



25 August 2016

Project Officer Proposal P1042
Food Standards Australia New Zealand
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Dear Sir/Madam

Joint Ministry of Health and Ministry for Primary Industries Submission: Proposal P1042 Low THC Hemp Seeds as Food

Thank you for the opportunity to comment on this Proposal. The Ministry for Primary Industries (MPI) has the following comments to make. MPI has consulted the New Zealand Ministry of Health (MoH). The MoH supports the comments made in this submission. Please refer to this as a joint submission representing the views of both agencies.

MPI and MoH have provided comments in relation to the following matters the Forum requested be considered as part of the proposal. For ease of reference our comments are provided in the order these matters are presented in the Call for Submissions paper, under three main headings. Comments are also provided on the Draft Variation, followed by some concluding comments on other legislative changes required if the proposal is approved by Ministers.

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

The New South Wales survey results demonstrate that low delta-9-tetrahydrocannabinol (THC) hemp seed products do contain low levels of CBD. However, like THC, CBD and other cannabinoids that fall within the classification of tetrahydrocannabinols, or isomers, esters, ethers and salts of these tetrahydrocannabinols are class B1 controlled drugs under the Misuse of Drugs Act 1975 in New Zealand, meaning that no amount of CBD, THC or any other tetrahydrocannabinols are acceptable in food, unless the legislation is amended.

We appreciate that under Australian law, CBD is classified as a prescription medicine in preparations for therapeutic use except when containing more than 2% of other cannabinoids found in cannabis. However, from a New Zealand perspective, having no maximum limit for CBD in food is problematic, even if it is reclassified as a prescription medicine here.

Currently New Zealand is following the standard harmonisation processes taken when a controlled drug is reclassified in Australia. The Expert Advisory Committee on Drugs (EACD) is considering whether there should be a change in the New Zealand classification of CBD. The EACD met in April 2016 and considered a submission by the MoH. It reserved its decision until its next meeting in October 2016. If the EACD recommends a change in the classification of CBD to a prescription medicine, the change will take some time to be implemented and other tetrahydrocannabinols may not be affected.

New Zealand's preference is to set a limit for CBD in the Code, irrespective of whether it is reclassified from a controlled drug to a prescription medicine for the following reasons:

1. To legitimise and set a standard for the very low levels of CBD that may be present (due to contamination of the seed coat, during processing). Having no stated upper limit in food allows **any** level of naturally occurring CBD contamination to be in food.
2. The reasoning for not setting a CBD limit was that there was no risk to public health in the low levels of CBD that should be present in low THC hemp seed foods. However the low levels can only be assured by setting a limit for CBD.
3. CBD is currently a controlled drug in New Zealand at any level and cannot be in a food. If it remains a controlled drug then an exemption will have to be made in legislation to allow for the low levels proposed in hemp seed foods. This will be difficult without an upper limit in the food standard.
4. If CBD is reclassified as only a prescription medicine in New Zealand, it can be in food only as long as the concentration of the CBD is not greater than 10ppm. At levels above this it is a prescription medicine. While a higher maximum limit could be specified for CBD in the prescription medicine schedule, 10ppm would seem to be an obvious upper limit to choose (it is noted that the maximum level found in some hemp seed oils tested was above this level).
5. Naturally occurring contamination of hemp foods by CBD will not have a therapeutic effect, within normal consumption levels, however naturally occurring contamination of THC will not cause a psychoactive effect either, yet a limit is being set for THC.
6. The problem arises if foods are fortified. Although not permitted by the draft variation of the food standard, this already occurs and is difficult to detect. If fortification of a food product is suspected it would be difficult to prove and take action if there was no limit set for the CBD content of food
7. It is possible that the CBD could be extracted from a fortified food product in a more concentrated form. The MoH has recently had advice of an intention to export hemp flour (produced from the whole plant) for this very purpose. While it is not hemp **seed** flour, it demonstrates how products that appear to be food can be high in CBD.
8. The MoH considers that people are likely to attempt to use hemp seed products medicinally. While a dose of 120mg /day of CBD has been estimated by FSANZ to be the lowest human therapeutic dose if taken orally and swallowed, a (relatively high) therapeutic dose of Sativex® buccal spray of 10 sprays

daily administers a CBD dose of 25mg. Cannabinoids are not usually administered by the oral route as much of the dose is inactivated by the liver but there is potential for hemp seed oil to be used medicinally by buccal administration.

