**8 November 2012**
**[26-12]**

# Approval Report – Application A1039

# LOW THC HEMP AS A FOOD

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Dr Andrew Katelaris MD to approve the use of *Cannabis sativa* with low levels of tetrahydrocannabinol, in both seed and seed oil, as a food.

On 7 December 2011, FSANZ sought submissions on a draft standard and published an associated report. FSANZ received 53 submissions.

FSANZ approved the draft variation on 31 October 2012. The COAG Legislative and Governance Forum on Food Regulation[1] (Forum) was notified of FSANZ's decision on 6 November 2012. The Forum is required, within 60 days after the notification, to either request a review of the variation of the standard or inform FSANZ that it does not intend to request a review.

This report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

[1] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

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## Supporting documents

The following documents used to prepare this report are available on the FSANZ website at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1039lowt4708.cfm

SD1 Safety Assessment
SD2 Economic analysis
SD3 Commentary on studies relating to oral fluid and urine testing
SD4 FSANZ discussions with police agencies and forensic analysts
SD5 Australian, New Zealand and International Hemp Regulations

The Assessment Report including the draft variations to the Code and supporting documents for that report are also available on the FSANZ website from the same link.

# 1. Executive summary

Application A1039 was submitted by Dr Andrew Katelaris MD on 4 December 2009, seeking approval for the use of the seed and seed products of *Cannabis sativa (C. sativa)* with low levels of delta 9-tetrahydrocannabinol (THC) as food. Standard 1.4.4 – Prohibited and Restricted Plants and Fungi in the *Australia New Zealand Food Standards Code* (the Code) prohibits all species of cannabis from being added to food or sold as food in Australia and New Zealand.

*C. sativa* is well known as a source of the psychoactive substance, THC. However, varieties of *C. sativa* that contain no THC, or very low levels of THC do not have psychoactive properties. These varieties of *C. sativa* are commonly referred to as hemp, industrial hemp or industrial cannabis. In this report, low THC varieties of C. sativa are referred to as hemp (including reference to the seeds and foods produced from the seeds).

Hemp is cultivated in Australia and New Zealand under strict licensing arrangements. Certain hemp products are legitimately marketed in Australia and New Zealand, including fibres, textiles, paper, building materials and cosmetics for external use. Hemp seed oil is permitted to be sold as a food in New Zealand (under a New Zealand standard), but other hemp food products remain subject to the prohibition in Standard 1.4.4.

A previous Application (A360)[2] to FSANZ seeking permissions to use industrial hemp as a food was approved by FSANZ. However, it was rejected in May 2002 by the Australia and New Zealand Food Standards Council (Ministerial Council)[3] based on concern that the use of hemp in food may send a confused message to consumers about the acceptability and safety of cannabis and concerns about law enforcement, particularly potential issues relating to distinguishing between high and low THC varieties of cannabis.

FSANZ is satisfied that low THC hemp foods are safe for consumption when they contain no more than specified maximum levels (MLs) of THC. FSANZ has also recognised that foods derived from hemp seeds may provide a useful alternative dietary source of many nutrients and polyunsaturated fatty acids, particularly omega-3 fatty acids.

FSANZ has approved a variation to Standard 1.4.4 that permits the sale of foods derived from the seeds of low THC varieties of *C. sativa*. Requirements for MLs of THC that may be present in hemp foods have been specified. Hemp seeds may only be sold if they are non-viable. Since publishing the Call for Submissions, the drafting has been amended to reflect that only low THC varieties of *C. sativa* can be used as a source for food and that only naturally occurring THC may be present in hemp based food.

This approval was made in accordance with the FSANZ objectives in the FSANZ Act, and after consideration was given to the matters required by the Act in FSANZ's assessment of an application to amend the Code. A risk assessment was conducted by FSANZ and the other matters FSANZ gave regard to included concerns raised by stakeholders, consultation with international jurisdictions in which hemp foods are legally available (including Canada and some European countries), and an evaluation of the potential impacts on stakeholders.

A number of concerns were by stakeholders regarding the potential impacts that the legal availability of hemp foods may have on drug testing (where it is suggested that consumption of hemp foods may result in detectable residues), the effects on drug reduction strategies and law enforcement activities relating to illicit drug use.

[2] http://www.foodstandards.gov.au/foodstandards/applications/applicationa360hempasanovelfood/index.cfm
[3] Now known as the COAG Legislative and Governance Forum on Food Regulation

In respect of drug testing, the FSANZ assessment concluded that the consumption of hemp foods is unlikely to adversely impact on urine drug testing. FSANZ also examined the concerns that were raised regarding the possible adverse impact of consumption of hemp foods on oral fluid drug testing. There is limited evidence on this subject. FSANZ extrapolated the results of an unpublished study and this exercise suggested that this concern is unlikely to eventuate; however this evidence is suggestive only, rather than being definitive.

FSANZ considers the requirement in the approved variation to Standard 1.4.4 for hemp seeds to be hulled and non-viable will mitigate the concerns of law enforcement agencies relating to the possession of illicit cannabis seeds. These issues are expanded on in sections 4.1 to 4.7.

FSANZ conducted an economic analysis to support the assessment. Obtaining accurate and relevant data on benefits and costs was difficult and the economic consideration of options was based largely on qualitative considerations. The economic analysis notes the draft variation provides moderate benefits to industry and consumers while seeking to minimise the potential costs to government and law enforcement agencies that may arise from hemp food permissions. However, whether the approval of the draft variation is likely to result in an overall positive net benefit to the community is dependent on how likely it is that it will cause complications and costs to law enforcement activities related to illicit drugs, and the magnitude of those costs if they do exist. More information on the economic analysis is in section 6 and SD2.

FSANZ considered some matters raised by stakeholders to be outside of the matters that FSANZ can take into consideration when developing a food regulatory measure (see section 4.8). FSANZ acknowledges these matters in this report, for information, and believes they would be more appropriately considered by Ministers in a broader policy context. Some information is also provided on other legislation in Australia and New Zealand, other than the Food Standards Code, such as Customs and Misuse of Drugs, which could impact on the legality of hemp foods. Whilst FSANZ acknowledges the importance of these matters, they go beyond FSANZ's authority and, instead, sit with governments responsible for administering this legislation.

# 2. Introduction

## 2.1 The Applicant

FSANZ received an Application from Dr Andrew Katelaris MD on 4 December 2009.

## 2.2 The Application

Standard 1.4.4 prohibits all species of *Cannabis sativa* (*C. sativa*) from being added to food or sold as food in Australia and New Zealand, regardless of THC content.

The Application sought to amend Standard 1.4.4 to permit the use of the seed and seed products of *C. sativa,* with low levels of delta 9-tetrahydrocannabinol (THC), as food.

This assessment addressed only hemp seeds and foods derived from hemp seeds. The use of other parts of the hemp plant for food was not considered by FSANZ.

## 2.3 Reasons for accepting the Application

The Application was accepted for assessment on the basis that:

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that warranted the variation of a food regulatory measure.

A previous Application to FSANZ, Application A360, requested the approval of industrial hemp as a food. A360 was progressed as a novel food application. During the assessment of A360, FSANZ did not identify any safety concerns arising from the potential consumption of hemp foods. FSANZ recommended removing the total prohibition on *Cannabis* species in the Standard and the introduction of MLs for THC in specified hemp foods.

However, in May 2002, the then Ministerial Council rejected the FSANZ recommendation for A360. The Ministerial Council was concerned that the use of hemp in food may send a confused message to consumers about the acceptability and safety of cannabis. The Ministerial Council also highlighted concerns about law enforcement, particularly potential issues relating to distinguishing between high and low THC varieties of cannabis. The Ministerial Council considered that the total prohibition on all *Cannabis* species in the Code should remain.

FSANZ agreed to accept Application A1039 after it was recognised that an assessment could take into account a number of developments since the assessment of A360, including the increased uptake of hemp foods internationally and the development of industrial hemp licensing arrangements in Australia and New Zealand.

## 2.4 Background

### 2.4.1 The current standard

Under Standard 1.4.4, all *Cannabis* species are currently prohibited from being added to food or sold as food. An exception to this prohibition exists in New Zealand where hempseed oil is permitted to be sold as a food. The New Zealand *Food (Safety) Regulations 2002* include a provision to permit the sale of hempseed oil as a food in New Zealand. Other hemp food products are not permitted in New Zealand and remain subject to the prohibition in the Standard.

### 2.4.2 Properties of hemp

*C. sativa* is well known as a source of the psychoactive substance, THC. Varieties of *C. sativa* that contain levels of THC that are considered to be psychoactive, are known by various names, including marijuana. Varieties of *C. sativa* that contain no THC, or very low levels of THC, are commonly referred to as hemp, industrial hemp or industrial cannabis. Hemp has typically been used for industrial purposes, such as textiles, fibres, paper, building materials (fibrous parts of plant) and also as a food source (seeds).

Hemp does not have any psychoactive properties. The level of THC in hemp typically varies from zero to 0.5%, while the THC level in cannabis used as a drug varies from 3% to in excess of 15%. The seeds are the main part of the hemp plant used as a source of food. Hemp seeds, and even marijuana seeds, do not contain any THC. However, the seeds of *C. sativa* plants are wrapped in specialised leaves called the calyx. The calyx can produce THC, and can therefore cause some contamination of the outside of the seed coat. Rigorous cleaning methods, including washing, sieving and shelling, can reduce or remove any THC contamination of seeds. Shelled seeds, also known as hulled seeds, have the outer hull or coating of the seed removed. It is considered unlikely that consumption of residual THC that may be present on hemp seeds will be at a level where psychoactive effects could occur (see SD1).

Hemp seed is a nutritious food containing sizable amounts of protein, polyunsaturated fats and dietary fibre. Hemp seed also contains micronutrients such as thiamin, vitamin E, phosphorus, potassium, magnesium, calcium, iron and zinc. Hemp seed has a favourable fatty acid profile, with more than 80% of the fatty acid content being unsaturated. Like nuts and other seeds, hemp seed and hemp seed oil are a good alternative source of a number of nutrients.

### 2.4.3 Previous safety assessment on hemp

Application A360 requested the approval of foods derived from low THC or industrial hemp. FSANZ's assessment of A360 did not identify any safety concerns arising from the potential consumption of hemp foods. FSANZ recommended the removal of the total prohibition on *Cannabis* species in Standard 1.4.4 and the introduction of MLs for THC in specified hemp foods.

A full safety assessment of hemp foods was conducted as part of A360 and no public health and safety concerns were identified in relation to the consumption of food products containing derivatives of hemp (at maximum permitted levels of THC).

## 2.5 Assessment of the Application

### 2.5.1 Procedure for assessment

The Application was assessed under the General Procedure.

### 2.5.2 Assessment of the current application

The FSANZ approach to the safety assessment of this Application was an update of the previous safety assessment for A360, taking into account new studies that might influence the conclusions from the previous safety assessment on A360. FSANZ also reviewed the experience of other countries where hemp foods are permitted to be sold.

FSANZ has addressed a number of issues in relation to potential direct impacts resulting from an approval of hemp foods. These issues relate to the following:

- potential for consumers to be misled by labels or advertisements that suggest hemp foods may have a psychoactive effect
- controlling the type of cannabis that enters the food supply
- distinguishing between hemp seeds and seeds from drug varieties of cannabis
- drug testing for illicit cannabis use.

These issues were considered by FSANZ in developing food regulatory options for this Application and are addressed in detail in sections 4.1 to 4.6 of this Report.

A number of additional issues have been identified in both the previous and current assessments of hemp foods:

- the possible application and impact of other legislation to and on hemp foods;
- the possible application of international conventions on narcotic substances to hemp foods; and
- concern that the availability of hemp foods may have some influence on community attitudes towards illicit drug use (e.g., cannabis).

