



15 February 2012

Project Officer Application A1039
Food Standards Australia New Zealand
PO Box 10559
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WELLINGTON 6036

FS350-117-1039

Dear Sir/Madam

Application A1039 – Low THC Hemp as a Food - Assessment Report

Thank you for the opportunity to comment on this application. The Ministry of Agriculture and Forestry (MAF) has the following comments to make. MAF has consulted the Ministry of Health, the Ministry of Justice, the New Zealand Police, the New Zealand Customs Service, the Civil Aviation Authority of New Zealand (CAA), the Commerce Commission New Zealand, the Ministry of Transport, the Land Transport Agency, and the Institute of Environmental Science and Research (ESR) during the preparation of this submission.

General comments

MAF considers the management of hemp seeds under the New Zealand Misuse of Drugs Act 1975 (MODA) is a key issue and as such would need to be fully addressed before New Zealand could consider supporting Application A1039, and thereby expanding the availability of hemp seeds and hemp-seed products in New Zealand.

MAF notes the benefits of the sale of foods derived from hemp seeds in terms of their nutritive value, and that there do not appear to be any safety issues associated with hemp-seed foods.

The Ministry of Health notes however that there is a lack of data relating to potential health consequences of regularly ingesting small quantities of delta 9-tetrahydrocannabinol (THC). Data on acceptable trace levels of THC would assist in determining a maximum level of THC permitted in hemp-seed foods, however the slow excretion of THC from the human body would complicate the determination of a maximum level.

MAF understands that there is no way to visually distinguish between hulled hemp seeds and the hulled *Cannabis* seeds. Hulling would generally allow one to distinguish between hulled and non-hulled seeds, but theoretically hulled hemp and hulled *Cannabis* seeds are indistinguishable without further testing. As a result it could make it difficult for law enforcement agencies to enforce legislation that prohibits the possession of *Cannabis* seeds (whether hulled or not).



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If the preferred option was adopted, there would likely be significant additional costs to the New Zealand Ministry of Health in terms of processing and issuing of licenses for handling viable hemp seeds (including producing, transporting, processing, manufacturing, importing and exporting) but licensing would not be required for handling 'hulled, non-viable seeds'. Licensing costs would be primarily associated with establishing the necessary additional systems, but the cost of individual licenses would be recovered from licensees. There are also likely to be enforcement costs for those government departments responsible for enforcing drug control legislation. There may also be additional costs to those employers that monitor for employee drug use for operational safety reasons (for example, airlines).

It is not clear from the report, until you look very closely at the drafting, that the proposed draft standard allows the use of viable and non-hulled hemp seeds to be used in the manufacture of food such as hemp seed oil, beverages, or flour. This is addressed in more detail in our comments that follow, as MAF considers more clarity on this issue is required in the draft standard.

MAF considers that there is the potential for positive economic benefits from permitting low THC hemp-seed foods in New Zealand both in terms of the nutritive value of hemp seed products, and the suitable growing conditions in New Zealand. The wider use of hemp-seed in food may increase the productivity of industrial hemp production beyond those products already permitted (e.g. for products such as textiles and paper).

Although a regulatory impact statement is not required for this application, MAF considers that there would be benefit in the Food Standard Australia New Zealand (FSANZ) cost-benefit analysis capturing the full costs associated with licensing systems in New Zealand and Australia.

Legislative amendments in New Zealand

If the proposal in A1039 is accepted, amendments would be required to the New Zealand Misuse of Drugs Act 1975 (the MODA) and regulations made under the MODA (principally, the Misuse of Drugs (Industrial Hemp) Regulations 2006, or the development a new regulation). In addition it is likely that an amendment to the New Zealand Food (Safety) Regulations 2002 (made under the Food Act 1981) would be required.

Given any decision in relation to extending the permission for the use of hemp seeds in foods would require coordination across government departments, and potentially Cabinet consideration (due to the implications for existing regulations and legislation), MAF requests that FSANZ clearly signal as early as possible when the Approval Report for A1039 is likely to be released. Regular updates on progress would also be appreciated.

The regulatory and legislative changes required in New Zealand are described below.

