

**7 December 2011**  
**[24-11]**

## **APPLICATION A1039**

### **LOW THC HEMP AS A FOOD**

---

#### **Executive Summary**

Food Standards Australia New Zealand (FSANZ) received an Application from Dr Andrew Katelaris MD on 4 December 2009. The Application seeks approval for the use of the seed and seed products of *Cannabis 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. 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, 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 is cultivated in Australia and New Zealand under strict licensing arrangements that control the varieties of hemp that can be grown and the levels of THC that may be present in the hemp crops. 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 to FSANZ, Application A360, also requested the approval hemp foods. 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 total prohibition on *Cannabis* species in Standard 1.4.4 and the introduction of maximum levels for THC in specified hemp foods.

However, in May 2002, the then Australia New Zealand Food Standards Council (ANZFSC)<sup>1</sup> 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.

---

<sup>1</sup> Now known as the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council)

The FSANZ assessment of Application A1039 has updated the full safety assessment of hemp foods conducted as part of Application A360. FSANZ is satisfied that the conclusions of the safety assessment for A360 remain valid and that low THC hemp foods are safe for consumption.

FSANZ released a Consultation Paper in March 2011, which sought information from stakeholders on a number of issues relating to the potential impacts the availability of hemp foods may have in Australia and New Zealand. FSANZ received almost two hundred submissions to the Consultation Paper. The majority of submissions were in support of the approval of hemp foods in Australia and New Zealand. These issues are discussed in more detail in this report.

FSANZ has also sought information from international regulatory agencies and other Governmental organisations with respect to their experiences related to hemp foods. The information received in response to this request for information has been used to assist in addressing the issues discussed in this report.

FSANZ has also requested information, via targeted consultation, on potential cost impacts of approving hemp foods for sale in Australia and New Zealand. This information has been used to assist in the analysis of the potential impacts of the regulatory options identified by FSANZ.

### **Risk assessment**

FSANZ is satisfied, based on the safety assessment conducted as part of Application A360 and the updated assessment as part of this Application, that hemp foods are safe for human consumption. The FSANZ safety assessment concluded that consumption of hemp foods that contain specified maximum levels of THC was safe. FSANZ proposes that maximum levels of THC should be specified in the Code if hemp foods are approved.

The nutrition assessment for this Application reinforces the outcome of the Application A360 nutrition assessment, and concludes that hemp 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).

### **Risk management**

The FSANZ assessment of this Application has identified a number of issues relating to the potential approval of hemp foods. These issues have been taken into account in FSANZ's development of regulatory options for hemp foods. A brief summary of these issues is provided below.

#### *Labelling of hemp foods*

Hemp foods would be subject to the general labelling requirements in the Code that apply to all other foods, such as ingredient percentage labelling, requirement for a nutrition information panel and country of origin labelling. Some stakeholders have expressed concern that labelling and advertising of hemp foods could suggest these foods have psychoactive properties. This would be misleading as hemp foods do not have psychoactive properties. FSANZ is satisfied that consumer protection legislation in Australia and New Zealand regulates misleading and deceptive conduct and that additional measures in the Code are not required.

### *High THC entering the food supply*

Some stakeholders have expressed concern that an approval of hemp foods may result in high THC cannabis varieties entering the food supply. FSANZ is satisfied that the existing domestic licensing arrangements for the cultivation of hemp, coupled with maximum levels of THC being specified in the Code, provide sufficient control on the levels of THC that may be present in hemp foods produced domestically and in imported hemp food products.

### *Distinguishing seeds*

An approval of whole hemp seeds for sale as a food has the potential to impact on the ability of law enforcement agencies to enforce drug possession legislation. Hemp seeds and the seeds of drug varieties of cannabis are indistinguishable upon observation. It is possible that a person could be in possession of illicit cannabis seeds, but claim that the seeds are hemp seeds purchased as a food. Ensuring that hemp seeds are non-viable when sold as food may assist drug enforcement agencies because it is not likely that a person would be in possession of non-viable illicit cannabis seeds (they could not grow the plant for drug use). However, it is still likely that viable and non-viable seeds are not able to be distinguished upon observation. A germination test would still be required to establish that the seeds are non-viable, which would take time and resources and may inconvenience consumers who had legitimately purchased hemp seeds as a food.

FSANZ proposes that hemp seeds should only be approved for food use if they are hulled and are non-viable. Hemp seed products, such as flour, protein powder, oil and beverages should also be permitted. Hulled hemp seeds are readily distinguishable from whole seeds and are likely to be non-viable due to the removal of the outer hull of the seed. This proposal provides food manufacturers with a variety of potential hemp food products to market to consumers, while also lessening the concern of drug enforcement agencies with respect to enforcing drug possession laws.

### *Drug testing*

The FSANZ assessment considers that the consumption of hemp foods is unlikely to interfere with blood and urine tests aimed at detecting the use of illicit drugs. The levels of THC present in hemp foods is unlikely to result in a positive result for THC drug screens that are based on the collection of urine or blood. However, it is not known whether the consumption of hemp foods will interfere with screening tests that involve the collection of saliva, such as the tests used by some law enforcement agencies in roadside testing procedures in Australia. FSANZ notes that it has identified limited information at present to assist in the consideration of this issue. However, FSANZ also notes that saliva tests are generally not aimed at identifying impairment, but are rather aimed at detecting the presence of substances (such as THC) and can be quite sensitive (that is, they can detect very low levels). FSANZ is requesting that stakeholders provide additional information on this issue if it is available.

### *Outside of FSANZ scope*

Some of the issues identified in the assessment of this Application are outside of the scope of what FSANZ can take into consideration when developing food regulatory measures. FSANZ has noted these issues in this report, but has not commented on them in detail. The first of these issues relates to the potential impact of other legislation on any amendment to the Code to permit hemp foods. The use of cannabis is controlled through drugs and poisons legislation in Australia and New Zealand, and is generally prohibited.

If the Code approved the sale of hemp foods, it is likely that 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.

The other issues relate to whether hemp foods should be subject to international conventions on the control of narcotic drugs and whether use of hemp in foods may send a confused message to consumers about the acceptability and safety of cannabis (with high levels of THC).

### **Assessing the Application**

The Application is being assessed under the General Procedure.

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 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
- there are no other measures that would be more cost-effective than a variation to Standard 1.4.4
- any relevant New Zealand standards
- any other relevant matters.

### **Preferred Approach**

**To prepare a draft variation to Standard 1.4.4 – Prohibited and Restricted Plants and Fungi to permit the use of processed hemp seed products only (including hulled hemp seed, but excluding whole and viable seeds) as a food with maximum delta 9-tetrahydrocannabinol (THC) levels.**

### **Reasons for Preferred Approach**

FSANZ has prepared a draft variation to the Code to permit the use of processed hemp seed products as food, with maximum levels of THC, based on the following reasons:

- Hemp foods have been assessed as safe for human consumption at the recommended maximum levels of THC content.
- There are adequate controls in place to mitigate the risk of high THC cannabis products entering the food supply.
- There is no evidence of risk of consumers being misled by representations relating to connecting hemp foods with psychoactive effects of drug varieties of cannabis.
- The approval of hemp seed products including hulled seed but excluding whole and viable hemp seed will provide industry with a greater range of potential products to market to consumers, while limiting the possibility of drug enforcement problems relating to possession of whole hemp seeds.