FSANZ considered that these three issues were not ones that could be considered by FSANZ in developing a food regulatory measure, given the requirements of the FSANZ Act. FSANZ has noted these issues in this Report for information purposes (see section 4.8), but has not taken them into consideration in developing its decision.

## 2.6 Regulation of hemp

### 2.6.1 Other food regulations

The New Zealand *Food (Safety) Regulations 2002* include a provision to permit the sale of hemp seed oil as a food in New Zealand. This provision was introduced when the joint Code was introduced in 2000. Hempseed oil was previously permitted to be sold as a food in New Zealand and the Code would have prohibited such use. Therefore, the New Zealand *Food (Safety) Regulations 2002* were amended to allow a specific provision for hemp seed oil to continue to be sold as a food in New Zealand.

The *Trans-Tasman Mutual Recognition Act 1997* (TTMRA) states that goods produced in or imported into New Zealand, that may lawfully be sold in New Zealand, may be sold in Australia without the necessity for compliance with further requirements imposed by or under the law of that jurisdiction.

That is, a food that is lawfully produced or imported into New Zealand may be lawfully sold in Australia without having to comply with the requirements of the Code.

However, the *Customs (Prohibited Imports) Regulations 1956* are excluded from the trans-Tasman arrangements set up under the TTMRA. Cannabis (regardless of THC content) is a prohibited import under these Regulations (Schedule 4 controlled substance). Therefore, hempseed oil produced or imported into New Zealand, for human consumption, cannot be imported into Australia under the TTMRA.

### 2.6.2 Hemp and drug regulations

The cultivation, supply and use of *Cannabis* species, including hemp, are controlled by a variety of legislation in Australia and New Zealand. Misuse of drugs, controlled substances and poisons legislation are aimed at controlling the supply and availability of drug – containing varieties of cannabis.

Some exemptions are included in these areas of legislation to permit certain cannabis products to be produced and sold in both countries. These exemptions are generally provided on the basis that relevant cannabis products are not for human consumption[4] and have THC content below certain levels.

Industrial hemp regulations are an example of exemptions to drug control legislation. Industrial hemp regulations permit the cultivation of low THC varieties of cannabis in most states and territories in Australia and in New Zealand. Only licensed growers may cultivate hemp crops under these regulations, and crops are subject to analytical testing for THC content. For more information refer to SD5.

The potential impact of other areas of legislation is discussed in section 4.8.1 of this Report.

A variety of hemp products are available for sale in Australia and New Zealand. For example, in addition to hempseed oil as a food in New Zealand, hempseed oil and other hemp products for topical or cosmetic application, hemp clothing, hemp fibre and building products, animal feed and paper are currently available in both countries.

### 2.6.3 International permissions

Hemp seeds and hemp seed oils are sold as food and food ingredients in many international markets, including Canada, the United States of America (USA) and some parts of Europe (eg. Germany, the United Kingdom, The Netherlands, Belgium, Switzerland and Austria). Subsequent to FSANZ's assessment of A360, Belgium introduced MLs for hemp food products, based on the MLs proposed in the FSANZ assessment. More information on the international regulation of hemp and the sale of hemp foods is available in SD5.

# 3. Risk assessment

As noted in the introduction, the FSANZ approach to the safety assessment of this Application was to provide an update of the previous safety assessment in the Final Assessment Report for A360, which can be accessed on the FSANZ website. FSANZ is satisfied that the conclusions of the safety assessment conducted for A360 remain valid, and that low THC hemp foods are safe for consumption.

Full details of the chemical safety, dietary exposure and nutrition assessment for this application are provided in SD1.

## 3.1 Chemical safety

For the assessment of A360, FSANZ conducted a thorough risk assessment which concluded that, while the bulk of the human data on the toxicity of THC is derived from inhalation of cannabis rather than consumption of THC as a component of food, there was adequate human data to assess the toxicity of THC following oral administration and to establish a tolerable daily intake (TDI) for THC. The TDI is the amount of THC that can be ingested daily over a lifetime of daily consumption without appreciable health risks.

The TDI was based on the results of a human study investigating the effects of certain doses of THC on skill performance, cognitive function and mood. A TDI of 6 micrograms of THC per kilogram of bodyweight (6 µg THC per kg bw) was established. This value was based on the lowest dose level at which no adverse effects were observed, and applying a 10-fold uncertainty factor to this no observed effect level to take into account the possible variability in response in the human population.

[4] The exception to this is the permission to sell hempseed oil as a food in New Zealand

For the current Application, oral THC studies identified in a recent review were considered, along with any relevant studies published since the previous consideration, in order to establish whether new data indicate a need to change the TDI. The studies which underpin the Provisional Maximum Tolerable Daily Intake (PMTDI) of 0.4 µg THC per kg bw reported in the recent EFSA opinion on safety of hemp for use as animal feed were also considered. However, it was noted that the studies cited to derive the PMTDI have deficiencies which limit their use in the derivation of a health-based guidance value.

The FSANZ updated safety assessment concludes that the TDI of 6 µg THC per kg bw remains valid.

### 3.2 Dietary exposure

The assessment of Application A360 included dietary exposure to establish safe MLs for THC content of hemp foods.

The maximum limits for each hemp food category were derived using back calculations based on 95$^{th}$ percentile consumption of the most highly consumed proxy food within that food category (for example, olive oil was used as the proxy for hemp oil). Food consumption data for Australian children aged 2-12 were selected (the population group with the highest food consumption on a per body weight basis) to ensure that 95% of all population groups would consume less than the TDI of 6 µg THC per kg bw from a high level consumption amount of each hemp based food considered.

The chronic dietary exposure assessment substituted hempseed and associated products with similar 'proxy' foods which were likely to mirror potential use in the food supply (for example, consumption of salad oils such as rapeseed oil, soy bean oil, cotton seed oil, safflower oil, sesame seed oil, sunflower seed oil and olive oil, was used as a proxy for hemp oil). The assessment of A1039 included an update on the dietary modelling conducted for A360, including food consumption data from the recent national children's surveys in Australia and New Zealand, which were not available at the time of the A360 assessment.

It was concluded that even if all hemp foods contained THC at the proposed MLs, it was extremely unlikely that high consumers in the Australian and New Zealand populations would exceed the TDI of 6 µg THC per kg bw, as conservative assumption were used in the dietary exposure assessment that are likely to overestimate potential exposure.

### 3.3 Nutrition assessment

FSANZ considered the nutritional profile of hemp foods as part of the risk assessment for Application A360 and this Application. Low THC hemp seed contains a substantial amount of good quality protein, as well as many vitamins and minerals, similar to the nutritional profile of many nuts and seeds. Hemp seed and hemp seed oil are also potential dietary sources of polyunsaturated fatty acids, particularly omega-3 fatty acids.

The nutrition assessment for this Application reinforces the outcome of the A360 nutrition assessment, and concludes that hemp food products may provide a useful alternative dietary source of many nutrients and polyunsaturated fatty acids. Only small quantities of whole hemp seed or hemp seed oil need be consumed to meet the adult Adequate Intake for alpha-linoleic acid (an essential omega-3 fatty acid).

A number of submitters have commented on the favourable nutritional profile of foods derived from hemp seeds. The Dietitians Association of Australia supported the use of hemp seed (including the oil) based on its nutritional merit.

# 4 Risk Management

FSANZ assessed this Application and developed the food regulatory measure in accordance with the FSANZ Act and had regard to the matters required by that Act. A detailed discussion of how FSANZ has assessed these matters is included in sections 4.1 to 4.6 below. These matters are also addressed, in regard to the reason for FSANZ's decision to approve the variations to Standard 1.4.4 in section 7.

As noted above in the background section of this report, some of the issues raised in this assessment were considered to be outside of the matters that FSANZ can take into consideration in developing a food regulatory measure. These issues are noted for information purposes in section 4.8, but did not form part of the reasoning for FSANZ's decision.

## 4.1 Maximum THC levels in the Code

FSANZ received submissions questioning whether it was possible for the consumption of hemp foods to result in psychoactive effects and exceedance of the TDI.

FSANZ has concluded that foods derived from the seeds of low THC hemp are safe for human consumption (see section 3.1 and SD1).

In summary:

The TDI derived by FSANZ was based on the observations of a human study investigating the effects of drug levels of THC on study participants. The study identified the lowest dose level of THC that was observed to have no adverse effect on study participants. To derive the TDI, FSANZ applied a 10-fold safety factor to this no observed effect level, to take into account the possible variability in response in the human population. The adverse effect observed at doses immediately higher than the no observed effect level was a slight but reversible effect on skill performance. The lowest observed psychoactive effect was at a dose that was double that of the no observed effect levels. Therefore, in addition to the 10-fold uncertainty factor, the TDI is also based on a level of THC lower than that at which psychoactive effects were observed.

The TDI and MLs for THC content of hemp foods proposed under the previous risk assessment for A360 and the current application remain protective of human health and are below a level which could induce psychoactive effects. This was confirmed by the updated dietary exposure assessment that concluded that it would be extremely unlikely that high consumers of food derived from low THC hemp would be at any risk of having psychoactive effects or exceeding the TDI.

The MLs in the approved variation have been established for seeds and for three main categories of hemp foods derived from seeds. The MLs are reproduced below:

| **Hemp food product** | **THC mg/kg** |
|---|---|
| Seed of low THC *Cannabis sativa* | 5 |
| Oil extracted from the seed of low THC *Cannabis sativa*. | 10 |
| Beverages derived from the seed of low THC *Cannabis sativa* | 0.2 |
| Any other substance derived from the seed of low THC *Cannabis sativa* | 5 |

Hemp foods must have THC levels at or below these MLs before they can be sold. The MLs were initially derived during the assessment of A360 by estimating the maximum level of THC in the food commodity that would not result in the consumer exceeding the TDI for THC at a high level of consumption of that commodity. The estimated MLs were then used for the chronic dietary exposure assessment to ensure that they would not lead to a total dietary exposure greater than the TDI.

## 4.2 Labelling requirements

### 4.2.1 Potential to mislead consumers

During the FSANZ assessment of A360 and A1039, issues were raised about the risk that representations (including labelling and advertising) for hemp foods could suggest psychoactive properties (relating to consumption of those foods). Hemp is not considered to have psychoactive properties. Any representation suggesting that consumption of hemp foods would result in psychoactive effects would be misleading.

FSANZ has conducted a review of the scientific literature to ascertain whether any studies have been published on consumers' perceptions of hemp products, particularly whether consumers believe that hemp products would have psychoactive effects and whether the labelling of hemp products (including words, pictures and symbols) has any effect on this belief. No relevant articles were identified in the literature search.

FSANZ has been informed by New Zealand regulatory agencies that they have not had any issues associated with the labelling and representation of hemp foods brought to their attention.

FSANZ also liaised with overseas regulatory agencies in regions where hemp food products are permitted, to ascertain whether they had experienced any problems in relation to hemp foods being marketed in such a way as to suggest they may have psychoactive properties. Most respondents indicated they were not aware of such problems in their respective countries. However, Belgium noted that while producers do market the nutritional qualities of hemp foods, some products have been marketed with large images of a cannabis leaf on the label and suggested that this may be viewed as making a connection with illicit cannabis use. The use of a cannabis leaf on a hemp food label is discussed later in this section.

In New Zealand, under the *Misuse of Drugs (Industrial Hemp) Regulations 2006*, hemp products may not be advertised to have psychoactive effects. From an international perspective, the Canadian Industrial Hemp Regulations include a requirement that no person can advertise industrial hemp, its derivatives or any product made from those derivatives to imply that it is psychoactive. FSANZ is not aware of any other country that has specific restrictions relating to representations on hemp foods.

FSANZ noted that consumer protection legislation in Australia and New Zealand covers misleading and deceptive labelling and advertising. Many submitters suggested that existing consumer protection legislation is sufficient to cover potential labelling of hemp foods that may be misleading. FSANZ has discussed the issue of misleading representation with the Australian Competition and Consumer Commission and the New Zealand Commerce Commission. They have concurred that enforcement action could be used in the case of substantive misrepresentation.

