

15 March 2011
[5-11]

APPLICATION A1039

LOW THC HEMP AS A FOOD

CONSULTATION PAPER

Executive Summary

Purpose

The Application seeks to amend Standard 1.4.4 – Prohibited and Restricted Plants and Fungi of the *Australia New Zealand Food Standards Code* (the Code) to permit the use of products from *Cannabis sativa*, with low levels of delta 9-tetrahydrocannabinol (THC), as food. All *Cannabis* species are currently prohibited under Standard 1.4.4 from being added to food or sold as food, regardless of THC content.

THC is the compound responsible for the psychoactive properties of marijuana, and is present in drug cultivars of *Cannabis* at levels ranging from 3-15%. Varieties of *Cannabis sativa* that contain no, or very low levels of THC, are commonly referred to as hemp, industrial hemp or industrial *Cannabis*. Hemp, or industrial hemp, contains no, or very low levels of, THC (up to 0.5%) and does not have any psychoactive properties. Hemp is cultivated worldwide, including in Australia and New Zealand, and is used as a source of many products, ranging from foods, to cosmetic products, to clothing and building products.

Hemp foods are widely available in many overseas markets, including Europe, Canada and the United States of America. Hempseed oil is permitted to be sold as a food in New Zealand. However, the use of hemp as a food in Australia, and for foods other than hempseed oil in New Zealand, is still prohibited.

FSANZ has conducted a safety assessment to determine whether there are any risks associated with the consumption of hemp foods. FSANZ has not identified any safety concerns relating to the consumption of hemp foods. Hempseeds, which are the main part of the hemp plant utilised as a food source, have a favourable nutritional profile and may offer an alternative plant source for a range of nutrients (including omega-3 fatty acids, protein and some vitamins and minerals).

However, a number of other issues associated with an approval of hemp foods have been identified by various government stakeholders and FSANZ. These issues include potential risks of high THC foods entering the food supply, hemp foods being represented to have psychoactive properties and consumption of hemp foods resulting in positive drug test results. Other issues relate to identifying and quantifying potential impacts of an approval of hemp foods on other food regulatory stakeholders, food manufacturers and consumers.

FSANZ believes that before it can present a preferred option in terms of any potential approval of low THC hemp foods, these issues need to be discussed by the broader community, including, consumers, the hemp industry, food regulators and other interested parties.

Therefore, FSANZ has prepared this Consultation Paper to present these issues and is seeking submissions in response to a number of questions included throughout the paper. Submissions to this Consultation Paper will assist FSANZ in continuing its assessment of low THC hemp foods and the preparation of a preferred position on any changes to the Code that may be required.

The Application is being assessed under the General Procedure.

Assessing the Application

In assessing the Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as prescribed in section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- Whether the costs that would arise from a food regulatory measure being developed or varied as a result of the Application would outweigh the direct and indirect benefits to the community, Government or industry.
- There are no other measures that would be more cost-effective than a variation to the Code that could achieve the same end.
- Any relevant New Zealand standards.
- Any other relevant matters.

Consultation

The purpose of this Consultation Paper is to seek input from stakeholders about the Application and to seek input on the likely regulatory impact at an early stage. At this stage, FSANZ is seeking public comment to assist in assessing this Application and is particularly interested in receiving further information on the questions asked throughout this paper.

Invitation for Submissions

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Changing the Code tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 27 April 2011

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

**Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222**

**Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
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SUPPORTING DOCUMENTS

The following material, which was used in the preparation of this Consultation Paper, is available on the FSANZ website.

SD1 Risk Assessment Report:

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1039lowt4708.cfm>.

Application A360 – Use of Industrial Hemp as a Novel Food
Final Assessment Report:

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa360hempasanovelfood/index.cfm>

Introduction

Food Standards Australia New Zealand (FSANZ) received an Application from Dr Andrew Katelaris MD on 4 December 2009. The Application seeks to amend Standard 1.4.4 – Prohibited and Restricted Plants and Fungi of the *Australia New Zealand Food Standards Code* (the Code) to permit the use of products from *Cannabis sativa*, with low levels of delta 9-tetrahydrocannabinol (THC), as food. All *Cannabis* species are currently prohibited under Standard 1.4.4 from being added to food or sold as food.

Cannabis sativa is well known as the source of the psychoactive substance, *delta 9-tetrahydrocannabinol* (THC). Varieties of *Cannabis sativa* that contain levels of THC that are considered to be psychoactive, are known by various names, including marijuana. Varieties of *Cannabis sativa* that contain no, or very low levels of THC, are commonly referred to as hemp, industrial hemp or industrial *Cannabis*. These low THC varieties of *Cannabis sativa* have typically been used for industrial purposes, such as textiles, fibres, paper, building materials and also as a food source. Hemp does not have any psychoactive properties. The level of THC in industrial hemp typically varies from 0.3 to 0.5% while the THC level in *Cannabis* used as a drug varies from 3-15%.

The seeds are the main part of the hemp plant used as a source of food. Hempseeds do not contain any THC. However, the hempseeds are wrapped in specialised leaves called the calyx that do produce THC, and can cause some contamination of the outside of the seed coat. Rigorous cleaning methods, including washing, sieving and shelling, can reduce the THC contamination of seeds. The level of THC produced by hemp plants is very low. Consumption of any residual THC that may be present on hemp seeds will not be at a level where psychoactive effects could occur.