- The draft variations provide a net benefit to the affected parties.
- No other measures would be more effective at achieving this outcome.

## Consultation

Public submissions are now invited on the draft variation and in response to the questions for submitters included throughout the Report. As this Application is being assessed under the General Procedure, this will be the final round of public comment. Submissions to this Report will be considered in the continuing assessment of this Application and by the FSANZ Board to come to a final decision on the draft variation.

## Invitation for Submissions

FSANZ invites public comment on this Report and the draft variation to the Code based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

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](mailto: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) 1 February 2012**

**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](mailto: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 6143  
NEW ZEALAND  
Tel (04) 978 5630**

# CONTENTS

<b>INTRODUCTION .....</b>	<b>3</b>
1. PREVIOUS ASSESSMENT .....	4
2. FSANZ CONSULTATION FOR APPLICATION A1039.....	4
3. ASSESSMENT OF APPLICATION A1039 .....	5
4. THE ISSUE / PROBLEM.....	6
2. BACKGROUND.....	6
2.1 <i>Current Standard</i> .....	6
2.2 <i>Other food regulations</i> .....	6
2.3 <i>Hemp and drug regulations</i> .....	7
3. OBJECTIVES .....	9
4. QUESTIONS TO BE ANSWERED .....	9
<b>RISK ASSESSMENT.....</b>	<b>9</b>
5. RISK ASSESSMENT SUMMARY .....	9
5.1 <i>Safety Assessment Summary</i> .....	10
<b>RISK MANAGEMENT .....</b>	<b>11</b>
6. ISSUES RAISED .....	11
ISSUES WITHIN SCOPE OF FOOD REGULATORY MEASURES .....	11
6.1 <i>Safety of hemp foods – maximum THC levels in the Code</i> .....	11
6.2 <i>Potential to mislead consumers – additional labelling requirements</i> .....	12
6.3 <i>High THC cannabis products entering the food supply</i> .....	14
6.4 <i>Distinguishing between hemp and cannabis seeds</i> .....	16
6.5 <i>Drug testing</i> .....	18
ISSUES OUTSIDE THE SCOPE OF FOOD REGULATORY MEASURES .....	20
6.6 <i>Impact of other legislation</i> .....	20
6.7 <i>UN Conventions</i> .....	21
6.8 <i>Acceptance of cannabis</i> .....	21
7. OPTIONS .....	22
8. IMPACT ANALYSIS (RIS ID: 11813).....	22
8.1 <i>Affected Parties</i> .....	23
8.2 <i>Cost Benefit Analysis</i> .....	23
<b>COMMUNICATION AND CONSULTATION STRATEGY.....</b>	<b>30</b>
9. COMMUNICATION .....	30
10. CONSULTATION.....	30
11. COMPLIANCE WITH FSANZ'S OBJECTIVES.....	31
<b>CONCLUSION.....</b>	<b>32</b>
12. CONCLUSION AND PREFERRED OPTION .....	32
12.1 <i>Reasons for Preferred Approach</i> .....	32
13. IMPLEMENTATION AND REVIEW .....	33
ATTACHMENT 1 - DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE.....	34
ATTACHMENT 2 - DRAFT EXPLANATORY STATEMENT.....	36

## **SUPPORTING DOCUMENTS**

The following material, which was used in the preparation of this Assessment Report, is available on the FSANZ website at <http://www.foodstandards.gov.au/foodstandards/applications/applicationa1039lowt4708.cfm>

- SD1 Risk Assessment Report  
SD2 Application A360 Final Assessment Report – available on FSANZ website at <http://www.foodstandards.gov.au/foodstandards/applications/applicationa360hempasanovelfood/index.cfm>

SD3 Cost Benefit Analysis  
SD4 Copy of FSANZ request for international information  
SD5 Australia and New Zealand Hemp Regulations  
SD6 International Hemp Regulations

## **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 in the *Australia New Zealand Food Standards Code* (the Code) to permit the use of the seed and seed products of *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.

*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).

In this report, low THC varieties of *C. sativa* will be referred to as hemp (including reference to the seeds and foods produced from the 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 3-15%. 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.

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 other nuts and seeds, hemp seed and hemp seed oil are a good alternative source of a number of nutrients.

Hemp seed 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. Hemp seeds and hemp seed oils are sold as food and food ingredients in many international markets, including some parts of Europe, Canada, and the United States of America (USA).

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, 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.

## 1. Previous assessment

A previous Application to FSANZ, Application A360 (see SD2), 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 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 then Australia New Zealand Food Standards Council (ANZFSC) 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 consider 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. FSANZ consultation for Application A1039

FSANZ released a Consultation Paper in March 2011. The Consultation Paper sought information from stakeholders on a number of issues relating to the potential impacts the availability of hemp foods may have in Australia and New Zealand. The issues identified in the Consultation Paper and the submissions received in response are addressed in section 6 of this report.

FSANZ received almost two hundred submissions to the Consultation Paper. The majority of submissions were in support of the approval of hemp foods in Australia and New Zealand. Submissions from consumers and industry were supportive of approval and highlighted the nutritional benefits of hemp foods and the opportunity for the hemp industry to be profitable if hemp foods were approved.

Some areas of government did not identify any objections to the sale of hemp foods, while other areas of government identified some potential issues and risks that may be encountered if hemp foods were approved.

Recognising that hemp foods are sold in a number of countries, FSANZ has also sought information from international regulatory agencies and other Governmental organisations with respect to their experiences related to hemp foods. The information received in response to this request for information has been used to assist in addressing the issues discussed in section 6 of this report.

FSANZ has also requested information via targeted consultation on potential cost impacts of approving hemp foods for sale in Australia and New Zealand. This information has been used to assist in the analysis of the potential impacts of the regulatory options identified by FSANZ. The impact analysis is included in section 8 of this Report (and includes consideration of a cost analysis which is provided in SD 3).

### **3. Assessment of Application A1039**

A full safety assessment of hemp foods was conducted as part of 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). The FSANZ approach to the safety assessment of this Application is to provide an update of the previous safety assessment for A360. FSANZ has investigated the literature to ascertain whether any new studies may influence the outcomes of the previous safety assessment.

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. The FSANZ risk assessment for A1039 is summarised in section 5 of this Report. More detail is available in SD 1.

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.

Hempseed oil is permitted to be sold as a food in New Zealand and has a history of human consumption in that country. It is therefore questionable whether hempseed oil could be considered to meet the definition of non-traditional food in Standard 1.5.1 and consequently be considered to be a novel 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 the prohibition on all *Cannabis* species in Standard 1.4.4 and whether other amendments to the Code may be required if hemp foods were approved.

The Applicant has requested the removal of the prohibition on all *Cannabis* species so that the seed and seed products of low THC hemp can be used as food in Australia and New Zealand. The FSANZ assessment of A1039 is restricted to the use of the seed and seed products as food and has not included an assessment of the use of other parts of the hemp plant in a food context.

