food supplements europe

Brussels, 18 September 2018

Comments on the Norwegian Draft Regulation (certain "other substances" than vitamins and minerals) amending the Norwegian Regulation on the addition of vitamins, minerals and certain other substances to foods
(TRIS notification number 2018/9010/N)

Dear Madam, Sir,

Food Supplements Europe would like to offer its assistance by providing the comments attached in order to help ensure that the draft Regulation mentioned above, notified by Norway does not create barriers to trade.

Given the nature of this draft law and its wide-reaching impact on products and the free movement of food supplements in the EU, we would strongly ask the Commission to oppose to this law.

The reasons and arguments are listed below.

We remain at your disposal for any clarification or questions you may have.

Yours sincerely,

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Director Scientific and Regulatory Affairs

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(TRIS notification number 2018/9010/N)

We believe this draft law has far-reaching consequences for the free movement of foods, including food supplements between the EU and Norway and constitutes an unjustified barrier to trade that is not based on scientific risk assessment, is unnecessary and disproportionate. This law should not be enacted in the form it is now presented and we would ask the Commission to act accordingly and object for the following reasons:

1. **The maximum limits proposed are not based on scientific risk assessment intended to identify upper safe levels, but to assess the safety of current practice**

   This draft Regulation establishes maximum limits for so-called 'other substances' that are acceptable in food supplements. The levels are based on opinions of the Panel on Food Additives, Flavourings, Processing Aids, Materials in Contact with Food and Cosmetics of the Norwegian Scientific Committee for Food Safety (VKM) at request of the Norwegian Food Safety Authority. However, these assessments are not assessments that establish safety-based upper levels. These assessments assess the safety of the levels that are currently found in food supplements that are on the Norwegian market. As such, these levels are lower than what is accepted and applied to similar products in some EU Member States and therefore are the basis of an unjustified barrier to trade.

2. **The proposal introduces an age limit for food supplements, which is contrary to Directive 2002/46**

   By introducing in Annex 3, a limitation to "food supplements intended for adults over the age of 18", we understand that this is a general ban of food supplements for children and adolescents, which is not based on scientific risk assessment and applies in a systematic way, which is contrary to the case-by-case assessment that should underlie risk management decisions. In addition, some VKM opinions do actually support the safety in younger age groups. It is also in breach of the EU food Supplements Directive that does not foresee an age restriction.

3. **The list of permitted substances is closed for all "other substances" as defined in Section 6, which means that excluded substances are prohibited until authorised.**

   The fact that the list of authorised substances is closed poses a huge challenge, given that it means that excluded substances are not permitted to be added to food supplements. This will create a major disruption of the market and a significant barrier to trade, which is not acceptable as Norway is part of the EEA where mutual recognition applies.

   This is also contrary to EU law and in particular Directive 2002/46 and Regulation 1925/2006 that do not foresee the possibility for prior authorisation of ingredients used in food supplements and fortified foods.

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4. **The Norwegian market will be disrupted**

   The list of permitted substances is incomplete, and many other substances frequently used in food supplements currently sold in Norway are missing from that list as well as substances that have been authorised as novel food for use in food supplements. Those substances are conventional ingredients used also in various Member States. They don't necessarily need to be included on a positive list but their use in food supplements should be possible (e.g. Arabinogalactan, Lactase, Papain, Undenatured type II collagen, Ubiquinone, Zeaxanthin, etc).

   Other substances are not defined, this term comprises many compounds, including botanical preparations that now would no longer be allowed in Norway. This would also pre-empt the initiatives by the European Commission following the RFIT exercise on how to further harmonise such products.

5. **Duly authorized novel foods should be clearly authorised**

   Many novel foods such as, but not limited to, N-Acetyl-D-neuraminic acid, L-Alanyl-L-Glutamine, Chondroitin sulphate, Citicoline, Epigallocatechin gallate, Glucosamine sulphate KCl and NaCl, Lactitol, Phytosterols have been authorised for use in food supplements under the novel food regulation. Their status should be clearly specified in this draft.