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

Hempseed oil is permitted to be sold as a food in New Zealand. The *New Zealand Food (Safety) Regulations, 2002* include a separate 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 Standard 1.4.4. Hempseeds and hempseed oils are also sold as food and food ingredients in many international markets, including Europe, Canada, and the United States of America.

Hemp crops are permitted to be grown in the majority of Australian states and territories, and in New Zealand, under strict licensing arrangements. Licensing arrangements are set out in respective industrial hemp regulations. Only licensed growers may cultivate hemp crops under these regulations and crops are subject to analytical testing for THC content. 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 some of the currently available hemp products.

A previous Application to FSANZ, Application A360, requested the approval of industrial hemp as a food. During the assessment of Application A360, FSANZ did not identify any safety concerns arising from the potential consumption of hemp foods.

FSANZ recommended the removal of the prohibition on all *Cannabis* species in Standard 1.4.4 and the approval of hemp foods, subject to maximum limits of THC and conditions on the representation of hemp food products.

However, in May 2002, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) rejected the FSANZ recommendation for Application 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.

The FSANZ approach to the assessment of the current Application is to provide an update of the previous safety assessment for Application A360 and to consider the concerns raised by the Ministerial Council previously. A full safety assessment of hemp foods was conducted as part of Application A360 and no public health and safety concerns were identified with the use of food products containing derivatives of hemp (at maximum permitted levels of THC). FSANZ has investigated the literature to ascertain whether any new studies may influence the outcomes of the previous safety assessment under A360.

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. However, as noted above, a number of additional issues have been identified in the previous assessment of low THC hemp foods.

The concerns raised by the Ministerial Council relate to potential impacts on drug policies and enforcement of illicit drug use, rather than to safety aspects of low THC foods in particular. While FSANZ acknowledges these concerns, drug policies and enforcement issues are outside of the scope of the food regulatory environment.

A number of other issues have been identified in relation to potential direct impacts resulting from an approval of low THC hemp foods. These issues relate to drug testing for illicit *Cannabis* use, controlling the type of *Cannabis* that enters the food supply and the potential for consumers to be misled by labels or advertisements that suggest low THC foods may have a psychoactive effect. These have been addressed in the consultation paper.

Consultation Paper

This Application is to be assessed under a General Procedure. A General Procedure requires the preparation of an Assessment Report by FSANZ, which is released for public comment. After the public comment period, FSANZ prepares an Approval Report for consideration by the FSANZ Board before it is sent to the Ministerial Council for consideration.

However, there are a number of issues associated with the assessment of this Application, particularly relating to potential impacts of an approval of low THC hemp foods in the Code. FSANZ believes that before it can present a preferred option in terms of any potential approval of low THC hemp foods, these issues need to be discussed by the broader community.

Therefore, FSANZ has prepared this Consultation Paper to present these issues and is seeking submissions in response to a number of questions that are included throughout the paper.

Submissions on this Consultation Paper will assist FSANZ in continuing its assessment of low THC hemp foods and the preparation of a preferred position on any changes to the Code that may be required. The consultation on these issues before the preparation of an Assessment Report (and preferred regulatory option) is an additional step not normally undertaken in the assessment of an application under the General Procedure. This additional step in the process will extend the timelines normally associated with the assessment of a General Procedure application.

1. The Issue / Problem

The Applicant has requested that the seed and seed oil of *Cannabis sativa* with low levels of THC be permitted to be supplied as a food in Australia. Standard 1.4.4 prohibits all species of *Cannabis sativa* from being added to food or sold as food in Australia and New Zealand, regardless of THC content.

An application to vary the Code is required to amend a prohibition in Standard 1.4.4. A pre-market assessment and approval is required before the current prohibition on the use of *Cannabis* spp. could be amended to allow for the use of industrial hempseed and hempseed oil as foods.

2. Background

2.1 Current Standard

All species of *Cannabis* are included in Schedule 1 of Standard 1.4.4. 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 in Australia or New Zealand. Therefore, *Cannabis sativa* is currently prohibited from being added to food or sold as food in Australia or New Zealand, regardless of THC content.

An exception to this prohibition exists in New Zealand. The New Zealand *Food (Safety) Regulations 2002* includes a provision to permit the sale of hemp seed oil as a food in New Zealand. This provision was introduced when the joint *Australia New Zealand Food Standards Code* was introduced. 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. In Australia, hempseed oil continues to be subject to the prohibition of all *Cannabis* species in Standard 1.4.4.

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 the Customs 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.

2.2 Previous Assessment

FSANZ has previously assessed hempseed, hempseed oil and other hemp foods under Application A360. Application A360 was progressed as a novel food application. FSANZ recommended the removal of the total prohibition on *Cannabis* species in Standard 1.4.4 and the introduction of the following maximum levels for THC in specified hemp foods:

Hemp food product	THC mg/kg
Seed of <i>Cannabis</i> spp. or any substance derived therefrom (other than oil extracted from the seed)	5
Oil extracted from the seed of <i>Cannabis</i> spp.	10
Food derived from <i>Cannabis</i> spp. (other than seed or any substance derived therefrom and oil extracted from the seed of <i>Cannabis</i> spp.)	0.2

Cannabis species were also to be included in Standard 1.5.1 – Novel Foods as an approved novel food with the following condition of use:

Food containing Cannabis spp. or derivatives or parts of Cannabis spp. must not be represented in a form which expressly or by implication suggests that the food has any properties associated with illicit drugs.