A number of issues have been identified in relation to potential direct impacts resulting from an approval of hemp foods. These issues relate to the 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 and drug testing for illicit cannabis use. These issues have been taken into consideration by FSANZ in the development of food regulatory options and are addressed in section 6 of this Report.

A number of additional issues have been identified in both the previous and current assessments of hemp foods. These issues relate to the impact of other legislation on hemp foods, the applicability of international conventions on narcotic substances to hemp foods and the concern that the availability of hemp foods may have some influence on the acceptance of illicit cannabis use. These issues have been considered by FSANZ to be outside the scope of the considerations that can be taken into account in developing food regulatory options. However, FSANZ notes the removal of the prohibition on all *Cannabis* species in the Code, and the potential availability of hemp foods, may have an impact on these areas. These potential impacts are described in section 6 of this Report and noted in the impact analysis in section 8. While these potential impacts have been noted, they do not form part of the benefit cost assessment in section 8.2 of this Report.

## **4. The Issue / Problem**

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

Therefore, this Application seeks an amendment to this prohibition in Standard 1.4.4 for foods derived from the seeds of low THC *C. sativa*. 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.

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

## **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, *C. sativa* is currently prohibited from being added to food or sold as food in Australia or New Zealand, regardless of THC content.

### **2.2 Other food regulations**

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 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.

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.

### **2.3 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 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 and have THC content below certain levels.<sup>2</sup>

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 Australia and New Zealand. The regulation of hemp in Australia and New Zealand is described in more detail below. The potential impact of these other areas of legislation is discussed in section 6.1 of this Report.

#### *2.3.1 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% 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.

The requirements in each Australian jurisdiction, and for imported goods, are outlined in SD5.

---

<sup>2</sup> The exception to this is the permission to sell hempseed oil as a food in New Zealand

### 2.3.2 *New Zealand Hemp Regulations*

Hemp cannot be cultivated in New Zealand unless it is cultivated by a person licensed under the *Misuse of Drugs (Industrial Hemp) Regulations 2006*<sup>3</sup>. The Regulations are administered by the New Zealand Ministry of Health. The Regulations establish conditions for approval of cultivars and licence holders. In particular, THC content in industrial hemp is generally expected to be below a level of 0.35% dry weight and not above 0.5% (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.

### 2.3.3 *International Hemp Regulations*

Many jurisdictions, including Canada, Germany, the United Kingdom, The Netherlands, Belgium, Switzerland and Austria allow hemp to be used in foods. FSANZ distributed a questionnaire (SD 4) to contacts in various jurisdictions in North America and Europe which permit the sale of hemp foods. Responses were received from Canada, European Commission, Belgium, Austria, Germany, Ireland, Cyprus, Italy, Denmark and The Netherlands.

The requirements relating to production of industrial hemp and THC content in food varies considerably from very explicit and specific (Canada) to less rigorous (Ireland). Where explicit controls do exist this is generally through a licensing system covering obtaining seeds for planting to end of processing hemp products.

The THC content in food is generally controlled via the use of low THC hemp cultivars, with some regions also setting THC limits in foods. Only Canada has specific detailed requirements regarding how to render and confirm seeds as non-viable. For other regions the lack of rules around viability seems to be a result of exemption of seeds from misuse of drug type regulations. The reasons for these exemptions were not explicit in the information reviewed but are likely to be due to the common understanding that the seeds do not contain THC.

With regard to the potential for the consumption of low THC hemp foods to result in positive drug tests for THC, the feedback from the questionnaires indicated that there was either no evidence of issues or no information was available. Some respondents made reference to research carried out on consumption of hemp foods and analysis of blood and urine for THC content. The overall conclusion was that consumption of food containing low levels of THC did not interfere with such tests. No information was provided on saliva drug testing and consumption of foods containing THC.

Similarly, the feedback did not indicate any relationship between the availability of hemp foods and an increase in illicit drug use. The USA does have regulations to allow the cultivation of industrial hemp, including food use. However, obtaining licences has been difficult, if not impossible, due to the USA government concerns about the message it may give to the general public regarding illicit cannabis use. Several countries, including New Zealand, have legislation in place which prohibits any reference to psychoactive activity appearing in any advertisement associated with hemp products.

---

<sup>3</sup> Available at <http://www.legislation.govt.nz/regulation/public/2006/0163/latest/DLM389407.html>

Further details on international hemp regulations can be found in SD 6.

### **3. Objectives**

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 assessment report 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?
- What are the potential impacts on stakeholders that may result from an approval of hemp foods, particularly on industry and government and law enforcement agencies?
- Can the experience of international regulators, in countries where hemp foods are permitted, provide assistance in dealing with the issues identified in this assessment?

## **RISK ASSESSMENT**

### **5. Risk Assessment Summary**

As noted in the Introduction, the FSANZ approach to the safety assessment of this Application is to provide an update of the previous safety assessment for AA360.

The safety assessment for A360 is available as part of the Final Assessment Report (SD2), which can be accessed from the FSANZ website.

A summary of the updated safety assessment is included below.

## **5.1 Safety Assessment Summary**

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

### *5.1.1 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 were adequate human data to assess the toxicity of THC following oral administration and to establish a tolerable daily intake (TDI) for THC. 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.

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. The recent EFSA opinion on safety of hemp for use as animal feed, which derived a Provisional Maximum Tolerable Intake (PMTI) of 0.4µg THC per kg bw was also considered. However the risk assessment concluded that this PMTI did not take account of more recent information on the effects of THC on skill impairment.

The FSANZ updated safety assessment concludes that the TDI of 6 µg THC per kg bw remains valid and that the maximum levels for THC content (referred to in section 6.1 of this Report) of hemp foods are protective of human safety.

### *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 95<sup>th</sup> 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 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 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 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 to the Consultation Paper 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.

## **Risk Management**

### **6. Issues raised**

As noted above, some of the issues raised in this assessment are outside of the scope of what FSANZ can consider in assessing potential changes to food regulatory measures. The issues raised below have been split into those issues that FSANZ can comment on in a food regulatory sense and other issues that fall outside of the scope of food regulation.

#### **Issues within scope of food regulatory measures**

The Consultation Paper identified a number of issues and asked a series of questions relating to the sale of hemp foods. These issues and submitters' responses to the questions raised are addressed below. Submissions to the Consultation Paper and additional stakeholder consultation by FSANZ raised additional issues that are also addressed below. FSANZ has taken these issues into account in the development of potential food regulatory options identified in section 7 below.

##### **6.1 Safety of hemp foods – maximum THC levels in the Code**

FSANZ proposed, as part of the assessment of A360, to set maximum levels in the Code for the THC content of hemp foods. These limits were derived by estimating the maximum level of THC in the food commodity that would not result in the consumer exceeding the TDI for THC.

The proposed maximum levels were then used for the dietary exposure assessment to ensure that they would not lead to a total dietary exposure greater than the TDI.

Based on typical concentrations of 5 µg/g of THC in hemp oil and 2 µg/g of THC in seeds (Leson et al. 2001), to reach the TDI, a 100 kg person would need to consume approximately 125 mL (approx 25 teaspoons or half a cup of oil) or 300 g of seeds, daily.