Some submitters noted that the intended target market for hemp foods is health conscious consumers, including people with intolerances and allergies to other food products; and that the marketing of the majority of hemp foods overseas focuses on the nutritional profile of hemp, rather than attempts to make connections with drug like effects.

Submitters suggested that consumers would respond negatively to any suggestion of THC contamination or psychoactive properties of hemp foods. Submitters noted that if anything, manufacturers may choose to focus on the lack of THC content or psychoactive effects when marketing hemp foods.

Some submitters noted that consumers could be misled if the cannabis leaf was used in relation to hemp foods, as this is the image the population associates with drugs. A beer product from the UK bearing a cannabis leaf on the label was noted by one submitter as an example of the potential marketing of hemp food products that may occur. Some submitters (including hemp industry submitters) considered that some controls over the labelling of hemp foods (particularly use of the leaf and any reference promoting hemp food as being psychoactive) could be beneficial.

FSANZ considers that as hemp is a variety of cannabis, the representation of a cannabis leaf on a hemp food label would be a truthful representation of the plant source of the product. However as noted above, FSANZ does not have evidence for or against whether such a representation would mislead consumers to believe that the hemp food has psychoactive properties.

Some submitters commented that additional regulation is required to ensure that hemp foods are not labelled and advertised in ways that undermine attempts to reduce the illegal use of cannabis. FSANZ considers that imposing regulation on a food for the purposes of reducing the risk of harm from illegal drugs is outside the scope of matters that can be included in food regulation measures made under the FSANZ Act.

### 4.2.2 General labelling requirements of food for retail sale

Standard 1.2.2 – Food Identification Requirements, requires that a name or description of a food sufficient to indicate the true nature of the food is provided (where there is no prescribed name for the food in the Code). Standard 1.2.4 – Labelling of Ingredients requires ingredients to be declared in the statement of ingredients by either the common name of the ingredient or a name that describes the true nature of the ingredient. For foods containing low THC hemp as an ingredient, product and ingredient names that may be considered acceptable under these Standards include ‘Hemp’ and ‘Low THC cannabis’. Currently in New Zealand, hemp seed oils observed by FSANZ use the name ‘Hempseed Oil’. In addition to Standards 1.2.2 and 1.2.4, there are other generic labelling provisions in Part 1.2 – Labelling and other Information Requirements of the Code that would apply to low THC hemp foods and foods containing low THC hemp as an ingredient, when sold for retail sale. These requirements include:

- date marking (Standard 1.2.5)
- requirement for a nutrition information panel (Standard 1.2.8)
- percentage labelling (Standard 1.2.10)
- country of origin labelling (Standard 1.2.11) (Australia only).

In addition, there are currently provisions in Standard 1.2.8 regulating nutrition claims on foods, such as claims in relation to polyunsaturated fatty acids, monounsaturated fatty acids and the omega fatty acid content of foods. FSANZ considers that these conditions are appropriate for low THC hemp foods and foods containing low THC hemp as an ingredient.

Standard 1.1A.2 – Transitional Standard – Health Claims will also apply to low THC hemp foods and foods containing low THC hemp as an ingredient. This Standard prohibits food labels and advertisements from making certain representations, for example, any word, statement, claim or design that directly or by implication could be interpreted as advice of a medical nature.

Claims of a therapeutic or prophylactic action and reference to a disease or physiological condition are also prohibited under this Standard.

#### *4.2.3 Labelling conclusion*

The generic labelling provisions in the Code will apply to hemp foods and foods containing hemp as an ingredient. It is proposed that no specific conditions relating to the labelling and representation of hemp foods will be added to the Code as a result of this Application. The labelling of hemp foods will need to comply with relevant trade practices and consumer protection legislation, which regulates misleading conduct. FSANZ has not identified sufficient evidence to justify additional controls in the Code on representations for hemp foods.

## 4.3 High THC cannabis products entering the food supply

Submitters have noted a potential concern that high THC cannabis products may enter the food supply if hemp foods were permitted. Existing hemp licensing arrangements in Australia and New Zealand impose restrictions on THC levels that may be present in hemp crops.

Industrial hemp regulations define industrial hemp as varieties of *C. sativa* that contain or produce THC at levels below a certain percentage (generally 0.3 to 0.5% THC). These regulations also restrict the type of hemp cultivars that may be grown and prescribe mandatory analytical testing of THC levels in crops prior to harvest.

Hemp seeds do not contain THC. Any contamination of hemp seeds with THC arises from the calyx (surrounding the seeds) of the plant, albeit from low THC producing plants, and can largely or totally be removed by appropriate washing and processing of the seeds. The existing controls on the cultivation of hemp, coupled with appropriate processing of hemp seeds, are likely to provide sufficient control on the level of THC that may be present in hemp foods derived from domestically cultivated hemp.

Some submitters were concerned that the controls referred to above may not be sufficient to control the THC levels of imported hemp food products, particularly if imported from markets where regulatory controls on hemp production may not be as stringent. Some countries e.g. Canada, have import certification schemes in place for imported hemp food products. However, such schemes are not currently in place in Australia. In New Zealand, imported hemp seed oil is required to be checked and authorised for sale by an accredited laboratory. Additional systems will likely be required if a wider variety of hemp foods are permitted.

MLs in the Code would provide a level of control on the THC content of hemp foods imported into Australia and New Zealand. A food that exceeds the maximum level for THC would not be compliant with the Code. MLs in the Code would also provide a testing reference point for food law enforcement agencies that wish to test hemp foods for THC levels. The establishment of maximum THC levels in the Code would provide an additional level of control for both domestically produced and imported hemp food products. The knowledge that there are MLs prescribed in the Code may also increase consumer confidence in hemp food products.

Hemp seed oil has been permitted to be sold as a food in New Zealand for more than twelve years. Preliminary consultation with New Zealand health and food safety government representatives has not identified the risk of high THC cannabis entering the food supply as a concern in relation to the permission to sell hemp seed oil. However, the New Zealand government submission in response to the draft variation noted extra controls and added costs would be required to mitigate this risk.

This concern appears to relate particularly to the seed itself, rather than food products produced from the seed (this issue is discussed in more detail in section 4.4). FSANZ was advised of one instance of an oil product imported to New Zealand from India containing 800 mg/L of THC. This would obviously be non-compliant with the maximum level for hempseed oil (10 mg/kg) in the approved variation.

Submitters noted the availability of hemp foods in international markets and the apparent lack of evidence to suggest that high THC cannabis products have entered the food supply in these countries. The feedback FSANZ received from international regulatory agencies is that they have not observed any evidence to suggest that the production and processing of industrial hemp, including for food use, has resulted in high THC cannabis products entering the food supply. In general, only certified or published varieties of hemp may be grown and used for food production in these international markets.

In Austria, hemp food products are periodically tested for THC content. In recent years, the Austrian Food Inspection Authorities have discovered only one sample from around 100 tested samples of hemp food products that contained THC at levels considered high enough to remove the product from the market (these levels are based on THC content that will not result in human exposure of greater than 1-2 µg/kg of body weight/day and on specific product guidance values – see SD5). Austria also conducts testing on hemp crops, which are permitted to contain a maximum of 0.2% of THC. Each year, around 100 samples from hemp crops are tested for THC content and all samples have complied with the 0.2% THC level to date. More information on the international regulation of hemp and hemp foods is available in SD5.

Submitters noted that hemp seed and fibre crops are currently being grown in Australia and New Zealand with no apparent policing concerns. For example, hempseed feed for animals is legally sold where no issues have been raised in relation to the transport, manufacturing and retail sectors. The same is true for hempseed oil sold for cosmetic purposes. Submitters also noted that criminal laws exist to deal with people who may attempt to sell illegal high THC cannabis products in the food industry.

### 4.3.1 Conclusion

FSANZ considered the existing controls on the cultivation of hemp, coupled with appropriate cleaning and processing of hemp seeds are likely to provide sufficient control on the level of THC that may be present in hemp foods derived from domestically cultivated hemp. In order to provide the same levels of control to all imported hemp food products, FSANZ could recommend that the growing of hemp needs to comply with specified conditions (a similar approach is taken in Standard 4.2.4A – Primary Production and Processing Standard for Specific Cheeses where specified conditions for the production of Roquefort cheese must be met before importation is permitted).

However, FSANZ recognises that specific hemp cultivation arrangements exist in other jurisdictions and that a similar level of control for imported hemp food products would be achieved more simply, and with fewer enforcement difficulties, by the introduction of MLs of THC in the Code (for hemp foods). MLs for THC content of hemp foods would also provide food law enforcement agencies with a testing reference point for hemp food products should they wish to test them for THC content.

## 4.4 Distinguishing between hemp and cannabis seeds

Regulatory and law enforcement agencies have noted the concern that the sale of whole hemp seeds as food could create problems for drug law enforcement agencies.

Submitters have noted that it is impossible upon observation to differentiate between hemp seeds and the seeds of drug varieties of cannabis. It would therefore be difficult for an enforcement agency to determine whether the seeds a person is in possession of are hemp seeds or the seeds of a drug variety. The purported risk associated with this concern is that it would be possible to possess seeds derived from high THC cannabis while attempting to pass these seeds off as hemp seeds (which would be legal to possess as a food).

At present, only individuals or companies licensed under industrial hemp regulations are permitted to possess hemp seeds. It is not legal to possess high THC cannabis, including the seeds, as any part of this plant or its derivatives is subject to prohibitions in other legislation (noting there are some permissions may be granted, such as for academic research purposes). Loose seeds (and seeds sold in packets) are currently regarded as Class 1 controlled drugs in New Zealand under the *Misuse of Drugs Act 1975*.

Therefore, it is likely that even if whole hemp seeds were permitted to be sold as food in the Code, other legislation will require amendment before the seeds could be legally sold (and not regarded as drugs or be subject to licensing arrangements).

Submissions from regulatory agencies suggested that rendering hemp seeds non-viable before they are sold as food may be a potential mitigating factor in relation to law enforcement impacts. Rendering hemp seeds non-viable before sale as a food would also protect the licensing arrangements currently in place for hemp cultivation. A licence would still be required to possess viable hemp seed and to grow hemp plants. Some international hemp regulations require hemp seed to be proven non-viable before it can be released for human consumption. FSANZ considers that hemp seed sold as food should be non-viable.

One regulatory agency indicated that if non-viable whole hemp seeds were permitted as food, a simple germination test could be conducted to determine whether seed is viable. Non-viable hemp seeds will not germinate. If the seed germinates, it would be viable and therefore not permitted, regardless of whether it was a hemp seed (only non-viable seed would be permitted) or the seed of a drug variety of cannabis (generally prohibited by other legislation). However, a germination test would take time and require the resources of enforcement agencies in addition to potentially inconveniencing consumers who have purchased hemp seeds legitimately.

The submission from Queensland Health indicated that its Scientific Services group was currently developing a DNA-based analytical method that should be able to distinguish between low THC hemp and illicit drug varieties of cannabis. This analytical method needs to be fully validated. If validated, this would be a major advance for law enforcement authorities to address this issue.

The ability to distinguish between seed types will also be important for authorities at the border for imported products. There may be a risk of the seeds of drug varieties of cannabis being imported under the guise of hemp seeds. Establishment of an import certification scheme by quarantine authorities under quarantine laws could ensure that imported hemp seeds have been rendered non-viable and are derived from certified low THC hemp plants. However, FSANZ considered the potential alternative solution to only permit the retail sale of hemp seed products, including hemp seeds that have been processed and are easily identified as being non-viable. For example, hulled hemp seeds (below left) are visually different from whole hemp seeds (below right).