However, in May 2002, the Australia and New Zealand Food Regulation Ministerial Council rejected the FSANZ recommendation for Application A360 and decided to retain the prohibition in the Code on all *Cannabis* species.

2.3 Approach to assessment of Application A1039

A full safety assessment of industrial hemp foods was conducted as part of Application A360. As indicated in section 2.2 of this report, FSANZ considered there were no public health and safety concerns associated with the use of food products containing derivatives of industrial hemp (at maximum permitted levels of THC). The FSANZ approach to the safety assessment of this Application is to provide an update of the previous safety assessment for Application A360.

Application A360 was assessed as a novel food application. Novel foods are prohibited from being added to food or sold as food in Australia and New Zealand unless they are listed in the Standard. In order to be listed in the Standard, novel foods must have undergone a pre-market safety assessment by FSANZ. Novel foods are defined as non-traditional foods (in Australia and New Zealand) that require an assessment of public health and safety considerations. Therefore, a novel food must be a non-traditional food and require an assessment of public health and safety.

As noted in section 2.1 (and section 2.5), hempseed oil is permitted to be sold as a food in New Zealand. Hempseed oil has a history of human consumption in New Zealand. It is therefore, questionable as to whether hempseed oil could be considered to meet the definition of non-traditional food in Standard 1.5.1. In order for a food to meet the definition of novel food in Standard 1.5.1, it must first meet the definition of non-traditional food.

As FSANZ considers it is unlikely that hemp foods, particularly hempseed oil, would continue to meet the definition of novel food, this Application has not been assessed in the context of the requirements for Standard 1.5.1.

The assessment of this Application will focus on whether to amend Standard 1.4.4 to remove the prohibition on all *Cannabis* species and whether there may be any consequential amendments required to other standards in the Code if hemp foods were recommended to be approved.

2.4 Australian Hemp Regulations

Most Australian states and territories permit the cultivation of industrial hemp under strict licensing arrangements (no provisions for cultivation exist in South Australia and Northern Territory). The arrangements for licensing and the cultivation of industrial hemp are legislated in each state and the Australian Capital Territory.

Industrial hemp is defined in respective legislation as being *Cannabis* that will produce no more than 0.5% of THC. All growers and processors of industrial hemp must be licensed and all licensees are subject to police checks before being granted a licence. Crops must be grown from approved seed sources and are subject to regular testing for THC content.

All *Cannabis* products intended for human consumption are prohibited to be imported into Australia, regardless of THC content (*Customs (Prohibited Imports) Regulations 1956*). The requirements in each Australian jurisdiction, and for imported goods, are outlined in Attachment 2.

2.5 New Zealand Regulation of Hemp

Hemp cannot be cultivated in New Zealand unless it is cultivated by a person licensed under the Misuse of Drugs (Industrial Hemp) Regulations 2006¹. The Regulations are administered by the New Zealand Ministry of Health. The Regulations establish conditions for approval of cultivars and licence holders. In particular, industrial hemp may contain no THC or THC below a level of 0.35 per cent dry weight (as set out by the Regulations). Analytical testing of cultivated hemp can be required by the Director-General of Health at any time and is currently a condition on licences. Cultivars are approved by the Director-General of Health, or an additional licence can be sought to grow unapproved cultivars for research and breeding purposes. The Regulations prohibit the publication of any advertisement that states or implies that hemp or hemp products are psychoactive. Bare stalks and hemp products (as defined in the Regulations) are exempted from the licensing requirements of the Regulations.

2.6 International Regulation of Hemp

Low THC hemp is permitted to be sold as a food in many international markets, including the European Union, Canada, and the United States of America (USA). In the European Union, industrial hemp certified to contain less than 0.3% THC is permitted to be grown, and there are no maximum permitted levels of THC in food in European Union regulations. However, Switzerland has set specific levels for THC in a variety of foods. In Canada, hempseed products that contain THC at a level of less than 10 mg/kg are exempt from the Controlled Drugs and Substances Act.

Hemp foods are sold in the USA. At the time of Application A360, producers of hempseed and hempseed oil were required to obtain a 'generally recognised as safe' (GRAS) notification. However, the US Drug Enforcement Administration (DEA) has since then indicated that it considers any level of THC in food is illegal in the USA because marijuana is included in Schedule 1 of the Schedule of Controlled Substances in the USA.

¹ Available: <http://www.legislation.govt.nz/regulation/public/2006/0163/latest/DLM389407.html>

However, a recent court ruling (covering nine states) in the USA has indicated that THC from industrial hemp is distinct from marijuana and therefore is not a Schedule 1 substance. The court stated that “The DEA has no authority to regulate drugs that are not scheduled, and it has not followed procedures required to schedule a substance”. That is, industrial hemp food products are not subject to Schedule 1 and are therefore not a controlled substance.

