Submission for Application A1039 Low THC Hemp as a Food

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Question for submitters:

Abstract

This submission addresses issues raised by Food Standards Australia and New Zealand's (FSANZ) final application A1039 Low THC as a Food document. The proposed maximum levels in the draft variations to the Australian New Zealand Food Standards Code in this document are similar to Canada, which supplies hemp seed products to the United States of America. This submission will therefore use Canadian and American examples to answer the 'question for submitters'.

The inclusion of maximum levels such as those in Canada will enable the production of hemp seed products which will contain very low levels of THC and therefore will not interfere with roadside saliva tests in Australia. These maximum levels can be easily achieved through licensing of minimum THC % in hemp crops and through additional cleaning of seeds. Cleaning procedures are also needed to remove other foreign particles such as weed seed and do not need to be expensive.

Studies from Canada and America have shown that THC in commercially available hemp foods is generally low or non-detectable. Many studies have also concluded that under the current licensing and testing protocol the consumption of hemp foods in America and Canada do not produce positive urine tests. Studies have also found that roasting of whole hemp seed may be a way to ensure hemp seeds are sterile while enabling them to be distinguished between drug seed varieties.

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?

According to Health Canada (2012) in theory ripened hemp seed contains no detectable quantities of THC, however residues from other parts of the plant may be detected on the seed. In Canada hemp seed oil is intended as a food product and therefore levels of THC are kept at extremely low. Health Canada has implemented an Industrial Hemp Technical manual including operational procedures on sampling and testing THC in hemp seed oils to ensure hemp seed oil contain the appropriate THC levels.

In Canada it is only legal to grow hemp seed purchased from a certified seed grower or importer. Seed is imported under specific regulations and all farmers are required to have an industrial hemp licence in which specifies crops must be tested or may exempt from testing if they are growing from a list of approved cultivars. (BCAF, 1999, Health Canada 2005).

Provided that hemp seed produced or imported into New Zealand is grown from low THC crops the hemp seed oil would contain low levels of THC (see table 4 below). Imported oil would need to be tested to ensure it also contain appropriate levels of THC. The inclusion of a maximum level in the code would therefore not be an issue given there are protocols for growing hemp crops in New Zealand and that hemp seed oil products imported into New Zealand and tested.

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

See answer below

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.

A study by Crew (2000) used dry heat processing methods to sterilise whole hemp seeds. The study compared existing grain drying, roasting and microwave sterilisation methods. The easiest and most cost effective dry heat sterilisation method was a modified dry heat coffee or nut roaster. This method was consistent in sterilising the seeds and rendering then non-viable while not over heating the seeds and reducing their nutritional values.

Table 1 below show the result for roasted hemp seeds. The study also looked at e-beam sterilisation which was an effective but expensive method, and grain drying which caused inconsistent heating and damage of the seeds.

Table 1: Hemp seed roasted for various times under various temperatures to determine condition to render seeds non-viable. Source: Crew (2000).

Sample	Germination %	Abnormal %	Dead%
215°F – 10 minutes	0%	5%	95%
215°F 15 minutes	0%	3%	97%
215°F – 20 minutes	0%	0%	100%
250°F – 5 minutes	0%	3%	97%
250°F – 10 minutes	0%	0%	100%
250°F – 15 minutes	0%	1%	99% *
350°F – 3 minutes	0%	1%	99%
350°F – 4 minutes	0%	1%	100%
350°F – 5 minutes	0%	1%	100%
350°F – 6 minutes	0%	1%	100%

** No explanation was sought to determine why only 99% of the seed was dead when 100% of the seed was dead when roasted for 5 minutes less than this sample. Both results were within the Health Canada guidelines for non-viable seed.*

The dry roasting whole hemp seed may produce commercially desirable product which would use regular processing equipment. It may also have the added benefits of making a distinguishable difference between hemp food varieties and drug varieties due to the evident roasted composition of the seeds.

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

From experience with importing hulled hemp seeds through Australian quarantine (AQIS) , none of the hulled hemp seed imported remained viable or showed any sign of sprouting. AQIS considers hulled hemp seed (containing no whole seed) to be sterile and is therefore able to pass quarantine protocols.

