

FoodDrinkEurope comments on the TRIS Notification 2023/116/F (France) 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

FoodDrinkEurope would like to comment 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:

The French Order is not aligned to European strategies

We believe this draft Order diverts from the actions already announced by the EU's "Chemicals Strategy for Sustainability" – as already stated in FoodDrinkEurope's comments to the TRIS Notification 2020/832/F and 2021/680/F.

The French Decree threatens the competitiveness of the industries 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 disrupt the EU founding principle of the Single Market and common rules, thus reducing the competitiveness of the European food industry.

Essential nutrients, either naturally present in certain foods or authorized in certain foods for nutritional purposes, should be excluded from the list of endocrine disruptors

We remain deeply concerned by the inclusion in the list of endocrine disruptors (EDs), as notified under 2021/680/F, of substances that are otherwise authorized in Europe for nutritional purposes, such as cholecalciferol (vitamin D3).

Vitamin D3 is well known for its role as a nutrient and a dietary supplement. It is used in Europe as a substance for nutritional purposes, both in specialized nutrition and in conventional foods, in full compliance with current regulations. We think it is important not to create uncertainties to consumers on its essential role for the population in a context of a nutrient where deficiencies are already present. We believe it is critical, not to divert them from products specially formulated for their needs, according to their ages and specific needs.

The draft Order provides for specific information for substances with health benefits, such as cholecalciferol: *"contains the substance [completed with the name of the substance as mentioned in the above-mentioned table Abis/Bbis]: this substance has health benefits according to the precautions for use and the dosage specified on the product's leaflet or label. In case of doubt, seek the advice of a health professional"*.

This message is very unlikely to be understood by consumers, who might doubt about the essential and indispensable character of vitamin D3 for the population and therefore divert from products specially formulated, according to age and specific needs. The average consumer lacks the needed expertise to understand the difference between endocrine activity and endocrine disruption, the complex concepts of having different lists for EDs classification, and the relevance of the simple presence of an ED in a food product. We consider that regulating the use of EDs and managing the risk are the responsibility of the authorities and this responsibility should not be indirectly delegated to consumers.

Therefore, we reiterate our request to exclude from the list of EDs those essential nutrients either naturally present in certain foods or authorized in certain foods for the fortification of foodstuffs or regulated in specialized foodstuffs in the view of a public health objective, as also highlighted by the French Agency for Food, Environmental and Occupational Health and Safety (ANSES). ANSES advised *"against including cholecalciferol in the list of substances to be mentioned as endocrine disruptors on food products, as part of implementation of the French AGECE law, because such information would contribute to an incorrect perception of the risk and thus worsen existing inadequate intakes"*.

The terms of application of information to consumers need to be specified

The draft Order specifies that the mandatory information applies to "the entire product and its primary packaging or sales packaging within the meaning of Article R. 543-43 of the Environmental Code, where the concentration of a substance with proven or presumed endocrine disrupting properties is greater than 0.1% as a percentage by mass either in the product or in its packaging".

When the ED is only present in the packaging, the obligation to provide mandatory information is disproportionate and will create confusion for consumers. This provision does not consider if the ED comes into contact with the (food) product or whether it migrates or not into the (food) product; the entire (food) product needs to be listed. A consumer will not be aware of this difference and will avoid buying the product.

The use of the terms "primary packaging or sales packaging" is confusing. Indeed, the sales packaging as delivered to the consumer can include grouping packaging (films, cartons, etc.), which correspond to secondary packaging according to the

Environmental Code. It is our understanding that this secondary and grouping packaging, such as film/cardboard, is excluded from the scope of this obligation. The Decree will benefit from clarification in this regard.

Furthermore, the threshold for the information obligation is set at 0.1% w/w for both the product and its packaging. In the case of packaging, our understanding is that the provision of mandatory information to consumers would align with the requirements to display information on substances of very high concern (SVHC, set by Art. 13.I of the AGECLaw). It would therefore apply as soon as a substance with proven or presumed endocrine disrupting properties is present in a concentration of more than 0.1% by mass in a substance, mixture or article, meaning of points 1, 2 and 3 of Article 3 of Regulation (EC) No. 1907/2006, with the exception of medicines. The Decree should clarify this point to avoid different interpretations of the reporting requirement.

The selection criteria for substances on the list are unclear

It would be useful that French authorities explain the criteria used to select certain substances from the European ED List. As an example, cholecalciferol was not identified as substances of very high concern (SVHCs) in accordance with Articles 57 and 59 of the REACH Regulation. This means, as pointed out by the Commission¹, that “cholecalciferol is not to be considered as an endocrine disruptor also in food”.

Precise information should be provided on the criteria chosen for the establishment of the list of product categories presenting a particular risk of exposure (Annex II). These criteria shall be based on robust scientific evidence and unanimously shared by the European assessment bodies. Besides, to ensure consistency with the decree on EDs published on 25 August 2021, each substance shall be assigned to the ED category that corresponds to it (“proven” or “presumed” in particular).

Need for consultation in case of any changes of the list of EDs

Any future modification of the list should be subject to prior consultation of operators to estimate its feasibility. It is essential that the qualification as an endocrine disruptor is based on solid scientific evidence, which will have to be compared and validated within an independent competent authority, at European level. Finally, for substances which will be later added to the list, only their inclusion in a regulatory text should be considered, not only their publication in scientific opinions or ECHA list.

¹ https://www.europarl.europa.eu/doceo/document/E-9-2022-000869-ASW_EN.html

The timeframe for implementation is too short

FoodDrinkEurope would like to reiterate, considering our concerns listed above, our opposition to the French Decree.

Ultimately, if introduced, the six-month implementation period defined in Decree No. 2021-110 seems unrealistic given the complexity of supply chains and the specificity of French requirements. As the list can be extended in the long term beyond European regulations, an implementation period of 18 months would be more appropriate from an operational point of view. It would allow economic stakeholders to adapt, especially since the confidentiality related to certain information could be a major hurdle to obtain the requested data.

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About FoodDrinkEurope

FoodDrinkEurope represents the food and drink manufacturing industry, made up of 294,000 businesses, of which 99% are SMEs, with 4.6 million employees.