



Brussels, 1 December 2019

TGA GUIDANCE SPORT SUPPLEMENTS

GME, the Gelatine Manufacturers Association of Europe, represents almost 100 % of the European gelatine production and 42 % of the gelatine production world-wide.

We took notice on the public consultation, published on 22 October 2019, on the proposed clarification that certain sports supplements are therapeutic goods and, as the proposed regulation could cause a major impact on the gelatine and collagen industry, we kindly ask the Australian TGA authorities to take the following considerations into account:

- Gelatine including Collagen Hydrolysate/peptide is one of the best regulated foods and considered a safe product. This was confirmed after thorough risk assessments done e.g. by EFSA (European Food Safety Authority), EMA (European Medicines Agency), FDA (US Food and Drugs Administration), FSANZ (Food Standards Australia & New Zealand), OIE (World Organisation for Animal Health).
- Gelatine including Collagen Hydrolysate/peptide are natural food ingredients that can look back on a long tradition. Due to its versatile properties, the pure protein offers many benefits and plays an important role in today's food industry.
- Beside other markets, our food ingredients are widely used in the manufacturing of diverse food supplements and also for foods and drinks specifically designed for sports nutrition. From a global view, all these products are covered and regulated in respective food laws (e.g. European Union, USA, China). This demonstrates a global common understanding, that nutrition has an impact on public health. And it is also globally accepted, that specific food ingredients have specific (scientifically proved) healthy properties. The conclusion is that foods or food ingredients are still classified as food, even if the food has specific nutritive and/or healthy functions. This is also covered in actual Australian food legislation, e.g. vitamins and minerals could be added to food products according to Food Standards Code – Standard 1.2.7 – Nutrition, health and related claims.
- The proposed regulation would directly hamper the international trading of such goods. But not only manufacturers of sports nutrition would be affected, also the ingredients industry would be deeply affected, because ingredients like Collagen Hydrolysate which are clearly defined as food ingredient would become a medicine and would be regulated as such.
- Another big concern is that products should be classified as food or ingredient only because of the dosage form. The proposed decision tree contains the following question: "Is the dosage form of the good a pill, tablet or capsule?" – If this is the case, the product would be classified as therapeutic good, independly of the composition and the claimed product properties. This means that products with identical composition and identical claims could be classified as food or therapeutic good, only because of their presented dosage form. This would of course have a major negative impact on our industry if

GME

Rue Belliard 40, B-1040 Brussels Belgium
Tel. +32.2.436.94.40 mve@cefic.be www.gelatine.org

A sector group of Cefic 

European Chemical Industry Council - Cefic aisbl

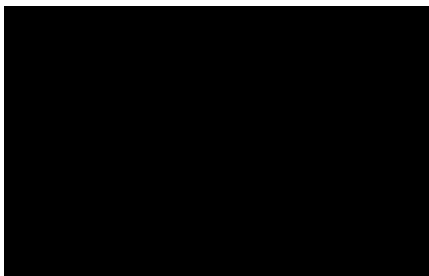
EU Transparency Register n° 64879142323-90



Gelatine or Collagen Hydrolysates/peptides would be considered as therapeutic good, consumers might not use those food ingredients anymore, because consumers interested in health nutrition are not willing to include medicines in the daily nutrition. By consequence, they would most probably not only avoid products provided in capsules, pills or tablets, but also other dosage forms.

- Such amendment would not only affect Collagen Hydrolysates, but also Gelatine used as capsule material.

Finally, GME advocates any actions which supports more consumer safety, but the proposed amendment would rather lead to a situation where consumers cannot differentiate between real medicines and food products which supports the needs of athletes (which would be considered as medicines according to the suggested amendment). It is highly likely that manufacturers of functional food ingredients are not willing to fulfill the new requirements to avoid confusion in sport nutrition. Taking all these considerations into account the proposed amendment should be revised to ensure that functional sport foods will still have a future on the Australian market.



Marc Vermeulen
GME – Sector Group of Cefic
European Chemical Industry Council - Cefic aisbl
Rue Belliard 40, B-1040 Brussels Belgium

