



Member Alert

Data Protection scheme for Assessed Listed Medicines CAFFEINE - Restrictions placed on retail foods and food imports

Data Protection (information exclusivity) Scheme for Assessed Listed Medicines

The TGA has confirmed progress on the data protection scheme for Listed Assessed medicines, an important MMDR initiative to help protect the research and innovation of complementary medicine sponsors.

The data protection scheme is designed to provide an incentive for sponsors of listed assessed medicines to innovate and undertake research by focusing on clinical trial data that is not publicly available.

Certain criteria must be met before data is considered to be restricted:

1. The information is provided in an application for the listed assessed pathway;
2. The information is derived from a clinical trial in relation to an indication that is not an existing permissible indication;
3. The information is not publicly available;
4. The length of time of exclusivity is no more than 3 or 5 years.

In practice, it is expected that the scheme will apply to:

- **existing ingredients for use in listed (assessed) medicines**
 - **that are associated with a new (clinical/therapeutic) use**
 - **via submissions made through the [L\(A\)3 application pathway](#).**

The Act will be updated in autumn 2020 to incorporate these changes. The TGA have requested feedback from industry about the data exclusivity scheme for Listed Assessed medicines, in particular regarding the duration of data protection conferred to successful applicants of **3 years or 5 years**, such that this can also be included in the Act amendments.

The amendment when introduced is expected to further the possibilities for innovation and research into new uses for complementary medicine substances.

CAFFEINE - Restrictions placed on retail foods and food imports

FSANZ and the Department of Agriculture have approved the restriction of the retail sale of foods or import of foods where caffeine is present. The restriction is in response to a death attributed to a pure or highly concentrated caffeine product.

The retail sales of foods, or imported foods, cannot contain more than:

- **5% caffeine in solid or semi-solid foods, or**
- **1% caffeine if in a liquid.**

Pure caffeine raw material, used for manufacture, is excluded from this mandate.

The amendment should not affect the sale and supply of caffeinated beverages or sports foods, providing the maximum amount of caffeine meets the thresholds outlined in their respective food standards.

Restrictions on concentrated caffeine has commenced on 12 December 2019, by way of an amendment titled [Food Standards \(Proposal P1054 – Pure and highly concentrated caffeine products\) Variation](#). Caffeine has been added to the list of prohibited substances in [Standard 1.1.1](#) subsection 10(5)(g):

- (5) Unless expressly permitted by this Code, food for sale must not be any of the following:
- (a) a *prohibited plant or fungus, a *restricted plant or fungus, or coca bush;
 - (b) if the food is for retail sale—a *novel food;
 - (c) a *food produced using gene technology;
 - (d) a food that has been irradiated;
 - (e) kava or any substance derived from kava;
 - (f) if the food is for retail sale – raw apricot kernels;
 - (g) **if the food is for retail sale—a food in which caffeine is present at a concentration of:**
 - (i) **5% or greater—if the food is a solid or semi-solid food; and**
 - (ii) **1% or greater—if the food is a liquid food.**

Imports of concentrated caffeine food products are similarly prohibited by an [Imported Food Control Amendment \(Pure and Highly Concentrated Caffeine Products\) Order 2019](#) which was made on 12 December 2019. More information on imports is on the [Department of Agriculture website](#).

Any foods that breach the 1% and 5% thresholds will be failed at the border and importers will be instructed to destroy or export their goods.

To view the proposal, submissions received throughout the consultation process and the final consideration report, go [here](#) on the FSANZ website.

All the details on the TGA Listed Medicine restrictions on caffeine is available in our [Technical Alert of 29 August 2019](#).