Misuse of Drugs Act 1975 and regulations

Hemp seeds are classified as a Class C drug under the MODA on the basis of being 'Cannabis seeds'. As such, a licence would be required for manufacture, supply or importation of hemp seeds. Any person who manufactures, supplies or imports hemp seeds without a licence is subject to a maximum penalty of eight years imprisonment. Where a person breaches a licence they are liable to a maximum penalty of three months in imprisonment and a \$500 fine.

The Misuse of Drugs (Industrial Hemp) Regulations 2006 (the Industrial Hemp Regulations) would need to be amended or replaced by new regulations to permit the wider use of hemp seeds in foods (i.e. beyond processing into hemp seed oil).

MAF notes FSANZ's suggestion (in section 6.4 of the Assessment Report, third paragraph) that State, Territory and New Zealand legislation would require amendment to allow the sale of hemp

seeds in Australia and New Zealand. As noted above, in New Zealand hemp seeds would continue to be classified as Class C drugs, and subject to licensing. However, once the hemp seeds are processed (e.g. for retail to the consumer) as hulled and non-viable seeds or as ingredients in food products (e.g. hemp seed oil, hulled hemp seeds in muesli bars), then they would not be subject to a licence for supply, manufacture and importation.

Those transporting whole viable hemp seeds (e.g. a grower to a food manufacture), or further processing viable hemp seeds (e.g. an oil presser or a food manufacturer) would be in possession of a Class C drug, and so would require a licence under the MODA.

Amendments to regulations made under the MODA would require Cabinet approval, and would be subject to legislative priority, drafting and related parliamentary process. Therefore, if A1039 is accepted, there would be a delay before it could be given legal effect in New Zealand.

Food (Safety) Regulations 2002

Regulation 26 of the Food (Safety) Regulations 2002, which permits the sale of hemp seed oil in New Zealand, expires on 30 October 2012. Given the uncertainty inherent in an application such as this, MAF will likely need to commence the process to address the expiry of the New Zealand hemp seed oil provision in May 2012.

If A1039 is approved, amendments would likely be required to Regulation 26 of the Food (Safety) Regulations to align it with the new standard (which could include revocation of Regulation 26). Amendments to the Regulation would depend on the scope of the detail of the FSANZ standard. Further, if A1039 is accepted, there is likely to be a period when both the provisions developed in the Food Standards Code and Regulation 26 of the Food (Safety) Regulations 2002 would apply in New Zealand.

Comments on draft variation - Attachment 1

We acknowledge the comment (in section 2 of the Draft Explanatory Statement (Attachment 2) to the Assessment Report), as to why there is no reference in clause (1) of the proposed draft standard to the use in food of solely low THC hemp-seed varieties. Instead, the umbrella term '*Cannabis sativa*' is used. MAF notes that the seeds of the *Cannabis* drug varieties also contain no THC. Therefore, MAF questions why the food standard cannot be specific that only 'low THC hemp-seeds' can be used in food or words of similar effect.

FSANZ may want to consider including a statement around the permission to use whole hempseed (i.e. not hulled, still viable) in the manufacture of hempseed products such as hempseed meal, oil and flour.

Questions for submitters

Section 6.1 – Safety of hemp-seed foods – maximum THC levels in the Code

Will the inclusion of a maximum level in the Code for hemp seed oil products be an issue for hemp seed oil products produced in or imported into New Zealand?

The setting of a maximum level as proposed in the consultation paper (i.e. seed of *Cannabis sativa* or any substance derived therefrom (other than oil extracted from seed) – 5 mg/kg, oil extracted from the seed of *Cannabis sativa* – 10 mg/kg, and beverages derived from the seed of *Cannabis sativa* – 0.2 mg/kg) would not see either a licensee or importer of hemp-seed oil in New Zealand disadvantaged.

