12 December 2001
06/02

DRAFT ASSESSMENT

[FULL ASSESSMENT - S.15]

APPLICATION A360

USE OF HEMP AS A NOVEL FOOD

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter**: 6 February 2002** (See under 'Invitation for Public Submissions' for details)

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EXECUTIVE SUMMARY

An application was received on 16 July 1998 from Ecofibre Industries Association of Australia to permit the use of products from low *delta* 9-tetrahydrocannabinol (THC) *Cannabis* spp. such as hempseed and hempseed oil as food. The *Food Standards Code* currently lists *Cannabis* spp. as a prohibited botanical. There is, therefore, currently no permission to sell as food, or in food, any of the varieties of *Cannabis sativa* or any part of this species in food in Australia. In New Zealand, there are no food regulations specifically related to *Cannabis* spp.

Cannabis sativa is well known as the source of the pharmacologically-active substance, *delta* 9-tetrahydrocannabinol (THC). Hemp or industrial hemp, while a *Cannabis* species, is a low THC variety and is not considered to have any psychoactive properties. THC is produced in specialised glands found only on the leaf surface of the *Cannabis* plant. The main food source, the seed, while containing no THC, is wrapped in specialised leaves called the calyx that do produce THC and cause some contamination of the outside of the seed coat.

The rationale for seeking to market hemp foods in Australia and New Zealand is largely based on the favourable nutrient profile of hempseed/hempseed oil. Hempseeds are an excellent source of unsaturated fatty acids and an additional source of essential fatty acids. The foods currently being made internationally with hempseed and hempseed oil include health bars, salad oils, non-soy tofu, non-dairy cheeses, non-dairy milks, additives to breads, biscuits and cakes, butter pastes, as well as whole seed, raw or roasted.

THC is associated with effects on the central nervous system, the immune system, reproduction, and post-natal development, as well as with psychotropic effects. In relation to the latter, the studies available indicate the more sensitive individuals require a minimum oral dose of 10 mg THC per person and most individuals require an oral dose of 15-20 mg per person in order to experience an effect. Thus, the lowest psychotropic effect level is in the order of 140 µg/kg bw (body weight).

The most sensitive effects observed in humans seem to be related to skill performance (standing steadiness, hand-eye coordination, reaction time, numbers test) following oral administration. In a study involving young adults, slight but reversible effects were seen at the lowest dose level of 5 mg/person (equivalent to 60 µg/kg bw in this study). There were no psychotropic effects observed at this dose level. In order to take account of the possible variability in response in the human population, an uncertainty factor of 10 was applied to this lowest-observable-effect level (LOEL) in order to derive an overall tolerable daily intake (TDI). Thus, the overall tolerable daily intake for the human population is 6 µg/kg bw.

The safety assessment report concludes that, on the basis of the data available, there is no evidence of adverse health effects in humans at low levels of THC exposure and a tolerable daily intake of 6 µg/kg bw can be established. If the products from low THC hemp plants are used as food, the level of THC in the final products should be such that the dietary intake of THC is no greater than 6 µg/kg bw.

Proposed MLs for various commodities containing hemp were derived by estimating a maximum concentration of THC in the commodity that would not result in consumers exceeding the tolerable daily intake for THC. On this basis, a maximum permitted level of 10 mg/kg is proposed for hempseed oil, 5 mg/kg for hempseed, 0.2 mg/kg for hemp-based beverages and 0.2 mg/kg for other hemp-containing foods.

It is proposed that hemp products be regulated under the recently finalised Novel Food Standard, Standard A19 in Volume 1 and Standard 1.5.1 in Volume 2. Products derived from *Cannabis* spp. are non-traditional foods in Australia and New Zealand because they do not have a history of significant human consumption by the broad community. They are also novel foods for the purpose of the Standard because there is insufficient knowledge in the broad community to enable safe use. Maximum levels of THC would be established in Standard A12 – Metals and Contaminants in Food - in Volume 1 of the *Food Standards Code* and in Standard 1.4.1 – Contaminants and Natural Toxicants – in Volume 2 of the *Food Standards Code*. In order to address the potential for misrepresentation of hemp-based foods as having an association with illicit drug use, a specific condition of use is proposed under the Novel Food Standard to prevent labelling and advertising of hemp-based foods in this way.

Cannabis spp. are also regulated under a range of State, Territory, Commonwealth and New Zealand legislation not related specifically to food. The proposed change to the food legislation will not alter the status of hemp products under other legislation. Other legislative changes may be required to allow the sale of hemp-based foods in all jurisdictions. The Ministerial Council on Drug Strategy is supportive of a coordinated national approach to the control of products derived from *Cannabis* spp. , including removal of the current total prohibition on the use of Cannabis spp. in food and its replacement with maximum permitted levels of THC in certain food products.

The conclusions of the Draft Assessment are:

- There are no public health and safety concerns associated with the use of food products containing derivatives of low-THC hemp, provided there is compliance with the proposed maximum levels for THC.

- Hemp products can provide an additional dietary source of essential fatty acids.

- Foods containing derivatives of low-THC hemp do not produce any psychotropic effects.

- The proposed change to the food legislation is consistent with the section 10 objectives of the *Australia New Zealand Food Authority Act 1991*.

- For the preferred regulatory option, namely, remove the prohibition on the use of *Cannabis* spp. in food and establish maximum levels for THC in food, the benefits of the proposed amendment outweigh the costs.

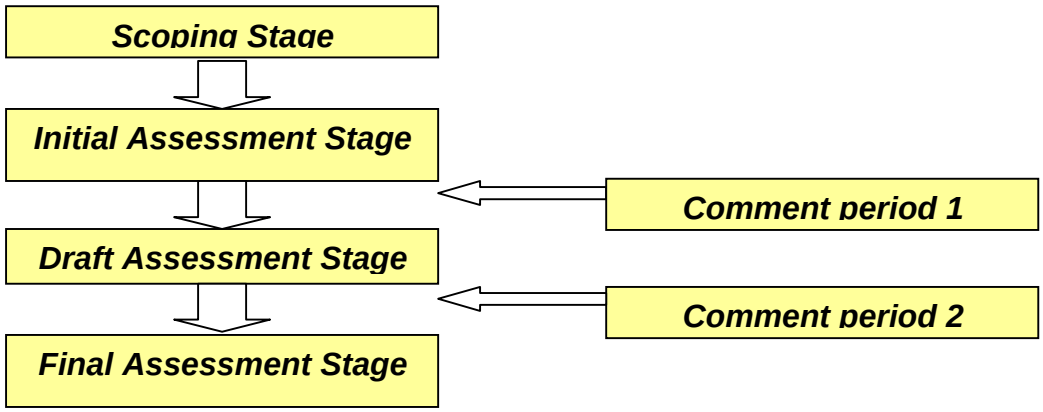
INVITATION FOR PUBLIC SUBMISSIONS

The process for amending the *Australia New Zealand Food Standards Code* (the Code) is prescribed in the ANZFA Act 1991. Open and transparent consultation with interested parties is a key element in the process involved in amending or varying the Code.

Any individual or organization may make an 'application' to the Australia New Zealand Food Authority (the Authority) seeking to change the Code. The Authority itself, may also seek to change the Code by raising a 'proposal'. In the case of both applications and proposals there are usually two opportunities for interested parties to comment on proposed changes to the Code during the assessment process. This process varies for matters that are urgent or minor in nature.

Following the initial assessment of an application or proposal the Authority may decide to accept the matter and seek the views of interested parties. If accepted, the Authority then undertakes a draft assessment including, preparing a draft standard or draft variation to a standard (and supporting draft regulatory impact statement). If a draft standard or draft variation is prepared, it is then circulated to interested parties, including those from whom submissions were received, with a further invitation to make written submissions on the draft. Any such submissions will then be taken into consideration during the final assessment, which the Authority will hold to consider the draft standard or draft variation to a standard.

Comment opportunities in the usual assessment process
to change the Australia New Zealand Food Standards Code
(Note: this process may vary for matters that are urgent or minor)



Content of Submissions
Written submissions containing technical or other relevant information which will assist ANZFA in undertaking an assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organizations. 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 presented should be in sufficient detail to allow independent scientific assessment.

Submissions may provide more general comment and opinion on the issue although those framing their submissions should bear in mind ANZFA's regulatory role specifically relates to food supplied for human consumption in Australia and New Zealand. The ANZFA Act 1991

sets out the objectives of the Authority in developing food regulatory measures and variations of food regulatory measures as:

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

In developing food regulatory measures and variations of food regulatory measures
The Authority must also have regard to the following:

(a) the need for standards to be based on risk analysis using the best available scientific evidence;
(b) the promotion consistency between domestic and international food standards;
(c) the desirability of an efficient and internationally competitive food industry;
(d) the promotion of fair trading in food.

Submissions addressing the issues in the context of the objectives of the Authority as set out in the *ANZFA Act 1991* will be more effective in supporting their case.
Written submissions containing technical or other relevant information which will assist the Authority in undertaking a final assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.

Submissions providing more general comment and opinion are also invited. The Authority's policy on the management of submissions is available from the Standards Liaison Officer upon request.

Following its draft assessment of the application the Authority may prepare a draft standard or draft variation to a standard (and supporting draft regulatory impact statement), or decide to reject the application/proposal. If a draft standard or draft variation is prepared, it is then circulated to interested parties, including those from whom submissions were received, with a further invitation to make written submissions on the draft. Any such submissions will then be taken into consideration during the inquiry, which the Authority will hold to consider the draft standard or draft variation to a standard.

Transparency
The processes of ANZFA are open to public scrutiny, and any submissions will ordinarily be placed on the public register of ANZFA and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to ANZFA, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires ANZFA 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 reasonable be expected to be destroyed or diminished by disclosure.

