Comments on notifications TRIS 2023/116/F and 2023/117/F

We call the European Commission and the Member States to submit detailed opinions on the notifications TRIS 2023/116/F and 2023/117/F, because:

- Despite one detailed opinion (Hungary) and several comments (Commission, Germany, Hungary, Netherlands), **the French Authorities intend to keep vitamin D3 in the list of substances with verified and presumed endocrine disrupting properties** referred to in Article L. 5232-5 of the French Public Health Code (*see notification TRIS 2021/680/F*).
- France intends to accompany the information by a disclaimer explaining that, at the same time cholecalciferol is an endocrine disruptor and is also an essential nutrient. The proposed sentence: " ***contains cholecalciferol: 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***."
- Listing vitamin D3 as an endocrine disruptor, whereas it is an essential nutrient for humans, would set a precedent, and it will bring huge confusion for the consumers on the role and importance of this essential nutrient for which most of the European population has insufficient intakes.
- France should keep into account the opinion of the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) which “advises against including vitamin D3 in the list of substances to be mentioned as endocrine disruptors on food products, as part of implementation of the French AGEC Act".
- Providing unclear and confusing information on food containing vitamin D and on vitamin D is an infringement to the food information to consumers regulation (1169/2011), to the health claims regulation (1924/2006).
- France intends to use the Scan4Chem app, which was developed to inform European citizens on the presence of substances of very high concern (SVHC), to inform on the presence of vitamin D3. This is a misuse of the app and will bring more confusion for consumers.
- A pragmatic approach, taking into account the public health impact, the consumer’s understanding, the specificity of food products which are regulated with the principle of risk assessment and not hazard assessment, is needed.

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Therefore, food related uses of vitamin D3 should be exempted from the draft Orders.

Background:

Law No 2020-105 of 10 February 2020 on combating waste and the circular economy, so-called "AGEC".

- Article 13-II provides that any person placing products on the market for consumers containing substances for which the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) classifies the endocrine disrupting properties as verified or suspected must "provide information to the public by electronic means, in an open, easily reusable and exploitable format by an automated processing system, for each of the products concerned, to identify the presence of such substances in those products". This obligation also applies to certain categories of products with a particular risk of exposure, for substances which endocrine disrupting properties are suspected by ANSES.

Decree No 2021-1110 of 23 August 2021 on the provision of information identifying endocrine disruptors in a product.

- During the TRIS consultation (2020/832/F) Finland, Germany, Hungary, Italy, Spain and Sweden made comments.[1]

October 2021: France notified a 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 (TRIS 2021/680/F). Vitamin D3 is on the list.

- Comments were made by the European Commission, Germany, Hungary, Netherlands and a detailed opinion was issued by Hungary.[2]

Notification TRIS 2023/116/F[3]

The draft: "Draft Order of 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"

The Order specifies 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 concerning:

[1] https://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2020&num=832
[2] https://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2021&num=680
[3] https://ec.europa.eu/growth/tools-databases/tris/index.cfm/fr/search/?trisaction=search.detail&year=2023&num=116&mLang=FR

- the presence of substances with endocrine disrupting properties that are verified and presumed in the products defined in Article R. 5232-19 of the Public Health Code;
- the presence of substances with endocrine disrupting properties that are suspected in the categories of products with a particular risk of exposure referred to in II of Article L. 5232-5 of the Public Health Code.

The substances concerned by this specific information are mentioned in the tables Aa and Ba annexed to the 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, mentioned in Article R. 5232-19 of the same Code: this Order was the subject of a previous notification (reference 2021/0680). The drafting of this Order, which has not yet been published to date, has been revised following comments from the Commission and the Member States and Hungary's detailed opinion. It is attached for information purposes to this notification.

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 to indicate that these substances present health benefits according to the precautions for use and dosage specified on the package leaflet or labelling of the product and that in case of doubt the advice of a health professional should be sought.