Hulled hemp seeds may be non-viable due to the removal of the outer hull of the seed. FSANZ has not definitively established whether all hulled hemp seeds would be rendered non-viable as a result of removal of the hull, however, informal discussions with a police botanist suggests most hulled seeds are likely to be non-viable. Regardless, manufacturers of hemp seed products would need to ensure that the seed is non-viable before sale to consumers. Hulled hemp seeds are an established product in markets where hemp foods are permitted and appear to retain much of the beneficial nutritional profile of hemp seeds (more detail on the nutritional profile of hemp seeds is available in section 2.4 of SD1). Hemp seed products, such as flour, oil, protein powder and milk are more obviously processed and would not contain any whole or viable seeds. Permitting hemp seed products only would allow a significant number of hemp food products to be sold and will mitigate the concern of drug enforcement agencies having to distinguish between hemp seeds and the seeds of drug varieties of cannabis.

One submitter noted there may also be difficulty in differentiating between hulled hemp seeds and hulled seeds of drug varieties of cannabis. FSANZ considers the value and likelihood of attempting to traffic hulled cannabis (drug) seeds is questionable. In addition to the high likelihood that the majority (if not all) seeds will be non-viable, the seeds themselves do not contain THC and may only have small amounts of THC present as a result of contamination. Therefore, it is unlikely that a psychoactive effect could be achieved by consuming the seeds of drug varieties of cannabis. Overall, it would appear to be an inefficient way of trafficking drug varieties of cannabis seeds and has not been raised as an issue in international jurisdictions.

One submitter suggested that growing sprouts from hemp seeds should be legal. This would not be possible for consumers if hemp seed was required to be non-viable before being sold as food to consumers. In addition, only licensed hemp growers are permitted to grow hemp plants. Existing hemp regulations would preclude the growing of hemp seed sprouts by consumers. It may be possible for licensed hemp growers to produce hemp seed sprouts for sale as food, if hemp seed products were permitted for sale.

### 4.4.1 Conclusion

It is not possible to visually differentiate between hemp seeds and the seeds of drug varieties of cannabis. FSANZ considers that the approval of processed hemp seed products only, including hulled seeds but excluding whole and viable hemp seeds, will reduce the impact on drug law enforcement agencies while still providing food manufacturers with a variety of hemp food product options to offer consumers. A germination test may still be required if enforcement agencies wish to test the viability of hemp seeds offered for sale as food. Such a test will require additional resources and potentially inconvenience consumers who have legitimately purchased hemp seeds. However, the availability of a fully validated DNA based analytical method in the future to differentiate seeds will be an important development for enforcement agencies.

FSANZ considers it is unlikely that seeds of drug varieties of cannabis sativa will be trafficked under the guise of hemp seeds, particularly if hempseeds are required to be hulled and non-viable before being sold as food. FSANZ considered the approval of hemp seed products only (including hulled seeds), in the Code, was the preferred method of approval.

## 4.5 Drug testing

Regulatory and law enforcement agencies expressed concern that the consumption of hemp foods may result in positive drug tests for cannabis use, based on body fluid testing. Police agencies are particularly concerned that hemp food consumption may interfere with roadside oral fluid drug testing arrangements. Urine and oral fluid (saliva) drug tests are also utilised in some workplace environments and for testing of athletes.

Australian Standards for both urine and oral fluid analysis have been established. These standards specify procedures for specimen collection, the detection and quantitation of THC and/or its metabolites, and cut-off levels for declaring positive tests.

FSANZ searched the published literature for human studies most relevant to the consumption of hemp foods and the effects on oral fluid and urine drug testing. A more detailed commentary on the available evidence for the potential impact of hemp food consumption on urine and oral fluid drug testing is available in SD3.

FSANZ has also held discussions with police agencies in Australia and New Zealand and a forensic laboratory in New Zealand. A summary of these discussions is included in SD4.

### 4.5.1 Urine

FSANZ assessed several published studies reporting urine levels of THC metabolites resulting from either hemp food consumption or oral administration of a THC pharmaceutical product, in particular, the study by Gustafson et al (2003) (refer to SD3).

FSANZ has concluded that it was considered unlikely that an individual could return a positive urine test due to the consumption of hemp foods complying with the proposed MLs of THC. For a detailed analysis refer to SD3. Furthermore, as detailed in SD1, the highest predicted dietary exposure is likely to be an overestimate because of the conservative assumptions used in the modelling. In addition, the lowest oral dose tested in the Gustafson et al (2003) study is 1.5-times greater than the modelled dietary exposure for a high consumer of hemp.

### 4.5.2 Oral fluid

Police agencies have advised that roadside oral fluid drug testing plays an important role in strategies to reduce drug driving and the trauma associated with drug driving attributable accidents. Police agencies expect random roadside oral fluid testing will have a similar effect on drug driving to the positive effect that random breath testing has had on reducing drink driving. Police have noted two main concerns in relation to hemp food consumption and oral fluid testing:

- uncertainty in relation to whether the consumption of hemp foods, even with low levels of THC, will produce a positive result for THC in oral fluid tests, resulting in additional confirmatory testing and potential subsequent court action if the confirmatory test is positive for THC.

- the potential for the consumption of hemp foods to be used as a legal defence against a positive THC oral fluid test result.

The second point is an extension of the first and is likely to be addressed if it can be shown that hemp foods consumption will not result in positive results for oral fluid drug tests.

There is limited evidence to indicate whether consumption of hemp foods is likely to interfere with oral fluid drug test results. The most relevant evidence available to FSANZ is summarised below (more detail provided in SD3):

- An unpublished study conducted by the Institute of Scientific Research (ESR) in New Zealand (Dickson et al 2012) investigated THC residues in oral fluids following smoking high THC cannabis cigarettes and consuming cookies containing high levels of THC. Using the data from this study, FSANZ estimated the levels of THC residues likely to be found in oral fluids after consuming hemp foods. The FSANZ extrapolation suggested that it is unlikely that consumption of hemp foods will trigger a positive result for an oral fluid drug test when the Australian Standard cut-off levels are utilised.

- A published study by Milman et al (2010), where subjects were administered oral doses of THC in capsules, resulted in a THC intake 140 to 430 times greater than the highest dietary exposure estimated to result from consumption of hemp foods.[5] However, despite the use of high oral THC doses, the highest level of THC measured was below the 10 ng/mL limit specified by the Australian Standard.

At present, any confirmed positive result, for THC, from a random roadside drug test in Australia is treated as an offence because the presence of THC in the body is an offence. (More information on police roadside testing procedures is available in SD4). If hemp foods were legally available for consumption, the test cut-off levels may have to recognise levels of THC that indicate impairment, rather than just presence in the body (as is currently the case for random breath test cut-off levels).

Oral fluid testing does not appear to have been utilised in international jurisdictions, although some jurisdictions may be investigating the merits of this methodology.

FSANZ also noted that the approach taken to driving under the influence of drugs appears different in New Zealand than in several states in Australia. The New Zealand *Land Transport Act 2009* deals with people driving under the influence of drugs. It is an offence to drive while impaired and with evidence in the bloodstream of a qualifying drug.

Before the New Zealand police can administer a blood test, there has to be evidence of impairment and the presence of a qualifying drug alone is not sufficient for an offence; there must first be impairment as demonstrated by unsatisfactory performance of the compulsory impairment test. The New Zealand police do not use the saliva test as it can only show drug presence and not impairment[6].

FSANZ noted that the Australian Civil Aviation Safety Authority (CASA) also uses oral fluid testing for detection of THC. However, the testing by CASA appears to relate more to impairment than illegal use. CASA acknowledges that the test is very sensitive and that an additional screening test is required before any action may be taken with regard to a person performing safety sensitive aviation activities[7].

[5] The Dietary Exposure Assessment for Application A1039 indicates that the 90$^{th}$ percentile exposure for the population group with the highest predicted exposure (New Zealand children 5-14 years of age) is 3.5 µg/kg bw/day. Dietary exposures are likely to be overestimated as discussed in SD1.

[6] http://www.transport.govt.nz/legislation/acts/QAsdrugimpaireddrivinglaw/

[7] http://www.casa.gov.au/wcmswr/_assets/main/rules/miscinst/2009/casa263.pdf

Some submitters have identified a number of studies aimed at assessing the effectiveness of various oral fluid drug testing kits (ROSITA, ROSITA 2, DRUID) and have expressed concern with respect to the usability and analytical reliability of oral fluid drug testing devices that may potentially be utilised in roadside drug testing environments. However, police agencies are confident that the current roadside oral fluid drug testing regimes are robust and effective in detecting illicit drug use in drivers.

One police agency suggested that if random roadside oral fluid testing was compromised by the legal availability of hemp foods, there could be an impact on road safety due to failure to reduce the incidence of drug driving. That is, that the potential impact on road safety could be viewed as an adverse impact on public health and safety, the protection of which is an objective of FSANZ (section 18 of the FSANZ Act). FSANZ notes that this concern is theoretical in nature and is based on the premise that hemp food consumption will adversely impact on oral fluid drug testing. As noted above, there is limited evidence to suggest whether this impact on oral fluid drug testing is likely or not, however, the results of the unpublished ESR study suggest that this is unlikely. Although FSANZ notes that any costs arising from impacts on roadside testing would be indirect costs of a food regulatory measure, FSANZ does not have sufficient evidence to consider this potential effect on public health and safety, resulting from impacts on road safety, in this assessment.

### 4.5.3 Conclusions

FSANZ noted there is little published evidence to indicate whether hemp food consumption is likely to trigger a positive oral fluid drug test result. However, a recent unpublished study suggests that this may be unlikely when oral fluid samples are analysed according to Australian Standard 4760-2006, even if hemp foods contain THC at the MLs prescribed by FSANZ.

Published results from studies on human volunteers indicate that it is unlikely that consumption of hemp foods containing THC at the prescribed MLs could result in positive tests when urine samples are analysed according to Australian/New Zealand Standard AS/NZS 4308-2008.

## 4.6 Issues related to the draft variation

Some submitters commented on the draft variation at Assessment Report. These comments are noted briefly in Table 1 and expanded on below.

### 4.6.1 Use of whole and viable seeds in manufacture of food

One government submitter noted that the proposed drafting allowed viable, non-hulled hemp seeds to be used to produce hemp seed food products, being oil, beverage and other food products. However, this allowance was not considered to be immediately apparent from the assessment report, the proposed draft variation or the Explanatory Statement.

FSANZ has amended the Explanatory Statement to reflect this intention and has provided additional commentary below.

FSANZ considered it appropriate for processing efficiency that food products produced from low THC hemp seeds do not need to be hulled and non-viable if they are to be subsequently processed in such a way as to render them non-viable and hulled in a final food product (for example, oil and flour products). However, seeds from low THC hemp would be required to be hulled and made non-viable before they can be sold as foods or food ingredients (for example, hulled hempseed hearts, hempseeds in muesli).

### 4.6.2 Ensuring only low THC hemp is used as a food source

Two government submitters requested the draft variation include a specific requirement that food may only be sourced from low THC hemp seed varieties. It was noted that drug cannabis hulled seeds also contain very low levels of THC, as seeds do not contain THC, and that relying only on MLs for THC in the Code does not fully address the possibility of using cannabis seeds to produce food. The inclusion of a specific requirement in the Code would provide an additional offence of the Code if high THC cannabis was used as a source of food. The development of validated DNA analysis of seeds may provide a relatively inexpensive method of analysis to determine whether an offence has been committed.

FSANZ included a requirement in the approved variation to ensure that only low THC hemp can be used as a source of seeds for food use. *Cannabis sativa* is defined as low THC *Cannabis sativa* if the leaves and flowering heads of the *Cannabis sativa* do not contain more than 0.5% THC. The 0.5% THC level was based on prescribed THC levels in existing hemp regulations. FSANZ notes that some jurisdictions have set lower prescribed levels of THC (e.g. 0.35% - see SD5).