For the above fundamental reasons, we strongly ask the Commission to object to this law.

Below are further aspects of this law that also warrant a fundamental revision before it is enacted and justify opposition from the Commission.

Section 6: Inappropriate and restrictive purity criteria

The draft Regulation specifies that substances used must have a purity of at least 50% or are concentrated 40 times or more. We are concerned that that is an arbitrary measure that will cover preparations that in other Member States are not considered as other substances, but as (botanical) preparations.

Section 7: Missing substances and categories of food

As indicated above, the list that is provided in annex 3 is a closed list; it is therefore not permitted to add substances to food other than those listed. Furthermore, many food categories to which such substances are added, are not listed. This is overly restrictive. It imposes a systematic safety assessment before a substance is permitted and does not allow for the use of substances that are safe but for which no decision is taken to include it in the list. This is contrary to the principles clearly spelled out by the Court of Justice of the EU (CJEU), which states that Member States are only permitted to impose bans or restrictions based on scientific risk assessment, and provided such measures are proportionate and necessary to achieve the intended objective (e.g. Case C-282/15). A prohibition without justification is therefore not possible.

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In addition, the categories of foods listed only include various forms of sports foods, meaning that the use of the substances in other food groups, including ordinary foods is not authorized. This is an undue restriction, as many such foods are on the EU market. This would also preclude the addition of such substances to foods in spite of the fact that EU approved heath claims with conditions of use allowing the use in food in general (e.g. Fatty acids (including ALA, EPA, DHA, alpha-cyclodextrin, Arabinoxylan, Beatine, Chitosan, HMPC, Lactulose, etc).

Section 9: Reversal of the legal burden of proof of safety and imposing a temporary suspension on the marketing on non-conforming products breaches the provisions of Regulation 764/2008

Section 9 requires the submission of safety information by business operators who may want to use an 'other substance' that is not compliant with the conditions of use specified in annex 3. This can cover products that are lawfully marketed in other member states and for which the principle of mutual recognition applies. In such cases, legally, in accordance with Regulation 764/208 and established case law of the CJEU, the burden of proof that the product is unsafe lies with the national authority. Without serious reasons that the product is unsafe, it is not possible to systematically request operators to provide information demonstrating that the product is safe (as requested in point 13 of annex 4). This reversal of the legal burden of proof is not in conformity with EU legal principles as laid down by the CJEU.

Also, the requirement for companies to wait for a certain period of time (six or three months) is fundamentally contrary to the procedure spelled out in Regulation 764/2008 (article 7), which explicitly states that Member States shall not temporarily suspend the marketing of the product during a challenge to mutual recognition (unless a serious risk to the safety and health of consumers has been identified).

The reference to the mutual recognition procedure of Regulation 764/2008 does not solve the above-mentioned breaches.

Section 10: Reversal of the legal burden of proof of safety and imposing a temporary suspension on the marketing of non-conforming products breaches the provisions of Regulation 764/2008

Section 10 relates to the addition of substances that are not listed in Annex 3 and includes a procedure for such situations. The breaches of the principle of mutual recognition raised under Section 9 apply equally to section 10.

Section 11: The information requested during the notification procedure for food supplements breaches the provisions of Directive 2002/46

Section 11 foresees that operators provide information to the authorities when they first market a product in Norway. Article 10 of Directive 46/2002 foresees that Member States may impose a notification obligation, in the form of a model label that is used for the product. We note that the information required by the Norwegian authorities goes beyond this requirement. Given that this is a systematic requirement, imposing a burden on companies and goes beyond the provisions of EU law, we would ask the Commission to object to this provision

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and ask the Norwegian authorities to only request more detailed information on a case-by-case basis from operators.

Section 11: Insufficiently long transition period to ensure legal certainty

Section 12 foresees transitional periods. A transition period of 6 months is very short and does not allow for product composition and labelling to be adapted.

