ESSNA'S POSITION ON THE NOVEL FOODS PROPOSAL 2013/0435 (COD)

The European Specialist Sports Nutrition Alliance (ESSNA) was set up in 2003 to campaign for appropriate European legislation on sports nutrition products. Today, ESSNA is a pan-European trade association with 46 members representing the interests of the sports nutrition sector across the European Union. Our members are large global businesses, smaller specialist brands, suppliers of ingredients, sports nutrition publications, as well as national associations.

ESSNA members welcome the Commission proposal for a Regulation on novel foods 2013/0435 (COD) that aims to improve access of new and innovative food to the EU market and simplify the authorisation procedure. Members believe, however, that certain concepts would benefit from further clarification so that the proposal delivers on its aims, particularly when seeking to ensure sufficient legal clarity and certainty for businesses. This draft piece of legislation will have a significant impact on sports nutrition products, and we outline in this document a number of further comments which our Members consider of importance for the future of the sector.

ESSNA's objectives for novel food legislation are:

- clear and comprehensive definitions
- centralised procedure for the determination of the novel food status
- legal certainty for the substances used in our products
- proportionate and time efficient authorisation and assessment procedure which ensures flexibility – in particular in terms of the evidence and data to be submitted for the assessment
- uniform implementation and enforcement, and a system of deterrent penalties

ESSNA's views on the proposal

ESSNA members welcome the Commission proposal which revises rules for the placing on the market of novel foods. We agree with the Commission that the current system of individual authorisation procedures was lengthy, costly and led to significant discrepancies in the market. Replacing the current system by generic authorisations, centralised at EU level, and creating a union list of novel foods will bring greater legal clarity and certainty. Members also greatly welcome the simplified authorisation for traditional foods from third countries, based on a history of safe use, which should facilitate the placing on the market of such foods. We believe, however, that a certain number of points within the proposal would benefit from further clarification. These include:

- **Definitions:** Whilst the definition of "novel food" proposed in Article 2.2 is already quite comprehensive, it does not address the issue of derivates/salts of existing substances (e.g. salts of amino acids, salts of creatine) made from compounds which are not harmful to human health. ESSNA's view is that such salts and other derivates should not be considered novel food, provided they are substantially equivalent to existing substances and unless they are the result of "new production processes" as defined in Article 2.2 (a)(i). ESSNA believes that the authorisation of a new novel food substance should apply to all its derivatives/salts.

  ESSNA takes a similar position regarding botanical preparations. We believe that different preparations of botanical substances which have been used for human consumption to a significant degree within the Union before 15 May 1997, should not be considered as novel food.

  Finally, ESSNA would also like to see some reassurances in the proposal that substances currently covered by Commission Regulation (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses, due to be repealed as a result of Regulation (EU) No 609/2013, are not considered as novel foods in the future - when used in sports nutrition products.

- **Determination of the novel food status:** According to Article 4 of the proposal it will be the responsibility of the food business operators, in consultation with the Member States, to determine the novel food status of a substance. Whilst the Commission may specify the relevant procedural steps of the consultation process through an implementing act, ESSNA members believe that such a decentralised procedure could lead to important discrepancies across the Member States, with Member States possibly taking different views on the same substances.

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It is our members' view that, similarly to the authorisation procedure, the determination of the novel food status should be centralised at EU level. In addition, our members believe that the burden of proof regarding the determination of novel food status should not rest solely on food business operators, but should be shared amongst the Member States' competent authorities. We believe that a formal mechanism should exist compelling competent authorities to liaise and share relevant information among them in order to facilitate the process of determining the status of a substance. We also believe that public consultation processes would also provide interested parties the opportunity to submit relevant information to help the determination of novel food status. ESSNA would therefore strongly recommend revising Article 4.

- **The procedure for authorising the placing of a novel food on the market – content of the application:** When applying for novel food authorisation, a food business operator must present an application containing a number of elements, including scientific evidence demonstrating that the novel food does not pose a safety risk to human health. The European Food Safety Authority's stringent approach regarding the evidence required is something which may prove difficult for small and medium size businesses in particular. ESSNA would therefore recommend greater flexibility as to the data required.

  In addition, and since novel food authorisation will be generic in the future, we would suggest that other operators are offered the chance to contribute to such applications through public consultations.

  Our members believe that once the placing of a novel food on the market has been authorised, its conditions of use should not restrict it to only a few categories of food, and instead a principle should exist in favour of authorising novel foods for all categories unless there are specific reasons not to.

  In addition, ESSNA believe that a pan-EU register of novel food applications should be set up and made available to the public. This would facilitate the sharing of information and could avoid operators wasting resources by duplicating previously submitted applications.

- **Specific rules for traditional foods from third countries – documented data demonstrating the history of safe food use in a third country:** For the purpose of authorisation of traditional foods from third countries, Article 13 requires the applicant to notify and submit to the Commission a number of pieces of information, including "documented data demonstrating the history of safe use in a third country". Article 2.2 (c) defines history of safe use in third country as meaning that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a large part of the population of a third country.

  Whilst the intention of these rules is to simplify the authorisation procedure for traditional foods from third countries, the extent of the data required may in fact render this procedure more difficult for food business operators than the generic one. The burden of proof is once again placed on the food business operators, something which will have a considerable impact on small and medium size businesses. ESSNA therefore believe that, once again, greater flexibility should be allowed. Other operators could be offered the chance to contribute to such applications, and formal cooperation between the Commission and third countries should be considered to alleviate the burden on businesses.

- **Confidentiality / data protection:** ESSNA greatly welcome provisions on data protection which we agree are needed to support innovation. We would like to note, however, that when multiple suppliers of the same novel food exist internationally (i.e. when patents do not restrict the supply of a novel food) granting data protection may restrict international trade. In this situation, finished goods made with the same novel food sourced from a different supplier in a third country could not be legally imported in the Union. Therefore, when deciding to grant data protection consideration should be given to whether it could disrupt international trade of finished goods.

- **Penalties:** Article 26 provides that Member States shall lay down effective, proportionate and dissuasive penalties for the infringements of the novel food regulation. This provision is greatly welcomed by ESSNA, as the lack of uniform enforcement of the novel food legislation across the European Union constitutes is a serious problem nowadays, having an important impact on consumer health and businesses. ESSNA would therefore recommend that, in addition, to notifying their national laws to the Commission, Member States are also encouraged to prepare enforcement plans.

Conclusion

ESSNA welcomes the proposed revised rules for the placing of novel foods on to the market but members will seek clarification of the above mentioned points within the proposal to ensure legal clarity and certainty.