Contact details for submitters are recorded so that the Authority can continue to keep them informed about progress of the application or proposal.

Deadlines
The deadlines for submissions are clearly indicated in the advertisements calling for comment and in the relevant Assessment Reports. While the Authority often provides comment periods of around 6 weeks, the periods allowed for comment may vary and may be limited to ensure critical deadlines for projects can be met. Unless the Project Manager has given specific consent for an extension, the Authority cannot guarantee that submissions received after the published closing date will be considered.

Delivery of Submissions
Submissions must be made in writing and should be clearly marked with the word 'Submission' and quote the correct project number and title. Submissions may be sent by mail, fax or email to one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2258
Fax (02) 6271 2278
email: slo@anzfa.gov.au

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
Fax (04) 473 9855
email: anzfa.nz@anzfa.gov.au

Submissions should be received by the Authority by: 6 FEBRUARY 2002

Submissions may also be sent electronically through the submission form on the ANZFA website www.anzfa.gov.au. Electronic submissions should also include the full contact details of the person making the submission on the main body of the submission so that the contact details are not separated.

Further Information
Further information on this and other matters should be addressed to the Standards Liaison Officer at the Australia New Zealand Food Authority at one of the above addresses.

Assessment reports are available for viewing and downloading from the ANZFA website or alternatively paper copies of reports can be requested from the Authorities Information Officer at info@anzfa.gov.au.

INTRODUCTION

The Australia New Zealand Food Authority (ANZFA) is a bi-national statutory body responsible for developing draft food standards and draft variations of standards, to make recommendations to the Australia New Zealand Food Standards Council (ANZFSC) in relation to those drafts, and to review standards. ANZFSC may then decide to adopt the draft standards or draft variations of standards, which results in their incorporation into food laws of the Australian States and Territories, and New Zealand.

On 24 November 2000, ANZFSC adopted the *Australia New Zealand Food Standards Code* (known as Volume 2 of the *Food Standards Code*) that apply in both Australia and New

Zealand. A two-year transitional period has been implemented at the conclusion of which Volume 2 of the *Food Standards Code* will be the sole Code for both countries. In the interim, for the majority of the food standards, there are two standards operating in Australia and three in New Zealand (including the New Zealand Food Regulations).

Application to ANZFA

An application was received on 16 July 1998 from Ecofibre Industries Association of Australia to amend the Food Standards Code to permit the use of products from low-THC *Cannabis* spp., such as hempseed and hempseed oil, as food. The term 'hemp' or 'industrial hemp' generally refers to a low *delta* 9-tetrahydrocannabinol (THC) variety of *Cannabis sativa*. Hemp-based foods are widely used in other Western countries and include health bars, salad oils, non-soy tofu, non-dairy cheeses, non-dairy milks, additives to breads, biscuits and cakes, butter pastes, as well as whole seed raw or roasted.

Hemp as a novel food

Since the Initial Assessment (previously known as the Preliminary Assessment) of this application, the Novel Food Standard has come into effect (16 June 2001). While this application was previously being considered in terms of an amendment to Standard A12/Standard 1.4.1 and Standard 1.4.4, it is appropriate now to also consider it in the context of Standard A19/Standard 1.5.1 – Novel Foods. Food products derived from *Cannabis* spp. are non-traditional foods in Australia and New Zealand because they do not have a history of significant human consumption by the broad community. They are also novel foods for the purposes of the Standard because there is insufficient knowledge in the broad community to enable safe use of these foods in the form or context in which they are to be presented. There are known adverse effects associated with the use of *Cannabis* spp. in other countries. Consideration of hemp and products derived from hemp as novel foods will not affect the progress of this application.

Novel Food Standard

Standard A19 – Novel Foods – was gazetted on 16 December 1999 and came into effect on 16 June 2001 following an 18-month implementation period. The Novel Food Standard is incorporated in both Volume 1 (as Standard A19) and Volume 2 (as Standard 1.5.1) of the *Food Standards Code*. Standard A19 and Standard 1.5.1 prohibit a novel food being sold by way of retail sale as food, or for use as a food ingredient, unless it is listed in the Table to clause 2 of the Standard, and complies with any special conditions specified in that Table. This Draft Assessment Report includes proposed draft variations for both Volume 1 and Volume 2 of the *Food Standards Code*.

The purpose of Standard A19 and Standard 1.5.1 is to ensure that non-traditional foods that have features or characteristics that may raise safety concerns will undergo a risk-based safety assessment before they are offered for retail for consumption in Australia or New Zealand. Because the Standards have a definition of a novel food that is based on the level of knowledge about the safe use of a food in the community, a preliminary assessment of this level of knowledge for a particular non-traditional food is needed in order to assess whether an application to amend the Standards is necessary. The Standards provide some assistance in this regard by indicating the factors to be taken into account in this decision-making process. Guidelines for assessing the novelty of a non-traditional food are provided in the ANZFA

document *Guidelines for amending the Food Standards Code: Standard A19/Standard 1.5.1 – Novel Foods.*

PROBLEM

Plants belonging to the genus *Cannabis* are currently listed as prohibited species in Standard A12/Standard 1.4.4 of the Food Standards Code. These plants, or any part or derivative of these plants, therefore, cannot be added to food or offered for sale as food. While the term 'hemp' or 'industrial hemp' generally refers to a low *delta* 9-tetrahydrocannabinol (THC) variety of *Cannabis sativa*, the legislation makes no distinction between low- and high-THC Cannabis varieties. There are no specific food regulations that control the use of *Cannabis* spp. or any part or derivative of this plant in New Zealand.

In New Zealand and in most States and Territories of Australia, there is also other legislation relating to the misuse of drugs that prevents possession of *Cannabis* spp. and may also prevent the sale of low-THC hemp foods. This is an unforeseen consequence of legislation designed to control the use of hallucinogenic high-THC *Cannabis* spp.

In recent years, there has been considerable interest in the potential use of hempseed and hempseed oil in food products in Australia and New Zealand. Hempseed and hempseed oil are considered to have nutritional benefits and are widely available in other Western countries.

OBJECTIVE

The applicant is seeking to change the food regulations to permit the use of products from low-THC *Cannabis* spp. such as hempseed and hempseed oil as food. The objective of this application, therefore, is to determine whether this can be achieved through an amendment to the current prohibition on the use of *Cannabis* spp. Such an amendment to the *Food Standards Code* will need to be consistent with the section 10 objectives of the *Australia New Zealand Food Authority Act* (1991) as current at the time the application was made to ANZFA.

The objectives (in descending priority order) of the Authority in developing standards and variations to standards at the time the application was made to ANZFA were:

(a) the protection of public health and safety; and
(b) the provision of adequate information relating to food to enable consumers to make informed choices and to prevent fraud and deception;
(c) the promotion of fair trading in food;
(d) the promotion of trade and commerce in the food industry;
(e) the promotion of consistency between domestic and international food standards where these are at variance.

OPTIONS

In the Initial Assessment, five potential regulatory options were provided to achieve the objective above. These are considered below:

Option 1: Retain the *status quo*, i.e. retain the prohibition on the use of *Cannabis* spp. in food.

This option, while not inconsistent with the primary section 10 objectives, would not promote the trade and commerce in the food industry, and could be considered contrary to the obligations of Australia and New Zealand under the World Trade Organisation agreements. This option would also disadvantage consumers by limiting the range of products providing a source of essential fatty acids.

Option 2: Remove the prohibition on the use of *Cannabis* spp. in food.

This option would be inconsistent with the first of the section 10 objectives, namely, the protection of public health and safety, as it would enable the use of both high- and low-THC *Cannabis sativa* varieties (or parts or derivative thereof) in food. The use of high-THC *Cannabis* spp. in food would allow the dietary exposure to THC to exceed the tolerable daily intake of 6 μg/kg/day. This option would be inconsistent with Australian and New Zealand government policy in relation to public health.

Option 3: Amend the prohibition on the use of *Cannabis* spp. in food to exclude hempseed and hempseed oil.

This option would be inconsistent with the first of the section 10 objectives, namely, the protection of public health and safety, as it would enable the use in food of hempseed and hempseed oil derived from both high- and low-THC *Cannabis sativa* varieties (or parts or derivative thereof). The use of hempseed or hempseed oil derived from high-THC *Cannabis* spp. would allow the dietary exposure to THC to exceed the tolerable daily intake of 6 μg/kg/day. This option would be inconsistent with government policy in relation to public health.

Option 4: Amend the current prohibition on the use of *Cannabis* spp. in food to specify a maximum level of THC in the *Cannabis* plant.

This option, while in principle consistent with the section 10 objectives, may have enforcement difficulties since manufacturers would need to demonstrate that only low-THC *Cannabis* plants were used. This may require an audit trail to ensure compliance as there would be no maximum THC level specified in the final food. This option would create enforcement difficulties for government.

Option 5: Remove the prohibition on the use of *Cannabis* spp. in food and establish maximum levels for THC in food.

This option is consistent with the section 10 objectives since it would require manufacturers to comply with the maximum levels for THC in food, which would protect public health and safety. Enforcement would be ensured by analysis of the THC levels in food. This option has benefits for industry, consumers and government.

This is the recommended option to meet the objective of this application.

IMPACT ANALYSIS

ANZFA has considered the impact of the various regulatory options on all sectors of the community, including consumers, the food industry and government in both Australia and New Zealand. For the preferred option, namely, the removal of the prohibition on the use of *Cannabis* spp. in food and establishment of maximum levels for THC in food, the benefits of the proposed amendment outweigh the costs. Other legislative controls on the use and possession of *Cannabis* spp. under State, Territory and New Zealand misuse of drugs acts will need to be considered by these jurisdictions. In Australia, this could be coordinated through the Ministerial Council on Drug Strategy (see below).