It is also not clear how this transition period applies to products that are subject to a procedure for which the timings may overlap. The transition period (6 months) does not seem to cover the time needed for products already marketed to obtain a decision. Therefore, for legal clarity the transition period for products submitted to notification should be extended until the issue of the new decision for marketing in Norway.

Annex 3: Comments in relation to specific substances included in Annex 3.

1. General

As indicated before, the list is not complete and many frequently used food supplement ingredients are missing, as well as substances that have been authorised as novel food for use in food supplements. Examples include: N-Acetyl-D-neuraminic acid, L-Alanyl-L-Glutamine, Chondroitin sulphate, Citicoline, Epigallocatechin gallate, Glucosamine sulphate KCl and NaCl, Lactitol, and Phytosterols, to name but a few. In addition, many substances authorised and used in food supplements in EU Member States are not listed, including, but not limited to Arabinogalactan, Lactase, Papain, Undenatured type II collagen, Ubiquinone, Zeaxanthin, etc, are not listed. The list should therefore not be closed. This would allow authorised novel foods and other substances lawfully marketed in food supplements in the EU Member States to continue to be available on the Norwegian market.

2. Inulin

Inulin is a widely used food ingredient both because of its technological (structure) and its functional (dietary fibre) properties. There is no reason to consider this ingredient as an 'other substance', as this is not even consistent with the definition provided in Section 7.b of the Draft Regulation itself, which intends to exclude substances that are used as food ingredients.

There is also no justification to limit the maximum daily amount in food supplements to 3 g/day, as the beneficial effect required in the context of a health claim relating to the contribution of normal bowel function is 12 g/day (Regulation 2015/2314). We assume that inulin is accepted by the Norwegian law for its addition to regular foods, with no restriction, which creates an unfair, unjustified, and disadvantageous competitive situation for food supplements. In this respect, it is also noted that for no other dietary fibre, a maximum limit is established.

We note that the basis for this value is linked to an assessment by the VKM that was not a risk assessment to establish an upper safe level, but an assessment of the quantity of 3 g/day, which was the value requested by the Norwegian Food Safety Authority. The report indicates that also doses up to 20 g/day may be well tolerated by most people.

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We therefore would ask the Commission to oppose to this provision.

3. Creatine

The proposal allows the addition of creatine to food supplements up to a maximum amount of 3 g per recommended daily dose but imposes a warning statement: “Should not be used for a continuous period of more than six months without consulting a doctor”.

This warning statement is not safety-based. Creatine is a natural substance and found in significant amounts in meat and fish. The maximum level of 3 g/d is in the range of the daily creatine turnover and close to natural creatine amounts in the diet. In 2004, EFSA stated that consumption of daily doses of up to 3g/d of supplemental creatine is unlikely to pose any risk. Two health claims have been authorised, both with a minimum quantity of 3 g creatine per day (Regulations 2017/672 of 432/2012). No warning statement is included in these decisions.

We would ask the Commission therefore to object to the warning statement in this provision.

There is also no scientifically justified reason why creatine is not permitted in foods, in particular in sports drinks (categories I and II) and Bars. This is in particular relevant since 2 EU health claims for creatine have been authorised, specifically for use in sports foods. Such products (at levels of 600 mg/100 ml and 3 g/bar) are legally sold in the EU and not accepting this in Norway creates unjustified barriers to trade.

4. Carnitine

Carnitine is permitted in food supplements and certain categories of sports drinks. Also in this case, a warning statement is imposed: “Should not be used by people with congenital metabolic diseases and kidney disease without consulting a doctor.”

This warning statement is not safety-based and in fact L-carnitine is an ingredient in a variety of specific clinical nutrition products, that are used in the dietary management of such disorders. Furthermore, consumers may not understand the warning statement or confuse "metabolic disease" with "metabolic syndrome”. Given the generally low prevalence of these specific diseases and L-carnitine's beneficial role in many of them, this statement is not appropriate, nor scientifically substantiated and should be removed.[1]

The second part of the warning is also not scientifically justified.[2] For the above reasons, we would ask the Commission to object to the inclusion of this warning statement.