As Vitamin D3 is still listed on the revised order subject to the previous notification (reference 2021/680/F), the information will be: ***« contains cholecalciferol: 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. »***

Comments:

- **The draft Order disregards the opinion from the French Agency for Food, Environmental and Occupational Health & Safety (ANSES).**

On 30 May 2022, ANSES received a formal request from the Directorate General for Health (Ministry of Health) and the Directorate General for Risk Prevention (Ministry of Ecology) to provide scientific and technical support for the following: Formal request relating to vitamin D3 in connection with implementation of the provisions of Article 13-II of Act No. 2020-105 of 10 February 2020 on waste reduction and the circular economy (the "AGEC Act"), concerning the availability of public information enabling the identification of endocrine disruptors in products.

On 26 October 2022, ANSES made public its opinion[4] and concludes:
"**Under the AGEC Act, 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[21]** , insofar as daily intakes of vitamin D associated with food consumption are below the tolerable upper intake level defined for cholecalciferol and, moreover, avoiding these products would exacerbate the situation of requirements not being adequately met that already concerns a significant proportion of the population (34.5% of the population had an inadequate vitamin D status in 2015), as pointed out by the HCSP in its report of 21 June 2022 recommending the consumption of foods rich in vitamin D (HCSP 2022)." [21] Even if it were correct on characterisation of the hazard.

On 28 October 2022, ANSES issued a news[5] for the general public with a strong and clear title: "Vitamin D: no endocrine disruptor label on food products". The main message: "**ANSES advises against including vitamin D3 in the list of substances to be mentioned as endocrine disruptors on food products, as part of implementation of the French AGEC Act**".

➔ The draft Order does not take into account the opinion of the French Agency for Food, Environmental and Occupational Health & Safety which advises not to include vitamin D3 in the list of substances to be mentioned as endocrine disruptors on food products. The opinion of ANSES provides scientific grounds to exempt food related uses of Vitamin D3.

- **The draft Order disregards the article 13-II of the French Law "AGEC"**

The French Law "AGEC" added an article to the French Public Health Code: article L. 5232-5 which provides that: "*Anyone who places on the market products intended for consumers which, at the end of the manufacturing process, contain* ***substances which the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) has indicated as having proven, presumed or suspected endocrine-disrupting properties*** *shall make available to the public electronically, in an open, easily reusable format that can be used by an automated processing system, for each of the products concerned, information making it possible to identify the presence of such substances in these products*."
It is clear from the opinion of ANSES issued in October 2022, that the French Agency for Food, Environmental and Occupational Health & Safety has not indicated that vitamin D3 when used in food products has proven, presumed or suspected endocrine-disrupting properties.

➔ The draft Order is not consistent with the requirements of article L. 5232-5 of the French Public Health Code. ANSES has not indicated that vitamin D3 when used in food products has proven, presumed or suspected endocrine-

[4] https://www.anses.fr/en/system/files/NUT2022AST0099EN.pdf
[5] https://www.anses.fr/en/content/vitamine-d-no-endocrine-disruptor-label-food-products

disrupting properties. Therefore, vitamin D3 should not be on the French list of endocrine disruptors.

- **The choice of the ED list is questionable.**

France took the decision to base its legislation on the ED-list 1, which includes cholecalciferol, whereas the ECHA list does not. The ED-list 1 includes more substances than the official list of endocrine disruptors defined by REACH despite the fact that cholecalciferol has been assessed under REACH provisions as a biocide (rodenticide).
The effect as a rodenticide is irrelevant for human exposure and requires intakes that are more than 200 times higher than the tolerable upper intake level of Vitamin D as established by the European Food Safety Authority.
This was underlines by Stella Kyriakides, EU Commissioner SANTE in May 2022[6] :
"*the Commission issued comments to the French authorities highlighting that these drafts may not be aligned with the regulation on classification, labelling and packaging of substances and mixtures[4] (breach of Article 51 on the free movement) and with the REACH Regulation[5] (breach of Annex XII read in conjunction with Article 128 on free movement).*
The Commission also pointed out that cholecalciferol was not identified as substances of very high concern (SVHCs) in accordance with Articles 57 and 59 of the REACH Regulation. ***This means that cholecalciferol is not to be considered as an endocrine disruptor also in food***."