9. The MoH does not know how effectively a hemp seed oil containing CBD (or THC) will be absorbed from the buccal mucosa but an oil product extracted from hemp seeds and stalks has been used for legitimate therapeutic purposes (prescribed by a medical practitioner) by this route in New Zealand due to the absence of pharmaceutical grade CBD product. This 18% CBD product was classified as food-grade in the particular state in the United States where it was produced.
10. Clinicians in a recent New Zealand consultation emphasized that CBD does interact with prescription medicines, in particular those used in epilepsy. Again this will not be an issue when orally consuming a hemp seed food containing a low amount of naturally occurring CBD. However by not defining an upper limit of CBD, a common, and incorrect, message is sent that CBD, unlike THC, is harmless.

MPI and MoH support the new drafting, with respect to the inclusion of the acid precursors.

2. Policy advice relating to restricting the marketing and advertising of low THC hemp as a food, in particular, 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**
- **Food derived from hemp seed being advertised as having psychoactive effects**

MPI and MoH remain concerned that the proposed draft variation does not contain a prohibition on representing (on a food label) low THC hemp products as cannabis. The term cannabis is used widely in society to refer to marijuana, so any reference to cannabis on the label of low THC hemp seed food could send a confused message to consumers about the true nature of the product, and suggest a link to illicit cannabis.

It is stated that other countries had not identified any problems in their countries with low THC hemp foods being marketed in such a way as to suggest they may have psychoactive properties. However, Australia and New Zealand jurisdictions noted that there is more of an illicit drug culture in our countries around the use of cannabis. It relates to the excellent growing conditions for cannabis in Australia and New Zealand which makes the products more readily accessible than in other countries where they may be more reliant on illegal imports.

Moreover, cannabis in small amounts is legal and readily available in Canada and some parts of Europe removing the need for marketing and labelling to distinguish between low THC hemp products and cannabis.

Current legislation in New Zealand could address the risk of linking low THC hemp food to cannabis but it will need to be amended to explicitly prohibit pictures of marijuana leaves or other links (implied or actual) to illicit cannabis. This is contained in regulation 62 of the *Misuse of Drugs (Industrial Hemp) Regulations 2006*, as follows:

(1) Every person commits an offence who publishes, or arranges for the publication of, any advertisement that states or implies that any of the following is psychoactive:

- (a) hemp or any material derived from hemp:
- (b) a product that contains hemp or any thing derived from such a product.

(2) In this regulation,—

advertisement means any words, whether written, printed, or spoken, and any pictorial representation or design, used or appearing to be used to promote the sale of, or to stimulate interest in,—

- (a) hemp or any material derived from hemp:
- (b) a product that contains hemp or any thing derived from such a product

We prefer that the proposed variation to standard 1.4.4 in the Food Standards Code include a more explicit prohibition on the use of cannabis leaves or links to illicit cannabis in the marketing and labelling of any low THC hemp foods.

Options for consideration include:

- Prohibit the use of the leaf of a cannabis plant on labels (and therefore in any advertising)
- Prescribe the name 'hemp' as the only permitted term to refer to the hemp seed or hemp seed derived product/ingredient added, and prohibit the words *Cannabis sativa*. The type of hemp would need to be qualified, eg hemp seed, hemp seed oil, hemp seed flour, hemp seed protein.
- Prohibit any reference to the illicit cannabis

MPI and MoH suggest that FSANZ considers the existing New Zealand provision as a starting point, with some additional wording (as suggested in the three bullet points above), for inclusion in the Food Standards Code.

New Zealand and Australia need to be consistent in their legislation with regard to the marketing, advertising and labelling of food and the suggested way is requirements in the Food Standards Code.

Persons selling low THC hemp seed food will use the Food Standards Code as the reference point for labelling. It will not be obvious to look elsewhere (such as in Misuse of Drugs Regulations) for any other labelling restrictions.

The FSANZ Act does not prohibit FSANZ from setting requirements in relation to the marketing and labelling of low THC hemp foods. This is supported by section 16 (1) (d) of the FSANZ Act and article 3 (2) (g) of the Food Treaty. The Code contains other prohibitions, for example, foods are not permitted to refer to "slimming".

3. Advice from the International Narcotics Board and the European Union approach when setting a low THC limit in food.

We support the view in the Call for Submissions paper that the advice does not impact on the assessment of this proposal.

Comments on the Draft Variation:

Application of the THC limits to low THC hemp seed foods –MPI has the following questions regarding the drafting:

1.4.4—6 (1) (a) (iii). It is our understanding that hemp seeds sold at retail (eg in bulk bins) must be hulled and non-viable. MPI supports this.

If the seeds are used to produce a food, and are whole in that food (eg in a packet of muesli, or in a baked product), are the seeds also required to be hulled and non-viable?

It is important that the Code is clear on this point. The draft variation at Approval and Review was clear – if the seeds were added to food, they must be hulled and non-viable.