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.

3. Objectives

The objective of this Assessment is to determine whether it is appropriate to amend Standard 1.4.4 to permit the use of industrial hempseed and hempseed oil as a food in Australia and New Zealand.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;

- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Questions to be answered

The key questions which FSANZ has considered in developing this consultation paper are:

- Are there any chemical safety concerns associated with the consumption of hemp foods?
- What is the nutritional profile of hemp foods?
- Are there any other risks, in a food regulatory sense, relating to an approval of hemp foods?

RISK ASSESSMENT

5. Risk Assessment Summary

As noted in section 2.3, the FSANZ approach to the safety assessment of this Application is to provide an update of the previous safety assessment for Application A360. A summary of the updated safety assessment is included in section 5.1 below. In addition, other potential impacts resulting from an approval of low THC hemp foods have been highlighted in section 5.2. The previous rejection of the FSANZ Application A360 recommendation by the Ministerial Council highlighted some potential concerns or risks associated with an approval of hemp food. These risks are not associated with the safety of hemp foods and fall outside of the food regulatory environment. They are presented for information purposes in section 5.3 below.

FSANZ encourages submissions in response to the questions raised in this section, in order to contribute to the consideration of regulatory options to address these risks.

5.1 Safety Assessment Summary

Full details of the chemical safety, dietary modelling and nutrition assessment for this application is provided in SD1. A brief summary of each assessment follows. As noted in section 2.3, the FSANZ approach to the safety assessment of this Application is to provide an update of the previous safety assessment for Application A360. The safety assessment for Application A360 is available as part of the Final Assessment Report (SD2), which can be accessed from the FSANZ website.

5.1.1 Chemical Safety

For the assessment of Application 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 were adequate human data to assess the toxicity of THC following oral administration and to establish a tolerable daily intake (TDI) for THC. A TDI of 6 micrograms of THC per kilogram of bodyweight (6 µg THC per kg bw) was established.

For the current Application, oral THC studies identified in a recent review were considered, along with any relevant studies published since the previous consideration, up to December 2010, in order to establish whether new data indicate a need to change the TDI.

This updated safety assessment concludes that the TDI of 6 µg THC per kg bw remains valid and that the maximum limits for THC content (referred to in section 2.2 of this paper) of hemp foods are appropriate.

5.1.2 *Dietary Modelling*

The assessment of Application A360 included dietary modelling to establish practical and safe maximum limits for THC content of hemp foods. The dietary modelling substituted hempseed and associated products with the most highly consumed 'proxy' foods which were likely to mirror potential usage in the food supply (for example, olive oil was used as a proxy for hemp oil). The maximum limits were derived using back calculations based on 95th percentile consumption of proxy food by Australian children aged 2-12 (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.

Using conservative estimates that are likely to overestimate potential exposure, the dietary modelling indicated that even if all hemp foods contained THC at the proposed maximum levels, it was likely that no consumers would exceed the TDI of 6 µg THC per kg bw.

The safety assessment for this Application also included an update on the dietary modelling conducted for Application A360. The updated dietary modelling included food consumption data from the recent national children's surveys in Australia and New Zealand, which were not available at the time of the Application A360 assessment. The dietary exposure assessment indicates that potential dietary exposures to THC are below the TDI of 6 µg/kg bw/day for all age groups for the Australian and New Zealand populations.

5.1.3 *Nutrition assessment*

FSANZ also considered the nutritional profile of hemp foods as part of the risk assessment for Application A360 and this Application. The nutrition assessments concluded that hempseed contains protein and many vitamins and minerals, like many nuts and seeds, but is much higher in omega-3 polyunsaturated fatty acids than other nuts and seeds, except for flaxseed. The protein quality² of hempseed is slightly lower than the quality of proteins from egg and soybean.

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

5.2 **Other risks**

5.2.1 *High THC Cannabis foods entering the food supply*

There is a potential risk that high THC varieties of *Cannabis* could enter the food supply if low THC hemp foods are approved. If the prohibition on use of *Cannabis* species in food is removed as a result of this application, FSANZ is likely to recommend maximum THC limits for foods derived from *Cannabis*.

² Protein quality is measured using the method of the protein digestibility corrected amino acid score (PDCAAS). The purpose of the PDCAAS is to enable the comparison of the relative ability of food protein sources (individually or mixed) to meet the human demand for amino acids and nitrogen, providing a measure of the overall efficiency of the protein utilisation of particular protein sources.

Exceeding the maximum limit would not be compliant with the Code.

Existing controls for the growing of hemp crops in Australia and New Zealand would provide a control over the THC level of food entering the food supply. However, this situation does not apply to imported food products. For these foods, the maximum limits in the Code would manage the risk. In addition, hempseed oil has been permitted to be sold as a food in New Zealand for some time. Preliminary consultation with New Zealand health and food safety government representatives has not identified this issue as a concern in relation to the permission to sell hempseed oil. Therefore, FSANZ considers the risk of high THC foods entering the food supply as a result of the permission to permit food from low THC hemp is low.