CONSULTATION

Public consultation

The Authority conducted an Initial Assessment (previously known as the Preliminary Assessment) of this application in December 1998 and public comments were called for on 13 January 1999. Fourteen submissions were received and the points made in these submissions are summarised in **Attachment 7**. The matters raised in these submissions together with other matters relevant to this application are addressed below under 'Issues addressed during Assessment'.

Consultation with Departments of Attorneys-General

Cannabis spp. are also regulated under a range of State, Territory, Commonwealth and New Zealand legislation not related specifically to food. In order to seek clarification of the legal status of hemp-based foods under the various Misuse of Drugs Acts, ANZFA wrote to the State, Territory and New Zealand Attorneys-General in September 1998. In Queensland, New South Wales, South Australia, Australian Capital Territory, Western Australia, Tasmania and New Zealand, there is other legislation related to misuse of drugs that may also prevent the sale of low-THC hemp foods. This legislation is directed to the control of high THC-containing *Cannabis* plants but there are no exclusions for low-THC plant varieties except in Victoria and the Northern Territory. In Victoria, food products prepared from Cannabis seeds that do not contain more than 10 mg/kg THC or whole seeds are exempt from the provisions of the Act.

Consultation with Australia New Zealand Food Standards Council and the Ministerial Council on Drug Strategy

The ANZFA Board initially considered the Draft Assessment for this application in February 2000. The Board, however, deferred making a decision on the application and sought further information from the applicant in relation to the levels of THC in hemp-based foods on the market overseas and also in relation to the legal status of hemp-based foods under other legislation. Following discussions with senior food policy officers from the State, Territory and New Zealand governments, ANZFA sought advice from the Australia New Zealand Food Standards Council (ANZFSC) in July 2000 on the appropriate course of action to progress this application. The concerns raised by ANZFA were in relation to the differing legislative controls between different jurisdictions on *Cannabis* spp. It was agreed by the Council that this matter should be referred to the Ministerial Council on Drug Strategy (MCDS) in order to seek a coordinated approach to the control of products derived from *Cannabis* species.

In the response received in April 2001, the MCDS indicated that most Ministers were supportive of adopting a coordinated national approach, including removal of the current total restriction on the use of *Cannabis* spp. in food and its replacement with a permitted maximum level of THC in certain food products. The MCDS also suggested that the matter be referred to the Standing Committee of Attorneys-General (SCAG). However, SCAG officers considered that the matters raised by Application A360 were primarily matters for the MCDS and ANZFA to determine, although they accepted that if legal matters were raised during consideration of the application, then referral to SCAG was appropriate.

It should be noted that Application A360 only relates to changes to the *Food Standards Code*. The outcome of this Application will not, in itself, make any change to the provision in other regulatory arrangements, obligations and prohibitions relating to *Cannabis* spp. and Cannabis-derived products.

Notification to the World Trade Organization

Australia and New Zealand are members of the World Trade Organization (WTO) and are signatories to the agreements on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and on Technical Barriers to Trade (TBT Agreement). In some circumstances, Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comments.

This application will be notified to the WTO because permission to use hemp-based foods could lead to a liberalising effect on trade. There are no international standards in relation to the use of hemp products as foods.

ISSUES ADDRESSED DURING ASSESSMENT

Cannabis varieties and THC

Cannabis sativa is well known as the source of the pharmacologically active substance, *delta* 9-tetrahydrocannabinol (THC). Hemp or industrial hemp, while a *Cannabis* species, is a low THC variety and is not considered to have any psychoactive properties.

Industrial hemp (low-THC *Cannabis*) is grown in various parts of Australia under State government licence. In Victoria, hemp plants grown must not exceed 0.35% dry weight THC. The fibre from this hemp is used for the production of textiles. The level of THC in industrial hemp varies from 0.3 to 0.5% while the THC level in *Cannabis* used as a drug varies from 3-15%. The major hemp growing countries are China, United Kingdom, France, Holland, Hungary and Russia.

THC is produced in specialised glands found only on the leaf surface of the *Cannabis* plant. No such glands are produced on or in the seed. The seed, however, is wrapped in specialised leaves called the calyx that do produce THC and can cause some contamination of the outside of the seed coat. Removal of leaf matter can reduce THC contamination but low levels persist in commercial seed preparations. Seeds are cold-pressed to extract the hempseed oil and much of the THC on the seed surface is likely to be transferred to the oil because of the high solubility of THC in oil.

Use of hemp-derived products in foods

The foods currently being made internationally with hempseed and hempseed oil include health bars, salad oils, non-soy tofu, non-dairy cheeses, non-dairy milks, additives to breads, biscuits and cakes, butter pastes, as well as whole seed raw or roasted.

A detailed food technology report is provided at **Attachment 3**.

Nutritional aspects of hemp-based foods

Hempseed and hempseed oil have been identified as an alternative to both linseed and soybean products because of their favourable nutrient profile, particularly the essential fatty acid content. Furthermore, availability of hemp products may assist individuals with allergies to soy-based products to obtain dietary sources of polyunsaturated fatty acids. There have also been claims that overseas consumers find hemp to be more palatable than either linseed or soybean products.

Permitting the use of hemp in food products provides another alternative for individuals to heed dietary recommendations to increase their intake of unsaturated fatty acids and consume a more appropriate omega 6:omega 3 polyunsaturated fatty acid ratio through a food product rather than a supplement. Additional benefits are also obtained by consuming other nutrients such as vitamins, minerals, fibre, protein, which are present in food and not ordinarily provided by a supplement.

A detailed report on the nutritional aspects of hemp-based foods is provided at **Attachment 4**.

Safety of *delta* 9-tetrahydrocannabinol (THC)

THC is associated with effects on the central nervous system, the immune system, reproduction, and post-natal development, as well as with psychotropic effects. The bulk of the data on the toxicity of THC is derived from inhalation of cannabis, rather than consumption of THC as a component of food. However, there is adequate data to assess the toxicity of THC following oral administration.

The parameters most sensitive to orally administered THC in studies in experimental animals appear to be changes to the endocrine hormones, however, the effects are transitory and not always dose-related. In oral studies in humans, either no effect or only transitory effects were observed on these parameters at the same dose levels. The effects observed in animals were not considered significant to the human health assessment.

In relation to potential psychotropic effects in humans, the studies available indicate the more sensitive individuals require a minimum oral dose of 10 mg THC per person and most individuals require an oral dose of 15-20 mg per person in order to experience a psychotropic effect. Thus, the lowest psychotropic effect level is in the order of 140 μg/kg.

The most sensitive effects observed in humans, however, seem to be related to skill performance (standing steadiness, hand-eye coordination, reaction time, numbers test) following oral administration. On the basis of the data available, it was not possible to establish a level at which no effects were observed, however, in a study involving young adults, the

lowest-observed-effect level (LOEL) was 5 mg/person, equivalent to a dose level of 60 μg/kg bw in this study. There were no psychotropic effects observed at this dose level.

In order to take account of the possible variability in response in the human population, an uncertainty factor of 10 was applied to the LOEL from this study in order to derive an overall tolerable daily intake for the human population. Thus, an estimate of the overall tolerable daily intake for the human population is 6 μg/kg bw

It is evident that there is considerable individual variation in relation to the potential effects of THC and the report concludes that on the basis of the data available, there is insufficient evidence of adverse health effects in humans to restrict the use of the products of low THC hemp plants in food, provided the level of THC in the final products does not lead to dietary intakes greater than 6 μg/kg bw.

A detailed report on the safety of *delta* 9-tetrahydrocannabinol (THC) is provided at **Attachment 5.**

Levels of THC in hempseed and hempseed oil

The level of THC in *Cannabis* plants can vary and is dependent on a number of factors, the most important of which is the plant variety. Other factors include the growing conditions, the time of harvest, the storage conditions and the seed cleaning method.

There are four major cannabinoids normally found in *Cannabis* varieties, namely, cannabidiol (CBD), *delta*-8-tetrahydrocannabinol (*delta*-8-THC), *delta*-9-tetrahydrocannabinol (*delta*-9-THC) and cannabinol (CBN). Plants are generally either drug-producing (THC-rich) or fibre-producing plants (CBD-rich).

For the non-drug type plants, the CBD:THC ratio is of the order of 10:1 to 30:1. The cannabinoid content of the *Cannabis* plant is greatest in the flowers, followed by the leaves, petioles, stems, seeds and roots. A recent report indicated that THC could not be detected inside the seed but may be attached to the shell of the fruit. Rigorous cleaning methods, including washing, sieving and shelling can remove plant debris and resin and reduce the THC contamination.

The concentration of THC in hempseed and hempseed oils reported in the literature vary widely. In seeds, the levels varied from 2 to 66 ppm, while in oils the levels varied from 10 to 1500 ppm and will depend on the level of leaf contamination.

In fresh *Cannabis* plant material, most of the cannabinoids are present in their acid form (THCA), which is the pharmacologically inactive form. The acids, however, readily decarboxylate to form the corresponding cannabinoid on storage, in light or on heating. The smoking of *Cannabis* leaves converts the THCA to THC, with the optimum temperature for conversion at 200-210^{o}C. At room temperature, there is still slow conversion of THCA to THC. Thus, THCA contained in fresh hemp products would be converted to THC during baking and food processing or gradually during storage. THC, itself, is also unstable and is degraded by light, heat, acids and oxygen, and prolonged storage would result in a decrease in total THC content.

The THC content of hemp ingredients, therefore, may be quite variable since it will depend on storage conditions, degree of processing, and the age of the product. The analysis of cannabinoids by gas chromatography, because it is conducted at 250^{o}C, will measure total THC/THCA.

