



26 April 2011

Dear Sir/Madam

## Application A1039 Low THC Hemp as a Food – Consultation Paper

Thank you for the opportunity to comment on this Consultation Paper. The Ministry of Agriculture and Forestry (MAF) has the following comments to make. MAF has consulted the Ministry of Health, the Ministry of Justice, and the New Zealand Police, during the preparation of this submission.

### *General Comments by MAF*

MAF has no particular concerns with the chemical safety assessment. The nutrition assessment could perhaps be expanded on in the Assessment Report. The Nutrition Assessment was based on just two narrative review papers published by Callaway (2004) and Rodriguez-Leyva and Pierce (2010) as well as some modeling by FSANZ. Since A360 was published in 2001/02 there have been many more papers appearing on the nutritional composition of hemp products and their suitability in human nutrition. MAF questions if these should have been considered in some systematic way, particularly as the Nutrition Assessment has formed quite an important part of the Risk Assessment Report.

MAF agrees however that the generic nutritional composition of low THC *Cannabis sativa* looks quite appealing as it has the potential to offer an alternative source of alpha-linolenic acid in the food supply.

MAF notes that the risk assessment did not consider the presence or absence of known food allergens in whole hempseed or hempseed oil. MAF considers that this should be included in the safety assessment.

There is an error in the last sentence of the executive summary to the Risk Assessment Report, where it is stated that “...the adult Adequate Intake for alpha-linoleic acid (an essential...”. This should of course read alpha-linolenic acid.

### *General comments by the Ministry of Health*

The Ministry of Health has no health concerns about hemp seeds in food as hemp seeds do not contain any THC and are not psychoactive.

The Ministry of Health has some concerns over the potential regulatory requirements needed to allow hemp seed in food. If the seeds were to be available loose in bulk bins or sold in packets, there would be considerable regulatory and enforcement costs. This is because loose seeds (ie not in a “hemp product”) are Class C1 controlled drugs under the Misuse of Drugs Act 1975 and their cultivation, distribution and possession requires a licence. Additionally, it is impossible to visually distinguish between hemp seed from a low THC plant and high THC *Cannabis* seed. The Ministry of Health therefore considers it



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necessary for the seeds to be non-viable to reduce the risk of high THC *Cannabis* seeds being sold as 'hemp' seeds and cultivated for illegal use. It would also prevent hemp plants being cultivated and protect the business interests of industrial hemp cultivators (who are required to adhere to rigorous licensing requirements).

It may already be the intention of allowing Low THC hemp as a food that the seeds are non-viable and the Ministry requests that options for ensuring the hemp seeds are non-viable and distinguishable from *Cannabis* seeds be presented. The Ministry of Health also requests that information is provided in the next FSANZ assessment on the regulatory requirements in other countries where hemp seeds are available for use in food. .

### ***General comments from the Ministry of Justice***

The Ministry of Justice comments that:

Hemp and THC are Class C and Class B controlled drugs (respectively) and therefore subject to the offences and penalties under the Misuse of Drugs Act 1975 (the Act). The cultivation, supply, possession, or use of hemp or THC is an offence under the Act, unless, there is licence approval or regulations made under the Act (such as those for industrial hemp). There would, therefore, appear to be legislative provision for the cultivation, and consumption of hemp (as a controlled drug) in food, subject to the exemptions.

If research shows that consuming food with less than 0.35% THC content affects behaviour (i.e. resulting in impairment), then this could have legal implications (eg, under the Land Transport Act, it is an offence to drive with any amount of a qualifying drug in your system AND to be impaired), or other contractual implications to be drug free in employment (eg, airlines, fisheries, athletes). Further research on the effect of low (less than 0.35%) THC content in food should therefore be undertaken before low THC content food can be bought or sold in New Zealand.

The easy availability of THC content products, such as food, for non-medicinal purposes, could be viewed as contrary to Government policy and practice. Consumable products with THC content are currently only available for restricted medicinal purposes; however, the application would make THC content products more easily accessible for non-medicinal purposes.

The Ministry is currently awaiting the Law Commission's review on the Misuse of Drugs Act 1975, and whether there will be any recommendations relating to *Cannabis* based products for medicinal purposes.

