

ESSNA's comments to 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.

27th September 2018

The European Specialist Sports Nutrition Alliance (ESSNA) welcomes the opportunity to provide comments to the 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 as [notified](#) on 28th June 2018 via TRIS.

ABOUT ESSNA

ESSNA is a pan-European trade association with more than 40 members representing the interests of the sports nutrition sector across the EU. Our members are large global businesses, smaller specialist brands, suppliers of ingredients, sports nutrition retailers, companies representing multi sports nutrition brands, as well as national associations. ESSNA's main aim is to campaign for appropriate policy and regulation for sports nutrition products in Europe, as well as to improve the reputation of the sector with regulators and the public. We do so by working to improve consumer knowledge of sports nutrition products and the industry.

ESSNA's position

ESSNA believes that the restrictions on the foods and food supplements to which other substances can be added, as outlined in the draft Regulation, do not comply with EU law and risk undermining the internal market.

If the provisions are implemented as such, there is a risk of significant barriers to trade being erected by Norway at the expenses of EU businesses –particularly SMEs –, while Norwegian food operators would continue to benefit from access to the internal market. The implementation of this draft Regulation in its current draft would entail that Norwegian businesses would gain a competitive advantage in the Norwegian market.

Non-observance of Mutual Recognition and Genuine Cooperation principles

ESSNA notes that the principle of Mutual Recognition and that of Genuine Cooperation between Member States (see judgment of 5 March 2009, Commission vs Kingdom of Spain, p..14), are not observed in the draft Regulation: products lawfully marketed in another Member State should not receive different treatment than those products marketed in Norway.

Although Reg. (EC) No 764/2008 is mentioned, the prior authorisation procedure set out in sections 9 and 10 of the draft Regulation are not justified and are non-proportional. Particularly, the six-months period established for the assessment process is not proportional for substances

which have been assessed by the European Food Safety Authority (EFSA), by other Member States or already included in the draft Regulation itself.

As a practical example, to use creatine in sports drinks (category II) with proteins, a food business operator would need to request an authorisation with a fee of over €12,000 for each product, would have to wait for the assessment to take place over a period of six months, and it would then need to repeat this procedure for every similar product. This equals to a significant barrier to entry into the Norwegian market.

Maximum amounts of amino acids

The draft Regulation provides for highly variable maximum levels of amino acids in food supplements and other foods. Despite evidence of their safety at much higher amounts and Norway's own VKM's opinions¹, the draft Regulation sets variable levels for each amino acid (e.g. leucine 1.3 gr per day in food supplements, glutamine 20 gr per day in food supplements). This appears not to be consistent with risks analysis and it does not take into consideration the Mutual Recognition principle.

The maximum levels established by the draft Regulation are not consistent with those established by Member States, which would make virtually impossible for businesses across the EU to market products in Norway.

As an example, Italy has a combined maximum level for leucine, valine and isoleucine of 5 g; Norway's proposal is for a combined maximum level in food supplements of 4.8 g. This would require an Italian food business operator to reformulate for the Norwegian market. Such scenario could be avoided through the application of a reasonable mutual recognition procedure. However, the Norwegian draft Regulation fails to provide such a procedure.

Authorisation procedure for amino acids and other substances in foods

Section 9 of the draft Regulation provides for a case by case authorisation procedure, that includes substances that have already been found safe in Norway. For example, the addition of creatine to bars would require a new authorisation, despite creatine being legally used in bars across the EU and having been found safe in Norway. It also appears that the addition of amino acids to meal replacement products, despite it being provided for by Reg. (EU) No 432/2012, would also require a new authorisation.

ESSNA believes that this provision is contrary to EU law and its application would create significant barriers to trade.

Considering the Court of Justice's ruling in Queisser Pharma GmbH & Co. KG Bundesrepublik Deutschland, judgment of January 2017 (p 66 and 68), and Norway's own risk assessment², Norway has not proven how this untargeted procedure is justified on public health grounds.

1

<https://vkm.no/english/riskassessments/allpublications/riskassessmentsofothersubstancesinfoodsupplementsandenergydrinks.4.2375207615dac0245aee173f.html>

2

<https://vkm.no/english/riskassessments/allpublications/riskcategorisationof30aminoacidsandaminoacidcompounds.4.72c3261615e09f2472f4723d.html>

Furthermore, while national authorities may monitor the use of such substances, establishing an authorisation procedure with high fees associated is not justified.