These are substantial amounts and it is considered that consumption of such high amounts is unrealistic. One submitter to the Consultation Paper, while agreeing such consumption appears unrealistic, suggested that it may be possible if the oil was in frying (or deep frying) and a large amount of the food was consumed. If such amounts were consumed, the proposed TDI would be expected to be exceeded. However, FSANZ dietary modelling has indicated that it is unlikely that even high consumers of hemp food products would exceed the TDI of 6 µg THC per kg bw (see section 5.1.2 for more detail on the dietary modelling).

The updated risk assessment (see section 5) notes that the TDI and maximum levels for THC content of hemp foods proposed under A360 remain protective of human health and are below a level which induces psychoactive effects. The maximum levels proposed under A360 included levels for hemp seed oil and other seed products. As noted in the Introduction to this Report, the FSANZ assessment of A1039 is restricted to the use of the seed and seed products as food and has not included an assessment of the use of other parts of the hemp plant in a food context.

Therefore, only the maximum levels for hemp seed oil and other hemp seed products are included in this assessment. These maximum levels are described below:

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

### 6.1.1 Conclusion

FSANZ considers that maximum levels of THC content in hemp foods have formed an important part of the risk assessment. FSANZ proposes that any amendment to the prohibition on all *Cannabis* species in the Code, to permit hemp foods, should include the setting of the maximum levels of THC content in those foods, as described above.

#### Question for submitters:

Will the inclusion of a maximum level in the Code for hemp seed oil products be an issue for hemp seed oil products produced in or imported into New Zealand?

## 6.2 Potential to mislead consumers – additional labelling requirements

During the FSANZ assessment of A360, and in the Consultation Paper for A1039, there has been discussion of 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 noted in the Consultation Paper that it 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. Respondents indicated that they were not aware of such problems in their respective countries.

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 in the Consultation Paper that consumer protection legislation in Australia and New Zealand covers misleading and deceptive labelling and advertising. Many submitters agreed that existing consumer protection legislation is sufficient to cover potential labelling of hemp foods that may be misleading.

Some submitters to the Consultation Paper 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 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 notes 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, we do not have evidence for or against whether such a representation would mislead consumers to believe that the hemp food has psychoactive properties.

#### *6.2.1 General labelling requirements of food for retail sale*

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 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.

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.

#### 6.2.2 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 legislation, which regulates misleading conduct. FSANZ has not identified sufficient evidence to justify additional controls in the Code on representations for hemp foods.

### 6.3 High THC cannabis products entering the food supply

The Consultation Paper 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 requirements 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 of the plant, albeit from low THC producing plants, and can 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 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.

Maximum levels 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. Maximum levels in the Code would also provide a testing reference point for food 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 maximum levels 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 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 hemp seed oil. However, in response to the Consultation Paper, some New Zealand government agencies noted extra controls and added costs would be required to mitigate the risk of high THC cannabis entering the food supply. 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 6.5.

Submitters to the Consultation Paper 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.

Hemp food products are tested for THC content periodically in Austria. 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 SD6). 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 SD6.

Submitters noted that hemp seed and fibre crops are currently being grown in Australia and New Zealand with no apparent policing concerns. For example, hemp 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 to the Consultation Paper also noted that criminal laws exist to deal with people who may attempt to sell illegal high THC cannabis products in the food industry.

### 6.3.1 Conclusion

FSANZ considers 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 where specified conditions for the production of Roquefort cheese must be met before importation is permitted). However FSANZ recognises that the similar level of control for imported hemp food products may be achieved more simply, and with fewer enforcement difficulties, by the introduction of maximum levels of THC in the Code (for hemp foods). Maximum levels for THC content of hemp foods would also provide food enforcement agencies with a testing reference point for hemp food products should they wish to test them for THC content.

### 6.4 Distinguishing between hemp and cannabis seeds

As noted in the Consultation Paper, and in some submissions from regulatory agencies, there is a concern that the sale of whole hemp seeds as food would create problems for drug 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 a person in possession of cannabis seeds has hemp seeds or the seeds of a drug variety. The risk associated with this concern is that it would be possible to possess high THC cannabis seeds 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. 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 under the requirements of 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. However, 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 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. An import certification scheme could ensure that imported hemp seeds have been rendered non-viable and are derived from certified low THC hemp plants. Such a certification scheme would require additional resources to establish and is outside the scope of what FSANZ can consider in a food regulatory measure.

A potential alternative solution to the issue of identifying seeds is 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 are visually different from whole hemp seeds. As noted above, FSANZ considers that hemp seeds sold as food should be non-viable. Hulled hemp seeds may be non-viable due to the removal of the outer hull of the seed; however manufacturers of hemp seed products would need to ensure that the seed is non-viable before sale to consumers if hemp seed products were approved. FSANZ will investigate the viability of hulled hemp seed as it continues the assessment of this Application, and encourages comments from submitters on this issue (see questions for submitters below). Hulled hemp seeds are an established product in markets where hemp foods are permitted and retain much of the beneficial nutritional profile of hemp seeds (more detail on the nutritional profile of hemp seeds is available in SD1). Hemp seed products, such as flour, oil, protein powder and milk are more obviously processed and would not contain any viable seeds. Permitting hemp seed products only would still allow a significant number of hemp food products to be sold and is likely to lessen the concern of drug enforcement agencies having to distinguish between hemp seeds and the seeds of drug varieties of cannabis.

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 may 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.

#### *6.4.1 Conclusion*

It is not possible to visually differentiate between hemp seeds and the seeds of drug varieties of cannabis. The availability of whole hemp seeds as food may impact on the ability of drug enforcement agencies to effectively enforce prohibitions on drug varieties of cannabis, particularly with respect to the possession of seeds. Ensuring that hemp seeds are non-viable when sold as food may assist these agencies. However, the seeds will still be indistinguishable upon observation and a germination test may be required. A germination test will involve additional resources and potentially inconvenience consumers who have legitimately purchased hemp seeds. An import certification scheme may assist in ensuring that whole hemp seeds are non-viable and sourced from certified low THC hemp crops; however this is outside of the considerations that FSANZ can take into account in this assessment.

Alternatively, the approval of processed hemp seed products only, including hulled seeds but excluding whole and viable hemp seeds, may reduce the impact on drug enforcement agencies while still providing food manufacturers with a variety of hemp food product options to offer consumers. FSANZ considers that the approval of hemp seed products only, in the Code, is the preferred method of approval at this stage.

**Questions for submitters:**

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

Are there other methods of rendering hemp seeds non-viable that will also result in the whole seed being distinguishable from the seeds of drug varieties of cannabis? Please provide evidence in support of these methods.

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

**6.5 Drug testing**

Concerns have also been expressed on the possibility that consumption of hemp foods may result in positive drug tests for cannabis use, based on body fluid testing (for example, urine). This is of particular relevance for workplaces that may have drug testing protocols, athletes and for roadside drug testing.

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.

FSANZ addressed the issue of drug testing as part of the assessment of 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 that were well below 15 ng/mL. The highest THC concentration found in urine was 5.2 ng/mL.