### ***Questions for submitters***

#### **1. Are you aware of any evidence that consumers believe low THC hemp foods have psychoactive effects?**

MAF is not aware of any evidence

#### **2. Are you aware of any evidence that representations on low THC hemp foods (including labelling and advertising) mislead consumers by leading them to believe that low THC hemp foods have psychoactive effects when consumed?**

No. As noted in the Consultation Paper, Regulations in New Zealand prohibit the publication of any advertisement that states or implies that hemp or hemp products are psychoactive. If such representations were made, they would be misleading.

**3. Can you provide any evidence in addition to that presented in this Consultation Paper whether or not the consumption of low THC hemp foods can return a positive result for a THC drug test?**

MAF comments that 125 ml of oil, while we agree it appears unrealistic, could in fact be consumed if the oil was used for frying or deep frying, and a large portion of food was eaten.

MAF notes that the Consultation Paper states (page 2) that hempseeds do not contain any THC, but that because they get wrapped in specialised leaves, they then get contaminated. MAF considers that this 'wrapping' needs to be more fully explained in the Assessment Report. Is this 'wrapping' describing the growing of the plant, and/or is this a post harvest practice?

The New Zealand Police currently arrange for testing to determine if the plant or material is *Cannabis* or not. The hemp seeds would have a trace of THC on them, because they come from the flowering head. This should not show up in human drug tests.

The Ministry of Justice notes that the consultation document argues that it is unlikely that people consuming low THC products will return a positive result when tested but data on this issue is limited. If research shows that consuming food with less than 0.35% THC content is a problem in terms of affecting behaviour (ie, resulting in impairment), then this could have legal implications (for example, under the Land Transport Act, it is an offence to drive with any amount of a qualifying drug in your system and to be impaired), or other contractual implications to be drug free in employment (for example, airlines, fisheries, athletes).

**4. Can you provide information on THC drug testing procedures in Australia and New Zealand, particularly with regard to regulatory limits of THC that may be set?**

MAF does not hold this information

**5. Can you provide information to indicate whether there will be an impact on the cost of testing for THC in humans that could arise from an approval of hemp foods?**

MAF does not hold this information. It is possible that this is held by the New Zealand Department of Labour ([www.dol.govt.nz](http://www.dol.govt.nz)).

**6. Do you agree that there are adequate controls currently in place, or that would be achieved by imposing maximum limits for THC, to mitigate any risk of high THC *Cannabis* varieties entering the food supply?**

MAF anticipates that if the application succeeds, increased monitoring of the licensing and cultivation of hemp crops would be required.

The Ministry of Health does not consider that there are adequate controls currently in place. Imposing maximum limits for THC to mitigate the risk of high THC *Cannabis* varieties entering the food supply would be insufficient. Irrespective of the fact that they contain no THC and can only germinate low THC strain plants hemp seeds are *Cannabis sativa* and as such are Class C1 controlled drugs under the Misuse of Drugs Act 1975.

The only way to determine whether a seed is hemp or *Cannabis* seed would be to grow the plant and measure the THC. This could only be done by a licensed laboratory and would take a significant period of time to grow the plant then analyse the leaf/flower to determine THC content. Therefore, hemp seeds destined for use in food would need to be able to be distinguished from all other *Cannabis* seeds. Another requirement would be that they would need to be non-viable so cultivation could not occur. Without more information about how the seeds would be made non-viable and about their proposed appearance, the Ministry of Health is unable to comment fully about the controls that would be necessary.

Currently it is unlawful for anyone (unless they possess a licence issued under the Misuse of Drugs legislation) to possess any type of *Cannabis* seed. There would need to be legislative amendment to allow for the supply and possession of seeds for food. For further details, see question 12. Consideration would also need to be given to the possibility of internet sales and on-line orders from overseas which could be used to illegally import *Cannabis* seeds.

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) comment that a raft of extra controls and added cost would be needed to mitigate any risk of high THC *Cannabis* varieties entering the food supply. As a person currently needs a license to grow hemp, it would mean that a license would be needed to possess and or sell the seeds. Possession of *Cannabis* seeds is an offence under the Misuse of Drugs Act.

**7. Do you consider that trade practices legislation in Australia and New Zealand is sufficient to mitigate the potential risk that representations (including and advertising) of hemp foods could suggest psychoactive properties relating to consumption of those foods? If not, what other conditions regarding labelling and representations of hemp foods should be considered?**

In MAF's view, the legislation as summarised by FSANZ is sufficient. Enforcement of the provisions is integral to further managing the risk.