While New Zealand supports the inclusion of a maximum level, it questions the inclusion of a maximum permitted level derived by estimating the maximum level of THC in the food commodity that would not result in the consumer exceeding the TDI (tolerable daily intake) for THC (as noted in Section 6.1 of the Assessment Report). Hemp seeds themselves contain no THC with any THC identified being the result of contact with other parts of the hemp plant. Careful processing can reduce this to very low levels. Therefore, it is New Zealand's view that the maximum level for THC in foods should be as low as reasonably possible. We note that some countries have a zero tolerance level for THC in hemp-seed based foods. Such an approach would also be consistent with MODA. If the maximum level of THC is reduced (and FSANZ states that this is under consideration in section 6.5 of the Assessment Report) to close to zero, this may address some of the concerns associated with the effect of hemp seed foods on drug testing.

New Zealand questions whether the draft standard should explicitly state that only naturally occurring THC may be present in hemp-seed based foods. While it would be unlikely that synthesized THC would be added to food, we do not want this practice to be inadvertently permitted given the levels of THC proposed, which are significantly higher than the levels that are likely to be present in foods containing hemp-seed based ingredients. We suggest the inclusion of a clause stipulating 'for the avoidance of doubt only naturally occurring THC may be present in hemp-seed based foods'.

MAF has reviewed the Risk Assessment Report, and we have several comments. In our view, Section 1.2 of the Risk Assessment Report (SD1) could benefit from reviewing in greater depth the other studies collated in the Zuurman et al. 2009 review.

The toxicological basis for the THC TDI is primarily discussed in paragraph 1 of Section 1.2. It is derived from the Chesher et al. 1990 study and described as the lowest dose producing an effect on skill performance. In paragraph 6, the dose is deemed to represent the NOAEL, with the indication that the dose of 10mg/person from this study represents the LOAEL.

While the six studies listed in paragraph 5 that used doses between 7.5 and 20mg/person would not be suitable for deriving a lower TDI (as noted in the risk assessment), they may be of value if they indicated a higher NOAEL value was supported. In particular if the toxicological assessments of these studies do not raise the same concerns regarding the subjective self-assessment of intoxication (paragraph 8) and statistical concerns (paragraph 6) from which the Chesher et al. study is subject to, they could add value to the risk assessment.

We believe that the updated FSANZ risk assessment would benefit from further discussion regarding the continued reliance on the Chesher study for establishing the threshold dose, particularly as more recently conducted studies, those forming part of the Zuurman et al review, have been referenced but are not reviewed in the current risk assessment.

A further comment we wish to make relates to section 6.1 of the Assessment Report, where intake calculations are provided, based on a 100 kg person and THC levels from Leson et al 2001. MAF considers that these calculations should be removed from the Approval Report, as the body weight is not consistent with the body weights used for dietary exposure assessment, and the THC concentrations are not the same as those proposed by FSANZ.

Section 6.4 Distinguishing between hemp and cannabis seeds

Are there other methods of distinguishing between the seeds of hemp and drug varieties of cannabis? Please provide evidence in support of these methods.

Are there other methods of rendering hemp seeds non-viable that will also result in the whole seed being distinguishable from the seeds of drug varieties of cannabis? Please provide evidence in support of these methods.

Can you provide any evidence on whether hulled hemp seeds remain viable?

MAF is pleased to note that FSANZ is investigating the issue of the viability of hulled hemp seeds (as noted in section 6.4 of the Assessment Report). MAF understands that hulled seeds are potentially viable; however we are researching this further and will provide information if this becomes available. The Ministry of Health advises that ESR has done some trials with *Cannabis* plants. The Ministry of Health understands that hulled seeds that have been held in a carefully controlled humid environment, or in a vacuum pack can potentially remain viable. If there was any question of some of the material being viable, then UV irradiation or heat treating would need to be investigated as a food safe treatment to render the seeds non-viable. The viability of hulled hemp seeds should be tested by a testing laboratory.

New Zealand notes that Canada uses steam heat and infra-red cooking processing. These methods appear to be well documented in the manuals that accompany the regulations. If the standard proceeds as currently drafted, enforcement agencies would need to develop suitable methods and systems for assessing compliance with both the requirement for hulling, and rendering seeds non-viable.

Section 6.5 Drug Testing

Are you aware of any studies reflecting the effect of consumption of hemp foods on the results of saliva THC tests?

Can you provide information on the type of saliva tests that are available, including sensitivity of the tests?

