

SUBMISSION ON APPLICATION A1039 LOW THC HEMP AS FOOD (CONSULTATION PAPER)

**Food Policy and Programs Branch, SA Health
20 April 2011**

Thank you for the opportunity to provide comments to the Consultation Paper for A1039.

General Comments

As stated on page 3 of the Consultation Paper, SA Health agrees that many of the issues of concern such as the impact on drug policies, enforcement and community opinion, lie outside of the scope of food regulation. However while these issues exist, amending the Food Standards Code to allow the sale of food containing hemp is considered premature.

Additionally, the South Australian Controlled Substances Act 1984 and the Controlled Substances Regulations 2000 currently prohibit the cultivation, possession and consumption of cannabis and cannabis plants. An exemption exists for the sale of hemp seed oil for external use. Any permission in the Food Standards Code would therefore be at odds with this legislation.

It is recommended that views be sought from the Ministerial Council on Drug Strategy.

Specific Issues

The following information is offered in response to specific questions in the consultation paper.

Questions for submitters

Question 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?

Journal articles showing the results of testing overseas are attached for your information. (Attachment 1)

Questions 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?

Drug testing in SA is conducted via an immuno-based assay for serum levels as described on page 11 of the consultation paper and by LCMS for metabolites.

Question 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?

This issues needs to be considered at a broader level than food regulation.
Further advice should be sought from drug enforcement agencies.

Question 7

Do you consider that trade practices legislation in Australia and New Zealand is sufficient to mitigate the potential risk that representations (including labelling 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?

While misleading statements about the properties of a food are sufficiently controlled by Trade Practice legislation and by parallel clauses in the SA Food Act, the implications of hemp in food are broader than simply being misleading. Use of the word 'hemp' and symbols such as the hemp leaf on hemp products may infer a connection with drug use without actually being misleading or untruthful. If this application progresses, the additional requirements as proposed for A360 such as restrictions on the placement of such symbols and words (eg. only in the ingredient list) should be considered.

Question 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?

Additional resources may be needed to adequately investigate breaches particularly as an interface with police and drug enforcement agencies may be required.

Question 12

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

SA Controlled Substances Act 1984 and Controlled Substances Regulations 2000 prohibit the cultivation and possession of cannabis and its products apart from hempseed oil for external use.

Question 18

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

Further work should be done on drug policy and legislation before consideration is given to progressing this application.

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**SA HEALTH SUBMISSION TO FSANZ Consultation Paper – LOW THC HEMP AS A
FOOD** **Attachment 1**

Journal Article Extracts re drug content of hemp foods.

Delta9-tetrahydrocannabinol content of commercially available hemp products.

Holler JM. Bosy TZ. Dunkley CS. Levine B. Past MR. Jacobs A.

Journal of Analytic Toxicology 32 (6) : 428-432 2008 July-Aug

Delta9-Tetrahydrocannabinol (THC) is the main psychoactive compound present in marijuana. THC can also be found, as a contaminant, in some commercially available hemp products marketed in health food stores and on the internet as a good source of essential fatty acids. The products range from oil to alcoholic beverages to nutritional bars to candies, with oil being the most popular and commonly available. The analytical results are separated into two groups, products tested prior to and after publication of 21 CFR Part 1308, "clarification of listing of tetrahydrocannabinols." The data presented are a summary of 79 different hemp products tested for THC. THC was separated by a liquid-liquid or solid-liquid extraction, depending upon the product matrix. THC concentrations range from none detected to 117.5 microg THC/g material. Typical limits of detection for the assay (depending on matrix) are 1.0-2.5 microg THC/g material. Products that were of aqueous base (beer, tea) had much lower limits of detection (2.5 ng/mL). No THC was detected in 58% of the products from group 1 and 86% of the products from group 2. The amounts indicate that THC levels in currently marketed hemp products are significantly lower than in those products available before 2003 and reported in previous studies. The results reported here may be used as a general guideline for the THC content of hemp products recently found in the marketplace today.

Hemp products on German food market: THC content and forensic meaning.

Below E. Roenstock S. Lignitz E.

Blutalkohol 42 (6) : 442-449, 2005 Nov

In infringements or other offences with respect to hemp products, the accused often make protection statements concerning their drug-consumption. For example, they deny the abuse of hashish pretending the consumption of several bottles from hemp-beer or -cola and tracing the proven blood THC exclusively to that. 26 different cannabis products - therein 16 beverages (7 kinds of beer) as well as 9 hemp foodstuffs and one sort of hemp blooms for room air condition improvement - were investigated with respect to their THC content. At the same time, the question was examined whether or not the aforementioned products are able to cause positive blood and urine test results. It can be concluded that the majority of the free-for-sale hemp products, particularly beverages, does not contain psychotropic-acting THC amounts or does contain only very small amounts from psychotropic-acting THC at the most. Even an excessive consumption of beverages and/or food with detectable THC content does not lead to positive cannabis tests in blood or urine samples.

Analysis and toxicological evaluation of cannabinoids in hemp food products: a review

Electronic Journal of Environmental Agricultural and Food Chemistry 4 (1) 2005 Jan-Feb

http://ejeafche.uvigo.es/component/option,com_docman/task,doc_view/gid,58/Itemid,33/

Also published as
Current status of THC in German hemp food products.
Lachenmeier DW. Walch SG.
Journal of Industrial Hemp 10 (2) : 5-7 2006

"First studies after emergence of hemp food products, containing significantly higher THC levels than nowadays, described positive results in forensic-toxicological drug tests for hashish and marihuana after the consume of hemp oil [37,41,64-67] and other hemp food stuff [38,40]. Most of the studies were conducted in 1996-1997 with THC concentrations of more than 50 mg/kg. For example, after few hours of oral administration of hemp oil (151 µg/ml THC), THC-COOH could be detected in urine. After the application of 40-90 ml oil, THC-COOH could be detected in urine for up to 80 hours. THC serum levels up to 6 ng/ml were determined after intake of 40 ml of hemp oil [37,40, 67].

