

Application to amend the ANZ Food Standards Code to permit the use of Adenosine 5' Triphosphate (ATP) as a nutritive substance in Standard 2.9.4 Formulated Supplementary Sports Foods.

Date 7 May 2020

Executive Summary

This application is submitted by TSI Pharmaceuticals Pty Ltd. The application seeks an amendment to include Disodium Adenosine 5' Triphosphate (Na₂ATP) as a substance that may be used as nutritive substances in formulated supplementary sports food (S29—19) up to a maximum level of 400 mg Na₂ATP per one day quantity. The applicant supplies Na₂ATP, under the commercial name PEAK ATP®. The applicant notes that Na₂ATP may be considered interchangeable with ATP in a physiological context. Furthermore, “ATP” is commonly used as a synonym or generic name for both the free acid and for generic or specific salts. It is therefore proposed that it would be consistent with the regulation of other nutritive substances, such as vitamins and minerals, for either “Adenosine 5' Triphosphate” or “ATP” to be used as names that describe *the true nature of the ingredient* for ingredient labelling of ATP salts (including Na₂ATP).

The purpose of adding Na₂ATP to formulated supplementary sports foods is to support the body's natural response to exercise. Studies consistently indicate that exogenous Na₂ATP at a level of 400 mg per training event or day may enhance exercise-induced increase in blood flow to muscles, reduce fatigue, allow for a more intense training and support faster recovery.

Standard 2.9.4 Division 3 currently permits relevant health claims on a range of Formulated Supplementary Sports Foods (High carbohydrate, High energy, or Energy supplements) which may be supported by the addition of Na₂ATP as an ingredient up to the level of use requested. Specific claims related to the presence of Na₂ATP are not sought in this application.

There are no costs to consumers in general arising from this application. Consumers who wish to make an informed choice to purchase formulated supplementary sports foods containing added Na₂ATP may pay a premium price. There are potential benefits for consumers and government in terms of improved health outcomes and for industry in the form of business opportunities. There are no apparent adverse impacts arising from this application in regard to international trade. However, there also are potential opportunities for Australian and New Zealand food manufacturers to develop sports foods supplemented with ATP Disodium for export markets, particularly the USA and EU.

The application contains a comprehensive review and copies of studies demonstrating the safety of ATP when used as proposed. There are no safety assessment reports for ATP prepared by the WHO or by other national or supranational agencies responsible for food safety or public health. Na₂ATP (PEAK ATP®) manufactured by the applicant has been assessed as GRAS for use in foods in the USA.

The application proposes that fortification of Formulated Supplementary Sports Foods be permitted at a level enough to supply 400 mg per one day quantity through consumption of 2-3 servings of

fortified foods. The foods most likely to be fortified are sport bars, drinks and drink pre-mixes, foods for which there is adequate consumption data for Australia and New Zealand.

Disodium ATP has been notified as a food supplement in Italy, France, Germany, Netherlands, and United Kingdom and is affirmed as GRAS in the US where it is available in Sports foods and drink powders. The application contains Confidential Commercial Information about products containing PEAK ATP® and total annual sales in these markets.

It is expected that sports people choosing to use Formulated Supplementary Sports Foods supplemented with ATP will use them in accordance with label directions and consume no more than necessary in a way that is consistent with achieving their overall specific nutritional or performance goals.

The applicant does not hold an Australian patent in relation to the manufacture of Disodium ATP nor in relation to its use as requested in this application. Consequently, this application does not confer a commercial capturable benefit on the applicant.