The Ministry of Health comments that, while it is not lawful currently in the Misuse of Drugs (Industrial Hemp) Regulations 2006 for hemp products to be advertised to have psychoactive effects, enforcement of hemp food products by the Ministry of Health under the proposed amendment to the Food Standards Code has not been scoped, but would be likely to be costly and impose significant resourcing pressure.

**8. What is the potential opportunity cost for current producers of hemp crops if hemp foods continue to be prohibited? Please provide quantitative data if available.**

No comment.

**9. What are the potential benefits to food manufacturers if hemp foods were approved for use?**

No comment.

**10. Are there likely to be any additional costs for food manufacturers wishing to supply hemp foods? Please provide quantitative data if available.**

The Ministry of Health comments that there is the potential for hemp manufacturers to incur additional costs, dependent upon the legislative changes that are made, if hemp seed is allowed in food. Presently, the legislation would require each manufacturer to have a hemp licence and every imported consignment of hemp seed would need an import licence. A new regulatory regime would be required to permit the sale of hemp seeds for food and the Ministry of Health has not scoped out the likely costs to manufacturers of this.

**11. Would the approval of low THC hemp foods increase the cost of food enforcement beyond what would be expected of the approval of any other substance added to food, or other food regulatory change?**

MAF notes that as hemp seed oil is already permitted as a food in New Zealand, any additional costs would relate to the cost of enforcing the sale of the seed. Because the seed could be confused with

high THC *Cannabis* seeds, or viable seeds confused with non-viable seeds, it is expected that the cost of enforcement would be greater than for other new foods. As noted in the Consultation Paper, there is also an expectation that the level of enforcement would be greater than for other newly permitted foods or ingredients.

The Ministry of Health notes that to avoid very costly enforcement and an onerous regulatory regime for manufacturers and users, the seeds would need to be non-viable and distinguishable from *Cannabis* seeds.

Another area of concern would be the licensed hemp growers. If hemp seeds for food were not rendered non-viable, people could purchase hemp seed and cultivate it at home without being licensed. This would interfere with the hemp growing industry, and also create further enforcement issues for the Police in determining if the plants are hemp or high THC *Cannabis*.

The New Zealand National Drug Intelligence Bureau comments that there is no visual way to tell hemp and *Cannabis* seeds apart. DNA testing or fully growing the plants and testing for THC levels are the only ways to distinguish between hemp and *Cannabis* seeds. Both are costly options. There are therefore enforcement issues around distinguishing hemp seeds and *Cannabis* seeds, with a large forensic cost to the New Zealand Police to prove the seeds are illegal. Even if efforts were made to distinguish hemp seeds, such as colouring, this effect could easily be mimicked for *Cannabis* seeds.

## **12. What other legislation in Australia and New Zealand would affect or be affected by approval of hemp foods?**

Amendments would be required to the Misuse of Drugs Act 1975 and regulations made under the Misuse of Drugs Act, and the Food Safety Regulations 2002.

### ***Comments from the Ministry of Health***

The Misuse of Drugs Act 1975 is administered by the Ministry of Health. The Ministry of Health has provided the following information:

According to preliminary legal advice, the Misuse of Drugs Act 1975 would need to be amended to establish a new regulatory regime similar to the existing industrial hemp regulations. New regulations would therefore need to be drafted.

It would also be necessary to amend the Misuse of Drugs Regulations 1977 (Reg 22) to exempt hemp seeds from the need for ministerial approval for the supply of a C1 controlled drug.

Depending upon the scope of the new regulatory regime, the Misuse of Drugs (Industrial Hemp) Regulations 2006 would need a number of changes which would potentially include:

- Reg 4 : Interpretation – to define hemp seed for food etc
- Reg 35 : Hems seeds may be procured only from a licence holders
- Reg 49 : Seed Register – changes to incorporate sales for food
- Reg 63 : Offence to supply hemp to unauthorised persons
- Reg 67 : Permission – amendment for hemp seeds for use in food

The Ministry of Health notes that possibly more changes would be required to allow for the new distribution of seed to food producers, procedures around making the seeds non-viable and distinguishable, and who could undertake this activity (if not the grower).