In the section 1.4.1-6(1) we recommend the word ‘whole’ be inserted eg *Cannabis sativa* seed may be a food for sale or used **whole** as an ingredient in food for sale.

If seeds are used to produce foods where the seeds are not whole, eg oil, flour, or crushed and used to make a beverage (they are therefore an ingredient) then it is our understanding the seeds can have their hull on.

1.4.4—6 (2) (b) it is our interpretation that the THC limit applies to the final beverage, eg a hemp seed milk containing other ingredients. Is this the correct interpretation?

1.4.4—6 (2) (c) this section relates to the remaining types of hemp seed foods, such as flours or protein powder. In our view, the term ‘substance that is extracted’ is not correct terminology, to refer to these foods. Extracted substances could be taken to be a novel or nutritive substance. In order for this to be clear that this section refers to foods that are eaten as such, we suggest deletion of the words “extracted or”, so that it reads: *any other substance that is derived from* .

1.4.4—6 (3) is ‘product’ the correct term? We think the term ‘seed product’ is clearer. This is consistent with the wording in the header to 1.4.4—6 (2).

We suggest that the word “extracted” is removed, for the reasons outlined above.

The suggested text is therefore: *The only cannabinoids in the seed product must be those that were naturally present in or on the seeds from which the product was derived.*

A further point for consideration is the use of the term ‘products’, in relation to the use of this term in other parts of the Code (for example fruit juice products, which is not defined and has caused interpretation issues for New Zealand). The term ‘products’ in relation to the types of foods captured needs to be clear and unambiguous.

1.4.4—4 We understand this is to allow for viable and unhulled seeds to be used in food processing, eg to make hemp seed oil, hemp seed beverages, hemp seed flour or protein powder.

Level of THC in the plant – we note that drafting has been amended, and that maximum level of delta 9 tetrahydrocannabinol in the leaves and flowering heads is 1%, consistent with the limit in some Australian jurisdictions. The limit in New Zealand is 0.35-0.5%, and this is the value that would still apply to the

production of low THC hemp seed foods in New Zealand, as this limit is in force under the *Misuse of Drugs (Industrial Hemp) Regulations 2006*.

Cannabis with 1% THC is cannabis not hemp in New Zealand. Seed from such plants would not be able to be licensed as hemp seed. This change in drafting is problematic for New Zealand. The conflict would cause confusion in New Zealand for growers of hemp and persons processing hemp seed under any new Food Code permission in New Zealand, as the values under the *Misuse of Drugs (Industrial Hemp) Regulations 2006* would apply to the plants used to produce any such foods produced in New Zealand from New Zealand grown hemp. Foods imported into New Zealand would have to comply with the limits set in the Food Standards but complications could arise if the seeds from which they are produced are not considered hemp seeds in New Zealand legislation. We would be happy to talk this issue through with FSANZ.

A further point is that the limit set in these regulations refers to THC measured on a dry matter basis, ie: *THC content, in relation to a hemp plant, means the content of THC of the plant expressed as a percentage of the dry weight of the plant*. We have not been able to find out if it is standard procedure in Australia to analyse for THC on a dry matter basis, but this could be a further point for consideration by FSANZ.

Further New Zealand legislative changes required if low THC hemp is permitted as a food.

Several changes will need to be made to New Zealand legislation to enable hulled hemp seed and hemp seed products to be sold as food.

These are:

- Legislation will need to be amended to enable the proposed maximum level of THC for the four categories of hemp foods. The *Misuse of Drugs (Industrial Hemp Regulations) 2006* allows for a THC level of 0.35%-5% in the industrial hemp plant. This was not intended to be an allowable level in food. The expectation was that the THC level (and the level of any other controlled drugs, including CBD) in the hemp seed oil, the only currently allowable hemp seed food in New Zealand, would be 0%.
- CBD is currently a controlled drug and, as with delta-9-tetrahydrocannabinol and other tetrahydrocannabinols, cannot currently be in a food at any level. If it remains a controlled drug then a similar amendment will have to be made in legislation to allow for the low levels in hemp seed foods. This will be difficult without a specified maximum level in the food standard.
- If CBD is rescheduled as a prescription medicine the concentration in food will need to be below 10ppm i.e. 10 mg/kg (or some other level defined in the medicines schedule) otherwise hemp seed products will be defined as medicines.
- Currently a licence is required to possess hulled hemp seed. It will need to be exempted, probably by defining as a hemp seed product, to enable it to be sold by retail as a food.

The proposal to define industrial hemp as containing up to 1% THC will present alignment issues between Australia and New Zealand (1% is higher than most international industrial hemp definitions).

Yours sincerely


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