus lead to an increase in deficiencies in the population.

We therefore ask for nutrients and for substances authorized in food supplements to be excluded from the scope of the present French scheme.

SYNADIET is the national trade union for food supplements.

With close to 300 members (consultants, manufacturers, processors, ingredient suppliers, distributors, analysis laboratories, etc.), SYNADIET is uniquely representative in France. It is the largest national trade union in the European Union in its sector of activity.

Synadiet aims to federate and support its members in the exercise of their profession, which is to contribute to preserving and improving the health of consumers, through the use of food supplements & other natural health products, and to engage them in a responsible and transparent approach.

[3] ANSES. (2022). Scientific and technical support note on the application to cholecalciferol (vit D3) of the provisions relating to substances with endocrine-disrupting properties under Act no. 2020-105 of 10 February 2020, known as the "AGEC Act" (Request no. 2022-AST-0099). Maisons-Alfort: ANSES, 18 p.