



Title Proposal P1042 - Low THC Hemp Seeds as Food

Department Food Standards Australia New Zealand (FSANZ)

Date of submission 25 August 2016

Relationship to previous decisions Application A1039 - Low THC Hemp as a Food, 16 December 2014.

Application A1039 - Low THC Hemp as a Food, 8 November 2012

Application A1039 was submitted on 4 December 2009, seeking approval for the use of the seed and seed products of *Cannabis sativa* (*C. sativa*) with low levels of delta 9-tetrahydrocannabinol (THC) as food.

Application 360 – use of industrial hemp as a novel food

Result of consultation 2016: Ministerial Forum on Food Regulation recommended that research reports comment on marketing and labelling issues, legal and Treaty implications and maximum levels of cannabidiol (CBD) to address information gaps identified in considering the adoption of low-tetrahydrocannabinol (THC) hemp as a food

2015 Not agreed: The Forum rejected the draft variation resulting from Application A1039 - citing a report was required to address cannabinoid levels, legal and treaty issues, and concerns around messaging to consumers.

Application 360 – was rejected by the Forum 2002

Legislative change Yes: A range of Commonwealth, New Zealand and State and Territory legislation that currently prohibits the sale of low-THC hemp as a food would have to be amended to enable low-THC hemp to be sold as a food

Regulatory impact Decreased

Submission type Legislation

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1 Recommendation(s)

It is recommended that:

- i) the Australian and New Zealand Ministerial Forum on Food Regulation approve FSANZ Proposal 1042 to permit low-THC hemp to be legally designated as a food.
- ii) In permitting low-THC hemp as food, there should be no explicit requirement to set a cannabidiol (CBD) limit to distinguish foods from therapeutic goods.
- iii) Additional labelling or advertising requirements are not required in the Code for low THC hemp seed foods.

2 CMA Position Summary

2.1 On the 31 March 2016 the Australian and New Zealand Ministerial Forum on Food Regulation (the Forum) met on the latest updates regarding investigations into low THC hemp as a food. The Forum requested that FSANZ develop a proposal to enable low-THC hemp to be legally designated as a food for further consideration by the Forum. Proposal P1042 outlines, as required, a risk analysis and has now undergone stakeholder consultation.

2.2 Complementary Medicines Australia (CMA) supports that low-THC hemp be legally designated as a food. This approach would align with decisions made by comparable regulatory authorities internationally.

2.3 CMA supports the draft variation to Standard 1.4.4 – *Prohibited and restricted plants and fungi* that permits the sale of foods derived from the seeds of low THC varieties of *C.sativa*. In particular CMA supports that:

2.3.1. by permitting low-THC hemp as food, there should be no explicit requirement to set a cannabidiol (CBD) limit to distinguish foods from therapeutic goods. No evidence has been presented to indicate that establishing such a limit is required from a public health and safety perspective.

2.3.2. FSANZ is not proposing a CBD limit in the Code to permit low THC hemp seeds as foods. Although a limit for CBD has not been included in the draft variation, FSANZ has proposed additional drafting to make it clear the draft variation does not permit CBD (or other cannabinoids), including CBD extracted

or derived from seeds of low THC *C. sativa*, to be a food for sale or used as an ingredient in a food for sale. However, International jurisdictions have not set CBD limits for hemp foods (or for hemp cultivation). A CBD limit in the Code may present a trade barrier and impose additional compliance costs that are out of alignment in other markets and are not justified from the evidence base currently available.

2.3.3. It should be noted that traces of THC and CBD contamination of the seed may occur due to residual contamination of the outside of the seed coat, even under good agricultural/manufacturing practice. Rigorous cleaning methods can assist in mitigating this issue, including washing, sieving and shelling, to help reduce or remove any cannabinoid contamination of seeds. It is recommended that all manufacturers use washed whole seed as a starting material for all food production for safety.

2.3.4. FSANZ proposed maximum levels of THC that may be present in low THC hemp seed foods be drafted as 'total THC', defined as the total amount of THC and the acid precursor delta 9-tetrahydrocannabinolic acid (THC-A).

2.3.5. FSANZ is not proposing additional labelling or advertising requirements in the Code for low THC hemp seed foods as there is no relevant scientific evidence available that can be used as a basis of risk analysis to apply any such measures.

2.3.6. The advice from the International Narcotics Control Board does not impact on the assessment of P1042.

3 Proposal

3.1 Proposal 1042 – Low THC Hemp Seeds as Food was developed to consider a food regulatory measure on how, if it is considered appropriate, it would permit the sale of food derived from the seeds of low delta 9-tetrahydrocannabinol (THC) varieties of *Cannabis sativa* (*C.sativa*) (low THC hemp).

3.2 The Forum requested that the proposal expressly 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.
- Policy advice relating to restricting the marketing or advertising of low THC hemp as a food, in particular the following point which are not in alignment with government policy:
 - use of cannabis leaf or any representation that states, suggests or implies a link with illicit cannabis in any marketing or advertising of hemp seed food
 - food derived from hemp seed being advertised as having psychoactive effects
- Advice from the International Narcotics Control Board and the European Union approach when setting low THC limits in food.

3.3 Hemp seed oil is currently permitted to be sold as a food in New Zealand (under a New Zealand standard). However other hemp foods are currently subject to the prohibition

outlined in Standard 1.1.1 – Structure of the Code and general provisions in the *Australia New Zealand Food Standards Code* (the Code) – prohibited plants and fungi – from being used as an ingredient or component of a food for sale.

- 3.4 FSANZ is satisfied that low THC hemp seed foods are safe for consumption when they contain no more than the proposed maximum levels (MLs) of THC. Ministers have not raised concerns around the FSANZ assessment confirming that low THC hemp seed foods are safe for human consumption.
- 3.5 Further, FSANZ analysis recognises that low THC hemp seed foods may provide a useful alternative as a dietary source of many nutrients and polyunsaturated fatty acids, particularly omega-3-fatty acids.
- 3.6 FSANZ has proposed a draft variation to Standard 1.4.4 – *Prohibited and restricted plants and fungi* that permits the sale of foods derived from the seed of low THC varieties of *C.sativa*.

ENDS