Many submitters to the Consultation Paper noted the availability of hemp foods overseas and the apparent lack of concern regarding effect on drug testing. Submitters noted that a number of elite athletes consume hemp foods and have not returned positive test results for THC. Submitters also noted that the actual levels of THC in crops and food products is likely to be lower than the levels referenced in the Leson study (Leson et al. 2001), primarily due to the existing controls on hemp cultivation and adequate cleaning of seeds during processing.

However, some concern was expressed by one Australian regulatory agency with respect to roadside drug testing that utilises a saliva swab, rather than urine or blood, to test for THC. The concern is that consumption of hemp foods may result in more positive results for this screening test, which will require confirmatory testing that will impose additional costs on enforcement agencies. FSANZ has not identified any data to assist in consideration of this issue.

FSANZ notes that the Australian Civil Aviation Safety Authority (CASA) also uses the saliva test 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<sup>4</sup>.

<sup>4</sup> [http://www.casa.gov.au/wcmswr/\\_assets/main/rules/miscinst/2009/casa263.pdf](http://www.casa.gov.au/wcmswr/_assets/main/rules/miscinst/2009/casa263.pdf)

FSANZ also notes 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 take 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<sup>5</sup>.

One submitter noted that there should be some burden of proof on testers (and manufacturers of testing equipment) to show that their tests indicate actual drug impairment rather than banning foods that may cause false positives on their tests. FSANZ is not able to comment on this issue, but notes that the consumption of cannabis is not currently legal in Australia and therefore the presence of THC in body fluids indicates illegal exposure. Any future approval of hemp foods may require further consideration of these issues outside of the food regulatory environment.

In the absence of experimental data on levels of THC in foods which may trigger positive results in saliva tests, FSANZ has conducted some preliminary calculations for the purpose of encouraging further consideration of the issue of the potential impact of hemp foods on saliva THC testing. The proposed maximum levels of THC in hemp foods are based on the FSANZ safety assessment; whereas lower levels are achievable when low THC hemp is used for food production. The proposed maximum level of THC for hemp seed oil is 10 mg/kg. Assuming the limit of detection for a saliva swab test is 5 nanograms/mL (ng/mL), the consumption of only 0.005mL of oil that contains 10 mg/kg of THC may trigger a positive result for a saliva THC screen (assumes 10 mL saliva will dilute the level of THC present in the mouth by a factor of ten and that all THC consumed remains in the mouth and enters saliva and is present at the time of testing).

However, hemp foods, including hemp seed oil, can be produced to contain levels of THC that are much lower than the proposed maximum level. Tests conducted on hemp foods in the USA in 2003 show that the majority of the hemp products tested, including hemp seed oil, contained no detectable THC. Some hemp seed oil products contained between 7 and 8 mg/kg of THC.<sup>6</sup> Assuming 1mL of hemp seed oil remains in the mouth after consumption and using the same assumptions as described above; FSANZ calculated the lowest concentration of THC that may be present in hemp seed oil that may trigger a positive result for a saliva THC screen would be 0.05 mg/mL. It should be noted that these calculations are based on an exaggerated and unlikely scenario, including assumptions that the saliva test screen detection limit is very low (5 ng/mL), all the THC present in the food enters the saliva, and all THC present at the time of consumption is still present at the time of testing (despite the likelihood that some time may have passed between consumption and testing).

Based on the information provided above, there is evidence that hemp foods can be produced to contain no THC or levels of THC well below the maximum levels proposed by FSANZ. Given this potential, FSANZ may investigate setting lower maximum levels in the Code, if lower levels would lessen the possibility of hemp food consumption interfering with saliva THC screening tests. However, before FSANZ can investigate lowering the proposed maximum levels, more information is required on the current saliva testing arrangements in place and on whether the production of hemp foods can achieve lower levels of THC content.

---

<sup>5</sup> <http://www.transport.govt.nz/legislation/acts/QAsdrugimpaireddrivinglaw/>

<sup>6</sup> Holler JM, Bosy TZ, Dunkley CS, Levine B, Past MR, Jacobs A (2008) Delta<sup>9</sup>-Tetrahydrocannabinol content of commercially available hemp products. *Journal of Analytical Toxicology* 32:428-432

### 6.5.1 Conclusion

The data that FSANZ has identified on drug testing is limited. While it does not appear likely that consumption of hemp foods will cause a positive result for workplace or athlete cannabis tests (for example, urine and blood tests), it is unknown whether saliva swab testing methodology will result in positive screening results that will require additional confirmatory testing by enforcement agencies.

FSANZ is seeking comments from submitters in relation to any additional information that may be available on the possible impact of hemp food consumption on the results of saliva swab tests for THC.

#### **Questions for submitters:**

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

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

What saliva THC tests are currently in use in Australia and New Zealand? For these tests, what levels of detection of THC are currently used? Can you provide information on the methodology of these tests and the costs of conducting these tests?

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

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

Do you have data to indicate the levels of THC in current hemp food products? Is it likely that hemp foods could be produced to comply with lower maximum levels of THC?

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

## **Issues outside the scope of food regulatory measures**

### **6.6 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 approved 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).

## **6.7 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 to the Consultation Paper with respect to whether hemp foods should be subject to the UN Conventions. Views ranged from the sale of hemp foods being inconsistent with the UN Conventions to views that the UN Conventions should not apply to hemp foods at all.

### **6.7.1 Conclusion**

This discussion on the applicability of the UN conventions is provided for information only. This assessment will not comment on the applicability of the UN conventions to the sale of hemp foods in Australia and New Zealand. This is outside the boundaries of the considerations that FSANZ is able to take into account when developing food regulatory measures.

## **6.8 Acceptance of cannabis**

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). 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 issue, and have been managed.

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.

#### 6.8.1 Conclusion

The concern that the use of hemp foods may result in consumers being more accepting of the acceptability and safety of illicit cannabis use is 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 this concern.

## 7. Options

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The benefits and costs associated with the proposed amendment to the Code have been analysed using regulatory impact principles.

The specific objective of this assessment is to investigate the benefits and costs from allowing hemp foods in Australia and New Zealand, taking into account the range of issues identified.

An assessment of the monetary value of the potential benefits and costs of food derived from hemp was part of FSANZ's consideration of a preferred food regulatory option (refer to 8.2.1 below). For an analysis of the costings refer to SD3.

Four regulatory options were identified for this Application:

- Option 1: Reject the Application, thus not approving the use of low THC foods
- Option 2A: Prepare draft variations to permit the use of low THC hemp seed oil products only as food with maximum limits in the Code
- Option 2B: Prepare draft variations to permit the use of low THC processed hemp seed products (which includes hulled seed but excludes viable hempseed) as a food with maximum limits in the Code
- Option 2C: Prepare draft variations to permit the use of low THC whole hemp seeds (non-viable) and hemp seed products as food with maximum limits in the Code.

## 8. Impact Analysis (RIS ID: 11813)

In the course of developing food regulatory measures suitable 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 food industry and governments in both countries.

This impact analysis uses benefit cost analysis to estimate the impact of regulatory change on the industry, governments and consumers. However, it is not a regulatory impact statement as the Office of Best Practice Regulation were of the view that one was not required in this instance due to the deregulatory nature of the Application.

