



Sports Supplements Consultation
Complementary and OTC Medicines Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear Sir/Madam

Proposed clarification that certain sports supplements are therapeutic goods

Thank you for the opportunity to comment on this proposal.

The Department of Agriculture fully supports the proposal by the Therapeutic Goods Administration (TGA) to declare that sports supplements meeting certain criteria are therapeutic goods. The department strongly agrees that the declaration under sub-section 7(1) of the Therapeutic Goods Act proposed at Attachment A will remove much of the confusion about how these goods are regulated, by defining specific sports supplements as therapeutic goods and how these goods are presented and advertised for therapeutic use. This declaration will reduce the risk some of these goods pose to public health and safety as they will be subjected to more rigorous assessment before they are permitted to be imported.

Currently, the department inspects imported sports supplements under the Imported Food Inspection Scheme (IFIS) at the 5% surveillance rate. Inspection at the border involves an inspection of the labelling for certain prohibited substances and compliance with the labelling requirements in Chapter 1 and Standard 2.9.4 of the Australia New Zealand Food Standards Code.

A major challenge for regulating imported sports supplements is the uncertainty around whether these products are food or therapeutics. The TGA's proposal will provide much needed clarification around the regulation of these products. If this proposal proceeds, the department recommends the TGA develops guidance for industry, such as an online tool, to assist industry in determining whether their product is a therapeutic good as defined in the declaration or a food under the Food Standards Code.

To more effectively target imports of these products through the IFIS, the department has requested risk advice from Food Standards Australia New Zealand (FSANZ) on food safety hazards of concern with sports supplements with advice to initially focus on those containing highly concentrated caffeine. This is in response to the FSANZ proposal (P1054) to prohibit the retail sale of foods in which total caffeine is present in a concentration of 5% (5g/100g) or more.

Risk classifying sports supplements containing hazards of concern such as highly concentrated caffeine in the Imported Food Control Order 2019, will enable the department to more effectively enforce current and proposed restrictions on these foods in the Food Standards Code. This work together with TGA's proposal to clarify which sports supplements are therapeutic goods, will better protect consumers from the potential risk to public health and safety from these products.

Yours sincerely



Imported Food, Compliance Policy

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