5.2.2 *Potential to mislead consumers*

There is a potential risk that representations (including labelling and advertising) of hemp foods could suggest psychoactive properties relating to consumption of those foods. This would be misleading as hemp foods do not have psychoactive properties.

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 also liaised with overseas food regulatory agencies in regions where hemp food products are permitted, to ascertain whether they had conducted any consumer research on this issue. However, no such consumer research has been conducted by these agencies.

Questions for submitters

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

5.2.3 *Drug testing issues*

Concerns have also been expressed about positive drug tests for *Cannabis* use, based on bodily fluid testing (for example, urine). The risk associated with this concern is that individuals may return a positive *Cannabis* (THC) result as a consequence of consuming low THC hemp foods. This is of particular relevance for workplaces that may have drug testing protocols, athletes and for roadside drug testing.

FSANZ addressed this issue as part of the assessment of Application A360 and noted a study that indicated the return of a positive THC test result is unlikely (Leson & Pless 2000). A more recent review of the literature did not identify any additional studies on this issue. However a paper, which included the results from the above mentioned study, was identified (Leson et al. 2001). The data contained in the Leson et al. (2001) paper showed repeated daily oral administration of 0.6 mg THC for 10 days resulted in THC urine concentrations which were well below 15 ng/ml. The highest THC concentration found in urine was 5.2 ng/ml.

The standard approach for THC testing is to initially run a sample through an immuno-based assay. These tests detect a variety of cannabinoids, active and inactive ones, the limit of detection for such a test is set around 50 ng/ml. If a sample comes up positive it goes through a GC-MS based test designed specifically for THC detection. For this later test, the limit is generally set at 15 ng/ml.

Based on typical concentrations of 5 ug/g of THC in hemp oil and 2 ug/g of THC in seeds (Leson et al. 2001), to achieve a 0.6 mg intake per day, a person would need to consume approximately 125 ml (approx 8 teaspoons of oil) or 300 g of seeds, daily. These are substantial amounts and it is considered that consumption of such high amounts is unrealistic. In addition, if such amounts were consumed, the proposed TDI would be expected to be exceeded. FSANZ dietary modelling has indicated that it is unlikely that even high consumers of hemp food products would exceed the TDI of 6 ug THC per kg bw (see section 5.1.2 for more detail on the dietary modelling).

The data that FSANZ has identified is limited, and while it does not give rise to concern regarding the potential for the consumption of hemp foods to result in a positive drug test for *Cannabis*, further information is desired for the development of regulatory options.

Questions for submitters

3. Can you provide any evidence in addition to that presented in this Consultation Paper whether or not the consumption of low THC hemp foods can return a positive result for a THC drug test?
4. Can you provide information on THC drug testing procedures in Australia and New Zealand, particularly with regard to regulatory limits of THC that may be set?
5. Can you provide information to indicate whether there will be an impact on the cost of testing for THC in humans that could arise from an approval of hemp foods?

5.3 Issues outside of the scope of this Application

The Ministerial Council highlighted two main concerns when rejecting the FSANZ approval of low THC hemp foods in 2002. During early consultation with jurisdictions, FSANZ has identified that these concerns still exist today among drug policy and enforcement agencies. However, these issues relate to matters outside of the scope of food regulations. FSANZ has acknowledged these concerns in this paper, but is not in a position to propose food regulatory measures that address these concerns. The concerns are outlined below.

The first concern is that approval of low THC hemp food will create difficulties in distinguishing between high THC *Cannabis* and low THC hemp products. This issue appears to relate to the whole seed of *Cannabis sativa*. The seed is the part of the hemp plant that is most suitable for use as a food. If hemp foods were approved for use without any limits imposed, it is possible that whole hemp seeds would be available to consumers.

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.

If whole hemp seeds were permitted to be sold to consumers, the perceived risk appears to be that it would be possible to possess high THC *Cannabis* seeds while attempting to pass these seeds off as hempseeds, which would be legal to possess as a food.

It is also possible that an increased availability of hemp seeds to consumers (as a food) may have an impact on the control of current licensing of hemp crops.

The second concern is 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). 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. These permitted uses of hemp are also subject to this second issue, and have been managed.

Risk Management

6. Issues raised

The risk assessment concludes that the consumption of hemp foods does not pose a public health and safety risk. The risk assessment also highlights a number of other issues that have been identified in relation to the use of low THC hemp foods. Given the lack of a safety concern associated with the consumption of hemp foods, this section has identified potential options relating to approval of hemp foods, taking into consideration the other risks identified in section 5.2.

FSANZ has identified potential risk management options below, where necessary, noting that these options will be explored in more detail after responses to the Risk Assessment questions have been evaluated. The potential options will highlight the type of risk management options that are available in the context of the Code. It is possible that some of the issues identified in this paper are better suited to controls available in other legislation, rather than the requirements of the food standards in the Code.

Issues relating to law enforcement of illicit *Cannabis* use and the potential for the availability of low THC hemp foods to impact on consumer acceptability of illicit *Cannabis* use are not issues that FSANZ can address in terms of a food regulatory measure.

