European Federation of Associations of Health Product Manufacturers

EHPM Contribution in the context of the TRIS notification: **2022/395/S**

On the draft measure amending the current Swedish Food Agency Regulation (LIVSFS 2003:9) on dietary supplements Dnr 2018/02027, with regard to the maximum levels of vitamin D and iodine

06/09/2022

The European Federation of Associations of Food 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 2022/395/S on the Swedish draft measure amending the current Swedish Food Agency Regulation (LIVSFS 2003:9) on dietary supplements Dnr 2018/02027, with regard to the maximum levels of vitamin D and iodine (hereinafter "draft measure").

Questioning the setting of maximum levels in compliance with legislation

EHPM would like to question whether the maximum permitted levels laid down in the Swedish draft measure are set in compliance with principles laid down in *Directive 2002/46*[1] and those of the TFEU[2] relating to the free movement of goods and ECJ case law (*Noria case*[3]), looking at the divergence between the proposed levels for Vitamin D and Iodine, and the upper levels proposed by EFSA, and Swedish reports showing no new scientific research with evidence.

Legislation and Recent Case law

In article 5 of Directive 2002/46, the principles are laid down that need to be met when setting maximum levels. 5.1(a) reads "upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into account, as appropriate, the varying degrees of sensitivity of different consumer groups". In this respect, ECJ judgement on Case C-672/15 ("*Noria*") issued on 27 April 2017 has to be taken into account by the Swedish Authorities when revising its maximum levels.

The key point from the *Noria* judgement from an EHPM perspective is that while it confirms that national governments are free to set levels in the absence of EU harmonisation, a clear scientific and robust basis that takes into account **recent international scientific opinions** is needed to justify any levels established – see point 3 of the judgement below:

[1] Consolidated text: Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (Text with EEA relevance), Text with EEA relevance: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02002L0046-20210330

[2] Consolidated version of the Treaty on the Functioning of the European Union: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A12012E%2FTXT

[3] *NORIA* Judgement: http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:62015CJ0672&from=EN

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"The provisions of Directive 2002/46 and those of the TFEU relating to the free movement of goods must be interpreted as precluding that the scientific assessment of the risks referred to in Article 5(1)(a) of that directive, prior to the establishment of upper safe limits which must in particular be taken into account in order to set the maximum amounts referred to in Article 5 thereof, be carried out solely on the basis of national scientific opinions, even though recent international scientific opinions concluding in favour of the possibility of setting higher limits are also available on the date of the adoption of the measure at issue."

Scientific safety levels

EHPM thinks adjustments are needed to the levels proposed by the Swedish Authorities for these levels to reflect scientific analysis provided by EFSA and levels applied widely in other EU Member States without any history of adverse effects.

Moreover, the European Commission has recently resumed the work on setting harmonised maximum levels for vitamins and minerals in the EU in accordance with Article 5 of *Directive 2002/46*. EFSA has been requested to review previous opinions on the Tolerable/Safe Upper Levels (ULs) issued by the Scientific Committee on Food (SCF) and the EFSA Dietetic Products, Nutrition and Allergies (NDA) Panel, and to take account of recent scientific developments and evidence, for eight micronutrients: Vitamin A, Vitamin B6, **Vitamin D**, Vitamin E, ß-carotene, Folic Acid / Folate, Iron, Manganese.

In this context, EHPM updated its model on setting maximum and minimum levels for vitamins and minerals[4]. The table below looks at the levels proposed in the Swedish draft measure in comparison with the ULs set by EFSA[5] and the maximum levels proposed by EHPM.

	Livsmedelsverket Swedish Food Agency	efsa European Food Safety Authority	ehpm European Federation of Associations of Health Product Manufacturers
	Swedish proposed levels	**EFSA recommended ULs**	**EHPM proposed levels (P95)**
Vitamin D	80 µg (3200iu)	100 µg (4000iu)	85 µg (3400 iu)
Iodine	200 µg	600 µg	325 µg

The EHPM model is based on the most recent data from countries with mature markets for both fortified foods and food supplements and deemed to be of sufficient quality; these are from National dietary surveys in Ireland and the Netherlands and include intake from fortified foods. The intake data is for the

[4] EHPM proposal for maximum and minimum levels for vitamins and minerals: Food Supplements for Adults and Children sold in Europe, December 2021: https://ehpm.org/wp-content/uploads/2022/03/2021_02_EHPM_Max_Min_Levels_for_Vit_and_Min.pdf

[5] Scientific Committee on Food Scientific Panel on Dietetic Products, Nutrition and Allergies, *TOLERABLE UPPER INTAKE LEVELS FOR VITAMINS AND MINERALS*, European Food Safety Authority, February 2006: https://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/ndatolerableuil.pdf

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95 percentile, i.e. representing the 5% of consumers with the highest intakes, as the ULs themselves include a considerable level of precaution.
On the contrary, no clear scientific and robust explanation has been given for the notified Swedish revision of it maximum levels for Vitamin D and Iodine. This is in conflict with the ECJ judgement in the *Noria* case.

No procedure for pre-market approval

When national maximum levels are set, the national authority should foresee in a procedure to apply for placing on the market products containing amount exceeding these levels, on the basis of mutual recognition. This Swedish draft measure does not foresee or refer to a procedure to fulfil this obligation.
As confirmed in the Noria verdict, "The provisions of Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements and those of the TFEU relating to the free movement of goods must be interpreted as precluding legislation of a Member State, such as that at issue in the main proceedings, which does not provide for a procedure for the placing on the market of that Member State of food supplements whose content in nutrients exceeds the maximum daily doses set by that legislation and which are lawfully manufactured or marketed in another Member state"[6].

Conclusion

The maximum permitted levels proposed in the notified measure of the Swedish Authorities are not established in a way referred to in Article 5 of Directive 2002/46, as they do not reflect the generally accepted scientific data. Moreover, a procedure is lacking to apply for placing on the market products containing amounts exceeding these levels. Therefore, it forms an unacceptable barrier to trade in the internal market.
EHPM trust the EC to safeguard the principles laid down in Directive 2002/46 and those of the TFEU relating to the free movement of goods and ECJ case law when evaluating this Swedish notification.

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About EHPM
The European Federation of Associations of Health Product Manufacturers (EHPM) was created in 1975 and since then EHPM is the voice of the food supplement sector in Europe. Through its 14 National Associations and 12 Member Companies, EHPM represents approximately 1600 health-product manufacturers and distributors in 17 European countries, the majority of which small- and medium-sized enterprises (SMEs).
EHPM proactively develops concrete proposals through its technical working groups and task forces to help improve the EU regulatory framework for food supplements and to establish and promote industry best practices for product quality, safety, and efficacy.

[6] *NORIA* Judgement: http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:62015CJ0672&from=EN

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