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

A study by Leson and Pless (2001) under a Canadian government research project (ARDI) looked at any potential conflicts between the extended consumption of hemp foods and work place drug testing programs. The test involved giving one of four different daily doses of hemp oil/canola oil mixes to 15 individuals for a period of 10 days. None of the 15 tested individuals showed a positive urine test result for THC even with doses of up to 600 µg/day. Table 2 below shows that 600 µg of THC per day corresponds to 300g or 6 tablespoons of hemp oil per day. This would be considered a large amount of hemp seed or oil food to consume on a daily basis.

Table 2. THC concentration in oil, daily doses and corresponding oil and seed consumption Source: Leson and Pless (2001).

Study period (10 days each)	Oil dose	THC dose	Corresponds to daily consumption of		
			Hulled hemp seeds	Hemp seed oil	
#	(mL/day)	(mg/day)	(g/day) at 2 µg/g THC	(mL/day) at 5 µg/g THC	(mL/day) at 20 µg/g THC
1	15	0.09	45	19	5
2	15	0.19	95	40	10
3	15	0.29	150	63	16
4	15	0.45	225	95	24
4	20	0.60	300	126	32

The study concluded cleaning and quality control measures limiting THC in hemp oil and seed to 5 µg and 2µg respectively was effective in ensuring the consumption of hemp food did not interfere with work place drug tests. The results showed levels of THC were consistent less than 5 ppb (parts per billion) (Leson and Pless, 2001). A number of other studies have also confirmed that in the U.S under the current THC concentration limits hemp food would be unlikely to produce a positive urine test (Leson and Pless, 2001., Holler, 2008, Goodwin et.al., 2006).

Saliva THC rates are known to be generally relative to urine tests (Cone et.al, 2002). Table 3 below shows worldwide minimum detectable concentrations of THC which would trigger a positive saliva test. The Australian saliva test limits are set to a threshold of 10 ng/mL of THC in saliva, which is equivalent to 10 ppb (Drummer 2006). Saliva tests are used for road side testing in Europe (ROSITA) and in the U.S (SAMHSA) where hemp foods have already been legalised (Cone et.al 2002, Huestis 2009).

Table 3. Recommended minimum detectable concentrations in oral fluids. Source: Drummer (2006)

Drug	SAMHSA cut-offs (ng/mL)	ROSITA cut-offs (ng/mL)	Standards Australia proposed target concentrations (ng/mL)
6-AM	4	-	10
Morphine	40	-	25
Cocaine	8	5-10	25
THC	2	1.9	10
Methamphetamine/MDMA/amphetamine	50	70-90	25

6-AM = 6-Acetylmorphine, MDMA = methylenedioxymethamphetamine, THC = Δ^9-tetrahydrocannabinol.

According to these limits and assuming THC cut off limits in food would be similar to Canada, it would be unlikely that the consumption of hemp food could trigger a positive THC saliva test.

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

The saliva testing device DrugWipe®, is used in Australia and involves swiping the collection pad on the tongue for a brief second. If tested positive the test is repeated using Rapiscan®/™ following repeat collection of oral fluid with the Cozart® Drummer (2006).

Saliva testing is usually representative of recent cannabis use. Oral THC concentrations correlate with blood plasma cannabinoid concentrations and is used and an indicator of drug impairment (Huestis 2002, Kintz et.al 2002).

These devices can be programmed with a cut-off or threshold detection limit (Cone 2002) as discussed before. If set to the current limit of 10ng/ml, even the consumption of large amounts for consecutive days of hemp foods would not result in a positive drug test.

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?

See answer above

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

These tests would be similar to urine tests performed in U.S please read answer to the consumption of hemp foods on the results of saliva THC tests above.

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

Unknown

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?

A study by Crew (2000) tested levels of THC in six varieties of hemp seed grown for food production in Manitoba, Canada, using Health Canada's approved testing protocols. Table 4 below shows all the varieties tested had THC levels below allowable limits by Health Canada of 10 µg/g (equivalent to parts per million).

Table 4. THC in Whole hemp seed grown in Canada. Source: Crew (2000).