However, for the purposes of evaluating the potential regulatory options identified above, FSANZ has obtained some monetary estimates of potential costs and benefits that may result from an approval of hemp foods. These estimates form part of the benefit cost analysis presented in section 8.2 of this Report. However, at present, these costs are indicative rather than definitive. FSANZ will further develop these costs for inclusion in the continuing assessment of this Application. The benefit cost analysis identifies and evaluates, though is not limited to, the costs and benefits of the regulation, and its health, economic and social impacts. Approval of hemp foods has the potential to impact on many sectors, namely, consumers, industry and governments.

## **8.1 Affected Parties**

The affected parties include:

- those sectors of the food industry wishing to market the food products produced from 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 and customs, that enforce illicit drug legislation.

## **8.2 Cost Benefit Analysis**

### *8.2.1 Economic Cost Benefit Analysis*

The economic analysis will attempt to measure the benefits and costs from the different regulatory options. The principal benefit to be considered is the potential growth of the hemp industry and the expected gains for businesses from this market. The principal costs to be considered are the economic burden for businesses and governments created by regulation. Other possible impacts from permitting hemp foods will also be considered to ensure an appropriately broad analysis. These include the potential health benefits of increased consumption of low THC hemp and broader industry development.

Other costs are the potential for difficulties and complications imposed on law enforcement agencies if hemp foods are approved. However, significant difficulties are anticipated in quantifying these costs and benefits and a qualitative consideration of them may be the only option.

The proposed methodological approach for estimating the market growth related benefits is to compare the Australian and New Zealand market with the Canadian hemp market with regard to hectares produced, number of licences, export value and import value. Whereas the approach for the costs of regulation imposed on industry and governments is based on the current regulatory approaches in Australia and New Zealand using activity based costing. The analysis is described in detail in SD3.

Extrapolating from the Canadian market data with regard to number of businesses and returns to the hemp industry to likely uptake in Australia and New Zealand indicates that the hemp industry may benefit significantly from introducing a broader range of hemp products. It is assumed that the number of businesses in the market will increase with the range of products permitted.

However, an Australian and New Zealand hemp market will require time to develop, approximately 7 to 10 years.

Additional costs for businesses are mainly linked to licensing requirements and testing of seeds. Testing of whole seed with regard to viability would also increase costs for businesses, but would possibly only be required in option 2C. Costs for governments increase because the number of licences to assess will increase and because methods for enforcement, other than food enforcement, might need to be revised. As for hemp fibre and hemp oil, costs of licences are partly recovered at the moment. Initial estimates would suggest that the yearly turnover and potential profits of hemp food businesses may be sufficient to offset the regulatory costs.

The benefits to industry and many of the variable costs of regulation are likely to be highly correlated. If cost recovery arrangements are in place, this will fully or partially offset the cost to governments, while at the same time increasing costs to industry.

In summary:

- Option 1 assumes no changes.
- Option 2A limits the potential market to low THC oil products. Only a modest number of new businesses will be assumed for the purpose of analysis.
- Option 2B provides an opportunity for low THC processed hemp seed products (which includes hulled hemp seeds). A moderate number of new business entrants will be assumed for the purpose of analysis.
- Option 2C permits low THC in whole hemp seeds and hemp seed products as food. Option 2C provides for the largest range of hemp food products, but costs may also increase because of stricter compliance and enforcement measures. This option may also introduce additional costs for law enforcement agencies due to the potential for confusion between viable seeds for prohibited and permitted varieties of cannabis. The largest number of new industry entrants will be assumed under this option.

**FSANZ requests the following information from submitters:**

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

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

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

*8.2.2 Consideration of benefit and costs against options*

A number of issues have been identified in relation to potential direct impacts resulting from an approval of low THC hemp foods. As noted in section 6 of this report, some of these issues are outside of the scope of what FSANZ can take into consideration in developing food regulatory measures. While FSANZ has identified the potential impacts an approval of hemp foods may have, only those impacts that FSANZ can consider in developing a food regulatory measure are outlined in detail below.

**8.2.2.1 Option 1: Reject the Application, thus not approving the use of low THC foods**

This option requires no amendment to the Code. The **benefits** of option 1 have been identified as follows:

<b>Affected party</b>	<b>Benefits</b>
Consumers	No benefits were identified.
Industry	No benefits were identified.
Government	There would be no need to amend the existing state/territory legislation for the growing of hemp crops in Australia and New Zealand which currently controls the THC level of food entering the food supply.

The **costs** of option 1 have been identified as follows:

<b>Affected party</b>	<b>Costs</b>
Consumers	Access to hemp foods in Australia and New Zealand (other than hemp seed oil in New Zealand) will continue to be denied to consumers, despite wide availability internationally. There is strong support from the Dietitians Association of Australia and individual nutritionists for the use of hempseed (and oil) for its nutritional benefits.
Industry	Food manufacturers are disadvantaged through a limited ability to innovate and access market opportunities for developing food products derived from hemp.  The hemp industry would not be able to add value to hemp crops or increase the viability of hemp crops by supplying hemp seed for food products.
Government	There is no identified cost on government or food or law enforcement agencies.

**8.2.2.2 Option 2A: Prepare draft variations to permit the use of low THC hemp seed oil products only as food with maximum THC levels specified in the Code**

The **benefits** of option 2A have been identified as follows:

<b>Affected party</b>	<b>Benefits</b>
Consumers	Would allow access to hempseed oil which may offer nutritional benefits for consumers.  Maximum levels in the Code for THC content of foods provides additional assurance for consumers that high THC products are unlikely to enter food supply.
Industry	This option offers a small benefit by allowing the sale of hempseed oil products into the food supply. Allows the Australian hemp industry to produce hempseed oil food products, similar to the New Zealand industry.
Government	Provides consistency between Australia and New Zealand with respect to sale of hempseed oil as a food and a limited removal of existing trade barrier for internationally produced hemp seed oil products.  Maximum levels of THC for hemp foods in the Code would assist in ensuring appropriate low levels of THC in imported hemp food products.  State/Territory and New Zealand jurisdictions that enforce the Code would be able to take necessary enforcement action if hemp foods exceeded the maximum levels in the Code.