As noted by the Court of Justice in the Queisser Pharma GmbH judgment, EU law is based on risk analysis and, as such, it is not compatible with EU law to require an individual authorisation for each amino acid in a category of food, when the safety of such an addition has been already determined. Therefore, sections 9 and 10 of the draft Regulation that provide that "The notification only applies for the addition of the relevant "other substance" to the specific food, including food supplements" should be modified.

Definition of botanicals

The draft Regulation is wide ranging and includes botanical preparation if obtained by any method other than basic aqueous extraction, which implies that most botanical preparations on the market would be covered, as well as several other substances of interest to the sports nutrition sector, such as amino acids or derivatives.

ESSNA notes that section 6 of the draft Regulation differentiates botanicals based on concentration and purity. These distinctions are not in line with EU novel food legislation, do not correspond to any definition currently enshrined in EU law and are not based on risk analysis. ESSNA believes that without the inclusion of a mutual recognition clause, this will result in significant barriers to trade.

Technical rules on sports foods

The draft Regulation mentions sports foods as a category, but such category does not exist under EU law after the repeal of Directive 2009/39, with sports food now being regulated under General Food law. The arguments that led to the repeal of the Directive, as set out in Reg. (EU) No 609/2013 and, more recently, in the Report from the Commission to the European Parliament and the Council on food intended for sportspeople, argue against the use of these categories.

ESSNA believes that by introducing such categories in a way that applies to food products from other Member States, the draft Regulation would create a barrier within the internal market, by way of a technical rule, with no justification under the Treaties. A food producer from another Member State would be forced to comply with the Norwegian definitions of sports food, in terms of energy content, even though the definition has no health protection purpose.

In light of the above, ESSNA believes that a definition of "sports foods" should not be provided in the Draft Regulation.

Conflict with Reg. (EC) No 1924/2006 resulting in a barrier to trade

The definitions also infringes Reg. (EC) No 1924/2006, in that, by restricting the foods to which other substances may be added, they also restrict the foods on which claims may be made, despite article 22 of said Regulation stating "*Without prejudice to the Treaty, in particular Articles 28 and 30 thereof, Member States may not restrict or forbid trade in or advertising of foods which comply with this Regulation by the application of non-harmonised national provisions governing claims made on certain foods or on foods in general*". For example, the provisions on "Bars" prohibit the authorised health claim on creatine on such foods.

ESSNA believes that the draft Regulation should be amended to avoid barriers to trade for products that comply with Reg. (EC) No 1924/2006. Such products should be notified without fees.

Notification procedure

Article 15 of Reg. (EC) No 1925/2006 provides for a monitoring procedure by Member States. Section 9 and 10 of the draft Regulation far exceed the monitoring procedure foreseen under article 15, which refers to the label only. This would represent a further barrier to trade.

Fees and notification procedure

ESSNA believes that the fees put in place as amendments to Regulation No 406 of 13 February 2004 are of such nature that they could, in the context of the EEA, constitute a quantitative restriction to trade within the meaning of the Treaties. These fees could potentially exclude from the Norwegian market food products manufactured by SMEs, even if these products comply with EU law and fall within the scope of mutual recognition provisions.

As an example, an SME with 4 sports nutrition bars, with creatine, glutamine and/or EPA/DHA, would face an administrative cost of over €48,000 to access the Norwegian market, while the same products would face no administrative cost in the EU. This represents a significant barrier to entry in the Norwegian market.

Requirement for national authorisation of novel foods

The draft Regulation does not provide for any exemption for authorised novel foods included in the EU list provided by Regulation (EU) 2015/2283. Even if authorised at EU level in specific categories, authorised novel foods would need to be re-authorised at the national level for specific categories.

ESSNA believes that authorised novel foods should be fully exempted from the Regulation.

Conclusion

ESSNA asks Norway to withdraw, or substantially modify, the draft Regulation, and asks the Commission to deliver a detailed opinion to this effect and to adopt a similar position in the context of the notification under article 11 of Reg. (EC) No 1925/2006.

For further information, please contact:

European Specialist Sports Nutrition Alliance
Tel: +44 (0)20 7463 0620
Email: info@ESSNA.com
225 Metal Box Factory
30 Great Guildford Street London
SE1 0HS UK (United Kingdom)