6.1 High THC *Cannabis* foods entering the food supply

The inclusion of maximum limits in the Code for THC content of hemp foods, and the existing controls on the licensing and cultivation of hemp crops in Australia and New Zealand, are considered appropriate to mitigate the potential risk of high THC *Cannabis* foods entering the food supply. In addition, this risk has not been identified as an issue associated with the permission to sell hempseed oil as a food in New Zealand (after preliminary consultation with New Zealand health and food safety government representatives).

Question for submitters

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

6.2 Potential to mislead consumers

Conditions around the labelling and representations of food could address the concern that the representation of hemp foods may mislead consumers with respect to psychoactive properties. The consumption of low THC hemp foods will not result in a psychoactive effect. The risk is that the representation of hemp foods could suggest the food has psychoactive properties, which would be misleading.

Standard 1.2.2, which 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), would apply to hemp foods. For foods containing low THC hemp as an ingredient, Standard 1.2.4 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. 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, fair trade legislation in Australia and New Zealand prohibits representations that are false or likely to mislead or deceive consumers.

The New Zealand *Misuse of Drugs (Industrial Hemp) Regulations 2006* prohibit the publication of any advertisement that states or implies that hemp or hemp products are psychoactive. Under Application A360, FSANZ proposed to include a condition of use for hemp foods that they must not be represented in a form which expressly or by implication suggests that the food has any properties associated with illicit drugs.

Question for submitters

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

6.3 General labelling provisions

In addition to Standards 1.2.2 and 1.2.4 there are other generic labelling provisions in Part 1.2 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.

The Transitional Standard 1.1A.2 – 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.

6.4 Issues outside of the scope of this Application

As noted in section 5.3 above, the concerns that the availability of low THC hemp foods will create difficulties in distinguishing between high THC *Cannabis* and low THC hemp products and may send a confused message to consumers about the acceptability and safety of *Cannabis* (with high levels of THC), 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. However, the potential impact of an approval of low THC hemp foods on other legislation, both within and outside the food regulatory environment, is considered below in the context of potential costs and benefits (section 8).

7. Options

FSANZ has identified a number of potential regulatory options in section 6 above. However, these potential options are proposed on the basis that additional information is required in the further development of options for this Application. It is recognised that these potential options may or may not address the risks identified in this Consultation paper. Public submissions to this Consultation paper are expected to provide information to assist in the development and evaluation of regulatory options as the assessment of this Application progresses.

8. Impact Analysis

In developing food regulatory measures for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the relevant food industries and governments. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits arising from the regulation and its health, economic and social impacts. The level of analysis is commensurate to the nature of the application and significance of the impacts.

The regulatory impact analysis is designed to assist in the process of identifying the affected parties and the likely or potential impacts the regulatory provisions will have on each affected party. Where medium to significant competitive impacts or compliance costs are likely, FSANZ will seek further advice from the Office of Best Practice Regulation (OBPR) and estimate compliance costs of regulatory options.

FSANZ will conduct a more detailed impact analysis for the Assessment Report for this Application. The regulatory options identified at the Assessment stage will be influenced by the information obtained in response to the questions raised in this Consultation Paper. For the purposes of this Consultation Paper, FSANZ has identified the potentially-affected parties to this Application and provided a broad impact analysis based on the broad potential regulatory options identified in section 6.

A number of questions for submitters are posed in the benefit cost analysis section below.

8.1 Affected Parties

The affected parties to this Application include:

- those sectors of the food industry wishing to market the food products containing industrial hemp
- consumers, who will be exposed to the availability of hemp food products, including those who choose to consume hemp food products
- Australian, State, Territory and New Zealand Government enforcement agencies that enforce food regulations
- the hemp industry including farmers wishing to cultivate hemp commercially
- importers who wish to import hemp products
- other law enforcement agencies, including police, that enforce illicit drug legislation.

8.2 Benefit Cost Analysis

This benefit/cost analysis is focussed on two broad potential regulatory options. The first is maintaining the current prohibition on all *Cannabis* species in the Code. The second is approving low THC hemp foods. Analysis of the second option relates to approving hemp foods in general. It does not separate out the costs of a general approval for all foods derived from hemp compared to a more restricted approval, such as prohibiting the sale of whole hempseeds. Therefore, the impacts described below are generic and the specific impacts will be addressed in more detail when a preferred option is presented in the Assessment Report for this application. Section 6 of this paper includes detail on the potential risk management options identified.

8.2.1 Option 1 – Maintain the prohibition on all *Cannabis* species

This option requires no amendment to the Code.

- Food manufacturers may be disadvantaged through limited ability to innovate and access market opportunities for developing food products derived from hemp
- consumers may be disadvantaged through the inability to access hemp food products, which are available internationally and which have some potential nutritional benefits
- the hemp industry cannot value add to hemp crops or increase the viability of hemp crops by supplying hemp for food products
- there is no identified impact on government or law enforcement agencies
- this option could result in the continuation of inconsistency with permissions to sell hemp foods in international markets

Question for submitters

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

8.2.2 Option 2 – Approval of low THC hemp foods

The approval of low THC hemp foods would be a relaxation of existing regulation. Business entities will determine whether there is a benefit to using hemp on the basis of the commercial gains they hope to create by reducing their cost or providing something consumers will value.

