

115 Veterans Parade  
Collaroy Plateau NSW 2097  
AUSTRALIA

December 12th, 2019

To whom it may concern,

**Re: TGA GUIDANCE SPORTS SUPPLEMENTS**

*The GMAP (Gelatine Manufacturers of Asia Pacific) represents the majority of Asian, Indian and Oceanic gelatine and collagen peptide manufacturers, including 100% of Australian gelatine production.*

We are writing in response to the proposal raised by the TGA that certain sports supplements be regulated as therapeutic goods. This proposed regulation will cause major financial impacts on the gelatine and collagen industry and we request that the TGA take into consideration the following points related to gelatine and gelatin hydrolysates/peptides.

- Gelatine and gelatin hydrolysates/peptides have been in use in food and pharmaceutical products for decades. They are used extensively in the nutraceutical industry. They are one of the best regulated foods and considered a safe product. This was confirmed after thorough risk assessments by EFSA (European Food Safety Authority), EMA (European Medicines Agency), FDA (US Food and Drugs Administration), FSANZ (Food Standards Australia & New Zealand), OIE (World Organization 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 specifically designed for sports nutrition. Coming 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 of public health. And it is also globally accepted, that specific food ingredients have specific (scientifically approved) 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.



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- The proposed regulation would directly hamper the international trading of such goods. 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 a food ingredient would become a medicine and would be regulated as such.
- Another big concern of the proposed clarification 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 case, the product would be classified as therapeutic good, independently 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 goods. This would of course have a major negative impact on our industry – because if our ingredients would be considered as therapeutic goods (only because of the presented dosage form!), consumers might not use those food ingredients anymore. Consumers interested in health nutrition are not willing to include medicines in their daily nutrition. They would most probably avoid not only products provided in capsules, pills or tablets, but also other dosage forms.
- Such an amendment would not only affect Collagen Hydrolysate, but also gelatine used as capsule material would become a pharmaceutical excipient for such products.

The GMAP supports any actions which promote consumer safety. The proposed amendments though will lead to a situation where consumers cannot differentiate between real medicines and food products which support the needs of athletes; these will be considered as medicines according to the suggested amendment. It is highly likely that manufacturers of functional food ingredients are not able to or are not willing to fulfill these new requirements. Therefore, the GMAP requests that the proposed amendment should be revised to ensure that that functional sport foods remain as foods and not medicines and thus will still have a future on the Australian market.

Yours sincerely,

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[Redacted contact information]