The **costs** of option 2A have been identified as follows:

Affected party	Costs
Consumers	<p>This option would limit the potential hemp seed food market to oil products only, without a specific public health and safety reason.</p> <p>Similar costs to consumers as per option1 in regard to potential nutritional benefits.</p> <p>May send a confused message to consumers about the acceptability and safety of illicit cannabis. There is little evidence to support or refute this concern and it falls outside the scope of consideration of a proposed food regulatory measure.</p> <p>There is a possibility of misleading representations (including labelling and advertising) suggesting hemp foods have psychoactive properties. However, such representations would be misleading as hemp foods do not have psychoactive properties. Consumer protection legislation in Australia and New Zealand regulates misleading conduct.</p>
Industry	<p>The scope of the food market would be rather limited and the industry may not reach full market potential similar to overseas countries (e.g. EU, Canada, the USA and other countries) which currently approve the sale of hemp foods. However, a small number of businesses, probably regionally limited, may produce hemp oil for local markets and establish export markets.</p>
Government	<p>As for approvals of other new foods or ingredients in the Code, there is likely to be a cost for food enforcement agencies testing compliance of hemp foods with the requirements of the Code. However, given the nature of the risks identified, 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.</p> <p>This option may result in more licence requests from hemp growers and processors. However, hemp licensing is conducted on a cost recovery basis, so is not likely to be a large cost impact on government agencies that issue licences.</p> <p>May introduce an additional cost with respect to drug testing if consumption of hempseed oil resulted in more positive screening test results. This would create ongoing costs for confirmatory testing if there was an increase in positive screen results. However, the current controls on the level of THC permitted in hemp crops, adequate cleaning of seeds during processing and processing into hemp seed oil products only, should mitigate this risk.</p> <p>Although it is outside the scope of food regulations, legislation relating to drugs and controlled substances, including import legislation, may require consequential amendment (in addition to any amendment in the Code) before hemp foods could legally be available for human consumption. This may impose costs on regulatory agencies responsible for these areas of legislation.</p>

**8.2.2.3 Option 2B: Prepare draft variations to permit the use of low THC processed hemp seed products (which includes hulled hemp seed but excludes viable hemp seed) only as a food with maximum THC levels specified in the Code**

The **benefits** of option 2B have been identified as follows:

Affected party	Benefits
Consumers	<p>In addition to those benefits identified for option 2A:</p> <p>Consumers would have access to a greater range of hemp food products than under options 1 and 2A.</p>

<b>Affected party</b>	<b>Benefits</b>
Industry	<p>This option would provide a greater range of products (e.g. hempseed oil, protein, flour) than option 2A while ensuring that no whole hemp seeds would be in the possession of unauthorized persons. Industry is provided with more options than option 2A to develop new products from hemp.</p> <p>Provides greater opportunity for businesses to enhance profits from producing hemp products. Experience in overseas markets indicates that the ability to market hemp foods makes other aspects of the hemp industry more viable (for example, hemp fibre).</p>
Government	<p>Similar benefits to option 2A.</p> <p>Promotes more consistency between domestic and international approvals for the sale of hemp foods overseas (e.g. in the EU, Canada and USA).</p> <p>Does not give rise to a law enforcement concern regarding possession of cannabis seeds.</p>

The **costs** of option 2B have been identified as follows:

<b>Affected party</b>	<b>Costs</b>
Consumers	<p>This option would limit consumer access to hemp seed products only but would not be as restrictive as option 2A.</p> <p>The other costs to consumers are similar to option 2A.</p>
Industry	<p>Limits the availability to processed hemp seed products only and does not allow whole seeds to be legally sold as food.</p> <p>This option may incur greater costs than option 2C because of the requirement to render seeds non-viable.</p>
Government	Similar costs to option 2A.

8.2.2.4 Option 2C: Prepare draft variations to permit the use of low THC in whole hemp seeds and hemp seed products as food with maximum THC limits specified in the Code

The **benefits** of option 2C have been identified as follows:

<b>Affected party</b>	<b>Benefits</b>
Consumers	Consumers may be advantaged by access to a greater range of hemp food products than in options 2A and 2B.
Industry	This option provides the greatest potential for the hemp food industry as it allows for the sale of whole hempseeds and hence a greater range of products to be sold than options 2A or 2B. 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.
Government	Eliminates a trade barrier to importation of hemp foods from Europe, Canada and the USA or hemp oils from New Zealand. The Government would be viewed as enhancing innovation for the hemp industry.

The **costs** of option 2C have been identified as follows:

<b>Affected party</b>	<b>Costs</b>
Consumers	Similar costs to options 2A and 2B.

Affected party	Costs
Industry	No costs were identified.
Government	<p>Costs are the same as option 2B but there are likely to be additional costs for drug enforcement agencies in distinguishing between low THC hemp seeds and high THC cannabis seeds.</p> <p>May impose an additional cost on food enforcement agencies, which may need to develop new methods to test THC-containing foods or widen the scope of their enforcement activities.</p> <p>Government agencies responsible for granting licences to cultivate industrial hemp may experience an increase in demand for licence approvals if hemp seeds 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.</p>

### 8.2.3 Comparison of Options

#### 8.2.3.1 Option 1

This option limits the viability of the hemp industry in Australia and New Zealand by the continuation of the prohibition on use of hemp in food. There is also a continuation of the current inconsistency with permissions to sell hemp foods in international markets and the permission to sell hempseed oil as a food in New Zealand. This places Australia at a disadvantage in competing with other markets and creates a trade barrier without a sound public health and safety justification to keep the status quo.

In contrast, it does benefit governments by not introducing a cost of amending legislation for the growing of hemp for use in foods, enforcement costs for exceedances of any proposed maximum limits in the Code and costs of a potential increase in the number of expensive confirmatory tests needed to evaluate positive saliva roadside test results if consumption of hemp foods resulted in a positive result.

#### 8.2.3.2 Option 2A

This option provides a limited permission for hemp products and may enable the hemp food industry to grow. It limits the hemp seed food market to oilseed products only but would create a consistency in food regulation between Australia and New Zealand for the sale of hempseed oil food products.

Robust controls around production, manufacturing and importing will mean only low THC oil seed products should be present in the market which could lessen any impact on the testing of THC in humans. The proposed MLs in the Code would be an additional safeguard and testing reference point for food enforcement agencies and also offer a level of control for imported hempseed oil products (in the absence of other mechanisms to control levels in hempseed oil products).

Other costs, such as potential need to amend legislation relating to licensing, transport, processing and manufacturer of hemp seed oil food products, and a possibility of increased confirmatory tests for any positive results arising from roadside saliva testing of motorists are identified, but fall outside of the scope of food regulation.

This option does not give rise to law enforcement concerns regarding possession of cannabis seeds.

#### 8.2.3.3 Option 2B

This option would allow the sale of a broader range of hemp foods and thus provides a greater potential for market development. Hemp licensing arrangements, coupled with appropriate processing of hemp seeds and maximum levels for THC specified in the Code would provide sufficient control of THC levels in both domestically produced and imported hemp food products.

From a legal perspective the transport of seeds may need to be permitted, licensed and monitored, which might involve costs via activities such as additional licensing of processors and manufacturers, sealing and weighing freight. However, these costs are outside of the scope of food regulation.

As per option 2A, a number of these identified costs fall outside the scope of food regulation. This option does not give rise to law enforcement concerns regarding possession of cannabis seeds.

#### 8.2.3.4 Option 2C

This option provides the greatest potential for the hemp food industry as a greater range of foods could be sold. The existing hemp licensing arrangements and proposed maximum levels in the Code would be appropriate measures to mitigate the risk of high THC cannabis entering the food supply. The seed could be confused with high THC cannabis seeds, or viable seeds confused with non-viable seeds. The process of turning hemp into food derivatives destroys the viability of the majority of seeds, which further reduces the risk of any viable high THC seeds entering the food supply. However, the availability of whole hemp seeds as foods, even if they are rendered non-viable, may still require additional resources for drug enforcement agencies responsible for enforcing the illegal possession of the seeds of drug varieties of cannabis.

