Comments on notification
TRIS 2023/116/FR

NèreS is the trade association representing pharmaceutical companies manufacturing and selling selfcare products (such as food supplements, consumer medical devices and OTC medicines) in France.

Through this note, NèreS submits its comments on the draft decree submitted to the Technical Regulation Information System (TRIS) : "*Arrêté précisant les modalités relatives au contenu et aux conditions de présentation des informations prévues aux I et II de l'article L. 5232-5 du code de la santé publique*".

While we recognize the importance of providing appropriate and accurate information to consumers, we would like to draw your attention to the following points in this draft decree:

- The draft Executive Order refers to molecules listed in another draft executive order (which has not been subject to a new consultation despite substantial amendments made by the French government after a 1st TRIS consultation). In order to ensure a transparent TRIS consultation, we feel it is essential that the new draft listing the substances considered to be endocrine disruptors be also included in the present TRIS consultation, so as to enable the European Commission and member states to carry out a full analysis of the envisioned regulation and its impacts on the EU Internal Market;

- The draft Executive Order also refers to specific substances, such as cholecalciferol (the chemical name for vitamin D3).

We would like to expand on these two major points below:

On a partial consultation that fails to present the entire framework:

We consider that the current TRIS consultation on the draft executive order on modalities doesn't enable the European Commission and the Member States to consider the whole framework, without a new submission of the draft executive order establishing the list of substances presenting endocrine disrupting properties mentioned 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 mentioned in II of article L. 5232-5 of the Public Health Code.

Indeed, the analysis of the impact of the provisions of the draft executive order on the modalities need to consider the substances being considered to be endocrine perturbator and ultimately included in the new version of the draft. Given that the list of endocrine disruptors (originally submitted to TRIS consultation under number 2021/680/F) has changed significantly since this consultation, it would be appropriate to submit the updated draft Executive Order to a new TRIS procedure.

On the mention of cholecalciferol in the draft executive order:

Mentioning of cholecalciferol in the draft executive order does not seem appropriate for two reasons:

- On the form: as a separate executive order specifically lists substances deemed to be endocrine perturbators, the executive order defining modalities should not also list substances.

- On the substance (the description of cholecalciferol as an endocrine pertubator)

Anses scientific opinion has not been taken into account

In view of the detailed opinion received from the Member States when the list of endocrine disruptors was first notified (number 2021/680/F), and the requests for explanations from professional organizations, the French Directorate General for Health (DGS) and the Directorate General for Risk Prevention (DGPR) commissioned to the French National Agency for Food, Environmental and Occupational Health Safety (ANSES) its scientific and technical support which will be the report on the *Referral relating to the substance cholecalciferol (vitamin D3) as part of the implementation of the provisions of article 13-II of law no. 2020-105 of 10th February 2020 more specifically the provision to the public of information enabling the identification of endocrine disruptors (EDs) in a product*.

ANSES published its report on October 27, 2022 and summarizes its key opinion on its website with the unequivocal headline "Vitamin D: no PE labelling for food products"[1]. ANSES advises against the inclusion of vitamin D3 in the list of substances to be displayed as endocrine disruptors on food products. Unfortunately, the draft executive orders don't reflect this scientific opinion.

European views and opinions not taken into account

In 2022, European associations, member states including a detailed opinion from the Hungarian authority, and also amongst others a statement from the European Commissioner for Health and Food Safety, Stella Kyriakídes reacted to the draft executive order establishing the list of substances with endocrine-disrupting properties mentioned in I and II of article L. 5232-5 of the French Public Health Code, notified under reference 2021/680/F The Commissioner made her official statement on 13th May 2022, stating that "cholecalciferol should not be considered as an endocrine disruptor in food". In so doing, it has committed the European Commission, which "considers that the authorization of cholecalciferol as a source of vitamin D in food supplements and animal feed is scientifically justified". All the more so as **cholecalciferol is not listed as an endocrine disruptor in the European Regulation on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)**.

European harmonization

European studies on endocrine disruptors are currently underway. The EU's strategic approach - based on the precautionary principle - aims to minimize overall human and environmental exposure to endocrine disruptors, develop a thorough research base for effective decision-making, promote dialogue and enable all stakeholders to make their

[1] Free translation of the original title : "". Article here: https://www.anses.fr/fr/vitamine-d-pas-affichage-perturbateur-endocrinien-produits-alimentaires

voices heard and work together. We therefore believe that the French should be fully aligned with the European regulatory and scientific principles. ECHA provides a list of well documented and reliable endocrine disruptors on its website. It turns out that the list of substances does not include any substances used in food (European list of endocrine disruptors, updated 4th May 2023[2]).