Approval of low THC hemp foods would increase the potential market for hemp growers. It is not clear whether there would be additional requirements imposed on industrial hemp that was destined for use as food. The extent of the market for hemp food products could be limited if whole seeds were not permitted to be sold to consumers. However, processed seed products could potentially still be sold to consumers, which would create a potential market that does not currently exist.

Questions for submitters

9. What are the potential benefits to food manufacturers if hemp foods were approved for use?
10. Are there likely to be any additional costs for food manufacturers wishing to supply hemp foods?

Please provide quantitative data if available.

Approval of low THC hemp foods may impose an additional cost on food enforcement agencies, which may need to develop new methods or widen the scope of their activities. This additional cost would include the cost of enforcing a new ingredient approval, similar to any other approval for a substance added to food or other food regulatory change resulting from an amendment to the Code. However, given the nature of the risks identified in this Consultation paper, it is possible that there would be a greater expectation on the level of testing compliance of hemp foods compared to other new food ingredient approvals.

Question for submitters

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

Approval of low THC hemp foods may impose consequential legislative changes on other government and law enforcement agencies. For example, the importation of hemp food products may require a change in the import licensing policy of Australian Customs. It is possible that licenses or permission to import low THC hemp food products could be provided. However, broader changes to the *Customs (Prohibited Imports) Regulations 1956* would be required to consider any importation of hemp foods without a license or permission.

It is not clear whether approval of low THC hemp foods would impact on existing industrial hemp regulations in Australia and New Zealand. For example, additional controls on the supply of hempseed and hemp products may be required for industrial hemp destined for use in foods.

Government agencies responsible for granting licenses to cultivate industrial hemp may experience an increase in demand for license approvals if hemp foods were approved. This increase in demand may result from increased market potential for the industrial hemp industry or from any potential consequential amendments to industrial hemp regulations that may be required as a result of hemp food approval. This may be offset by any cost recovery arrangements that may be in place for licensing.

Questions for submitters

12. What other legislation in Australia and New Zealand would affect or be affected by approval of hemp foods?
13. Would the approval of hemp food have an impact on existing hemp regulations in Australia and New Zealand? For example, would industrial hemp destined for use in food require additional controls to those already specified in industrial hemp regulations?
14. Would food manufacturers be required to be licensed under existing hemp regulations?
15. Would additional costs be incurred by government agencies responsible for granting licences for the cultivation of hemp as a result of approval of hemp foods?

Consumers may benefit through the availability of a new food source of omega 3 fatty acids and other nutrients.

Questions for submitters

16. Can you identify other risk management options that have not been considered in the impact analysis? Comments on the possible costs and benefits are welcome.
17. Can you identify any other costs and benefits for any of the risk management options considered in this paper?
18. Do you have a view about an appropriate preferred regulatory option regarding the approval of hemp foods, based on benefits and costs?

Communication and Consultation Strategy

9. Communication

FSANZ will notify subscribers and any interested parties about the availability of the consultation report for public comment and will place the report on the FSANZ website.

A media release will also be issued and items relating to the report will be placed on Facebook and Twitter.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. The purpose of inviting public submissions is to obtain the views of interested parties on the issues raised by the application and the impacts of regulatory options.

The Applicant, individuals, and organisations making submissions on this Application, will be notified at each stage of the Application. If low THC hemp foods were approved, FSANZ would consider public education options and fact sheets to communicate the various properties and perceived risks that may be associated with hemp foods.

10. Consultation

FSANZ is seeking comment from the public and other interested stakeholders to assist in further assessing this Application. After receiving submissions on the Consultation paper, FSANZ will develop an Assessment Report, which will identify a preferred regulatory option. The Assessment Report will also be released for public comment.

Comments are sought about certain aspects of the Application including any potential costs or benefits associated with the use of hemp as a food or food ingredient.

This application requires input from interested parties other than those directly involved in food regulation. Therefore, commentary is sought from a wide range of stakeholders, particularly from Government bodies involved in other regulatory environments. Ideally, a whole of government response is sought at a national, state and territory level to ensure all issues have been considered in the appropriate context.

11. References

Leson G & Pless P. (2000) Evaluating interference of THC in hemp food products with employee drug testing (summary available at www.testpledge.com/PDF/THCStudySummary.pdf)

Leson G, Pless P, Grotenhermen F, Kalani H, Mahmond E.A (2001) Evaluating the Impact of Hemp Food Consumption on Workplace Drug Tests. *Journal of Analytical Toxicology*, 25: 691-698.

ATTACHMENTS

1. Australian Hemp Regulations

Australian Hemp Regulations

Western Australia

Western Australia's Industrial Hemp Scheme is administered by the Department of Agriculture and Food under the *Industrial Hemp Act 2004* and the *Industrial Hemp Regulations 2005*. Suitable companies or individuals may obtain a license to cultivate, harvest and/or process industrial hemp. Industrial hemp is defined as *Cannabis* containing no more than 0.35% THC in the leaves and flowering heads. Industrial hemp seed is that which is certified as having been produced from industrial hemp or that which will produce industrial hemp when cultivated. Crops must be grown from approved seed sources, and seed harvested and intended for further crop production must be cleaned at a Registered Seed Works, and officially sampled, tested and labelled by the Department of Agriculture and Food.