As per options 2A and 2B, FSANZ acknowledges that there may be costs involved in amending licensing regulations to include the growing of hemp foods, but these costs are outside of the scope of food regulation. Distinguishing hemp seeds destined for food use from all other cannabis seeds could lead to additional cost and resources with this option.

#### *8.2.4 Overall conclusion*

In options 2A to 2C the costs to businesses and consumers were expected to be outweighed by the benefits. Costs incurred by industry will be voluntary as entering the hemp food market will be a commercial decision. Costs to some sectors of government may be significant but were considered unlikely to outweigh the overall benefits.

Overall, FSANZ decided to prepare a draft variation to the Code based on **Option 2B**. This option was considered to provide the best overall balance for stakeholders with respect to the potential economic, health and social benefits and costs.

This option most clearly achieved the objectives of providing assurance of the safety of hemp food products, the provision of a nutritious food source for consumers and the facilitation of trade and international competitiveness of the food industry, while also limiting the potential additional costs for law enforcement agencies that may be associated with an approval of whole hemp seeds as food.

With this option, Government and industry education initiatives could make clear the distinction between hemp foods and illicit cannabis.

## **Communication and Consultation Strategy**

### **9. Communication**

FSANZ has communicated widely on this Application. As noted below, 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. FSANZ has issued a media release about the consultation paper and updated its hemp fact sheet on the FSANZ website. A further media release will be issued and the fact sheet updated on release of the assessment report for public comment. FSANZ will continue to notify interested parties and email alert subscribers to the availability of the Assessment Report and draft variation to the Code for public comment and will place the Report on the FSANZ website.

### **10. Consultation**

FSANZ released a consultation paper in March 2011 which sought comments on a range of issues. The responses to this paper have been used to develop this Assessment Report. Submissions are available on the FSANZ website.

FSANZ also sought comment from Canadian, US and European jurisdictions where the sale of hemp foods are permitted on their legislative and licensing controls, their experiences with drug testing in relation to the consumption of hemp foods, their views on any impacts on drug strategies and other matters. The questionnaire is attached (SD4). The responses have been used to develop this assessment report.

FSANZ is now seeking comment from the public and other interested stakeholders to assist in further considering this Application. Once the public comment period has closed there will be no further round of public comment.

Comments are sought in relation to any aspects of the Application, particularly in response to the questions for submitters included in the report. Comments are also sought on the proposed draft variation (**Attachment 1**) to the Code.

#### *10.1 World Trade Organization (WTO)*

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

A number of countries permit the sale of hemp foods and a permission to allow the sale of foods derived from hemp in Australia and New Zealand would provide a liberalization of trade opportunities.

Therefore, notification to WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements is not considered necessary.

## 11. Compliance with FSANZ's objectives

FSANZ is required by its legislation to meet the section 18(1) objectives of the FSANZ Act when it is developing or varying a food standard as noted in section 3 of this Report.

The primary objective relevant to consideration of this Application is the protection of public health and safety. However the other two objectives and other related matters have also been considered and these are addressed below.

### 11.1 *Risk to public health and safety*

FSANZ's risk assessment concluded that the consumption of foods derived from hemp would not pose any public health and safety concerns at the proposed maximum levels of THC content, as detailed in the Risk Assessment (SD1).

### 11.2 *Providing adequate information to enable informed consumer choice*

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 deemed necessary to recommend any additional information.

### 11.3 *Prevention of misleading and 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 6). FSANZ concluded that no further risk management measures are required in the Code.

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.
- 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 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. The representation of hemp foods was addressed in section 6.
- any written policy guidelines formulated by the Ministerial Council. There are no policy guidelines relevant to this application.

### 11.4 *Other matters*

In assessing the Application and the subsequent recommendation of a food regulatory measure, FSANZ has had regard to the following matters as prescribed in 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 presented in section 8 and is supported by a cost analysis (SD 3). Further information on costing is sought and the cost impact evaluation will be further developed prior to further consideration by the FSANZ Board.
- There are no other measures that would be more cost-effective than a variation to the Standard that could achieve the same end. As the sale of hemp foods is currently not permitted in the Code, a variation to it is required to permit their sale.
- Any relevant New Zealand standards. The sale of hemp oil is permitted in New Zealand and a more general permission for hemp food 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 6.6.
- Any other relevant matters. A number of other matters have been raised by submitters to the consultation paper and during 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 and cannabis seeds 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 but have not been used to reach a decision on the preferred option.

## **Conclusion**

### **12. Conclusion and Preferred Option**

#### **Preferred Approach**

**To prepare a draft variation to Standard 1.4.4 – Prohibited and Restricted Plants and Fungi to permit the use of processed hemp seed products only (including hulled hemp seed, but excluding whole and viable seeds) as a food with maximum delta 9-tetrahydrocannabinol (THC) levels.**

#### **12.1 Reasons for Preferred Approach**

A draft variation to the Code have been prepared to permit the use of processed hemp seed products as food, with maximum levels of THC, based on the following reasons:

- Hemp foods have been assessed as safe for human consumption at the recommended maximum levels of THC content.
- There are adequate controls in place to mitigate the risk of high THC cannabis products entering the food supply.

- There is no evidence of a risk of consumers being misled by representations relating to connecting hemp foods with psychoactive effects of drug varieties of cannabis.
- The approval of hemp seed products (excluding viable hemp seed) will provide industry with a greater range of potential products to market to consumers, while limiting the possibility of drug enforcement problems relating to possession of whole hemp seeds.
- The draft variations provide a net benefit to the affected parties.
- No other measures would be more effective at achieving this outcome.

### **13. Implementation and Review**

The proposed draft variation to the Code will come into effect on gazettal.

#### **ATTACHMENTS**

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Draft Explanatory Statement

**Draft 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), 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 germinate.

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

### Draft 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.

The Authority 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 prepared a draft Standard.

#### 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 draft variation is proposed to permit the sale, as a food, including as an ingredient of a food, seeds and seed products from *Cannabis sativa*. The seeds can be whole seeds or parts of seeds, and must be hulled seeds, but cannot be viable seeds. The levels of THC for seeds and seed products from *C. sativa* are as follows:

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

There is no common definition of low THC hemp and therefore it is inappropriate to use this term in a draft regulatory measure. However domestic and international legislations relating to drug control of high THC varieties of *C. sativa* and to hemp cultivation, together with the specified maximum levels for THC in food, will adequately ensure that high THC cannabis is not used for food use. Therefore the draft variation does not specify that the derivation of hemp foods can only be from low THC hemp varieties.

#### 3. Documents incorporated by reference

The variation does not incorporate any documents by reference.

#### **4. Consultation**

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1039 will include one round of public consultation following an assessment and the preparation of draft variation. A Report (which includes the draft Standard) will be released for a six-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. Variation**

##### ***5.1 Item [1]***

This item inserts an exception to Schedule 1, Prohibited Plants and Fungi to permit the addition to food or sale as food of the seeds and seed products from low THC varieties of cannabis plants. To be permitted in food, the seeds (whole or part) need to be non-viable and hulled (outer coat removed). Seeds and seed products are required to have a THC content no more than the specified maximum level.