Sampling programme and methods of analysis

THC analyses are generally performed using gas chromatography/mass spectrometry. The Food Standards Code is generally not considered to be an appropriate reference for sampling plans and methods of analysis since these change regularly and enforcement agencies need to be able to adapt to changing circumstances. While consistency is important in testing methods, this may be better achieved through co-operation between enforcement agencies.

Reversion of low-THC varieties of hemp to high-THC varieties

Wild type *Cannabis* is naturally low in THC and does not generally revert to a high THC variety. High THC varieties have been selected specifically for their THC content and the normal selection pressures are more likely to cause reversion to the low THC wild type variety. The low-THC varieties grown in Australia, therefore, are not likely to change in relation to the THC content.

Establishing maximum levels (MLs) for THC in foods

The proposed MLs for THC in various food commodities were derived by determining the maximum level of THC in each individual food such that consumption of that food alone at the 95th percentile level would not exceed the tolerable daily intake (TDI). The highest 95th percentile consumption figure for an individual food in each commodity group was used. Proposed MLs have been derived from the worst case scenario, usually from the maximum concentration for children aged 2-12 years old, by use of the convention of rounding down to the nearest 1, 2, 5 or 10 mg/kg figure. These calculations assume that the entire commodity contains THC and that it is the only product consumed. An exception was made for wheat flour, where it was considered unrealistic to assume 100% of the commodity would contain hemp; therefore 10% of the 95th percentile consumption of wheat flour was used. Using these calculations, the proposed ML for hemp oil is 10 mg/kg. The proposed ML for hemp seed alone, based on these calculations, is 20 mg/kg although the ML for hemp flour is only 8 mg/kg, therefore, as hemp flour is a product of hemp seed, the proposed ML for hemp seed and hemp flour is rounded down to 5 mg/kg.

For hemp-based non-dairy milk, the ML was calculated to be 0.1 mg/kg, but it was concluded that 0.2 mg/kg would be appropriate because it is very unlikely that hemp based beverages would replace all mammalian milk consumption. In other countries, hemp based beverages are sold in 125 ml containers and it is therefore unlikely that it would be consumed in the large quantities (1.4-1.6L) that have been reported in the 1995 NNS for milk. There is very limited data available on the actual levels of THC in commercial food products, but on the basis of the data available, the proposed levels should be achievable.

Dietary exposure estimation based on proposed MLs

The proposed MLs based on a 95th percentile level of exposure to individual foods were used in the dietary exposure assessment in order to ensure that consumption of food containing THC at the ML would not lead to a total dietary exposure of THC which was greater than the

TDI. The dietary exposures assessment confirmed that potential dietary exposures to THC when consumed as part of a normal diet are below the TDI of 6 μg/kg bw/day for all age groups. The exposures obtained are likely to be an overestimate because THC levels were assumed to be at the proposed ML and it is unlikely that the proportion of foods containing hemp would be as high as that assumed (3% for milk and 10% for all other foods).

A detailed report on the estimated dietary exposure is provided at **Attachment 6.**

Labelling and advertising of hemp-based foods

The association of hemp and THC with illicit drug use has raised concerns in relation to the potential for the misrepresentation of hemp-based foods in labelling and advertising. There has been some evidence of such misrepresentation in relation to hemp-filtered beer products. In order to address these concerns, it is proposed to apply a condition of use to the permission under the Novel Food Standard such that misrepresentation of hemp-based food in this way would not be permitted.

International and other national regulations

Codex
Codex does not have specific regulations for hempseed foods or for the maximum levels of THC in food.

European Union (EU)
In the EU, hemp certified to contain less than 0.3% THC is permitted to be grown. In December 1997, the EC directed that low-THC hemp be not considered a 'novel food' under the Novel Food legislation. There are no maximum permitted levels for THC in food in the EU regulations.

Switzerland
In Switzerland, there are specific levels for THC in a variety of foods, including hempseed oil (50 mg/kg) and hempseed (20 mg/kg), baking and durable bakeware (5 mg/kg), pasta (5 mg/kg), spirits (2 mg/kg), vegetable (2 mg/kg), alcoholic and non-alcoholic beverages (0.2 mg/kg), herbal teas (0.2 mg/kg).

USA
Producers of hempseed and hempseed oil based foods are required to obtain a 'generally recognised as safe' (GRAS) notification.
Recent action by the US Drug Enforcement Agency (9 October 2001) has placed the *Cannabis* plant and tetrahydrocannabinols into Schedule 1 of the Schedule of controlled substances. The effect of this interim rule are still being debated but may effectively make illegal hemp seed or oil containing any amount of THC.

Canada
Hempseed products that contain THC at a level of less than 10 mg/kg are exempt from the *Controlled Drugs and Substances Act*.

Controls on the import of hemp products

The *Customs (Prohibited Imports) Regulations* require that a licence or permission must be obtained before a Schedule 4 substance (a drug) can be imported – this includes the *Cannabis*

plant and part of the *Cannabis* plant, including hempseed oil. A recent review of the regulations has recommended that certain lower risk products containing hempseed oil should be exempted from import controls, such as shampoos, soaps and cosmetics for purposes other than internal human use, where the concentrations of THC does not exceed 50 mg/kg. This change is expected to be in place by the end of 2001. Pure hempseed oil will continue to require a licence or permission for importation.

RISK ANALYSIS

The toxicological review conducted on *delta* 9-tetrahydrocannabinol (THC) has established a tolerable daily intake (TDI) of 6 μg/kg bw based on the most sensitive effect seen in humans, namely, negative effects on skills performance (standing steadiness, hand-eye coordination, reaction time, numbers test) at 5 mg/person (equivalent to 60 μg/kg bw). An uncertainty factor of 10 has been applied to this figure to take into account possible variation in the human population. There is no evidence of psychotropic effects at this dose level.

On the basis of this TDI, maximum allowable levels of THC have been proposed for hempseeds, hempseed oil, hemp-based non-dairy milk and for foods prepared from hemp flowers and leaf on the basis of the expected intake of a high consumer. Consumption of foods containing THC at these levels will not lead to intakes above the proposed tolerable daily intake. On the basis of this data, products derived from low-THC hemp plants may be used in foods provided the level of THC does not exceed the proposed maximum levels.

In order to address the potential for misrepresentation of hemp-based foods as having an association with illicit drug use, a specific condition of use is proposed in the Novel Food Standard to prevent labelling and advertising of hemp-based foods in this way.

CONCLUSIONS

- There are no public health and safety concerns associated with the use of food products containing derivatives of low-THC hemp, provided there is compliance with the proposed maximum levels for THC.
- Hemp products can provide an additional dietary source of essential fatty acids.
- Foods containing derivatives of low-THC hemp do not produce any psychotropic effects.
- The proposed change to the food legislation is consistent with the section 10 objectives of the *Australia New Zealand Food Authority Act 1991*.
- For the preferred regulatory option, namely, remove the prohibition on the use of *Cannabis* spp. in food and establish maximum levels for THC in food; the benefits of the proposed amendment outweigh the costs.

FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. On 24 November 2000,

Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt the new *Australian New Zealand Food Standards Code*. The new Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries. It aims to reduce the prescription of existing food regulations in both countries and lead to greater industry innovation, competition and trade.

Until the joint *Australia New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as the joint *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984*, but not a combination thereof. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *(Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999.*

- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as the joint *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code*, but not a combination of the two.

- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code* as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand *Food Regulations 1984.*

- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code*, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the New Zealand *Food Regulations 1984.*

- **Food manufactured in Australia and sold in Australia** must comply with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the Australian *Food Standards Code* but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand *Food Regulations 1984.*

In addition to the above, all food sold in New Zealand must comply with the New Zealand *Fair Trading Act 1986* and all food sold in Australia must comply with the Australian *Trade Practices Act 1974*, and the respective Australian State and Territory *Fair Trading Acts.*

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the Australian *Food Standards Code* or

to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

ATTACHMENTS

1. Draft variation to the *Food Standards Code*
2. Draft Statement of Reasons
3. Food Technology Report
4. Nutrition Report
5. Safety Assessment Report
6. Dietary Exposure Report
7. Summary of public comments

ATTACHMENT 1

DRAFT VARIATION TO THE *FOOD STANDARDS CODE*

APPLICATION A360 - USE OF HEMP PRODUCTS AS FOOD

To commence: On gazettal

The Food Standards Code is varied by –

[1] *omitting from column 1 and column 2 of the Table to Clause 8 in Standard A12 in Volume 1, respectively –*

Cannabis spp.* Hemp, Marihuana;

[2] *inserting immediately following paragraph (8)(b) in Standard A12 in Volume 1 –*

(c) Subject to paragraph (8)(d), beverages prepared from the seed of the *Cannabis* spp. may contain not more than 0.2 mg/kg *delta* 9-tetrahydrocannabinol.

(d) Subject to paragraph (8)(e), seed of the *Cannabis* spp. or any substance derived therefrom, may contain not more than 5 mg/kg *delta* 9-tetrahydrocannabinol.

(e) Oil extracted from the seed of *Cannabis* spp. may contain not more than 10 mg/kg *delta* 9-tetrahydrocannabinol.

(f) C*annabis* spp., other than seed or oil extracted from the seed, or any substance derived therefrom, may contain not more than 0.2 mg/kg *delta* 9-tetrahydrocannabinol.

[3] *inserting in the Table to clause 2 in Standard A19 in Volume 1, the following -*

Column 1 **Novel food**	**Column 2** **Conditions of Use**
Cannabis spp. Derivatives or parts of *Cannabis* spp.	In accordance with clause (8) in Standard A12 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.