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[1] The term "congenital metabolic diseases" covers a wide class of rare inborn errors of metabolism. Typically, treatment of congenital metabolic diseases involves specific dietary restriction or clinical nutrition. L-carnitine is an ingredient in a variety of such products. The VKM based their conclusion around L-carnitine's effect in inborn errors of metabolism on a Cochrane review published by Nasser in 2012, who themselves concluded that data are not sufficient to come to any conclusion (Nasser 2012).

[2] The VKM risk assessment report mainly refers to concerns raised in a Monograph prepared by Health Canada in 2013, which references, among others, a publication by Bain. Bain and coworkers found that trimethylamine (TMA) and trimethylamine-N-oxide (TMAO) accumulate in end stage renal disease patients and are removed by hemodialysis (Bain 2006). When carnitine, but also betaine or choline, are not completely absorbed in the intestine, gut microbiota can metabolise them to TMA which is then absorbed

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We would also like to remark that while for food supplements both L-carnitine and its most common salt form L-carnitine L-tartrate are listed in the proposal, for the sports drinks category only L-carnitine is listed. L-carnitine L-tartrate, which is easier to use in powder form, should also be permitted in the two categories of sports drinks as many drinks actually do use L-carnitine L-tartrate on the EU market. In 2003, EFSA concluded that the consumption of a daily dose of up to 3 g/d of supplemental L-carnitine L-tartrate (equivalent to 2 g L-carnitine) is unlikely to pose any risk.

As on the European market L-carnitine and L-carnitine L-tartrate are also added to other food categories such as shots and ampoules, bars or gels to create full sports nutrition product ranges of large sports brands, there is no reason to exclude the addition of L-carnitine and L-carnitine L-tartrate to these categories in Norway.

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into the blood and further metabolised by liver flavin-containing mono-oxygenases (FMOs; FMO3 in particular) to TMAO (Bain 2005). TMA and TMAO presence in urine after administration of L-carnitine has first been described by Prof Strack in 1963 (Strack 1963). During the last couple of years, however, several researchers have presented TMAO as a candidate risk factor for cardiovascular disease and other adverse health outcomes. Dysregulated TMAO levels have been associated with renal disease, neurological disorders and cancer (Tang 2015; Chhibber-Goel 2016). The relation between TMAO and chronic disease can be confounded by several factors, including kidney function, the gut microbiome, and FMO3 genotype. Thus, TMAO does not necessarily need to be considered a causative agent in human disease development and progression, but rather a marker of an underlying pathology. Importantly, dietary sources of TMAO have beneficial health effects and provide nutrients that have critical roles in many biological functions. Pre-emptive dietary strategies to restrict TMAO-generating nutrients as a means to improve human health warrant careful consideration and may not be justified at this time (Velasquez 2016).
A systematic review and meta-analysis concluded that oral L-carnitine supplementation has beneficial effects on inflammatory parameters, in the secondary prevention of cardiovascular disease, in diabetes mellitus, on serum lipid profile in hemodialysis patients, for adults with end-stage kidney disease on hemodialysis and for patients in maintenance hemodialysis (Serban 2016). According to Flanagan 2010, impaired kidney function leads to an accumulation of carnitine esters and related plasma carnitine insufficiency, as only free carnitine, but not carnitine esters, are metabolically active. Repeated hemodialysis is reported to delete carnitine stores and carnitine supplementation may replenish the muscle stores (Flanagan 2010).
Another recent systematic review and meta-analysis focused more on the malnutrition consequences of chronic kidney disease and the effect of L-carnitine supplementation, and found preliminary beneficial evidence, but concluded that more research was needed (Gholipur-Shahraki 2018).

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