### 4.6.3 Synthetic cannabinoids

Due to the recent emergence of synthetic cannabinoids, two government submitters suggested an additional drafting requirement that only naturally occurring THC may be present in hemp based food. This was considered to provide assurance that synthetic cannabinoids would not be added to hemp foods.

FSANZ considered it unlikely that synthetic cannabinoids would be added to hemp foods, particularly given the low prescribed MLs. The approved variation does not result in a permission for synthetic cannabinoids to be added to hemp foods.

### 4.6.4 Other cannabinoids and isomers of THC

Some submitters questioned whether the MLs prescribed for inclusion in the Code should address more than just THC. For example, Cannabis sativa contains other isomers of THC, such as delta-8 THC, and other cannabinoids, such as cannabidiol and cannabinol.

FSANZ noted that the delta-8 isomer of THC has minor pharmacological activity relative to the delta-9 isomer. The delta-8 isomer is also present at lower levels than the delta-9 isomer in Cannabis extracts; however, FSANZ is not aware of data on the delta-8 content of hemp foods. FSANZ has conducted its assessment on delta-9 THC, which is the main psychoactive component of cannabis that has been studied. Therefore, the evidence that FSANZ has assessed, supports prescribed MLs for delta-9 THC only.

FSANZ noted that Canada tests hemp crops for delta-9 THC content and requires information on imported hemp derived products to indicate the delta-9 THC content is below 0.1% – in order to determine compliance.

In regard to whether FSANZ has considered the presence of cannabidiol (CBD) in hemp seed food products (as CBD is considered a class C drug in NZ), FSANZ notes that CBD is typically present in low-THC hemp foods. However, THC and CBD have opposing actions (with CBD only weakly binding to cannabinoid receptors with negligible psychoactive properties). Therefore, FSANZ considers it appropriate to specify MLs for THC alone as THC is the major cannabinoid of relevance to hemp foods.

FSANZ has therefore not amended the drafting to take into account other isomers of THC or other cannabinoids.

## 4.7 Risk management conclusions

The FSANZ decision to approve the draft variation, to permit hulled and non-viable hemp seeds as foods and as ingredients in foods, was influenced by the matters discussed above in sections 4.1 to 4.6. In particular:

- MLs for THC in various types of hemp foods have been included in the approved variation. The MLs are considered to be protective of public health and safety and to be achievable for industry.

- MLs in the approved variation, in addition to existing controls on the cultivation of hemp and appropriate cleaning and processing of hemp seeds, are likely to provide sufficient control on the level of THC that may be present in hemp foods derived from domestically cultivated hemp and for imported hemp food products. The approved variation also includes a requirement that only low THC varieties of *C. sativa* can be used as a source of seeds for food use. FSANZ considers these measures will protect against high THC cannabis products entering the food supply.

- The approved variation includes the requirement that hemp seeds sold as food or as ingredients in foods must be de-hulled and be non-viable. FSANZ considers this will mitigate the concern of law enforcement agencies in distinguishing between hemp seeds and the seeds of drug varieties of cannabis.

- FSANZ is satisfied that hemp food consumption will not impact on urine drug test results. The evidence to indicate whether hemp food consumption will impact on oral fluid testing results is limited and not definitive. FSANZ has extrapolated results from a study investigating the effect of consumption of high THC products on THC residues detected by oral fluid drug testing. FSANZ's extrapolation based on levels of THC that would be permitted under the approved variation suggests it is unlikely that hemp food consumption would trigger a positive oral fluid drug test result.

- FSANZ has not identified sufficient evidence to include specific conditions relating to labelling and representation of hemp food products. The generic labelling provisions in the Code will apply to hemp foods and foods containing hemp as an ingredient.

- To avoid doubt, FSANZ has included in the approved variation a requirement that only naturally present THC may be present in hemp foods. This ensures that synthetic cannabinoids cannot legally be added to hemp foods.

## 4.8 Issues noted for information

### 4.8.1 Impact of other legislation

The legalisation of sale of hemp foods in Australia and New Zealand (other than hemp seed oil in New Zealand) may require more than an amendment to the Code. Legislation relating to the control of drugs and controlled substances, including poisons, may still impact on the legal sale of hemp foods, even if the Code did not prohibit them.

The use of cannabis is controlled through drugs and poisons legislation in Australia and New Zealand, and is generally prohibited. Some exemptions to these prohibitions exist, such as the hemp crop licensing arrangements and sale of hemp products such as clothing, paper, cosmetics and building materials. However, these exemptions are generally provided on the basis that hemp and hemp products are not intended for human consumption.

That is, hemp products intended for oral consumption (other than hemp seed oil in New Zealand) are still subject to prohibitions and controls in other areas of legislation outside of the Code.

If the Code allowed the sale of hemp foods, it is likely that some existing drugs and poisons legislation would also need to subsequently be amended before hemp foods could legally be sold and consumed in Australia and New Zealand. It is important to recognise that amending the Code to permit the sale of hemp foods may not automatically make the sale of hemp foods legal in Australia and New Zealand (other than hemp seed oil in New Zealand).

Examples of the type of legislation that may need to be amended before hemp foods can legally be sold include:

- misuse of drugs acts in each Australian state and territory and in New Zealand
- Schedule 9 of the Standard for the Uniform Scheduling of Medicines and Poisons, which is included the Poisons Standard t referenced in poisons legislation in each Australian state and territory
- the (Australian) *Customs (Prohibited Imports) Regulation 1956*
- industrial hemp regulations may require amendment to permit the human consumption of hemp seed products.

#### *4.8.1.1 Conclusion*

An approval for foods derived from hemp in the Code may not be sufficient in itself to permit the marketing or import of such foods, because of other legislation.

### 4.8.2 UN Conventions

There are three United Nations drug control conventions currently in place. The International Narcotics Control Board (INCB) is the independent monitoring body for the implementation of these international drug control conventions.

These conventions are designed to assist international governments put in place measures to control the supply and distribution of narcotic drugs and psychoactive substances. Australia and New Zealand are signatories to these conventions. The conventions are outlined briefly below.

The *Single Convention on Narcotic Drugs, 1961* prohibits the production and supply of specific narcotic drugs and drugs with similar effects, including cannabis. However, the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes is not subject to the convention.

The *Convention on Psychotropic Substances of 1971* includes controls on psychoactive drugs and has led to the development of psychoactive substances legislation, including Misuse of Drugs legislation, in numerous countries. This convention includes controls on cannabis.

The *Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances* includes measures to support the development of enforcement mechanisms for the requirements of the other two conventions. It includes controls related to possession and trafficking of narcotic drugs and psychoactive substances.

Medicinal use of cannabis is identified as a potentially justified use in these conventions, and is permitted in some countries. However, the medicinal use of cannabis is not approved in Australia. One cannabis product is permitted for medicinal use in New Zealand.

There were some differing views expressed in submissions with respect to how hemp foods were controlled by the UN Conventions. Views ranged from the sale of hemp foods being prohibited by the UN Conventions to views that the UN Conventions should not apply to hemp foods at all, given the exemption of industrial hemp from these conventions.

#### *4.8.2.1 Conclusion*

This discussion on the applicability of the UN conventions is provided for information only. This assessment will not comment on the applicability to the sale of hemp foods in Australia and New Zealand of the UN conventions and the specific Australian and New Zealand laws that implement them domestically. This is outside the boundaries of the considerations that FSANZ is able to take into account when developing food regulatory measures. FSANZ notes that hemp foods are permitted to be sold in a number of international jurisdictions that are also signatories to UN conventions on narcotic drugs.

### 4.8.3 Acceptance of cannabis and impacts on drug reduction strategies

Some stakeholders are concerned that the use of hemp in foods may send a confused message to consumers about the acceptability and safety of cannabis (with high levels of THC) and that drug reduction strategies may be adversely affected. Hempseed oil is permitted for sale as a food in New Zealand. In addition, a variety of hemp products are available for sale in Australia and New Zealand. For example, hempseed oil and other hemp products for topical or cosmetic application, hemp clothing, hemp fibre and building products, animal feed and paper are currently marketed uses of hemp products. FSANZ is not aware of any evidence to suggest that these permitted uses of hemp have adversely impacted on the acceptance of cannabis and drug reduction strategies.

The responses received by FSANZ from international agencies noted that this did not appear to be an issue in those countries where hemp foods are permitted.

Appropriate education initiatives that clearly differentiate between hemp and drug varieties of cannabis may be a possible non-food regulatory measure that can be investigated by industry and government in future if hemp foods are approved.

#### *4.8.3.1 Conclusion*

The concerns that the use of hemp foods may result in consumers being more accepting of illicit cannabis use, and that such use may adversely impact on drug reduction strategies are outside of the normal scope of considerations for a food regulatory measure. Therefore, FSANZ has not commented on potential food regulatory risk management options relating to these concerns.

## 4.9 Summary of submissions

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions.

FSANZ sought submissions on the draft variation to the Code between 7 December 2011 and 15 February 2012. FSANZ sought responses on specific questions in the report. Responses to these questions have been noted and addressed in this Report as appropriate.

Table 1 below contains a summary of issues raised in submissions and how FSANZ has responded to them; with cross links to appropriate sections of the report, supporting documents or drafting as needed.

Fifty-three submissions were received to the Assessment Report, with three late submissions that were not considered; however the issues noted in these late submissions were also noted in other submissions.

There was strong support for the approval of hemp foods in submissions received from hemp industry organisations, licensed hemp growers, hemp retailers and from the general public. The Australian and New Zealand Food and Grocery Councils also provided submissions expressing support for the approval of hemp foods. Hemp industry submitters noted the potential for the sale of hemp foods to make the hemp industry more viable. The positive nutritional profile of hemp foods was also highlighted by these stakeholders. Indeed, a number of submitters noted that the marketing of hemp foods is likely to be based on the nutritional profile of hemp foods, rather than any attempts at making links with illicit cannabis use. These submitters also strongly refuted the view of some government submitters that United Nations conventions on narcotic substances should apply to hemp foods, noting the legal availability of hemp foods in many countries that are also signatories to these conventions (this issue is noted in section 4.8.2). Some submitters questioned the accuracy and reliability of existing mobile oral fluid drug testing kits (utilised in some drug testing environments), noting international studies that have investigated this issue (see section 4.5.2).