[4] *inserting in the Table to clause 5 in Standard 1.4.1 in Volume 2, immediately before the entry for* erucic acid -

Column 1	Column 2
***delta* 9-tetrahydrocannabinol**	
Seed of *Cannabis* spp. or any substance derived therefrom	5
Oil extracted from the seed of *Cannabis* spp.	10
Beverage prepared from the seed of *Cannabis* spp.	0.2
Cannabis spp., other than the seed, beverage prepared from the seed or the oil extracted from the seed	0.2

[5] *omitting from column 1 and column 2 in Schedule 1 in Standard 1.4.4 in Volume 2, respectively –*

Cannabis spp.* Hemp, Marihuana;

[6] *inserting in Schedule 2 in Standard 1.4.4 in Volume 2, immediately before the entry for* Chrysanthemum balsamita*, the following -*

Column 1	Column 2	Column 3
Species name	**Common Name**	**Natural Toxicant**
Cannabis spp.	Hemp	*delta* 9-tetrahydrocannabinol

(7) inserting in the Table to clause 2 in Standard 1.5.1 in Volume 2, the following -

Column 1	Column 2
Novel food	**Conditions of Use**
Cannabis spp. Derivatives or parts of *Cannabis* spp.	In accordance with clause 5 in Standard 1.4.1. 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.

ATTACHMENT 2

DRAFT STATEMENT OF REASONS

A360 - USE OF HEMP PRODUCTS AS FOOD

FOR RECOMMENDING A VARIATION TO STANDARDS A12 AND A19 IN VOLUME 1 AND STANDARDS 1.4.1, 1.4.4 AND 1.5.1 OF VOLUME 2 OF THE *FOOD STANDARDS CODE* TO ALLOW THE USE OF HEMP AND DERIVATIVES OF HEMP AS NOVEL FOODS

The Australia New Zealand Food Authority (ANZFA) received an Application (A360) on 16 July 1998 from Ecofibre Industries Association of Australia to amend the *Food Standards Code* to permit the use of products from low-THC *Cannabis* spp., such as hempseed and hempseed oil, as food. The term 'hemp' or 'industrial hemp' generally refers to a low *delta* 9-tetrahydrocannabinol (THC) variety of *Cannabis sativa*.

Since the Initial Assessment (previously known as the Preliminary Assessment) of this application, the Novel Food Standard has come into effect (16 June 2001). While this application was previously being considered in terms of an amendment to Standard A12/Standard 1.4.1 and Standard 1.4.4, it is appropriate now to also consider it in the context of Standard A19/Standard 1.5.1 – Novel Foods. Food products derived from *Cannabis* spp. are non-traditional foods in Australia and New Zealand because they do not have a history of significant human consumption by the broad community. They are also novel foods for the purposes of the Standard because there is insufficient knowledge in the broad community to enable safe use of these foods in the form or context in which they are to be presented.

The Australia New Zealand Food Authority recommends the adoption of the draft variation, as amended, for the following reasons:

- Hempseeds are an excellent source of unsaturated fatty acids and an additional source of essential fatty acids. The foods currently being made internationally with hempseed and hempseed oil include health bars, salad oils, non-soy tofu, non-dairy cheeses, non-dairy milks, additives to breads, biscuits and cakes, butter pastes, as well as whole seed, raw or roasted.

- There are no public health and safety concerns associated with the use of food products containing derivatives of low-THC hemp, provided there is compliance with the proposed maximum levels for THC. On the basis of the data available, the proposed tolerable daily intake for the human population is 6 µg/kg bw, based on a human study where the most sensitive effects observed following oral administration was related to skill performance (standing steadiness, hand-eye coordination, reaction time, numbers test).

- Foods containing derivatives of low-THC hemp do not produce any psychotropic effects – the lowest dose level shown to produce this effect is in the order of 140 µg/kg bw.

- Hemp-based products will be regulated under the Novel Food Standard. Products derived from *Cannabis* spp. are non-traditional foods in Australia and New Zealand because they do not have a history significant human consumption by the broad community. They are also novel foods for the purpose of the Standard because there is insufficient knowledge in the broad community to enable safe use. Maximum levels of THC will be established in Standard A12 – Metals and Contaminants in Food - in Volume 1 of the *Food Standards Code* and in Standard 1.4.1 – Contaminants and Natural Toxicants – in Volume 2 of the *Food Standards Code*.

- The proposed change to the food legislation is consistent with the section 10 objectives of the *Australia New Zealand Food Authority Act 1991*.

- *Cannabis* spp. are also regulated under a range of State, Territory, Commonwealth and New Zealand legislation not related specifically to food. The proposed change to the food legislation will not alter the status of hemp products under other legislation. Other legislative changes may be required to allow the sale of hemp-based foods in all jurisdictions.

REGULATORY IMPACT ASSESSMENT

ANZFA is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, the food industry and governments in both Australia and New Zealand. The benefits and costs associated with the proposed amendments to the Food Standards Code have been analysed. For the preferred option, namely, removal of the prohibition on the use of *Cannabis* spp. in food and the establishment of maximum levels for THC in food, the benefits outweigh the costs.

WORLD TRADE ORGANIZATION (WTO) NOTIFICATION

Australia and New Zealand are members of the WTO and are bound as parties to WTO agreements. In Australia, an agreement developed by the Council of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the agreement between the Governments of Australia and New Zealand on Uniform Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

It is considered that the matters raised in the Draft Assessment require consideration under the Technical Barrier to Trade and/or the Sanitary or Phytosanitary Agreements of the WTO and therefore will be notified to the WTO.

ATTACHMENT 3

FOOD TECHNOLOGY REPORT

A360 - USE OF HEMP PRODUCTS AS FOOD

INTRODUCTION

Hemp (*Cannabis*) is an annual herbaceous plant, which is cultivated for its seed and fibre. Substantial quantities are grown in southern Europe, the former USSR, China, Japan and Chile (1).

Hemp seeds have been used for millenniums for nutritional purposes but, in recent decades, their nutritional value and taste have not been in demand. More recently a large number of food items primarily based on hemp seeds have appeared on the market in Europe, the USA and Canada (2).

Analysis of hemp seed and hemp seed oil

Composition of hemp seeds (3)

Moisture	5.7%
Fat	30%
Protein	22.5%
Ash	5.9%
Energy	503 calories/100g
Carbohydrates	35.8%
Insoluble Dietary Fibre	32.1%
Soluble Dietary Fibre	3.0%

Characteristics (typical values) of hemp seed oil (1).

Relative density, d^{25}_{25}	0.923-0.925
Refractive index, n^{45}_{D}	1.470-1.473
Saponification Value	190-193
Iodine Value	140-175
Unsaponifiable matter (%)	1
Oil content of seed (%)	30-35

Fatty Acid Composition (%) of hemp seed oil (1).

Palmitic acid 16:0	6
Stearic acid 18:0	2
Oleic acid 18:1	12
Linoleic acid 18:2	55
Linolenic acid 18:3	25

THC LEVELS

The psychoactive ingredient of *Cannabis* is tetrahydrocannabinol (THC), which is produced in specialised glands (glandular trichomes). These are found primarily in the flowers surrounding the seeds and, to a lesser extent, on the leaf surface of the Cannabis plant. No such glands are produced on or in the seed (2).

During seed harvesting and processing, residuals of the flowers may contaminate the hemp food, particularly the hemp oil. When seeds are removed they often brush against the surface of the calyx where THC resin can dislodge and attach to the outside of the seed coat. This is the point at which hemp seed is at risk of THC contamination. This applies in principle also to industrial hemp varieties with low THC contents. The amount of THC present in the final product will vary with the plant variety, the effectiveness of seed cleaning and possibly the removal of hulls (2).

Cleaning the seeds by removing excess leaf matter and residual THC is a means of ensuring hemp seed and hempseed oil remain relatively free of contamination. However, the applicant contends that it is difficult to ensure removal of all THC contamination from the seeds and standards are being considered around the world acknowledging an acceptable level of THC contamination in hemp seed based food products.

A number of countries are considering establishing maximum THC concentrations in food. For example, in Switzerland hempseed must contain less than 20 mg/kg and hempseed oil must contain less than 50 mg/kg of THC. Canada exempts products that contain THC at less than 10 mg/kg from the Controlled Drugs and Substances Act.

Industrial hemp varieties (low THC varieties) have THC levels ranging from 0.3-0.5% (w/w). *Cannabis* is generally only considered a drug at THC levels above 3% (w/w) for the plant. Generally, lists of hemp varieties for industrial use are maintained, subject to change and addition as new varieties are tested and approved.

MANUFACTURE

Currently, seed is harvested from registered crops and transported to processing facilities. At this point the seed is both washed and cleaned, or hulled to remove the outer pericarp. If required by state authorities, viable seed may also be rendered sterile, usually by some form of heat treatment. Washed or hulled seed is then sold either as whole seed or cold pressed into oil.

Hemp oil can be extracted from the hemp seed by mechanical or chemical methods, as is used for other oil seeds, such as flax, soyabean, etc (4). The oil is either squeezed from the seed using a press (hydraulic, screw, or a combination), or it is extracted using a solvent. Frequently the two methods are combined, depending on the nature of the seed and the cost of the operation (5)

Most oil seeds, except for rapeseed, are dehulled before extraction. This makes it easier to extract oil and increases yield by decreasing oil absorption by the hulls. The seeds are usually flaked, causing sufficient cell breakage to release the oil for ease of extraction. Mechanical extraction is simpler (and safer) but less efficient than solvent extraction (5).

USES OF HEMP SEED

The following hemp based raw materials are used in food production:

- hemp seeds - raw, roasted, hulled, as well as hulled and roasted;
- hemp oil - mostly produced by cold-pressing of the seeds;
- press-cake flour - the press cake remaining after the oil production can be ground into flour; and
- flowers and leaves - as a flavouring in drinks and pastilles. Usually the flavour carrying essential oils are extracted by steam distillation (2).