It is important for every European citizen to have reliable and consisten information in all member states, thus the importance of an European harmonization based on the work of an independent, competent authority at European: the ECHA.

Ambiguous communication to consumers

We fear that the wording considered for messages aimed at consumers will not provide confidence in the substances authorized for use in food products. For most European citizens, the classification of a substance authorized for use in food products as endocrine disruptors (according to specific characterizations and assessed doses) imply that such substance is highly hazardous to consumers' health.

Indeed, the juxtaposition of contradictory injunctions in the draft executive order makes the message had to understand for consumers. As it stands, it classifies vitamin D as an endocrine disruptor, but reiterates the substance's benefits by adding an additional message: "*this substance presents health benefits when its concentration in the product respects the upper safety limits set by the health authorities (refer to the product leaflet or manufacturer's information). Above these limits, the substance has proven or suspected endocrine-disrupting properties. If in doubt, seek the advice of a health professional*".

When reading the message, the consumer will first wonder about the availability of a consumer product containing endocrine disruptors, and the possibility of holding non-compliant food products if endocrine disruptor doses are not respected. This last point would lead consumers to believe that manufacturers can market dangerous products that do not comply with current regulations. This would certainly create suspicion, and even the risk of litigation, even though companies scrupulously respect the cholecalciferol thresholds defined by authorities.

But even more concretely, it will be up to the individual citizen to decide on their consumption according to the risk/benefit ratio, based on the information available to them and after reading the package leaflet. Given that the average citizen does not have the necessary expertise to understand the difference between endocrine disrupting activity and the presence of endocrine disruptors in food, this draft executive order will lead consumers to interpret that the safety of marketed products is not guaranteed, and therefore to make decisions solely on the basis of lists of substances present.

The end result of such an ambiguous message will be the population's distrust in consuming products that include substances authorized in food products and identified as endocrine disruptors. In the case of vitamin D3, the products concerned may be foods products such as milk, yoghurt, etc., but also other products impacted by media information, such as medicines used to combat cardiovascular disease.

In 2022 NèreS surveyed a sample of 1,003 French people to assess the impact of a message combining endocrine disruptors and health benefits. The results show that such a dual message is incomprehensible to the public, and goes against the desired objectives.

[2] European list of endocrine disruptors, updated on 4th May 2023

Some of the results of this study are worth highlighting:

- 9 out of 10 people currently have a good image of vitamin D
- At the same time, people have a very negative view of endocrine disruptors (EDCs): 9 out of 10 (87%) consider them to be dangerous to health, and 78% avoid exposing their children to them.
- If vitamin D is classified as an endocrine disruptor:
  - 79% of people indicate that their image of vitamin D will deteriorate significantly.
  - Furthermore, if this classification were to be accompanied by a government message on the benefits of vitamin D, 85% of respondents selected at least one negative feeling: incomprehensible, confusing, worrying, distrustful, etc.
    Moreover, still in this situation, 61% of the people would reduce or even stop consuming food supplements containing vitamin D.
  - Even without the obligation to inform the patient, medication would be affected: 58% of the general population would reduce or stop their vitamin D medication.

The results of this survey are available to the European Commission upon request.

In addition, as part of the TRIS 2023/116/EN notification, we would like to draw your attention to the following points:

In the draft Order on the provision of information to identify endocrine disruptors in a product by means of an application, the authorities suggest that manufacturers should use the Scan4Chem application, which has been developed to inform European citizens of the presence of substances of very high concern (SVHC), to provide information on the presence of endocrine disruptors. As a reminder, Scan4Chem is part of the European REACH regulation, which aims to protect European consumers and promote information.

As stated in the preamble to the draft order, "the Scan4Chem application is a possible means of making available information on the presence of substances of very high concern with known, presumed or suspected endocrine disrupting properties in articles within the meaning of the REACH Regulation". This is a European application.

However, it should be noted that not all the molecules that would be subject to the information obligation appear on the list of substances of very high concern with known, presumed or suspected endocrine disrupting properties under the REACH regulation, such as vitamin D.

With this provision, French consumers, or consumers in any other European country, will treat any endocrine disruptor as a SVHC, which raises the question of whether this draft decree fulfils the initial intention of the European authorities.

Instead of improving consumer information, the planned provision **risks increasing consumer confusion.**

A pragmatic approach, taking into account the impact on public health, consumer understanding and the specific nature of food products, which are regulated according to the principle of risk assessment rather than hazard assessment, is needed: vitamin D3 (used in food) should be withdrawn from the notified drafts.

* * *