➔ Therefore, the French notified Order is not consistent with the harmonized framework under REACH.

- **Food supplements will be the collateral damage whilst the targeted products (biocides) won't be in the scope of the draft Order!**

The classification of vitamin D3 as endocrine disruptor by France relies on a dossier under the biocides legislation (Regulations 528/2021 and 2017/2100). The dossier deals with the use of cholecalciferol as a rodenticide. The product is used by professionals to fight against rodents resistant to usual treatments.
If the draft Order is adopted, for the biocides currently on the French market there will be no information of the presence of endocrine disruptors, because the concentration of vitamin D3 in the biocidal products is below the threshold established in the draft Order, which is of 0.1%w/w. **So the biocidal products targeted by the draft Order would be out of the scope!**

France decided to maintain vitamin D3 on the list whereas the amount that is exacerbating endocrine disrupting effect is far above the daily dose found in foods and food supplements: 200 times higher than the tolerable upper intake level of Vitamin D as established by EFSA.

[6] https://www.europarl.europa.eu/doceo/document/E-9-2022-000869-ASW_EN.html

The issue comes from the selection criterion which is based on the concentration in the product (0,1%w/w). **Some vitamin D food supplements especially in drop dispensers are above this threshold and would have to give the information that they contain an endocrine disruptor**.

➔ The inclusion of Vitamin D3 in the French list is due to a biocidal product dossier. The draft Order will not apply to biocidal products currently on the French market, because of their concentration in vitamin D3 (<0.1% w/w) but will apply to some concentrated forms of food supplements.

- **From a public health perspective, the draft Order undermines public health recommendations on vitamin D.**

The obligation by the French Public Health Code to provide information on the presence of endocrine disruptors present in foodstuffs is likely to undermine public health recommendations aimed at increasing the intake of Vitamin D3 in the population. It is likely to deter consumers from consuming products that contribute to vitamin D3 intake in the diet.

Moreover, with the proposed sentence on the presence of Vitamin D3 (*« contains cholecalciferol: 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. »)*, the consumers will face contradictory information on Vitamin D3 that may put them in a higher risk of deficiency in Vitamin D. Indeed, Vitamin D deficiency is pretty high in the EU including in France with close to 70% of the population not reaching the reference values.

There is a risk that consumers stop consuming vitamin D3 containing foodstuffs (eggs, fatty fish, dairy products, infant formula, food supplements…), which would have a direct negative impact on the vitamin D nutritional status.

➔ The inclusion of an essential nutrient in the list of endocrine disruptors is contradictory to the public health recommendations on Vitamin D, while most of the European population has deficiency.

- **The draft Order disregards the requirements of the Food Information to Consumers Regulation**

The article 3 of the notified draft proposes to give two contradictory information to the consumer with the sentence: "*contains cholecalciferol: this substance has health benefits according to the precautions for use and the dosage specified on the instructions or the labeling of the product. If in doubt, seek the advice of a healthcare professional*". Reading this information, the consumer will question the safety of food products, despite the fact that they are compliant with the legal rules.

Article 7 of the Food Information to Consumers Regulation (No 1169/2011) provides that "***the food information shall not be misleading***" and the "***food information shall be accurate, clear and easy to understand for the consumer"***. The draft

Order, in its present form, could have the effect of misinforming consumers about the health risks associated with normal intake of cholecalciferol via food and food supplements.
Article 38 (national measures) of the Food Information to Consumers Regulation (No 1169/2011) provides that "*As regards the matters specifically harmonised by this Regulation, Member States may not adopt nor maintain national measures unless authorised by Union law*."
The notified draft may affect EU harmonised rules, by going beyond the applicable provisions of Regulation (EU) No 1169/2011 and can be potentially creating additional burden for food business operators and traders of such products that contain one or more of the substances listed in the notified draft in view of their marketing in France.