In whole seed processing the seed is left intact and incorporated as an ingredient in a mixture. For example, biscuits, fruit or nut bars, 'vegie burgers' etc. Hemp seed can also be toasted and eaten directly, and are included in many traditional eastern European foods such as sweets and soups. Raw or roasted hemp seed may be milled into a butter similar to nut butter (e.g. peanut butter), a product which has long been available in eastern Europe (4).

Hemp seed oil may be used in any product for which fat is an ingredient, for example, frozen deserts and baked goods. Salad dressing made using hemp seed oil is currently available in some countries (4).

Hemp seed can be processed very much as soybeans are for use in soymilk, tofu and secondary soy foods. As with soybeans, a larger hemp seed with higher protein content is best. It is claimed that there are few soy-based foods which could not be made from hemp seed (4).

CONCLUSIONS

- Hemp is an annual herbaceous plant traditionally used as a source of food and fibre in many counties. The hemp seed, hemp seed oil and essential oils from the leaves and flowers are commonly used as foods or ingredients of foods.
- Industrial varieties of hemp are used to produce hemp seed for food use. THC levels in industrial hemp range from 0.3-0.5% dry weight, compared with THC levels above 3% in *Cannabis* considered as a drug.
- Hemp seeds do not contain any THC but may be contaminated through contact with the hemp leaves and flowers during the harvesting process.
- Washing the seeds reduces the level of THC contamination but it is difficult to remove it entirely.
- A wide range of new food uses for hemp seeds and hemp seed oil are being developed, including breads, pastries, pasta, nut bars, chocolate, ice cream, cheese, salad dressings. Hemp seeds may be eaten raw or roasted, ground into a paste or butter (similar to peanut putter) and also be used as a replacement for soy products.

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ATTACHMENT 4

NUTRITION REPORT

A360 - USE OF HEMP PRODUCTS AS FOOD

Introduction

Hempseed and hempseed oil have been identified as an alternative to both linseed and soybean products because of their favourable nutrient profile, particularly the essential fatty acid content. Furthermore, availability of hemp products may assist individuals with allergies to soy-based products to obtain dietary sources of polyunsaturated fatty acids. There have also been claims that overseas consumers find hemp to be more palatable than either linseed or soybean products.

Internationally, hemp seed and hemp seed oil are being used in the production of a variety of foods including breads, biscuits, cakes, health bars, salad oils, non-soy tofu's, non-dairy alternatives to cheese and milk, tea, beer and soft drinks. Hemp seed is also available as whole raw or roasted seed (Grotenhermen, Jarus & Lohmeyer, 1998).

Nutritional Profile

Hempseed and hempseed oil are excellent sources of polyunsaturated fatty acids as approximately 80% of the fatty acid profile is polyunsaturated notably the essential fatty acids, alpha-linolenic acid (omega-3) and linoleic acid (omega-6). These particular fatty acids are required for vital functions within the body (Jones, 1997; Eschleman, 1996; Mahan and Escott-Stump, 1996).

Omega-3 and omega-6 fatty acids play a major role in a number of biological processes within the body including immune response, lipolysis, blood clotting, vascular dilation, and heart rate (Jones, 1997; Mahan and Escott-Stump, 1996). Polyunsaturated fatty acids also play a role in the maintenance of cell membrane structure and fluidity (NHMRC, 1992). Omega 6 fatty acids are found in vegetable oils, including corn, sunflower, safflower, and soybean oil (Jones, 1997; Gurr, 1993; NHMRC, 1992; National Research Council, 1989).

Omega-3 fatty acids are required for normal growth and development and can play a positive role in infant brain and eye development, rheumatoid arthritis, heart disease, diabetes and possibly cancer. They are found in oily fish, such as salmon, tuna and mackerel, and plant sources such as canola, linseed, soybeans and walnuts (Eschleman, 1996; Mahan and Escott-Stump, 1996). Fish oil supplements in capsule form are also available. The major sources of omega-3 polyunsaturated fatty acids in the Australian diet are margarines, spreads and oils containing canola oil.
There is some concern that some individuals may be missing out on these 'omega nutrients' due to the recent emphasis on low fat diets.

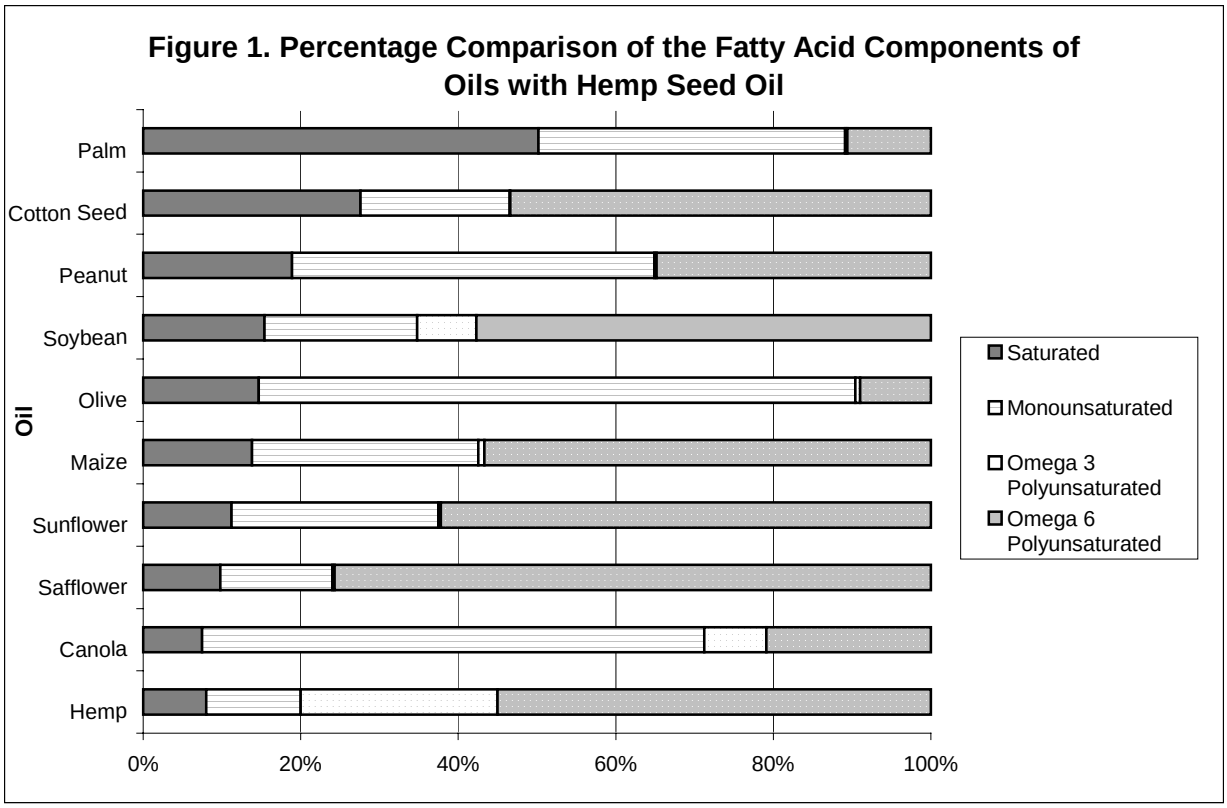
Although omega-3 fatty acids are classified as essential nutrients, no Recommended Dietary Intake (RDI) has been established. However, national guidelines recommend an increase in the consumption of omega-3 fatty acids from fish and plant sources (Jones, 1997). In addition, it has been estimated that a daily intake of approximately 2 grams per day of essential fatty acids is required for adults to meet metabolic needs (Jones, 1997; Gurr, 1993). This amount would be provided by 15-20 grams of hemp oil.

Most sources of polyunsaturated fat in the Australian diet contain omega-6 but little or no omega-3 fatty acids. Furthermore, Australians' intake of omega-6 rich polyunsaturates has increased substantially, mainly in the form of sunflower oils and margarines, since the 1970s and canola oils and margarines, since the 1990s (Lester, 1994; NHMRC, 1992). It should be noted that one of the main goals of the Australian Dietary Guidelines is to reduce fat intake and increase the proportion of unsaturated fatty acids in the diet with a more appropriate omega-6:omega-3 ratio. Presently it is estimated that the omega-6 to omega-3 ratio lies between 14:1 and 25:1. It has been recommended that this ratio be lowered to 5:1, which is the approximate ratio in human breast milk (Jones, 1997).

Researchers believe that improving the dietary balance of these omega nutrients may have positive implications for cardiovascular disease, diabetes, cancer, obesity and arthritis (Simopoulos, Leaf and Salem, 1999). The balance between omega-3 and omega-6 fatty acids is important, as both fatty acids are precursors to eicosanoids, which exhibit various metabolic effects, and often act in opposition to one another. For example, omega-6 fats promote blood clotting, whereas omega-3 fats do not. Because Omega-3 and omega-6 fatty acids compete for the same enzyme, large quantities of omega-6 fats will saturate the enzyme and thus limit the conversion of omega-3 fats (Simopoulos, Leaf and Salem, 1999; Jones, 1997; Gurr, 1993).

Analysis of hempseed oil fatty acids indicates a favourable omega-6 to omega-3 ratio of approximately 3:1 (see Attachment 3). Soybean oil, by comparison, provides an omega-6 to omega-3 ratio of approximately 7.5:1 (NHMRC, 1992). Figure 1 compares the fatty acid content of hemp with other oilseeds (Lewis et al, 1995; Chan, Brown and Buss, 1994; Padley, Gunstone and Harwood, 1986).