**Table 1: Summary of issues raised in submissions**

Abbreviations of submitters used in the Table:
AFGC: Australian Food and Grocery Council
FTAA Food Technology Association of Australia
NSWFA New South Wales Food Authority
NZ MPI New Zealand Ministry of Primary Industries (formerly the Ministry of Agriculture and Forestry)
Qld Health Queensland Health

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|---|---|---|
| **Maximum Permitted Levels** | | |
| Questions the rationale for setting the maximum permitted levels for the different food types so as not to exceed a consumer's TDI. Believes the maximum THC level should be as low as reasonably possible and suggests it should be close to zero. Doing so may address some of the concerns associated with the effect of THC levels from hemp based foods on drug testing. Should the maximum permitted limits be 'essentially' zero, or very close to zero. | NZ MPI | FSANZ is satisfied that the proposed MLs of THC in foods derived from hemp seeds are protective of public health and safety and are comparable with international limits, where these have been set (see SD 1 and SD5).<br><br>The explanations for arriving at the TDI and MLs are provided in sections 3.1 and 3.3. FSANZ dietary modelling indicates that high consumers of foods derived from hemp would not exceed the TDI, and, importantly, would not experience any psychoactive effect as a result of consuming large amounts of hemp foods.<br><br>FSANZ requested comment from the Australia and New Zealand industrial hemp industry in relation to whether levels of THC in foods lower than the MLs proposed by FSANZ were achievable. Industry responses indicated that the MLs proposed by FSANZ were stringent, yet achievable. There is strong evidence that THC levels in hemp foods produced in more mature international markets, particularly in Canada, are well below these MLs, but zero THC is not realistically achievable at this time.<br><br>Industry feedback indicated that lower levels may be achievable in time, but it would be unfair and unreasonable to expect an emerging and as yet undeveloped Australian and New Zealand hemp food industry to achieve lower levels – particularly when there is no public health and safety reason to do so. |

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|---|---|---|
| | | As indicated above, it may not be a realistic expectation at this stage that the Australia and New Zealand hemp industry could achieve lower levels than those proposed by FSANZ. 'Essentially zero' is a non-defined term that could not be used in terms of testing for compliance. The MLs proposed by FSANZ provide distinct analytical levels for compliance testing by enforcement agencies, while also protecting public health and safety. FSANZ has maintained the MLs proposed in the draft variation.<br><br>There is no evidence to indicate that the consumption of foods containing THC at the MLs will interfere with drug testing. Potential impacts on drug testing are discussed in more detail in section 4.5. |
| Other THC isomers should also be considered as part of the prescribed limits and not just the delta 9-tetrahydrocannabinol isomer as currently proposed. Another important psychoactive THC isomer, delta 8-tetrahydrocannabinol, needs to be considered. Rather than regulating only the delta 9 isomer both isomers should be analysed. One approach is that the limit should be for tetrahydrocannabinol, which is then defined as including both delta 9-tetrahydrocannabinol and delta 8- tetrahydrocannabinol. Alternatively the permission could be similar to the Queensland Drugs Misuse Act 1986 which refers to tetrahydrocannabinol and not any specific isomers. It is easier to analyse for both the delta 8 and delta 9 isomers. Qld Health has information relating to the chemistry and analysis of THC available to FSANZ if required. | Qld Health | FSANZ notes that the delta-8 isomer has minor pharmacological activity relative to the delta-9 isomer. The delta-8 isomer is also present at lower levels than the delta-9 isomer in Cannabis extracts; however, FSANZ is not aware of data on the delta-8 content of hemp foods. FSANZ has conducted its assessment on delta-9 THC, which is the main psychoactive component of cannabis that has been studied. Establishing MLs for the delta-9 isomer only is considered to be sufficiently protective. Therefore, the evidence that FSANZ has assessed supports prescribed MLs for delta-9 THC only.<br><br>FSANZ is aware that Canada tests hemp crops for delta-9 THC content and requires information on imported hemp derived products to indicate the delta-9 THC content is below 0.1% - in order to determine compliance. |

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|---|---|---|
| A single national standard be developed and written into the Code, consistent with the maximum level of THC in hemp produced across all regions of Australia noting seasonal variation, being a maximum level of 1% THC (in the plant). It is noted that Tasmania currently has a lower maximum concentration of 0.35% while other states have a limit of 1% (assumed this is for non-food uses of industrial hemp, but not for the seed). Such a limit would be within food safety concerns.<br><br>Any maximum limits should not be trade restrictive and should be harmonised with the current NZ regulations. | AFGC | The approved variation has been amended to include a requirement that only low THC *C. sativa* can be used as a source of hemp foods; and includes a definition of low THC *C. sativa* for the purposes of the Code. This requirement may address this concern to some extent.<br><br>However, the MLs of THC in hemp crops are prescribed in respective hemp legislation in Australia and New Zealand. These respective areas of legislation are administered by other government agencies and are outside of the remit of food regulation, particularly with respect to the Code.<br>The development of a single national standard relating to the cultivation of hemp crops is therefore a matter for consideration by other government agencies.<br><br>The MLs for THC in hemp foods will be consistent across Australia (including the states and territories) and New Zealand as they will be included in the Code. These MLs are also consistent with international regulatory limits for hemp foods and would not be trade-restrictive. |
| Concern that there is a lack of research data on the effects of consuming food derived from low THC hemp and the oral fluid analysis for THC, with the possibility of false positive results occurring. Police are now using these road-side screen tests for THC, with confirmatory tests performed on blood samples. A number of extra enforcement issues and concerns were raised for this scenario. | WA Police, Tasmania Police, NSWFA, Qld Health | There is a lack of evidence to indicate whether this concern is likely or not. This issue is explored in section 4.5.2 of this report and in SD3, including a discussion on the results of an unpublished study investigating the effects of consuming high THC cannabis products on oral fluid tests. Extrapolation of the results of this study suggest that it may be unlikely the consumption of hemp foods, containing THC at the MLs proposed by FSANZ, would trigger a positive result for an oral fluid test. However, this extrapolation is suggestive only and does not provide a definitive answer to this issue. |
| **Risk Assessment** | | |
| Are there any health risks for high consumers of regular amounts of food derived from low THC hemp (that are compliant with the proposed maximum permitted levels of THC)? Will such consumers be at risk of having a psychoactive effect? | NSWFA, NZ MPI | This issue has been addressed at assessment and in section 3.1 of this Report and SD1. FSANZ does not consider there are health risks. The TDI is the amount of THC that can be ingested *daily over a lifetime of daily consumption* without appreciable health risks. The TDI is based on the lowest observed levels of THC that may have an impact on skill performance, cognitive function and mood. FSANZ's dietary exposure estimates that high consumers of hemp foods will not exceed the TDI, even if the foods contain THC at the MLs established by FSANZ. |

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|---|---|---|
| Comments on the Risk Assessment presented with the Assessment Report (SD1).<br>• Review in greater depth other studies collated in the Zuurman et al 2009 review.<br>• Comments relating to the derivation of the TDI from the Chesher et al 1990 study. Further value could be added to the risk assessment by reconsidering some of the other studies.<br>• FSANZ should consider more recent studies as part of the Zuurman et al 2009 review and not rely on the older Chester et al 1990 study, to assist in establishing the threshold dose.<br>• | NZ MPI | Studies cited in the Zuurman review and subsequent studies were carefully considered by FSANZ. However the Chesher *et al* study remains the appropriate study for establishing the TDI as discussed in detail in the SD1. No other suitably designed oral study has been identified in which a No Observed Adverse Effect Level (NOAEL) can be established. |
| Has FSANZ considered the presence of cannabidiol (CBD) in hemp seed food products? CBD is considered a class C drug in NZ. Hemp flowers are high in CBD, but they have not been able to find information on its presence in hemp seeds or their products. | NZ MPI | FSANZ notes that CBD is typically present in low-THC hemp foods. However, THC and CBD have opposing actions (with CBD only weakly binding to cannabinoid receptors with negligible psychoactive properties). Therefore, FSANZ considers it appropriate to specify MLs for THC alone as THC is the major cannabinoid of relevance to hemp foods. This issue is also addressed in section 4.6.4. |
| Considers the calculations in Section 6.1 of the Assessment Report, based on a 100 kg person with THC levels from Leson et al 2001, should be removed. This is because this body weight is not that used for dietary exposure assessments and the THC concentrations are not the same as those proposed by FSANZ | NZ MPI | These calculations have been replaced with commentary on the unlikeliness of the consumption of hemp foods to result in exceedance of the TDI and the experiencing of psychoactive effects (Section 4.1). The dietary modelling conducted by FSANZ to support the risk assessment and the MLs of THC permitted to be present in hemp foods are discussed above in section 3.2 and in more detail in SD1. |
| Hemp-based beverages are sold in 1 L containers; therefore section 3.3.1 of SD1 should be amended. | NZ MPI | Minor amendment made to SD1 to reflect that sale of hemp-based beverages may be in containers of up to 1 L. |
| The nutritional composition of hemp seeds alters after hulling but only the non-hulled nutritional composition data is provided in section 2.4 of SD1. If the data is available for hulled hemp seeds then it should be provided. | NZ MPI | The nutrition assessment has been updated to reflect the information available to FSANZ on the nutrient profile of hulled hempseeds (see section 2.4 of SD1). |

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|---|---|---|
| **Labelling and information** | | |
| Suggests advisory statements should be placed on the labels of food containing low THC hemp seed products, such that:<br>-'Exceeding the recommended level of consumption could result in detection in the body after "x" hours.'<br>-'Consumption over the recommended level could have adverse physiological effects.' | FTAA | Hemp foods will be subject to the general labelling requirements in the Code that apply to all other foods. FSANZ did not identify a need for other specific labelling requirements for hemp foods, as FSANZ has concluded that at the MLs proposed for hemp foods there are no adverse physiological effects. Refer to sections 4.2 (labelling) and 4.1 (MLs).<br><br>Based on the evidence available to FSANZ, label advisory statements relating to potential detection in the body are not supported. |
| Seek FSANZ's view on whether additional labelling requirements should be required, in the context of potential contraindications of hemp with certain medication or medical conditions. | NZ MPI | FSANZ is not aware of any literature to suggest that hemp food consumption is associated with potential contraindications for certain medications or medical conditions. |
| Concern that use of the cannabis leaf symbol may mislead consumers to imply a psychoactive effect.<br><br>Any approval should include requirements that 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.<br><br>It should not be assumed that other agencies will appropriately address and enforce these issues. | Qld Health, WA Police | FSANZ did not put conditions around the use of symbols or terms that could mislead consumers to believe hemp foods have psychoactive properties because:<br>• of the difficulty in justifying prohibitions of representations that are literally true (e.g. use of cannabis leaf or name Cannabis) – FSANZ would need evidence that the terms are misleading.<br>• submitters note that industry is likely to promote the nutritional aspects of hemp rather than imply it has psychoactive properties, so this could be unnecessarily prescriptive.<br>• consumer protection legislation is able to address misleading or deceptive practices.<br><br>See Section 4.2 where this issue is addressed in more detail. |
| THC test results should follow the seed from testing through to the manufacturer as proof of product and compliance with THC levels. | Hemp Australia Pty Ltd | Sufficient information must be provided to the purchaser of a food or relevant authority, to enable the purchaser to comply with compositional requirements of the Code (clause 4 of Standard 1.2.1). FSANZ considers that this requirement addresses the issue of provision of information through the supply chain. |

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|---|---|---|
| **Hulled and non-viable hemp seed** | | |
| Unable to distinguish between hulled low THC hemp seeds and hulled cannabis (drug) seeds. | NZ MPI | The value of attempting to traffic hulled cannabis (drug) seeds is questionable. In addition to the high likelihood that the majority (if not all) seeds will be non-viable, the seeds themselves (including drug varieties) do not contain THC and may only have small amounts of THC present as a result of contamination. Therefore, it is unlikely that a psychoactive effect could be achieved by consuming the seeds of drug varieties of cannabis. Overall, this would appear to be an inefficient way of trafficking drug varieties of cannabis seeds.<br><br>Qld Health's submission indicates that an analytical method is being developed based on DNA difference between the two groups of seeds (low THC hemp and high THC cannabis used as a drug). If this analytical method can be validated then it should be appropriate to address this issue. |
| Enforcement issue for testing for non-viable seeds | NZ MPI | FSANZ has received information from the industrial hemp industry that hulled seeds are non-viable, although this has not been confirmed authoritatively. The enforcement approaches jurisdictions may need to undertake are outside FSANZ's control, but if such testing is required standard, seed viability testing could be performed, i.e. sprouting tests. As noted above, an analytical method based on DNA differences between low and high THC cannabis are being developed. |
| The report, Explanatory Statement and drafting needs to be made more explicit that for food products derived from low THC hemp seeds, they do not have to be hulled. This situation may have ramifications for licence agreements | NZ MPI | This issue is the same as noted under the 'Draft Variations' heading in this Table, and has been addressed more fully in the report in section 4.6.1. Consequential changes to the Explanatory Statement have also been made. |
| Concern is expressed that hulling does not completely ensure hemp seeds are non-viable. The Canadian regulations provide detailed requirements to ensure hemp seeds are non-viable, by the use of steam heat and infrared processing. The suggestion is that FSANZ should have similar requirements. | NZ MPI | As noted above, hulling is expected to ensure that the majority of (if not all) hemp seeds will be non-viable. The drafting includes a requirement that seeds offered for sale as food must be hulled *and* non-viable. The issue will be to ensure that processing conditions used completely hull all seeds as well as rendering seeds non-viable. How manufacturers meet the requirements of 'hulled and non-viable seeds' is up to them and their processes. |