➔ The proposed adapted information for the presence of Vitamin D3 in the draft Order brings confusion and is not easy to understand by the average consumers. Therefore, the sentence doesn't fulfil the requirements of Article 7 of the Regulation No 1169/2011.

- **The draft Order disregards the European rules on health claims**

The health claims regulation (No 1924/2006) defines health claim as "*any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health"*. The proposed sentence**:** "*contains cholecalciferol: this substance has health benefits according to the precautions for use and the dosage specified on the instructions or the labeling of the product. If in doubt, seek the advice of a healthcare professional*" refers to the health benefits of vitamin D3. **Therefore, the proposed sentence meets the definition of a health claim and should be compliant with requirements of the health claims regulation.**

➔ The proposed sentence (article 3 of the draft Order) is likely to be a non-permitted health claim.

- **The draft Order disregards the European rules on addition of vitamins to food and to food supplements**

The use of vitamins and minerals in food and in food supplements is regulated respectively by Regulation 1925/2006 and Directive 2002/46.
Should a Member State have serious grounds for considering that a food product or a food supplement endangers human health, the appropriate provisions to be applied are: article 13 for Regulation 1925/2006 and article 12 for Directive 2002/46.
France has decided to maintain vitamin D3 on the list of endocrine disruptors. So, it is presumed that France has serious grounds for considering that food products and food supplements which contain Vitamin D3, endanger human health. France should have used the appropriate regulatory framework to express its serious grounds.

➔ The draft Order disregards the European rules on addition of vitamins to food and to food supplements. The appropriate framework when a Member States has serious grounds for considering that a food product to which vitamin D has been added or a food supplement endanger the human health are article 13 for Regulation 1925/2006 and article 12 of Directive 2002/46.

Notification TRIS 2023/117/F[7]

The draft:
"Draft Order on the provision of information to identify endocrine disruptors in a product by means of an application"

The Order designates an alternative way of informing the public about the presence in products of substances which the Agency for Food, Environmental and Occupational Health & Safety qualifies as having verified, presumed or suspected endocrine disrupting properties.

The draft Order designates the application of Scan4Chem.

The Scan4Chem app was created through a project funded by the European Commission under the LIFE programme has resulted in the creation of a voluntarily updated database of companies on the presence of substances of very high concern in the articles as defined in the REACH regulation.
When the consumer scans the barcode of a product like clothing, sports equipment, toys etc, he gets information on the presence of substances of very high concern (SVHCs) above a 0.1% threshold in that product. https://www.askreach.eu/app/

Comments:

- **The choice of the Scan4Chem app is not consistent for Vitamin D3 used in food**

The objective of the Scan4Chem is to inform on the presence of substances of very high concern (SVHCs) above a 0.1% threshold in that product regulated under REACH.

Stella Kyriakides, EU Commissioner SANTE in May 2022[8] made it clear "*that **cholecalciferol was not identified as substances of very high concern (SVHCs) in accordance with Articles 57 and 59 of the REACH Regulation***."

[7] https://ec.europa.eu/growth/tools-databases/tris/fr/search/?trisaction=search.detail&year=2023&num=117
[8] https://www.europarl.europa.eu/doceo/document/E-9-2022-000869-ASW_EN.html

➔ The intention of France to use the Scan4Chem app to inform of the presence of Vitamin D3, which is not a substance of very high concern, will be a misuse of the Scan4Chem and will mislead the consumers.

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EU Specialty Food Ingredients represents a united voice for the specialty food ingredients industry on scientific, technical and regulatory issues relating to food products in Europe. It is our aim to ensure that all stakeholders - from manufacturers and retailers to regulatory authorities and consumers - are correctly informed of the use, safety and benefits of specialty food ingredients. In total, more than 200 international and national food ingredients companies are currently involved in the Federation's activities through direct membership or an association. 3-8% of EU specialty food ingredients manufacturers' turnover is dedicated to research and development.

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