What saliva THC tests are currently in use in Australia and New Zealand? For these tests, what levels of detection of THC are currently used? Can you provide information on the methodology of these tests and the costs of conducting these tests?

Can you provide any additional data on other THC testing methodologies that are used in Australia and New Zealand (for example, urine and blood)?

Which analytical laboratories currently conduct confirmatory THC testing, for example blood tests? How much do these tests cost?

Do you have data to indicate the levels of THC in current hemp food products? Is it likely that hemp foods could be produced to comply with lower maximum levels of THC?

Would additional processing costs be incurred in order to achieve lower THC levels in hemp foods?

MAF is not aware of any additional studies to those identified by FSANZ on the effect of consumption of hemp-seed foods on the results of saliva THC tests.

MAF has sought input from several New Zealand Government entities on drug testing. Advice from these agencies is summarised below.

The CAA advises that its usual testing modality is the evidential-standard urine drug screen.

The Ministry of Transport advise that New Zealand does not currently use oral fluid (saliva) screening devices for drug driving enforcement.

The New Zealand National Drug Intelligence Bureau (which is comprised of the New Zealand Police, the New Zealand Customs Service, and the Ministry of Health) advises that the New

Zealand Police use a blood test for testing for 'drug impaired' drivers. This test normally occurs after a person has passed the 'alcohol' impairment test and still appears impaired.

ESR advises that there are several laboratories in Australia that provide oral fluid drug testing (usually complying with the AS4760 standard). ESR is the only laboratory in New Zealand that provides oral fluid confirmatory drug testing (there are several companies that offer oral fluid screening devices). As with urine, oral fluid tests are split between screen and confirmation testing. ESR currently has four different immunoassay-based screen tests for THC in oral fluid and confirms the screen results using LC-MS/MS. The AS4760 standard indicates target cut-off values for THC of 25ng/ml and 10ng/ml for screen and confirmation test determinations. More recent guidelines for oral fluid testing (from SAMHSA and the EWDTS) have indicated much lower cut-offs of 4ng/ml and 2ng/ml (SAMHSA) and 10ng/ml and 2ng/ml (EWDTS).

ESR can also test for THC in blood and hair samples. ESR prices for drug testing are between \$50 and \$100 for urine samples, \$150 and \$250 for oral fluid, and \$550 for hair samples.

ESR considers that it is likely that the majority of manufacturing processes could be easily altered to increase or decrease the THC content. In this respect, ESR considers that it is likely that the major additional cost to manufacturers would be quality control testing to ensure the levels meet those proposed in A1039.

Section 8.2 Cost Benefit Analysis

FSANZ seeks advice on the number of hemp licences and hemp businesses in Australia and New Zealand to better calibrate the market potential.

FSANZ seeks advice on other cost items that might influence the analysis.

FSANZ seeks advice on possible entry barriers to a hemp food market.

Costs

The Ministry of Health in New Zealand advises that ten licences were issued to cultivate industrial hemp for the 2011-12 growing season. There are two types of hemp licences. A general licence application fee is \$511.11 (GST inclusive) and a research and breeding licence application fee is \$153.33 (GST inclusive). Research and breeding licence holders must have both licences. There is also an import/export fee of \$194.22 (GST inclusive) per application for each importation of viable hemp seeds.

If A1039 is accepted, there would be resource implications for the Ministry of Health in developing legislative changes to allow for wider use of hemp seeds in food. This would be primarily from an increase in staff time. There may also likely be an increase in the number of licence applications and auditing requirements, both of which are the responsibility of the Ministry of Health.

MAF understands that the Ministry of Health has already provided an estimate of FTE requirements for licensing and auditing the Hemp Regulations to FSANZ.

The CAA considers it is likely that the presence of hemp-seed food products on the market would lead to greater difficulty and complexity in the interpretation of urinary drug screen results. This would in turn, result in a potential increased cost to the aviation industry and probably other industries where drug safety is important. The CAA advises that the complexity in part relates to the fact that even if hemp seed products have zero or very little THC, where it is possible for people to consume large amounts of hemp leading to a positive test then there will be people who claim their positive tests are the result of hemp.