Queensland

In Queensland, Part 5B, *Commercial production of industrial Cannabis*, of the *Drugs Misuse Act 1986*, and Part 4, *Commercial production of industrial Cannabis*, of the *Drugs Misuse Regulation 1987*, allow for the processing and marketing of, and trade in, industrial *Cannabis* fibre and fibre products; and the processing and marketing of, and trade in, industrial *Cannabis* seed and seed products, other than for the purpose, directly or indirectly, of producing anything for administration to, or consumption or smoking by, a person. Industrial *Cannabis* may be grown under licence. Commercial industrial *Cannabis* plants grown for seed or fibre must not exceed 1% THC under the Act, and may only be grown from seed certified to produce plants with no more than 0.5% THC. The difference allows for variations in THC concentrations in the leaves and flowering heads of the plant due to environmental conditions beyond the grower's control.

New South Wales

The Hemp Industry Act 2008 authorises and regulates the cultivation and supply of low-THC hemp in New South Wales, along with the Hemp Industry Regulation 2008. Low-THC hemp, being hemp with no more than 1% THC in the leaves and flowering heads of the plant, may be cultivated under licence. Seed must be supplied on the basis that it will produce hemp with no more than 0.5% THC in the leaves and flowering heads, and a licensee must not supply hemp that exceeds 1% THC.

Australian Capital Territory

The Hemp Fibre Industry Facilitation Act 2004 allows for the processing and marketing of, and trade in, industrial hemp fibre and fibre products, and seed and seed products, as long as seed and seed products are not for administration, consumption or smoking. Industrial hemp must not exceed 1% THC in the leaves and flowering heads, and may be cultivated under licence from certified hemp seed. Certified hemp seed must be seed harvested from a plant with a THC concentration in its leaves and flowering heads of not more than 0.5%. The difference recognises that the leaves and flowering heads of plants grown using certified hemp seed may have more than 0.5% THC because of environmental conditions beyond a grower's control.

Northern Territory

The Misuse of Drugs Act 2010 has exemptions for processed fibre hemp products, processed products made from hemp seeds as long as they are not whole, and hemp seed oil for external use containing less than 0.005% tetrahydrocannabinols. *Cannabis* is defined as any plant of the genus *Cannabis*, and no further exemptions allowing for the legal sale and/or cultivation of low-THC varieties of hemp in the Northern Territory are made.

Victoria

The Drugs, Poisons and Controlled Substances Act 1981 and the Drugs, Poisons and Controlled Substances (Industrial Hemp) Regulations 2008 allow for the cultivation and processing of low THC *Cannabis* under authority in Victoria for commercial or research purposes relating to non-therapeutic use. *Cannabis* may be cultivated from seed harvested from low-THC *Cannabis*, and may be sold or supplied when substantially free of flowering heads and leaves and containing no more than 0.1% THC. Low-THC *Cannabis* is defined as containing no more than 0.35% THC in the leaves and flowering heads.

Under the Act processed fibre products may contain a maximum of 0.1% THC, must not contain whole *Cannabis* seeds, and must not be in a form suitable for ingestion, smoking or inhalation. Processed seed products may contain no more than 0.001% THC and must not contain whole seeds.

South Australia

Low trial yields have been demonstrated in South Australian research into the cultivation of hemp³, and at present there is no legislation in place in South Australia to allow for its commercial cultivation. The Controlled Substances (General) Regulations 2000 legislate controls over controlled drugs (including delta - 9 tetrahydrocannabinol) and controlled plants (including *Cannabis* plants). Some exemption is made under the Controlled Substances (General) Regulations 2000 to allow for the sale of hemp seed oil for external use containing no more than 50mg/kg THC.

Tasmania

The status of hemp under the Poisons Act 1971 and Misuse of Drugs Act necessitates the issue of licences for the growing of industrial hemp in Tasmania. Tasmania allows the growing of hemp plant material of up to 0.35% THC of dry weight under the conditions of licence. All hemp seed is in schedule 8 of the Tasmanian Poisons List and this allows the ability to issue licences to trade in the seed. Schedule 9 (Prohibited Substances) of the national Standard for the Uniform Scheduling of Medicines and Poisons allows an exemption from scheduling for "processed hemp fibre containing 0.1% or less of THC and products manufactured from such fibre". The substance THC is also captured by Schedule 9 and an exemption is allowed for hemp seed oil containing 50mg/kg or less of THC.

³ from *An Information Paper on Industrial Hemp (Industrial Cannabis)*, accessed 7 July 2010 from http://www.agric.wa.gov.au/objtwr/imported_assets/aboutus/as/information_paper_2008.pdf

Imports

The *Customs (Prohibited Imports) Regulations 1956* prohibit the import into Australia of a Schedule 4 (of the Regulations) controlled substance unless the person importing the drug holds a licence or permission to import that substance (licenses and permissions are granted by the Secretary of the Department of Health). *Cannabis*, *Cannabis* resin, and tetrahydrocannabinols, including all alkyl homologues of tetrahydrocannabinols, are all listed in Schedule 4 as controlled substances. There is no distinction in the Regulations between *Cannabis* and low THC hemp. All *Cannabis* products intended for human consumption are prohibited to be imported into Australia under the Regulations.