Variety	Sub-Sample Size (grams)	Sample Size Analyzed (mg)	Δ^9-THC Range (µg/g)	Δ^9-THC Level (µg/g)
Fedora 19	10.0	200	2.19 – 2.96	2.53
USO 14	10.0	200	0.40 – 0.66	0.54
Felina 34	10.0	200	2.15 – 2.84	2.55
Fin 314	10.0	200	2.17 – 3.05	2.57
Fasamo	10.0	200	2.19 – 2.79	2.46
Ferimon 12	10.0	200	2.62 – 4.66	3.57

In Canada cleaning of hemp seeds ensures THC levels in oil and hulled seeds are less than 5 and 2 ppm (parts per million), respectively (Leon and Pless 2000). Table 4 above shows that even before cleaning these varieties had THC limits of less than 5ppm with an average of 2.37 ppm.

A study in the U.S looked at the content of THC in commercially available hemp products. The study concluded that the hemp products tested had low concentrations of THC and were unlikely to cause a positive urine analysis. Most of products tested, had non-detectable levels of THC (Holler et.al 2008).

The information obtained from Canada and the U.S indicates that using hemp seed grown from crops under licensed conditions and with additional cleaning if

necessary, hemp foods products can be easily produced to comply with lower maximum levels of THC such as those used in Canada.

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

General seed cleaning equipment is used to remove foreign material and weed seeds form hemp seeds. The removal of hemp leaf or flower material can easily be performed when the seed is dry (Province of Manitoba, 2012). Table 4 above indicates that in general hemp seeds grown from crops with THC levels of less of than 0.3 % contain low levels of THC. Therefore only basic cleaning methods are required to achieve target THC concentration for food production.

In the study by Crew (2000) the seed of one variety of commercially grown hemp seed was cleaned using a variety of methods. The results are presented in table 5 below. This study concluded that a variety of methods can be used to easily reduce THC from hemp seed including just water which reduced levels by 48%.

Table 5. THC levels of seeds of a commercially grown hemp variety after cleaning in test solutions. Source: Crew (2000)

Test Solution	N	Δ^9-THC Range (µg/g)	Average Δ^9-THC Level (µg/g)
Fasamo whole seed (baseline)	**3**	**2.19-2.79**	**2.46**
Food grade detergent	3	0.39-0.43	0.41
Food grade degreaser	3	0.28-0.32	0.30
Oxilink (regular strength)	3	0.76-0.82	0.80
Oxilink (double strength)	1	5.01-6.06	5.54
Hydrogen-peroxide	3	1.76-2.19	1.98
Food grade ethanol/water	3	0.27-0.35	0.31
Water only	3	1.11-1.28	1.17

n = number of replicates. Each replicate consists of a duplicate analysis of the sample.

This information shows that general seed cleaning to remove foreign particles and weed seed may be sufficient in lowering levels of THC. Processing costs for seed cleaning would not need to be highly expensive to achieve lower levels of THC in food and would be the similar for any other type of seed.

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

Hemp Seeds Australia (HSA) currently sells a range of hemp products. HSA currently receives a number of inquiries about hemp food and hemp food legislation and would expect a considerable market for sales of hemp food products.

If hemp seed production was allowed in Australia the numbers of licences to grow hemp and hemp related businesses would rise significantly and would also support the hemp fibre industry.

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

Current Australian hemp licensing already restricts the THC content of hemp plants depending on the state or territory. Testing of crops is required as part of the licence and costs around $250 - $500 depending on the laboratory. There would not need to be any additional major cost items assuming that hemp processors purchase low-THC hemp products from licensed hemp seed growers.

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

The hemp food market will rapidly develop in Australia due to a high demand from health-conscious consumers. There only barrier would be in any restriction that would not allow the sale of whole and hulled seed products and hemp oil.

Conclusion

Hemp seeds Australia wishes to see the use of low THC whole hemp seeds and hemp seed products as food with maximum THC limits specified in the Code. These limits could be similar to Canada's with the exception of using dry roasting method of sterilisation of hulled hemp seeds instead of steam sterilisation which would enable drug authorities to distinguish between the two varieties.

It is evident that given protocols are put in place similar to in Canada the legalisation of hemp food in Australia would not interfere with drug tests. Hemp products with maximum THC levels could easily be produced in Australia with minimum infrastructure requirements. The addition of hemp food products would have added benefits to the health of Australian's and the Australian economy.

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