Hemp oil also contains a small quantity of gamma-linolenic acid (GLA). Researchers have suggested that GLA may play a prophylactic role in treating various chronic disease states, however this remains controversial (Fan & Chapkin, 2000). GLA is also present in evening primrose oil, blackcurrant oil and borage oil, which are available as dietary supplements in the form of capsules (Hwang, 1992; NHMRC, 1992).



Summary of nutritional profile

Permitting the use of hemp in food products provides another alternative for individuals to heed dietary recommendations to increase their intake of unsaturated fatty acids and consume a more appropriate omega 6:omega 3 polyunsaturated fatty acid ratio through a food product rather than a supplement. Additional benefits are also obtained by consuming other nutrients such as vitamins, minerals, fibre, protein, which are present in food and not ordinarily provided by a supplement.

Conclusion of the nutrition report

Hempseed and hempseed oil have been identified as an alternative to both linseed and soybean products because of their favourable nutrient profile, particularly the essential fatty acid content. Furthermore, availability of hemp products may assist individuals with allergies to soy-based products to obtain dietary sources of polyunsaturates. There have also been claims that overseas consumers find hemp to be more palatable than either linseed or soybean products.

Permitting the use of hemp in food products provides another alternative for individuals to heed dietary recommendations to increase their intake of unsaturated fatty acids and consume a more appropriate omega 6:omega 3 polyunsaturated fatty acid ratio through a food product rather than a supplement.

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ATTACHMENT 5

SAFETY ASSESSMENT REPORT ON 9-δ-TETRAHYDROCANNABINOL

INTRODUCTION

The plant *Cannabis sativa* has a long history of use as a medicinal herb. Over the centuries, it has been used in the treatment of pain, asthma and dysentery, for the promotion of sleep, the suppression of nausea and vomiting, and for the abolition of convulsions and spasms.

The beneficial effects of the plant are attributed to chemical compounds known collectively as the cannabinoids, which constitute the active ingredients of *Cannabis sativa* subsp. *indica*. The pharmacology of many of the cannabinoids is unknown, but the most potent psychoactive agent, delta-9-tetrahydrocannabinol (THC), has been isolated, synthesised and much studied. THC is not only the main psychoactive agent but is also responsible for many of the other pharmacological actions of *Cannabis* subsp. Certain other natural and synthetic cannabinoids have various medicinal uses.

Terminology (WHO, 1997)

Cannabis is a generic term used to denote the several psychoactive preparations of the plant *Cannabis sativa*. The Mexican term 'marijuana' is frequently used in referring to cannabis leaves or other crude plant material in many countries. The unpollinated female plants are referred to as *sinsemilla*. The resin from the flowering tops of cannabis plants is called *hashish*. Cannabis oil (hashish oil) is a concentrate of cannabinoids obtained by solvent extraction of the crude plant material or of the resin.

The THC content of *Cannabis* is typically in the range of 0.5-4%. Cannabis oil or hashish and sinsemilla all contain concentrations of THC exceeding that in the average plant material. Sinsemilla may have THC concentrations of 7-14%. THC content of hashish generally ranges from 2-8%, although it may be as high as 10-20%. The concentration of THC in cannabis oil varies between 15-20%.

METABOLISM AND KINETICS

Absorption

THC and other cannabinoids are rapidly absorbed on inhalation from smoked *Cannabis sativa* preparations (hereafter referred to by the generic term cannabis). Effects are perceptible within seconds and become fully apparent in a matter of minutes. When taken orally, absorption of THC is variable and generally much slower. The onset of effect is delayed (0.5-2 hours) but the duration of effect may be prolonged due to continual slow absorption from the gut. Blood concentrations reached are 25-30% of those obtained by smoking the same dose, partly due to the fact that some of the THC is degraded by first-pass metabolism in the liver, although the metabolite of THC, 11-hydroxy-delta-9-THC, is also psychoactive.

Distribution

After smoking or intravenous administration, THC and other cannabinoids are rapidly distributed throughout the body reaching first the tissues with the highest blood flow, that is brain, lungs, liver, adrenals, kidney, ovaries and testes. Maximum brain concentrations are reached within 15 minutes, coinciding with the onset of maximal psychological and physiological effects.

After oral administration, maximal effects occur after an hour or more but may last 5-6 hours because of continued absorption from the gut, but some psychomotor and cognitive effects persist for much longer, probably for more than 24 hours, regardless of the mode of administration. Cannabinoids can also cross the placenta, enter the foetal circulation, and are excreted into breast milk.

Cannabinoids are highly lipid soluble and accumulate in fatty tissues, from which they are only slowly released back into the bloodstream.

Metabolism and excretion

Cannabinoids are metabolised in the liver. A major metabolite of THC is 11-hydroxy-delta-9-THC which is possibly more potent than THC itself, and may be responsible for some of the psychological and physiological effects of cannabis. More than 20 other metabolites are known, some of which may also be psychoactive.

These metabolites are slowly excreted, over days or weeks, in the urine and faeces. There are large inter-individual differences in rates of metabolism, and metabolism is likely to occur more slowly in the elderly and in individuals suffering from liver disease.

Because of the sequestration in fat, and subsequent slow elimination from the body, cannabinoids can accumulate and continue to reach the brain over a long period. Complete elimination of a single dose can take up to 30 days (Maykut, 1985).

PHARMACOLOGY

Cannabinoids affect almost every body system including the central nervous system, cardiovascular system, respiratory system, immune system and reproductive system. Cannabinoids can also decrease intra-ocular pressure in the eye. Although the effects of cannabinoids are not yet fully understood, it is becoming clearer that the pharmacological actions occur as a result of the perturbation of an endogenous neurochemical system in the body via interaction with cannabinoid receptors (Adams & Martin, 1996).

Receptors

The psychotropic effects of cannabinoids are mediated through specific cannabinoid receptors in the human brain, distributed in discrete areas including those concerned with motor activity and postural control, memory and cognition, emotion, sensory perception and autonomic and endocrine functions. A second type of cannabinoid receptor has been detected in the macrophages (immune cells) of the spleen and probably mediates the immunological effects of cannabinoids. Both types of receptors are present in peripheral tissues.

The endogenous ligands, termed anandamides, for the cannabinoid receptors found so far are arachidonic acid derivatives that differ strongly from plant cannabinoids in their chemical structure.

The role of an endogenous cannabinoid neurochemical system, which has been found in a variety of mammalian species, is still under investigation. There is so far no direct evidence for a primary functional role, for example as a neurotransmitter system, but instead it appears to modulate the excitability and responsiveness of neurones in many other neurotransmitter/neuromodulator systems of the body.

The number of cannabinoid receptors in adults is several times the number in children.

Clinical observations in humans

THC produces effects on almost every system in the body with the most conspicuous effects on the central nervous system and cardiovascular system. The predominant physical effects are characterised by reddened eyes, a dry mouth and an increased heart rate.
The psychotropic effects range from a mild euphoria and enhanced sensory perception at low dose to varying degrees of dysphoria, fatigue and finally hallucinations associated with anxiety at higher doses. A substantial number of recent studies have confirmed that cannabis use consistently increases food consumption, especially high carbohydrate foods, but does so without an established connection with appetite (Mattes et al., 1994).

Many of the pharmacological effects are biphasic, with a rapid response observed at low doses and a slower response at the higher dose levels. Effects vary greatly between individuals and may be greater in elderly individuals.

The short term effects shown below have been observed in clinical or experimental studies (BMA, 1997). In each case, the effects are indicated with respect to increasing severity.

- psychological effects: euphoria, enhanced well-being, dysphoria, anxiety, increased sensory perception, hallucinations and psychotic states;
- sedative effects: fatigue, generalised CNS depression;
- cognition and psychomotor performance effects: fragmented thinking, enhanced creativity, disturbed memory, unsteady walk, slurred speech;
- nervous system effects: attenuation of pain, muscle relaxation, appetite enhancement, decrease in body temperature, vomiting, anti-emetic effects;
- cardiovascular system effects: increased heart rate and cardiac output, vasodilation, lowering of blood pressure, collapse;
- eye effects: reddened conjunctivae, reduced tear flow, and reduced intra-ocular pressure;
- respiratory system effects: broncodilation, dry mouth; and
- gastrointestinal tract effects: reduced bowel movements.

Other pharmacological effects have been variously reported with more long-term exposure to cannabinoids or at high experimental doses in laboratory studies. These are:

- hormonal system effects: changes in LH, FSH, testosterone, prolactin, somatotropin and TSH levels, reduced sperm count and sperm mobility and quality, suppressed ovulation and menstruation;

- immune system effects: impairment of cell-mediated and humoral immunity, anti-inflammatory and immune-stimulating effects; and
- foetal development effects: malformations, growth retardation, impairment to foetal and postnatal cerebral development.

TOXICOLOGY

Acute effects

The acute toxicity of cannabinoids is very low. When used as therapeutic agents, they are very safe and no deaths have been directly attributed to their use. Moreover, in clinical use pronounced side effects of THC are rare, even with high doses. Chronic heavy cannabis use is not related to increased mortality nor is it associated with any distinguishable adverse health features (Sidney et al., 1997).

The median lethal dose of THC for rats is in the range of 800-1900 mg/kg. No deaths were observed in either dogs (at 3000 mg/kg) or rhesus monkeys (at 9000 mg/kg) following administration of an acute oral dose of THC (Thompson et al., 1973).
The available data in humans indicate that the acute lethal dose in humans is likely to be very high.

The acute effects of cannabis on the brain have been reviewed by Castle and Ames (1996) who concluded that it caused an acute encephalopathy (pathological dysfunction of the brain) characterised by psychological effects, most, but not all, of which are pleasurable, psychotic effects, which are likely to be disabling, and other toxic effects, psychiatric and cognitive effects which may adversely affect behaviour and ability to think clearly an study effectively.

