

06/10/2020

EHPM Contribution in the context of
Draft Regulation amending the Regulation on Food Supplements
2020/9011/N (Norway)

To be submitted by the:

end of the Standstill period: 23:59 of the 07/10/2020

Dear Sir/Madam,

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 a contribution in the context of the TRIS notification number 2020/9011/N.

The EHPM, is the EU trade association representing the food supplement sector based in Brussels. The EHPM was created in 1975 and represents approximately 1,750 health-product manufacturers, distributors and suppliers in Europe, the majority of which are Small and Medium Size Enterprises (SMEs). EHPM represents National Associations of the food supplement sector in 14 European Countries, as well as individual companies. EHPM proactively cooperates with the European Institutions and stakeholders to strengthen the overarching strategy for a healthier Europe enshrined in the Farm to Fork and the European Green Deal.

Recent Case law & Proposed Levels

ECJ judgement¹ on Case C-672/15 (“Noria”) issued on 27 April 2017 has to be taken into account by the Norwegian proposal to revise its maximum levels.

The key point from the Noria judgement from an EHPM perspective was 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:

“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.”

In this context, EHPM thinks adjustments are needed to the levels proposed, 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. The table below looks at the levels proposed in the Norwegian law in comparison with the UL set by EFSA and the P95 intake from the Norwegian diet. With the exception of zinc, major differences can be seen between the proposed Norwegian maximum and the free space remaining when the P95 is subtracted from the UL. Looking at the various reports from 2017 of the Norwegian Scientific Committee for Food Safety, no clear explanation is given. For example, for vitamin B6, the VKM report² states that adults with an intake of 20 mg from dietary supplements remain below the UL.

For Zinc the VKM report used the ULs set by IOM (2001)/NHMRC (2005) at 40 mg zinc per day and concluded that dietary zinc intake at the 95th percentile and additionally 20 mg zinc from food supplements will lead to an intake below the tolerable upper intake level established by IOM. Nevertheless, the Norwegian legislative proposal sets a maximum level of 13,5 mg which is in contradiction with this fairly recent Norwegian report.

Looking at other EU member states, we see much higher maximum levels for Zinc in combination with the use of warning statements for long term use.

¹NORIA Judgement: <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:62015CJ0672&from=EN>

² <https://vkm.no/download/18.645b840415d03a2fe8f2653d/1499330353450/087ba2170f.pdf>

For example in the UK a label statement is used for products with more than 25 mg of Zinc 'Long term intake [of this amount of zinc]* may lead to anaemia.'³

Belgium also set a maximum permitted level for Zinc to 22.5mg. Additionally they oblige a warning statement for dosages ranging from 10mg-22.5mg 'The intake of zinc should be limited to a period of a few weeks/months.'⁴

Vitamin / mineral	UL EFSA / SCF	P95 diet	Free space	Norwegian proposed maximum
Vitamin B6 (mg/day)	25 ⁵	3 ⁶	22	12
Vitamin E (alfa-tocopherol equivalents) (mg/day)	300 ⁷	20 ⁸	280	250
Zinc (mg/day)	25 ⁹ (40)*	19,9 ¹⁰	5,1 (20,1)*	13,5
Iron (mg/day)	50 ¹¹	18,7 ¹²	31,3	21

*For Zinc VKM used the ULs set by IOM (2001)/NHMRC (2005) at 40 mg zinc per day.

Questioning the setting of maximum levels in compliance with legislation

EHPM would like to point out that they question whether the maximum permitted levels laid down in the National Norwegian legislation, are set in compliance with principles laid down in *Directive 2002/46* and those of the TFEU relating to the free movement of goods and ECJ case law (Noria case), looking at the divergence between the proposed levels for vitamin B6, vitamin

³ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/204323/Advisory_Statements_DH_FINAL.pdf

⁴ <https://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2016&num=615>

⁵ Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin B6: https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out80c_en.pdf

⁶ <https://vkm.no/download/18.645b840415d03a2fe8f2653d/1499330353450/087ba2170f.pdf>

⁷ Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Vitamin E: https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out195_en.pdf

⁸ <https://vkm.no/download/18.645b840415d03a2fe8f2653f/1499330377092/00bdf9f437.pdf>

⁹ Opinion of the Scientific Committee on Food on the Tolerable Upper Intake Level of Zinc: https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out177_en.pdf

¹⁰ <https://vkm.no/download/18.645b840415d03a2fe8f26465/1499330020541/db963cd632.pdf>

¹¹ JECFA/WHO. (2003) Iron, Joint Expert Committee on Food Additives.

¹² <https://vkm.no/download/18.645b840415d03a2fe8f26463/1499329995972/f91742ac27.pdf>

E, iron and zinc, and the upper levels proposed by EFSA, and Norwegian reports showing no new scientific research with evidence.

Articles 11 and 13 of the EEA Agreement correspond to Articles 34 and 36 of the TFEU. So Norway is under the same obligations according to those provisions as EU Member states are under Articles 34 and 36 TFEU.¹³

No procedure for pre-market approval

When national maximum levels are set, due to the Noria verdict, 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 Norwegian legislation doesn't foresee in or refer to a procedure to fulfil this obligation, nor is this set in any other Norwegian law.

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.¹⁴

Conclusion

The maximum permitted levels proposed in the notified legislation of Norway, not established in a way referred to in Article 5 of Directive 2002/46, form an unacceptable barrier to trade in the internal market.

EHPM trust the EC to safeguard the principles laid down in of Directive 2002/46 and those of the TFEU relating to the free movement of goods and ECJ case law when evaluating this Norwegian notification.

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EHPM Director General



¹³As consolidated in the EEA agreement by an amendment in the 14th of July 2020:

<https://www.efta.int/media/documents/legal-texts/eea/other-legal-documents/adopted-joint-committee-decisions/2020%20-%20English/105-2020.pdf>

¹⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:62015CJ0672&from=EN>