European Federation of Associations of Health Products Manufacturers

European Federation of Associations of Health Food Products Manufacturers

Comments on Proposal Changes to Norwegian Food Supplement Legislation

Listed below are EHPM's comments on TRIS Notification 2016/9040/N (Norway). EHPM was created in 1975 and represents approximately 1,750 health-product manufacturers in 14 European countries. Through our member associations, we aim to provide consumers with safe, science-based, high quality products as well as accurate and helpful information about their nutritional value and use. Over 90% of the companies that are members of EHPM through our national associations are SMEs.

1. Clarity of Wording

In EHPM's opinion, the statement "Food supplements that contains more than the recommended daily portion of consumption for {target group} shall be labelled…" in sections 7a, 7b and 7c of the Norwegian proposal, could create confusion in the identification of the food supplements subject to special labelling requirements under the proposal.

EHPM assumes that the statement mentioned above refers to the maximum amount per recommended daily dose of vitamins and minerals listed in Annex 1 of the proposal, in order to regulate a warning statement on products exceeding maximum daily dosages for these specific populations.
There is no need for products exceeding the Reference Intake to carry warning or advisory statements. The Reference Intake is the amount generally considered necessary to avoid deficiency in a nutrient. Products exceeding the Reference Intake do not need warning statements whereas products exceeding maximum amounts do. Advisory statements are used in this way in the UK for example.

EHPM Proposal:

- EHPM would like to indicate that in the heading of the table the wording 'Maximum amount per recommended daily dose' may cause confusion, as it communicates a recommendation, while the table gives maximum amounts. A change in wording to 'maximum amount per daily dose' will abate this confusion.
- EHPM suggests the statement "Food supplements that contains more than the recommended daily portion of consumption for {target group} shall be labelled …" in sections 7a, 7b and 7c, be replaced with the statement: "Food supplements that **exceed the maximum amount per daily dose** for {target group} shall be labelled …"

2. Clarity of terminology – Reference intake

EHPM considers that it is not clear what is meant by 'recommended daily portion of consumption'. If this is a reference of the values listed in Annex XIII of Regulation (EC) No 1169/2011, then the term 'Reference Intake' should be used for clarity rather than 'recommended daily portion'. Since 2014, there has been confusion as to whether the term 'Nutrient Reference Value' or 'Reference Intake' should be used to replace RDA on food supplement labelling. The latest Commission guidance[1] dated 13 December 2016 recommends the use of the term 'Reference Intake'.

EHPM Proposal:

- EHPM suggests all references to 'recommended daily portion' within the draft Norwegian legislation to be replaced with the term Reference Intake (RI) to ensure consistency in the information communicated to consumers in the European Economic Area (EEA).

3. Proposed Levels

In relation to the maximum amount per recommended daily dose for vitamins and minerals in Annex 1, EHPM believes that the maximum amount proposed for calcium (705 mg) and that the maximum amount proposed for magnesium for children from 3 years and up to 11 years old (120 mg) are too low.

- **Calcium:**

Regulation 1169/2011 establishes a Reference Intake for calcium in 800mg/day whereas the Norwegian regulation proposes a maximum dose of 775 mg for adolescents from 11 years and up to 18 years old and 705 mg for adults. Taking into account that the RI is generally considered the dosage needed to avoid deficiency; the proposed maximum amount is far too low to deliver a meaningful effect. Given that the latest scientific opinion on Calcium established a UL of 2,500 mg[2] so there sufficient scope from a safety perspective to allow for a higher dose.

- **Magnesium for children from 3 years and up to 11 years old:**

Regulation 1169/2011 establishes a Reference Intake for magnesium in adults in 375mg whereas the Norwegian regulation proposes a maximum dose of 350 mg for adults. As the Reference Intake is the amount generally considered necessary to avoid deficiency in a nutrient, EHPM considers that it is remarkable that the Norwegian regulation proposes a maximum dose for adults lower than the Reference Intake established in Regulation 1169/2011 therefore, the proposed maximum dose is too low to deliver a meaningful effect.

[1] Question 3.2 of updated Commission Q&A on Regulation (EC) No 1169/2011, (13/12/2016)

[2] https://www.efsa.europa.eu/en/efsajournal/pub/2814

Regulation 1169/2011 does not establish a Reference Intake for magnesium in children aged 3 to < 10 years, but EFSA in its Scientific Opinion on Dietary Reference Values for magnesium[3] defined the Adequate Intake (AI) for magnesium for children aged 3 to < 10 years in 230 mg/day. The Norwegian regulation proposes a maximum dose of 120 mg for children from 3 years and up to 11 years old which means that the level proposed is far too low than the Adequate Intake established by EFSA for this age group.

Furthermore, the UL (Tolerable Upper Intake Level) established by EFSA for magnesium **(**250mg/day) is for supplementation only[4], and SCF/EFSA indicated that there was no basis for considering that children are more susceptible than adults to the adverse laxative effects of magnesium[5].

The example mentioned above of the maximum dose proposed for adults lower than the Reference Intake established in Regulation 1169/2011 shows the tendency of the proposed maximum doses in the Norwegian regulation to be lower than the settled Reference Intakes.
Therefore, considering the example in adults and taking into account the EFSA's opinion on the Adequate Intake (AI) for magnesium for children aged 3 to < 10 years (230 mg/day), that the UL (Tolerable Upper Intake Level) established by EFSA for magnesium **(**250mg/day) is for supplementation only[6] and that EFSA indicated that there was no basis for considering that children are more susceptible than adults to the adverse laxative effects of magnesium[7], EHPM considers that the proposed maximum dose of magnesium for children from 3 years and up to 11 years old is too low.

EHPM Proposal:

- EHPM considers that 1000mg would be a more reasonable maximum amount per recommended daily dose for calcium in adults from 18 years old.
- EHPM considers that 250mg would be a more reasonable maximum amount per recommended daily dose for magnesium in children from 3 years and up to 11 years old.

[3] https://www.efsa.europa.eu/en/efsajournal/pub/4186
[4] EFSA / SCF. Compilation of the Scientific Opinions on Tolerable Upper Intake Levels for Vitamins and Minerals; 2006
[5] EFSA / SCF. Compilation of the Scientific Opinions on Tolerable Upper Intake Levels for Vitamins and Minerals; 2006
[6] EFSA / SCF. Compilation of the Scientific Opinions on Tolerable Upper Intake Levels for Vitamins and Minerals; 2006
[7] EFSA / SCF. Compilation of the Scientific Opinions on Tolerable Upper Intake Levels for Vitamins and Minerals; 2006