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|---|---|---|
| | | FSANZ does not consider it is needed or appropriate to mandate how to achieve this in the Code, as part of the minimal effective regulation approach undertaken for legal drafting. |
| **Analytical Methods** | | |
| Analytical methods would need to be developed (or available) to determine the levels of THC in various food matrices. | NSWFA | A number of published studies over the last decade or more have analysed the THC content of hemp foods. Some international jurisdictions have regulatory limits on the permitted THC content of hemp foods (see SD5). FSANZ expects that analytical methods for the detection of THC in hemp foods are available. |
| Concern about how to check and ensure compliance for mixed foods where some of the ingredients have been derived from low THC hemp seeds. The complication is when the proportion of the relevant ingredients in the food is not known or hard to obtain. It is stated that food manufacturers are not necessarily legally required to keep accurate records of the proportions of ingredients or obligated to provide this to enforcement officers. | Qld Health | This situation is not different to the current situation where there are limits on contaminants for individual ingredients that may be used in producing a mixed food.<br>It is not possible to provide an appropriate maximum permitted level to cover all possible mixed foods containing low THC hemp based ingredients. |
| **Draft Variations** | | |
| It is noted that the proposed drafting allows the use of viable non-hulled hemp seeds to be used to produce hemp seed food products, being oil, beverage and other food products. This is not immediately apparent from the report, the current proposed drafting or the Explanatory Statement. | NZ MPI | This issue has been expanded upon in the Explanatory Statement and in section 4.6.1 of this Report. FSANZ did not consider this issue required amendment to the drafting. As noted in the submission, it is appropriate for processing efficiency that food products produced from low THC hemp seeds do not need to be hulled if they are going to be subsequently crushed and further processed. This is different for whole seeds from low THC hemp which are required to be hulled and made non-viable before they can be sold as food ingredients. |
| A specific requirement is suggested to be added to the drafting that food may only be sourced from low THC hemp seed varieties. It is noted that drug cannabis hulled seeds also contain very low levels of THC, as seeds do not contain THC so relying only on THC limits does not fully address the possibility of using cannabis seeds to produce food. | NZ MPI, Qld Health | The drafting has been amended to reflect that only low THC varieties of *C. sativa* can be used as a source for food (see Attachment 1). |

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|---|---|---|
| Additionally if the Queensland DNA analytical test is validated and becomes available to differentiate between low THC hemp and high THC cannabis, then this requirement (food only allowed from low THC hemp) would be an additional offence of the Code and may be a cheaper and easier requirement to analyse and prosecute against. | | |
| Due to the recent emergence of synthetic cannabinoids, it is suggested that an additional drafting requirement be added that only naturally occurring THC may be present in hemp based food. The suggested additional clause: 'For the avoidance of doubt only naturally occurring THC may be present in hemp seed based foods.' | NZ MPI, WA Health | The drafting has not been amended as FSANZ considers this is adequately covered by other Control of Drug and other legislation and has not identified the adulteration of hemp foods by synthetic cannabinoids as a significant risk. |
| **Drug Enforcement Issues** | | |
| There are expected to be additional costs for licencing and enforcement for jurisdictions. This will involve increased compliance costs for the low THC hemp industry. | A number of jurisdictions | These costs are noted in the economic analysis (SD2). Jurisdictions have noted that licencing costs are based on a cost recovery system. The impact of licencing costs will be taken into account by businesses in determining whether to enter the market. |
| A number of amendments will need to be made to various state, territory and New Zealand drug regulations to prevent inconsistencies if the application is approved. | A number of jurisdictions | Whether or not these laws need or should be amended is a matter for the Governments concerned. FSANZ's focus remains the FSANZ Act and the statutory obligations that it imposes in relation to development of food regulation measures. FSANZ considered this concern to be outside of the considerations that can be taken into account by FSANZ in the development of a food regulatory measure. However, this issue is noted for information purposes in section 4.8.1. |

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|---|---|---|
| Regulation 26 of the Food (Safety) Regulations 2002 that permits the sale of hemp seed oil in New Zealand expires on 30 October 2012 and will need updating. | NZ MPI | NZ MPI has since extended the expiry date for this provision until 30 October 2017. |
| The potential private cultivation of low THC hemp for food purposes and subsequent enforcement difficulties and the requirement for testing of samples. | Tasmania Police | This seems to be a compliance issue related to hemp licensing, where people could be cultivating the crop without a licence. FSANZ has not commented further on this issue. |
| **Confused Messages to the Community** | | |
| It is felt that approving the food use of low THC hemp would send confusing messages to the community about the health risks of the cannabis drug usage. Such mixed messages to the community could reduce and ruin the public health message about the harmful effects of cannabis (drug) usage. | A number of jurisdictions | FSANZ considered this concern to be outside of the considerations that can be taken into account by FSANZ in the development of a food regulatory measure. There was no evidence that this concern is an issue in the countries that provided responses to the FSANZ international questionnaire.<br><br>However, this issue is noted for information purposes in section 4.8.3. |
| Hemp industry supporters did not consider this issue to be of concern. The availability of hemp foods in international markets was noted, as was the apparent lack of concern in these markets in relation to this issue. | Various | See the response immediately above. |

# 5 Risk communication

FSANZ has communicated widely on this Application. A Consultation Paper was released in March 2011 and FSANZ undertook targeted consultation with stakeholders to assist in its assessment. The Application has attracted significant interest from the media, those in the hemp industry, consumers and government stakeholders. In addition to the email alerts to subscribers about the publication of the Notification Circular, FSANZ issued a media release about the consultation paper and updated its hemp fact sheet on the FSANZ website. When the draft variation to the Code was released for public comment between 7 December 2011 and 15 February 2012, in addition to email alerts about the publication of the Notification Circular, a further media release was issued and the fact sheet updated

Reports and associated supporting documents were also published on the FSANZ website. FSANZ has also conducted additional targeted consultation with domestic and international jurisdictions, police agencies and the industrial hemp industry in Australia and New Zealand during the progress of this assessment.

# 6 Economic analysis

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 23 September 2010, advised that a regulatory impact statement (RIS) was not required for A1039 (RIS ID: 11813) because the application is deregulatory in nature. However, FSANZ conducted an economic analysis, including a commissioned report looking into potential outcomes on hemp seed production resulting from an approval of foods derived from hemp seeds.

Obtaining accurate and relevant data on the value of benefits and costs was difficult and the economic consideration of options was based largely on qualitative considerations. The economic analysis includes discussion of the four options presented in the Call for Submissions report. The draft variation presented in this document is based on the preferred option of permitting hulled and non-viable hemp seeds as foods and as ingredients in foods. The commissioned report indicates that, subject to a number of caveats and assumptions, the legalisation of hemp seed for human consumption in Australia and New Zealand would be expected to lead to increased demand, providing a stimulus for increased production. However, the magnitude of these changes may be small. Consumers may gain access to a range of new products and may benefit from the nutritious properties of hemp. Food manufacturers and retailers may also gain benefits from the sale of low THC hemp food.

These benefits would be weighed against the costs to governments of regulating the legal production of hemp based food, although some of these costs would realistically be recovered from industry. Law enforcement agencies may also incur increased costs from regulating hemp food production. The economic analysis notes that the approval of hemp foods (as proposed in this approval report) would provide moderate benefits to industry and consumers. However, whether the approval of the draft variation is likely to result in an overall positive net benefit to the community is dependent on how likely it is that it will cause complications and costs to law enforcement activities related to illicit drugs, and the magnitude of those costs if they do exist. FSANZ has addressed the two main illicit drug law enforcement concerns that have been raised in the assessment of this Application; namely oral fluid drug testing and distinguishing between hemp seeds and seeds of drug varieties. These issues are discussed in sections 4.4 and 4.5 respectively. In addition to the economic analysis, FSANZ must take other matters into consideration when developing or varying food regulatory measures. These matters are noted below in sections 7.1, 7.2 and 7.3. Full details of the economic analysis are in SD2.

# 7. Decision

The draft Standard as proposed following assessment, to permit hulled and non-viable hemp seeds as foods and as ingredients in foods, was approved with amendments.

The draft Standard, as varied after submissions were received, is at Attachment A. The draft Standard on which submissions were sought is at Attachment C.

## 7.1 Reasons for decision

The variation to the Code to permit the sale of foods derived from low THC hemp seed was approved based on the best available scientific evidence, for the following reasons:

- A detailed risk assessment has not identified any public health and safety concerns associated with the consumption of hemp foods.

- The variation offers the best balance between the potential benefits to consumers and industry and potential costs for government and law enforcement agencies.

- The variation is consistent with the section 18 objectives of the FSANZ Act.

- The variation is based on appropriate risk management measures for matters considered to be within the scope of considerations that FSANZ can take account of when developing a food regulatory measure.

### 7.1.1 Matters relevant to the decision

FSANZ had regard to the following matters under section 29 of the FSANZ Act:

- *Whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure.*

  FSANZ has investigated the possible benefits and costs to all parties impacted by the recommendation to permit the sale of hemp foods. This information is summarised in the consideration of options (section 7.2) and is supported by an economic analysis (section 5 and SD2).

  The economic analysis notes that approval of the draft variation provides moderate benefits to industry and consumers while seeking to minimise the potential costs to government and law enforcement agencies that may be arise from hemp food permissions. This view is also supported by FSANZ's assessment of other issues as noted in section 7.2 below. The economic analysis also includes general discussion of the approval of hemp foods compared with the status quo option (i.e. rejecting the draft variation). The economic analysis provides an important contribution to FSANZ's consideration of the options (section 7.2).

- *There are no other measures that would be more cost-effective than a variation to the Standard that could achieve the same end.*

  There are no other measures that would be more cost effective to achieve the same outcomes than variations to the Code.

- *Any relevant New Zealand standards.*

  The sale of hemp seed oil is permitted in New Zealand and a more general permission for foods derived from hemp seed in Australia and New Zealand could serve to enhance trans-Tasman trade in these products. The sale of other hemp derived foods in New Zealand may be affected by other legislation, which is documented in section 4.8.1.

- *Any other relevant matters.*

  A number of other matters have been raised by submitters and during the assessment of the previous application (A360). FSANZ has considered matters such as whether consumers are likely to be misled by hemp products, the likelihood of high THC cannabis entering the food supply if hemp foods are permitted, whether the similarity of hemp seeds and seeds from high THC cannabis may cause enforcement difficulties and the potential impact of hemp foods in drug testing.

  Some other matters fall outside FSANZ's responsibilities under the FSANZ Act, such as the impact of international narcotic drug conventions; and domestic legislation controlling cannabis. These are noted in the report (section 4.8) but have not been used by FSANZ to reach a decision.

## 7.2 Consideration of options

At Assessment, the draft variation, to permit hulled and non-viable hemp seeds as foods and as ingredients in foods, was the preferred option of the four options presented, with three options differentiating the types of hemp food products which would be permitted.

At Approval, FSANZ's options are to approve the draft variation (with or without amendments) or to reject the draft variation. These options are considered below:

*Option 1: Approve the draft variation*

The draft variation allows hulled hemp seeds to be sold, in addition to hemp seed products such as oil, beverages (for example, hemp milk), flour, hemp protein, muesli bars and baked goods. Therefore, a wide range of hemp seed food products may be marketed by food manufacturers, increasing consumer choice and providing an additional market for hemp producers. FSANZ has determined there may be a net benefit for the hemp industry from production of hemp for food (SD2). The net benefit to food manufacturers and retailers has not been quantified, but it should be noted that it would be a commercial decision based on potential benefits, to manufacture and sell hemp food products.

Ensuring that seeds are hulled and non-viable may be an additional cost for hemp producers and food manufacturers, however, the production and marketing of these products is voluntary and would be taken into account by businesses before undertaking the cultivation of crops or production of hemp food products.

