

**HEALTH PROTECTION DIRECTORATE**

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File Number: QCHO/2313 part 2  
Our Ref.: RS\_LT\_A1039\_Assessment  
Report\_FSANZ DL amended

15 February 2012

Standards Management Officer  
Food Standards Australia New Zealand  
PO Box 7186  
Canberra BC ACT 2610

Dear Sir / Madam

**Submission – Application A1039 – Low THC Hemp as a Food**

Thank you for the opportunity to provide a submission on the Assessment Report for Application A1039.

This submission provides technical advice and comments in relation to the issues discussed in the Assessment Report and the proposed variation to the Food Standards Code. It was prepared with input from officers from Queensland Department of Employment, Economic Development and Innovation (DEEDI), Queensland Police Service (QPS) and Queensland Health Forensic and Scientific Services (QHFS).

The submission does not represent a Queensland Government position regarding the support or otherwise of any of the options outlined in the Assessment Report. This will be a matter for the Queensland Government when notification is made by the FSANZ Board to the Legislative and Governance Forum on Food Regulation.

**Analysis of mixed foods**

The draft variation to the Food Standard Code described in Attachment 1 of the Assessment Report does not contain a prescribed limit for tetrahydrocannabinol (THC) in mixed foods, that is, foods made from different ingredients. This will create a number of enforcement and analytical difficulties.

Under the proposed variation, to determine whether a mixed food, such as a cake or biscuit that contains THC complies with the proposed standard, the analyst would need to undertake additional analyses to estimate the relative proportions of hemp derived ingredients (eg. oil or meal) in it. Then the analyst would need to determine whether the amount of THC present exceeds the sum of the maximum permitted levels of the combined hemp derived ingredients. Alternatively, the default maximum permitted level would be 10mg/kg of THC, if hemp oil may be present.

Depending on the type of mixed food, analysis to determine the relative proportions of hemp derived ingredients may be very difficult to accurately estimate. It also would significantly add to analysis costs and the time for analyses to be undertaken.

Obtaining information from a manufacturer on the specifications of a mixed food containing hemp products may help, but in many cases this information will not be available. This will particularly be the case with

imported products, where the food has been produced by someone who does not keep records (eg. individual making products to sell at a market) or where it is associated with criminal activities.

Furthermore, manufacturers are not necessarily legally required to keep accurate records of the proportions of ingredients or obligated to provide this to enforcement officers.

Department of Agriculture, Fisheries and Forestry (DAFF) Biosecurity (previously Australian Quarantine and Inspection Service) is likely to require a simple enforceable level of THC in mixed foods to effectively monitor whether imported hemp mixed food products comply with prescribed THC limits in the Food Standards Code.

### **Prescription of limits for only delta 9- tetrahydrocannabinol**

The proposed variation to the Food Standards Code only prescribes a limit for the presence of delta 9- tetrahydrocannabinol. However, a number of different tetrahydrocannabinol isomers and analogues are likely to be present that may have psychoactive properties. While delta 9- tetrahydrocannabinol is likely to be the most prevalent and psychoactive isomer, the presence in particular of delta 8- tetrahydrocannabinol needs to be considered.

Limits in the proposed standard need to be prescribed as tetrahydrocannabinol and not delta 9- tetrahydrocannabinol, and that tetrahydrocannabinol then be defined as including delta 9- tetrahydrocannabinol and delta 8- tetrahydrocannabinol. Alternatively, the variation could refer to tetrahydrocannabinol and not to a specific isomer, similar to the Queensland *Drugs Misuse Act 1986*.

This change would acknowledge that delta 8-tetrahydrocannabinol is also a significant psychoactive component that may be present. Since it is generally easier to analyse for the presence of both the delta 8 and the delta 9 isomers, it should be easier, quicker and cheaper to analyse for the presence of both isomers. Information on the chemistry and analysis of THC prepared by a Queensland Health analyst can be provided on request.

### **Need to prescribe hemp food derived only from low THC hemp plants to enable DNA analysis**

Queensland Health Scientific Services is currently developing an analytical method using DNA based techniques to distinguish between the fibre (low THC) and illicit drug varieties of *Cannabis sativa*. Once developed, the cost of a validated identification assay would be approximately one fifth of the cost of validated quantifiable tests for THC.

The proposed standard would need to include an additional requirement that only hemp seed products derived from low THC varieties of *Cannabis sativa* may be added to food.

This provides legal clarification that hemp seed products must only be derived from low THC varieties of *Cannabis sativa*. It also provides an additional offence in the Food Standards Code, which may be cheaper to test for. That is, if it can be proven, based on analysis, that a food includes illicit drug varieties of hemp, then it is a breach of the Food Standards Code. This would also provide enforcement officers with a greater range of evidence (eg. analyses, statements and documents) that can be obtained to prove high THC varieties of hemp were not used in the preparation of a hemp food.

The inclusion of an additional requirement that only hemp seed products derived from low THC varieties may be added to food should be in addition to prescribing limits for THC. This is because it will not always be possible to undertake DNA based analyses and because some jurisdictions may not have access to validated DNA based analyses.

## Labelling and advertising

FSANZ have argued that it would be misleading to promote psychoactive properties because hemp foods do not have psychoactive properties. Queensland Health does not consider existing consumer protection legislation is adequate in this regard and is concerned that FSANZ have rejected the need for additional labelling requirements. If low THC foods are permitted, additional regulation will be needed to ensure hemp foods are not labelled and advertised in ways that undermine attempts by health and policing agencies to reduce the illegal use of cannabis.