Possible entry barriers to the hemp-seed food market

New Zealand would be interested to learn if FSANZ has considered whether or not costs related to the requirement that hemp seeds be hulled (including the food technology limitation of hulled seeds - they are more prone to oxidation), could act as a deterrent for businesses that might otherwise intend to use hemp seeds in food.

The cost for a food processor or manufacturer to gain a licence may also be a barrier to entry to the hemp-seed food market. In addition, the development of a hemp-seed food market may be delayed by the necessary regulatory changes to give effect to an agreed joint standard for hemp-seed foods.

Additional comments

Potential impact on the Court System

The introduction of wider uses of hemp-seed in foods must not create a significant impact on the case load in the New Zealand court or prison systems by opening up the possibility for increased breaches of the MODA. If hemp seeds are available for consumption in New Zealand then a person could be liable for committing the following offences:

- manufacturing, supplying, importing hemp seeds without a licence, and/or
- manufacturing, supplying, importing hemp seeds in breach of a licence.

The impact of widening the permissions for use of hemp seeds in food depends on the likely number of breaches that would occur. However, the potential for breaches of the MODA cannot be managed by provisions in the Food Standards Code. It is also unlikely that legitimate manufacturers would purposely breach licensing conditions and risk the viability of their businesses. It is also unlikely that other people would choose to create a black market for these products if a legal market is operating. The impacts of the preferred option on the court system are therefore expected to be minimal.

Labelling

New Zealand seeks FSANZ's view on whether there would need to be additional labelling on hemp-seed foods in the context of potential contraindications of hemp with certain medication or medical conditions.

MAF notes that FSANZ suggests in section 6.2.1 of the Assessment Report that reference to *Cannabis* on the label of food (e.g. 'Low THC *Cannabis*') would be acceptable on the label of food if the preferred option was adopted. MAF is still considering if this reference is appropriate in the context of New Zealand's drug and fair trading laws.

Nutrition Assessment and Dietary Exposure Assessment – sections 2.4 and 3.3.1 of the Risk Assessment Report

MAF considers that it is worth noting in Section 2.4 that the nutritional composition of hemp seed alters upon hulling the hempseed, particularly as only whole hempseed nutrient composition values are presented in this document despite the preferred approach which limits the sale of whole hempseeds. As with hulling any seed, the carbohydrate (including fibre) content will decrease, with increases in the protein and fat fractions of the seed.

In relation to the dietary exposure assessment, MAF has evidence of hemp-based beverages for sale in 1L containers. Therefore the statement in section 3.3.1 may need to be amended from 125 mL containers to 1L containers. It is likely that hemp-based beverages can be consumed in a similar manner to soy beverages as some are represented as dairy milk alternatives.

Cannabidiol ("CBD") in hemp seed food products

Has FSANZ considered the presence of cannabidiol ("CBD") in hemp seed food products? When contained in plant material, CBD is considered a Class C drug in New Zealand. We are aware that hemp flowers are high in CBD, but we have not been able to identify information about its presence in hemp seeds or their products.

Draft explanatory statement to acknowledge the fact that a licence is required for those handling viable hemp seeds (including producers, transporters, processors and manufacturers)

Finally, as noted earlier in this document, the proposed draft standard would require hemp seeds, when used in foods as whole seeds (e.g. in a muesli bar, or packet of muesli), to be both hulled and non-viable.

However, if the hemp seeds are used to make other foods, such as hemp seed oil, beverages or flour, then the hemp seeds would not need to be hulled or rendered non-viable first. While this is sensible from a food processing point of view, it will impose additional costs on industry, as the person or company in possession of the viable hemp seeds for processing will require a licence. This point is not correctly acknowledged in section 2 of the Draft Explanatory Statement (Attachment 2) to the Assessment Report. The penultimate sentence in Section 2 states that all hemp seeds must be hulled and non-viable, but this does not apply to whole seeds that are used to make oil or other foods. As such, the Approval Report should note that those handling viable whole seeds would require a licence under New Zealand law, and FSANZ should consider how drafting of the standard can reflect that viable non-hulled hemp seeds can be traded and subject to further processing as food but only under license from the relevant jurisdiction.

Yours sincerely