



Australian Government

Department of Health

DEPUTY SECRETARY

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Dear Sir / Madam

Submission – Proposal P1042 – Low THC Hemp Seeds as Food

Thank you for the opportunity to provide a submission on the Assessment Report for Proposal P1042.

This submission provides comments in relation to the issues discussed in the Assessment Report and the proposed variation to the Australia New Zealand Food Standards Code (the Code). It was prepared with input from officers from the Australian Government Department of Health.

The submission does not represent an Australian Government position regarding the support or otherwise of the outcomes of the Assessment Report. This will be a matter for the Australian Government when notification is made by the FSANZ Board to the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum).

Delta 9- tetrahydrocannabinol (THC) Limit in the Code

The Department notes that the proposed draft variation to Standard 1.4.4 – *Prohibited and restricted plants and fungi*, is favourable in only allowing the use of hulled (thereby rendering the seeds non-viable) seeds of low THC varieties of *cannabis sativa*. Maximum levels of THC content that may be present in low THC hemp seed foods have been specified.

The Department is pleased to note that only seeds from low THC varieties of *cannabis sativa* could be used as a source of food and only naturally occurring THC may be present in low THC hemp seed foods.

The Department is satisfied that FSANZ has addressed the concern about the acid precursor delta 9-tetrahydrocannabinolic (THC-A) from being converted to THC at sufficient temperatures (i.e. 160°C) by proposing limits for Total THC, consisting of THC and its acid precursor. The Department is pleased that FSANZ's draft variation proposes maximum levels for total THC in low THC hemp seed foods, where total THC is the combined amount of THC and THC-A.

The Department also notes that Forum Members agreed that advice from the International Narcotics Control Board (INCB) be provided to FSANZ and requested that consideration be given to the European Union approach when setting a low THC limit in food. The Department notes that the INCB advice relates to a European Union (EU) Limit of THC in hemp crop only and that the EU has not developed THC limits for hemp seed foods. The Department agrees that FSANZ has adequately considered this advice. Furthermore, hemp can only be cultivated in Australia and New Zealand under strict licensing arrangements and crops are subject to regular testing of THC levels.

Cannabidiol (CBD) Controls in the Code

The Department notes that FSANZ are not proposing a CBD limit in the Code for low THC hemp seed foods but is proposing that any cannabinoids (including CBD) present in the seed or food product must be naturally present in the seeds used to make the food, that is, not fortified.

The Department notes that following advice was provided by the Forum for FSANZ consideration in the preparation of P1042.

The Forum requests that FSANZ consider the need to set a cannabidiol (CBD) limit to distinguish food from therapeutic goods, and include the respective acid precursors in any cannabinoid limits that are set.

The Department considers that establishing a CBD limit in the Code would ensure a food is distinguished from a therapeutic good. While the presence of Cannabidiol and other cannabinoids can be attributed to contamination and/or adulteration, 'hemp seed' oil poses a significant risk. Although hemp seed oil does not contain CBD or THC, some hemp seed oils are claimed and advertised to do so. These oils are in-fact hemp oil (cannabis oil) which is an extraction of the cannabis plant. Further some hemp oils are mixtures of seed and hemp oil and have had cannabinoids added. The terms hemp oil and hemp seed oil have been used interchangeably by some manufacturers of nutritional supplements. Hemp seed oil should not be used to describe products that contain hemp oil or have been adulterated with cannabinoids not present in hemp seed oil.

Therefore the Department considers a limit of CBD should be imposed – in addition to the provision of words within the draft variation 1.4.4-6 which states that cannabinoids in the product must be those that were naturally present in or on the seeds from which the product was extracted or derived (as an added control).

It is suggested that accepting the premise that cannabinoids in seed oil are a contamination or adulteration, a limit of total cannabinoid levels should be imposed such as 50mg/kg to ensure the food is distinguished from a therapeutic good.

Marketing and Labelling of Hemp Seed Foods

The Department of Health notes that FSANZ are 'not proposing additional labelling or advertising requirements in the Code for low THC hemp seed foods, primarily because no relevant available scientific evidence that can be used as the basis for risk analysis to apply such measures, has been identified'

The Department is of the view that more regard should be given to the policy advice provided by the Forum. The advice provided was as follows:

Forum Members also agreed to provide the following policy advice relating to restricting marketing and advertising, and requested that FSANZ take into account that the following points are not in line with government policy:

- *use of the cannabis leaf or any representation that states, suggests or implies a link with illicit cannabis in any marketing or advertising of hemp seed food; and*
- *food derived from hemp seed being advertised as having psychoactive effects.*

The Department believes it is not considered feasible to restrict advertising through Australian Consumer Law and that the Australia New Zealand Food Standards Code (the Code) is the most appropriate place to restrict the advertising of low THC hemp seed foods. The Department believes that a control in relation to labelling of hemp seed products should be included in the draft variation. This is an ongoing concern for Ministers and a number of jurisdictions believe it is best controlled within the Code.