Including requirements in the Food Standards Code to prohibit the association between hemp food and illegal activities would provide greater guidance for the food industry and make it easier to regulate associated labelling and advertising. It would also help ensure that strategies employed by health and police agencies to reduce illegal use of cannabis products are not undermined. Restrictions or prohibitions on labels and advertisements could be considered in relation to: the illegal use of marijuana; psychoactive effects and the use of names for illegal hemp products in association with hemp food such as 'cannabis', 'marijuana', 'bong', 'hashish' and 'hash'.

'Consumer protection legislation', as referred to by FSANZ, is enforced by a range of agencies, including the Australian Competition and Consumer Commission, State and Territory fair trading enforcement agencies, DAFF Biosecurity and State and Territory food regulators. Not including labelling and advertising requirements in the Food Standards Code, which is enforced by State and Territory food regulators, under the guise that it is already adequately covered by 'consumer protection legislation' increases the risk that it will not be effectively monitored and enforced by any agency.

## Saliva and blood tests

The proposed variation to the Food Standards Code will create enforcement difficulties because it is currently an offence under the Queensland *Transport Operations (Road Use Management) Act 1995* for an individual to have present in blood or saliva one of three relevant drugs including delta 9-tetrahydrocannabinol. Concern is raised that it will not be possible based on blood or saliva tests alone to distinguish between illegal and legal consumption.

## Responses to questions for submitters

In reference to question 1 of section 6.4 of the Consultation Paper regarding distinguishing between hemp and cannabis seeds, QHFSS provides the following response:

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

The QHFSS respondents provided information on a DNA based assay to distinguish between cannabis varieties and on oral fluid testing as carried out on drivers by QHFSS on behalf of the QPS.

Differentiation between legitimate 'fibre' cannabis and illicit 'drug' cannabis is an important facet of the regulation of the growth of *Cannabis sativa* as a legal crop and its use in food and as fibre. THC is the principal psychoactive compound present in cannabis and the final step in the synthesis of THC is the conversion of cannabigerolic acid (CBGA) into tetrahydrocannabinolic acid (THCA) catalysed by the enzyme THCA synthase.

A number of studies have been conducted into the variation of THC between drug and fibre varieties of *Cannabis sativa* by DNA based methods. Several of these studies have shown significant sequence variations within the THCA synthase gene between the drug and fibre varieties. The drug cannabis has either a homozygotic or heterozygotic active copy of the active gene, while fibre varieties have no (or low) active THCA synthase present due to changes to the amino acid sequences of the enzyme protein that stop or significantly down regulate its action. These published variations can be exploited to develop a DNA based diagnostic assay to determine the presence or otherwise of either the drug or fibre varieties in a sample or add mixture sample such as hemp based foods (e.g. hemp bread).

QHFSS has developed from these studies the capability to detect both drug and fibre cannabis varieties. The assay is currently not finalised or validated due to restriction on the availability of high quality drug and fibre materials. This assay could be brought into use if a panel of fresh cannabis leaf material could be obtained for DNA extraction. The extraction method is a total destructive methodology. Subsequent trialling against drug and fibre samples could establish the validation data necessary for a robust methodology.

Responses to certain questions posed in section 6.5 of the Consultation Paper regarding drug testing are provided by QHFSS as follows:

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

The QHFSS respondent has advised of no such knowledge. Most of the studies appear to be confined to urine testing, as noted in A1039. Ongoing monitoring of the literature is occurring. This is obviously an area where further work is required to gain a full understanding of the potential effects.

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

There are a wide variety of tests currently available in Australia for various drugs. These include initial screening tests as well as confirmatory testing. The relevant manufacturers should be contacted for further information. In terms of confirmatory testing, Forensic Toxicology in QHFSS carries out this work for the QPS.

**3. *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?***

Testing of oral fluid for THC usually involves one or more preliminary screening tests, either an onsite test kit or a laboratory based immunoassay. These tests are not definitive and any positive result is presumptive in nature. For an idea of the detection limits and the costs involved for the screening test, the manufacturer should be contacted.

A positive sample then undergoes a confirmatory test usually utilising gas or liquid chromatography coupled to a mass spectral detector. This test is considered to be definitive. In QHFSS, these tests are carried out according to the Australian Standard, AS 4760 for oral fluid collection and testing and the requirements of ISO/IEC 17025.

In the case of QHFSS, the limit of detection for the confirmation of THC in oral fluid is currently in the order of 1 ng/ml in the sample as received. The costs of these confirmatory tests are usually in the region of hundreds of dollars.

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

In a similar manner to oral fluid, testing of blood and urine for THC usually involves a preliminary screening test. This could be either an onsite test kit or a laboratory based immunoassay.

As discussed in question 3, these tests are not definitive and are presumptive in nature. Any positive sample then undergoes a confirmatory test usually utilising gas or liquid chromatography coupled to a mass spectral detector.

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

Most government forensic toxicology laboratories around Australia would have the capability to carry out confirmatory testing of blood samples. Costs would probably be in the region of \$100-\$200.

Biosecurity Queensland (part of DEEDI) provide the following response to question 1 of section 8.2:

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

Biosecurity Queensland currently has 14 hemp grower licences approved under the *Drugs Misuse Act 1986*, of which six are known to be actively growing hemp at this time.

In reference to question 3 of section 8.2, Queensland Health provides the following response to possible entry barriers to a hemp food market:

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

If low THC hemp food is included in the Food Standards Code, amendment of the Queensland *Drugs Misuse Act 1986* and the Australian Government *Standard for the Uniform Scheduling of Medicines and Poisons* (Schedule 9) will be required to legally permit hemp food to be sold in Queensland.

Amendments may also need to be made to the Commonwealth *Criminal Code Act 1995*. In addition, to import or export hemp food products, changes may be required to the relevant Australian Customs and Border Protection Service requirements and DAFF Bio-Security requirements.

Yours sincerely

**Executive Director  
Health Protection Directorate**