The draft variation creates potential costs for food enforcement agencies in relation to compliance of hemp food products with the Code and other food law requirements. However, this is a cost that would be incurred for any new food or food ingredient approval in the Code that was subject to conditions, such as maximum permitted levels of presence.

The economic analysis notes that the question of whether the approval of the draft variation is likely to result in an overall positive net benefit to the community is dependent on how likely it is that it will cause complications and costs to law enforcement activities related to illicit drugs, and the magnitude of those costs if they do exist.

Police agencies have suggested that the approval of hemp seeds food products will impact on the enforcement of illicit drug use and on random roadside drug testing procedures that utilise oral fluid samples from drivers. FSANZ has addressed these concerns in sections 4.4 (illicit drug enforcement related to identification of seeds) and 4.5 (drug testing). The draft variation includes a requirement that hemp seeds must be hulled and non-viable before being sold as food or used as ingredients in food that is sold to consumers. FSANZ considered that this mitigates the concern in relation to the potential for persons engaging in illegal activities to take advantage of visual similarity of hemp seeds and the seeds of illicit drug varieties of cannabis. FSANZ recognises that the evidence in relation to the potential for hemp food consumption to impact on oral fluid drug testing is not definitive. However, FSANZ has extrapolated results form an unpublished study by a New Zealand forensic laboratory, which suggests that this may not be likely.

Minor amendments to the draft variation at assessment have been made to make it clear that only low THC varieties of *Cannabis sativa* can be used as a source of seeds for food use and that any THC present in hemp foods can only be naturally occurring. These amendments provide clarification and do not affect this analysis.

FSANZ considered approval of the draft variation could provide a net benefit to the community by allowing a range of hemp seed food products to be manufactured and supplied to consumers, depending on whether there were any cost impacts on illicit drug enforcement activities. FSANZ notes the uncertainty around the effects of consumption of low THC hemp foods consequently affecting oral fluid drug testing. FSANZ considers the cost impacts on drug enforcement are similarly uncertain and can be considered as potential rather than substantive costs. FSANZ notes the draft variation includes the requirement that seeds be hulled and non-viable before they are sold as food and when they are included as ingredients in foods sold to consumers. This requirement may mitigate one of the concerns of drug enforcement agencies.

*Option 2: Reject the draft variation*

Option 2 is not supported, after having regard to the requirements of the FSANZ Act, including the objectives set by section 18. FSANZ has not identified any public health and safety concerns in relation to the consumption of hemp foods. As explained above, FSANZ's consideration of matters set out in provisions such as subsection 18(2) and section 29 of that Act also does not support the rejection of the Application. FSANZ did not consider option 2 to be supported by the assessment of this Application.

## 7.3 Addressing FSANZ's objectives for standards setting

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Application as follows.

### 7.3.1 Protection of public health and safety

FSANZ's risk assessment concluded that the consumption of foods derived from hemp seeds would not pose any public health and safety concerns at the proposed MLs of THC content, as detailed in section 3 and in SD1.

### 7.3.2 The provision of adequate information relating to food to enable consumers to make informed choices

For this Application, this objective is taken to relate to labelling of processed foods. Hemp ingredients would be required to be listed in the list of ingredients. It was not considered necessary to recommend any additional information (see section 4.2).

### 7.3.3 The prevention of misleading or deceptive conduct

FSANZ has considered this objective in relation to the representation of the product and its possible association with cannabis containing THC (see section 4.2). FSANZ concluded that no further risk management measures are required in the Code.

### 7.3.4 Subsection 18(2) considerations

Additionally, under section 18(2) of the FSANZ Act, FSANZ must also have regard to a number of other factors. These are addressed below:

- *the need for standards to be based on risk analysis using the best available scientific evidence*

  FSANZ has considered the safety of hemp foods as described in SD1. FSANZ has also considered the available scientific evidence relating to the potential effect of hemp food consumption on human drug testing.

- *the promotion of consistency between domestic and international food standards*

  Hemp foods are permitted in some countries but not others. There are no international standards for hemp foods. The MLs for THC content of foods derived from low THC hemp that are included in the approved variation are consistent with levels that are set in other countries (where applicable) and are achievable.

- *the desirability of an efficient and internationally competitive food industry*

  There are potential benefits to industry in permitting hemp foods and the permission would open up domestic and export markets.

- *the promotion of fair trading in food*

  There are no issues to address.

- *any written policy guidelines formulated by the Ministerial Council*

  There are no policy guidelines relevant to this application.

# 8. References

Australian Standard AS 4760-2006: Procedures for specimen collection and the detection and quantitation of drugs in oral fluid.

Australian/New Zealand Standard AS/NZS 4308-2008: Procedures for specimen collection and the detection and quantitation of drugs of abuse in urine.

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## Attachments

A. Approved variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement
C. Draft Food Regulatory Measure as consulted on in the Call for Submissions

# Attachment A – Approved variation to the *Australia New Zealand Food Standards Code*

**Food Standards (Application A1039 – Low THC Hemp as a Food) Variation**

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated X

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

**1 Name**

This instrument is the (Application A1039 –Low THC Hemp as a Food) Variation.

**2 Variation to Standards in the *Australia New Zealand Food Standards Code***

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

**3 Commencement**

These variations commence **on the date of gazettal**.

**SCHEDULE**

**[1] Standard 1.4.4** is varied by

[1.1] omitting subclause 1(1) and substituting

"(1) Subject to clause 1A, a plant or fungus, or a part or a derivative of a plant or fungus, listed in Schedule 1, or any substance derived therefrom, must not be intentionally added to food or offered for sale as food."

[1.2] inserting after clause 1 the following new clause

"**1A Exception for certain *Cannabis sativa* seeds and certain *Cannabis sativa* seed products**

(1) *Cannabis sativa* seeds may be added to food or offered for sale as food if the seeds –

(a) are seeds of low THC *Cannabis sativa*; and
(b) contain not more than 5 mg/kg delta 9-tetrahydrocannabinol which is naturally present; and
(c) are non-viable seeds; and
(d) are hulled seeds.

(2) All or any of the following seed products may be added to food or offered for sale as food –

(a) oil extracted from seeds of low THC *Cannabis sativa* if the oil contains not more than 10 mg/kg delta 9-tetrahydrocannabinol and the delta 9-tetrahydrocannabinol is naturally present in the oil;

(b) a beverage derived from seeds of low THC *Cannabis sativa* if the beverage contains not more than 0.2 mg/kg delta 9-tetrahydrocannabinol and the delta 9-tetrahydrocannabinol is naturally present in the beverage;

(c) any other substance extracted or derived from seeds of low THC *Cannabis sativa* if the substance contains not more than 5 mg/kg delta 9-tetrahydrocannabinol and the delta 9-tetrahydrocannabinol is naturally present in the substance.

(3) In this clause –

**hulled seed** means a seed where the outer coat or hull of the seed is removed.

**low THC *Cannabis sativa*** has the meaning given by subclause (4).

**non-viable seed** means a seed that is not able to geminate.

**seed** includes a part of a seed.

(4) *Cannabis sativa* is low THC *Cannabis sativa* if the leaves and flowering heads of the *Cannabis sativa* do not contain more than 0.5% delta 9-tetrahydrocannabinol."

## Attachment B – Explanatory Statement

### 1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1039 which seeks to approve the use of hemp seeds and hemp seed products as food. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

Following consideration by COAG Legislative and Governance Forum on Food Regulation[8], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislative Instruments Act 2003*.

### 2. Purpose and operation

Currently all Cannabis species (hemp, marijuana) and substances derived from Cannabis species are prohibited under Standard 1.4.4 from being intentionally added to food or sold as food. The Authority has approved an amendment to Standard 1.4.4 to permit the sale, as a food, including as an ingredient of a food, the seed and seed products from Cannabis species (spp.) with levels of delta 9-tetrahydrocannabinol (THC) as follows:

- seeds of low THC *Cannabis sativa* – maximum of 5 mg THC per kg of seeds
- oil extracted from the seed of low THC *Cannabis sativa* – maximum of 10 mg THC per kg of oil
- a beverage derived from the seed of low THC *Cannabis sativa* – maximum of 0.2 mg THC per kg of beverage
- any other substance extracted or derived from the seed of low THC *Cannabis sativa* – maximum of 5 mg THC per kg of seed or substance

The amendment includes a requirement that only seeds sourced from low THC varieties of *Cannabis sativa* can be used to produce foods and food ingredients. Low THC *Cannabis sativa* means *Cannabis sativa*, the leaves and flowering heads of which contain no more than 0.5% THC. In addition, the THC present in these seeds and seed products sold as food, or included as an ingredient in food, must be naturally present.

[8] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

The requirements for seeds derived from low THC varieties of *Cannabis sativa* to be non-viable and hulled, apply to seeds offered for sale to consumers as foods and seeds used as ingredients in foods sold to consumers. However, the amendment to Standard 1.4.4 does not preclude food manufacturers from using seeds that are viable and not hulled in the manufacture of foods, subject to industrial hemp licensing arrangements and any other applicable laws, before the foods are sold to consumers.

## 3. Documents incorporated by reference

The variation does not incorporate any documents by reference.

## 4. Consultation

An initial round of public consultation preceded the assessment and preparation of a draft variation. This initial public comment period called for public comment on 15 March 2011 for a six week consultation period.

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1039 has included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 6 December 2011 for a ten week consultation period.

A Regulation Impact Statement (RIS) was not required because of the deregulatory nature of the proposed variation to Standard 1.4.4.

## 5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

## 6. Variation

This item inserts a new clause 1A as an exception to Schedule 1 of Standard 1.4.4 – Prohibited Plants and Fungi, so as to permit the addition to food or sale as food of certain seeds and seed products from low THC varieties of *Cannabis sativa*. The permitted seeds and seed products can have a THC content no more than the maximum level set for specific food types and must be naturally present. Seeds must be non-viable and hulled (outer coat removed).

## Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* as consulted on in the Call for Submissions

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

**Food Standards (Application A1039 – Low THC Hemp as a Food) Variation**

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated X

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

**1 Name**

This instrument is the (Application A1039 –Low THC Hemp as a Food) Variation.

**2 Variation to Standards in the *Australia New Zealand Food Standards Code***

The Schedule varies the Standards in the *Australia New Zealand Food Standards Code*.

**3 Commencement**

These variations commence **on the date of gazettal**.

**SCHEDULE**

**[1]** ***Standard 1.4.4*** *is varied by –*

[1.1] *omitting subclause 1(1), substituting –*

(1) Subject to clause 1A, a plant or fungus, or a part or a derivative of a plant or fungus listed in Schedule 1, or any substance derived therefrom, must not be intentionally added to food or offered for sale as food.

[1.2] *inserting after clause 1 the following –*

**1A Exception for certain *Cannabis sativa* seeds and certain *Cannabis sativa* seed products**

(1) *Cannabis sativa* seeds may be added to food or offered for sale as food if –

(a) the seeds contain not more than 5 mg/kg delta 9-tetrahydrocannabinol; and
(b) each seed is a non-viable seed; and
(c) each seed is a hulled seed.

(2) All or any of the following seed products may be added to food or offered for sale as food –

(a) oil extracted from *Cannabis sativa* seeds if the oil contains not more than 10 mg/kg delta 9-tetrahydrocannabinol;
(b) a beverage derived from *Cannabis sativa* seeds if the beverage contains not more than 0.2 mg/kg/ delta 9- tetrahydrocannabinol;
(c) any other substance extracted or derived from *Cannabis sativa* seeds if the substance contains not more than 5 mg/kg delta 9-tetrahydrocannabinol.

(3) In this clause –

**hulled seed** means a seed where the outer coat or hull of the seed is removed.

**non-viable seed** means a seed that is not able to geminate.

**seed** includes a part of a seed.