With the gradual reduction of THC in hemp food, also a reduction of its metabolites in the urine of the consumers could be observed. In a study in 2001 with a maximum content of 5 mg/kg of THC and a daily intake of up to 0.6 mg THC, no positive urine tests were obtained [59]. In a recent study [10] after the consume of 6 cups (0.2 l) of hemp tea (0.23 mg/kg THC) over a duration of 2 hours, no THC metabolites were found in the urine of six probands using an immunochemical standard screening method. This confirms previous results of other working groups that excessive consume of currently available hemp food products (e.g. hemp beer) does not cause positive urinalyses [36, 39, 42, 44, 59, 68-70]. Only the consumption of hemp food products with high THC contents, which are no longer available on the market, can produce positive results [71, 72]. In cosmetic products as hemp shampoo, the THC content is negligible, so that no influence on forensic-toxicological hair analyses could be proven [70, 73-75]. Nowadays one can assume that fibre hemp products do not influence forensic-toxicological drug tests, if these products comply with the effective limits."

Urinary cannabinoid detection times after controlled oral administration of 9-tetrahydrocannabinol to humans.

Gustafson RA. Levine B. Stout PR. Klette KL. George MP. Moolchan ET. Huestis MA.
Clinical Chemistry 49 (7) : 1114-1124 2003 Jul.

Background: Urinary cannabinoid excretion and immunoassay performance were evaluated by semiquantitative immunoassay and gas chromatography-mass spectrometry (GC/MS) analysis of metabolite concentrations in 4381 urine specimens collected before, during, and after controlled oral administration of tetrahydrocannabinol (THC). Methods: Seven individuals received 0, 0.39, 0.47, 7.5, and 14.8 mg THC/day in this double-blind, placebo-controlled, randomized, clinical study conducted on a closed research ward. THC doses (hemp oils with various THC concentrations and the therapeutic drug Marinol) were administered three times daily for 5 days. All urine voids were collected over the 10-week study and later tested by Emit II, DRI, and CEDIA immunoassays and by GC/MS. Detection rates, detection times, and sensitivities, specificities, and efficiencies of the immunoassays were determined. Results: At the federally mandated immunoassay cutoff (50 mug/L), mean detection rates were <0.2% during ingestion of the two low doses typical of current hemp oil THC concentrations. The two high doses produced mean detection rates of 23-46% with intermittent positive tests up to 118 h. Maximum metabolite concentrations were 5.4-38.2 mug/L for the low doses and 19.0-436 mug/L for the high doses. Emit II, DRI, and CEDIA immunoassays

had similar performance efficiencies of 92.8%, 95.2%, and 93.9%, respectively, but differed in sensitivity and specificity.

Conclusions: The use of cannabinoid-containing foodstuffs and cannabinoid-based therapeutics, and continued abuse of oral cannabis require scientific data for accurate interpretation of cannabinoid tests and for making reliable administrative drug-testing policy. At the federally mandated cannabinoid cutoffs, it is possible but unlikely for a urine specimen to test positive after ingestion of manufacturer-recommended doses of low-THC hemp oils. Urine tests have a high likelihood of being positive after Marinol therapy. The Emit II and DRI assays had adequate sensitivity and specificity, but the CEDIA assay failed to detect many true-positive specimens.

Evaluating the impact of hemp food consumption on workplace drug tests.

Leson G. Pless P. Grotenhermen F. Kalant H, ElSohly MA.

Journal of Analytic Toxicology 25 (8) : 691-698 2001

Foods containing seeds or oil of the hemp plant (*Cannabis sativa* L.) are increasingly found in retail stores in the U.S. The presence of 9-tetrahydrocannabinol (THC) in these foods has raised concern over their impact on the results of workplace drug tests for marijuana. Previous studies have shown that eating hemp foods can cause screening and confirmed positive results in urine specimens. This study evaluated the impact of extended daily ingestion of THC via hemp oil on urine levels of its metabolite 11-nor-9-carboxy-9tetrahydrocannabinol (THC-COOH) for four distinct daily THC doses. Doses were representative of THC levels now commonly found in hemp seed products and a range of conceivable daily consumption rates. Fifteen THC-naïve adults ingested, over four successive 10-day periods, single daily THC doses ranging from 0.09 to 0.6 mg. Subjects self-administered THC in 15-mL aliquots (20 mL for the 0.6-mg dose) of four different blends of hemp and canola oils. Urine specimens were collected prior to the first ingestion of oil, on days 9 and 10 of each of the four study periods, and 1 and 3 days after the last ingestion. All specimens were screened for cannabinoids by radioimmunoassay (Immunalysis Direct RIA Kit), confirmed for THC-COOH by gas chromatography-mass spectrometry (GC-MS), and analyzed for creatinine to identify dilute specimens. None of the subjects who ingested daily doses of 0.45 mg of THC screened positive at the 50-ng/mL cutoff. At a daily THC dose of 0.6 mg, one specimen screened positive. The highest THC-COOH level found by GC-MS in any of the specimens was 5.2 ng/mL, well below the 15-ng/mL confirmation cutoff used in federal drug testing programs. A THC intake of 0.6 mg/day is equivalent to the consumption of approximately 125 mL of hemp oil containing 5 pg/g of THC or 300 g of hulled seeds at 2 pg/g. These THC concentrations are now typical in Canadian hemp seed products. Based on our findings, these concentrations appear to be sufficiently low to prevent confirmed positives from the extended and extensive consumption of hemp foods.