### ***Comments from the Ministry of Agriculture and Forestry***

The Food (Safety) Regulations 2002 are established under the Food Act 1981 and are administered by MAF (formerly NZFSA).

If the proposed FSANZ application for low THC hemp as a food (A1039) was approved, the need for change to the Food (Safety) Regulations 2002 would depend upon the detail of the FSANZ standard, as well as other requirements that New Zealand wishes to impose.

If the proposed FSANZ application for low THC hemp as a food (A1039) was approved in 2012, it will be a question of the timing of the acceptance of the application A1039, as to what course of action could be considered in terms of any changes to the Food (Safety) Regulations 2002. There are three possibilities:

- a) If the application is approved and Standard 1.4.4 of the Food Standards Code is amended after the Food Bill has been enacted MAF would need to amend the Food (Safety) Regulations 2002 given regulation 26 of the Food (Safety) Regulations provides that "Despite standard 1.4.4 of the Food Standards Code, oil extracted from hemp seed may be sold as food in New Zealand if it complies with the requirements set out in subclause (2)." (regulation 26(1)). The Food (Safety) Regulations may also need to be amended to include any requirements relating to the inclusion of low THC hemp in food.
- b) If the Food Bill has not been enacted, but is likely to be enacted in the near future, the options are to amend the (Food Safety) Regulations or to delay the commencement of the amendment to Standard 1.4.4 of the Food Standards Code until the Food Act has been enacted and the new Food Regulations have been promulgated.
- c) Finally, if the Food Act has not been enacted and it is unclear that it will proceed, MAF will need to amend the Food (Safety) Regulations.

**13. Would approval of hemp foods have an impact on existing hemp regulations in Australia and New Zealand? For example, would industrial hemp destined for use in food require additional controls to those already specified in industrial hemp regulations?**

The Ministry of Health has commented that there would need to be changes to the Misuse of Drugs Act 1975, Misuse of Drugs Regulations 1977, drafting of new regulations under the Misuse of Drugs Act, and potentially changes to the Misuse of drugs (Industrial Hemp) Regulations 2006.

The Ministry of Health considers that there would be additional requirements for hemp seeds destined for food use, namely for the seeds to be non-viable and distinguishable from all other *Cannabis* seeds (including hemp seeds for cultivation).

**14. Would food manufacturers be required to be licensed under existing hemp regulations?**

The Ministry of Health comments that under existing legislation food manufacturers would have to be licensed as it is currently unlawful to possess hemp seeds without a licence.

**15. Would additional costs be incurred by government agencies responsible for granting licences for the cultivation of hemp as a result of approval of hemp foods?**

The Ministry of Health comments that there would be likely to be significant additional costs to the Ministry on several levels. Processing and issuing hemp licences, processing and issuing import or export licences for hemp seeds, monitoring cultivators' sales of seed, issues with viability/non-viability of seeds, and associated enforcement of these activities.

**16. Can you identify other risk management options that have not been considered in the impact analysis? Comments on the possible costs and benefits are welcome.**

No comment.



**17. Can you identify any other costs and benefits for any of the risk management options considered in this paper?**

No comment.

**18. Do you have a view about an appropriate preferred regulatory option regarding the approval of hemp foods, based on benefits and costs?**

MAF notes that a number of issues arise if low THC hemp is approved as food, particularly around licensing, auditing, compliance costs, administration, enforcement, and the linkages between the number of agencies that would be involved. This needs to be balanced against the ability to produce a new food that may provide both an economic benefit and a nutritious food.

The Ministry of Health reiterates the comments made earlier that hemp seeds for use in food would have to be made non-viable and distinguishable from all other *Cannabis* seeds (including viable hemp seeds). A number of issues arise out of this and would need to be considered. There would be the need to involve an additional regulatory process to determine an acceptable non-viability process, who was able to perform this process (accreditation required?), who would oversee/administer this, how the non-viable seeds would be distinguishable, how enforcement (Police, Customs etc) would be able to identify these seeds in the community or at the border. The Ministry of Health would be very interested to know the details of methods used and issues faced in other countries where hemp seed is available in food.

The Ministry of Justice notes that the paper recommends that further information is gathered for the development of regulatory options. The Ministry of Justice agrees with this recommendation, and is of the view that further research should be undertaken into this area before low THC content food can be bought or sold in New Zealand.

Yours sincerely