If low THC hemp seeds as a food are permitted within the Code it will be important for this food to not be incorrectly linked to illicit drugs as this might further enhance the illicit drug culture in Australia and New Zealand. The availability of foods containing hemp seeds and seed products and the resulting recognisable and acceptable levels of THC in food might send a confused or mixed message to consumers regarding the acceptability and safety of Cannabis use more broadly. Such mixed messages to consumers could reduce or ruin the public health message about the harmful effects of cannabis (drug) usage.

To assist in FSANZ's considerations of this matter, the Department strongly urges FSANZ to add specific requirements to the drafting that takes into account the policy advice provided by the Forum. For instance specific labelling requirements within the new section 1.4.4-6 into Standard 1.4.4 could include (red font):

- 1.4.4-6 Exception relating to Cannabis sativa seeds and seed products
- 1) *Cannabis sativa* seeds may be a food for sale or used as an ingredient in a food for sale if:
 - a) the seeds:
 - (i) are seeds of low THC Cannabis sativa; and
 - (ii) contain not more than 5 mg/kg of total THC; and
 - (iii) if the food is for retail sale – are non-viable and hulled.
 - b) the only cannabinoids in or on the seeds are naturally present; and
 - c) **the packaging does not include:**
 - (i) use of the cannabis leaf image;**
 - (ii) any representation that states, suggests or implies a link with illicit cannabis; and**
 - (iii) advertising that implies the product has a psychoactive effect.**
 - 2) Subject to subsection (3), all or any of the following seed products may be a food for sale or used as an ingredient in a food for sale;
 - a) oil extracted from seeds of low THC Cannabis sativa if the oil contains not more than 10 mg/kg of total THC;
 - b) a beverage derived from seeds of low THC Cannabis sativa if the beverage contains not more than 0.2 mg/kg of total THC;
 - c) any other substance that is extracted or derived from seeds of low THC Cannabis sativa and contains not more than 5mg/kg of total THC.
 - 3) The only cannabinoids in the products must be those that were naturally present in or on the seeds from which the product was extracted or derived.
 - 4) In subsection (2) –
seeds of low THC Cannabis sativa includes viable and unhulled seeds.
 - 5) In this section –
hulled seeds means seeds from which the outer coat or hull of seeds has been removed.
low THC cannabis sativa has the meaning given by subsection (6).

non-viable seeds means seeds that are not able to germinate.

seeds includes a part of a seed.

total THC means the total amount of delta 9-tetrahydrocannabinol and delta 9-tetrahydrocannabinolic acid.

- 6) *Cannabis sativa* is low THC *Cannabis sativa* if the leaves and flowering heads of *Cannabis sativa* do not contain more than 0.5% delta 9-tetrahydrocannabinol

This suggested wording in the draft variation would be in addition to addressing marketing restrictions within a range of regulatory measures already in place in the Code. These include:

- Standard 1.2.2 – Identification Requirements – food identification
- Standard 1.2.3 – Information Requirements – mandatory warning and advisory statements and declarations
- Standard 1.2.4 – Identification Requirements – statement of ingredients
- Standard 1.2.7 – Nutrition, health and related claims
- Standard 1.2.8 – Requirement for a nutrition information panel
- Standard 1.2.10 – Percentage labelling

It is important that advertising should be limited to describing the nutritional qualities of hemp seeds, other claims such as implying the product has a psychoactive effect would move the product into the therapeutic goods space.

Legislative Implications

International Obligations

The Department is of the view that if the draft variation be accepted, Australia and New Zealand will remain consistent with international conventions, namely the *Single Convention on Narcotic Drugs 1961* and the *Convention on Psychotropic Substances 1971*. The INCB has also supported this position.

Domestic and Import / Export Legislation

The Department acknowledges that there is a range of Commonwealth, New Zealand and State and Territory legislation that currently prohibits the sale of low THC hemp seeds as food which would have to be amended before low THC hemp foods could be sold.

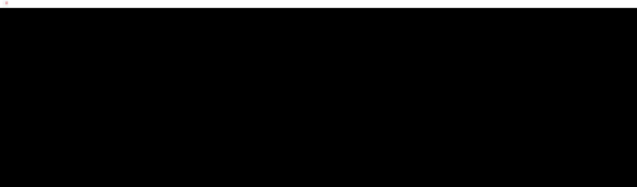
The Department of Health is collating an extensive audit of all Commonwealth, New Zealand and State and Territory legislation that may require amendment should this draft variation be accepted by the Forum.

In summary, the Department of Health's main area of concerns is:

- the need to set a cannabidiol (CBD) limit to distinguish food from therapeutic goods (and a limit of total cannabinoid levels); and
- the marketing and labelling of hemp products (the Department would like more consideration given to the policy advice provided by the Forum).

Should FSANZ require any further information about the issues discussed in this Submission, the Department of Health would be happy to assist.

Yours sincerely



National Program Delivery