Effects on the central nervous system

The long-term effects of THC are predominantly associated with neurotoxicity. In rats, morphological changes in synapses as well as hippocampal neuronal loss have been observed. In addition, several studies have shown learning and memory deficits months after the end of chronic cannabis administration to rats. Similarly, other studies have shown receptor down-regulation or neurotransmitter changes.

Slikker et al. (1992) showed that rhesus monkeys were impaired in their ability to perform operant tasks following chronic administration of cannabis for one year, but performance returned to normal 3 weeks after treatment. The effects of chronic exposure therefore were reversible with no apparent long-term behavioural effects.

Human studies on the long-term use of cannabis indicate that it leads to subtle and selective impairments of cognitive functioning. These include the organisation and integration of complex information involving various mechanisms of attention and memory processes, including verbal learning, card sorting, auditory attention, tone discrimination, and the filtering of irrelevant information. Prolonged use may lead to progressively greater impairment, which may not recover with cessation of use for up to 6 weeks, and which could potentially affect functioning in daily life. Studies also indicate subtle signs of disturbances of brain function in chronic cannabis users.

In addition to the behavioural and neurological observations, a range of pharmacological effects on other body systems have been reported following longer term use of cannabis preparations in humans.

Effects on the immune system

Cannabinoids, especially THC, have been found to modify the function of a variety of immune cells, increasing some responses and decreasing others. In addition, although the results have not been entirely consistent, several animal studies have demonstrated impairment of resistance to bacterial or viral infections in mice exposed to THC at intraperitoneal doses ranging from 15 - 50 mg/kg. While many research studies have clearly established that THC can act as an immunomodulator, these effects are produced only at relatively high concentrations or doses. Furthermore, the health impact of these effects is not yet clearly determined as many effects appear to be relatively small and are completely reversible.

Effects on reproductive hormones

In female rats, delta-9-THC alters pituitary secretion of luteinising hormone (LH), follicle stimulating hormone (FSH), and prolactin when administered either acutely or repeatedly to both intact and ovariectomised experimental animals (Steger et al., 1980, 1981). In addition to suppressing normal circulating levels of LH in female rats, THC also inhibits the surges of LH and FSH that are essential for ovulation. As a consequence, THC blocks ovulation in intact rats and monkeys (Smith et al., 1979) and disrupts the normal rhythm of menstrual cycles in monkeys. The levels of luteining hormones and follicle stimulating hormone (FSH) were both reduced at dose levels of 0.625 mg/kg and greater following intramuscular injection (Smith et al. 1978).

Other animal studies indicate that cannabis can disrupt the interactions of hypothalamus and the pituitary gland. THC can alter pituitary gonadotropin levels in animals after acute or chronic treatment that may be mediated through direct effects on catecholamines such as norepinephrine (Wenger et al. 1992). Murphy et al (1990) showed that oral administration of THC to rats at a single dose of 0.5 mg/kg reduced LH levels at 60 minutes after dosing but not at 30 or 120 minutes. In a similar study by Steger et al (1990), single oral dose levels of 0.1, 1 or 10 mg/kg THC reduced both plasma LH and testosterone at 60 minutes, but there was no dose-response effect. In other studies conducted using lower dose levels and the iv and ip routes of administration, slight changes were also observed, but the relevance of these changes to orally administered THC is questionable.

In animal studies conducted in the 1980's, it was reported that THC may impair the function of male reproductive hormones and cause a decrease in the weights of sex organs, but these reports were not further substantiated by subsequent studies. There are numerous reports of a lowering of plasma testosterone levels following THC administration at various doses in laboratory animals. Furthermore, Zimmermann et al. (1979) reported that THC administered to mice for five days at either 5 mg/kg or 10 mg/kg caused a significantly higher incidence of abnormal sperm at both doses.

The potential effects in humans are unclear, with early studies reporting that cannabis exposure produced either no effect or a transient reduction in the levels of plasma LH and testosterone.

More recent short-term studies indicate that cannabis use (or, in one study, an oral dose of 10 mg THC three times a day for 3 days) had no effect on the circulating levels of these reproductive hormones in subjects who were prior cannabis users. The conflicting results in human studies may reflect differences in experimental procedures and the possible effect of prior cannabis exposure giving rise to tolerance. All of these factors complicate a clear interpretation of the data, although there is general agreement that cannabinoids do alter reproductive hormones controlling testicular function.

Effects on other endocrine hormones

In animal studies, typical doses of 2-50 mg/kg THC stimulate the secretion of adrenocorticotropin (ACTH), a hormone secreted by the adenohypophysis that stimulates the synthesis of the glucocorticoids in the adrenal. Acute THC administration also elevates plasma corticosterone levels in both male and female rats. Landfield et al. (1988) observed that THC administration induced ageing-like degenerative changes in rat brain tissue similar to those resulting from elevated corticosterone. However, a latter report (Block, 1991) found no alterations in cortisol levels in men who were heavy cannabis users, and this finding is generally consistent with other human data from earlier studies.

There is inconclusive evidence that THC may inhibit growth hormone secretion, following early studies in male rats. More recently, it has been shown that infusion of THC directly into the brain of adult male rats suppresses growth hormone secretion. This finding suggests that further study of the effect of THC on growth hormone secretion in both males and females is warranted. Similarly, circulating thyroxine levels were reduced following acute or chronic THC administration in male rats and rhesus monkeys. THC treatment may also affect the release of the posterior pituitary hormone, oxytocin (Tyrey & Murphy, 1988).

Effects on reproduction

Studies of the effects of THC on male and female reproductive systems indicate complex and significant adverse effects on the secretion of reproductive hormones in both males and females, including increased obstetric risks for females. In addition, animal studies show that cannabinoid exposure reduces testicular, seminal vesicle and prostate weights, decreases ovarian weight and increases pituitary and adrenal weights (WHO, 1997).

Most of the human reproductive studies have typically investigated the effects of smoked cannabis that may contain variable amounts of THC. In these studies, therefore, the concentration of active compound in the placenta or crossing to the foetus was unknown, and there was often a lack of knowledge of other substances in use by these subjects. These issues complicate the interpretation of research data on the hormonal and other effects of THC on pre- and post-natal development. Consequently, isolated observations in the 1980's of an elevated risk of birth complications, abnormal progress of labour or premature births in cannabis users have not been confirmed. Effects that have been observed probably occur by the same mechanism as cigarette smoking, namely, foetal hypoxia (WHO, 1997).

Bailey et al. (1987) clearly demonstrated the rapid transfer of THC across the placenta to the developing foetus. In this study, it was reported that an intravenous dose of 0.3 mg/kg given to pregnant rhesus monkeys resulted in peak plasma THC values after 3 mins in the maternal blood and after 15 mins in the foetus. By 3 hours post administration, the maternal and foetal plasma THC levels were equal.

This primate data is considered to be predictive of the human situation, although human time-course studies of the placental transfer of THC have not been reported. It is known also that THC can, through hormonal effects, inhibit milk production and release, with possible adverse implications for post natal growth.

Studies in animals, although generally well-controlled, provide data only in response to very high doses of THC, and encounter the important methodological problem associated with cannabinoid administration to animals, namely, that these compounds depress maternal food and water consumption (Abel, 1985). For example, studies in which pregnant rats received oral THC at 15 or 50 mg/kg daily, report a dose-related decrease in birth weight and decreased weight gain in the offspring. However, the decrease in birth weight observed was considered to be due to poor maternal nutrition and dehydration in the THC treated group, rather than from any direct toxic effects (Hutchings, 1985). Such studies are unlikely to be relevant to low-dose human exposure.

Effects on intrauterine and post-natal development

While there have been reports of teratogenic effects in animal studies following administration of THC, these studies were considered to be poorly conducted (Abel, 1985) and have not been supported by other well conducted oral studies (e.g. Fleischmann et al. 1975). The available studies in animals suggest that early gestational exposure can induce dose-related maternal toxicity and embryotoxicity. Malformations were only observed following high dose intraperitoneal exposure and the only consistent finding was a decrease in birthweight (Abel, 1985).

The available epidemiological studies do not support any evidence for an increase in congenital malformations following cannabis use during pregnancy. Hingson et al (1982), after examining 1690 patients for the effects of cannabis and alcohol use reported an association between cannabis use and a foetal syndrome known as alcoholembryopathy. Subsequently epidemiological studies have not established any relationship between cannabis use and foetal malformations (Knight et al., 1994; Astley, 1992; Witter & Niebyl, 1990).

Delta-9-THC crosses the placenta to the vascular system of the foetus although in rats, sheep, dogs and monkeys foetal plasma concentrations were found to be lower than maternal concentrations. The first cannabinoid receptors in the brain are detected at foetal age but the number increases progressively after birth. In rats, there is a five-fold increase in cannabinoid receptors between birth and adulthood (sixty days).

Recent animal studies using THC at lower doses than those used in foetal toxicity studies showed that the daily administration of 5 mg/kg THC to pregnant rats generated a doubling of the activity of tyrosine hydroxylase in specific foetal brain cells (Hernandaz et al. 1997). While this effect is not considered adverse, it indicates that THC is not without physiological effects at low dose levels. Behavioural alterations were only found in the offspring of dam exposed to extremely high levels of THC. In a study by Abel (1984) where dams were exposed to 50 mg/kg THC, there were no behavioural alterations in the offspring.

However, there were significant THC-induced reduction of food and water intake by the pregnant rats during treatment in this and other studies at lower dose levels (15 mg/kg, Hutchings et al. 1987) which it is assumed partially accounts for the observations of poor foetal development.

In human studies, the overall neurological effects on the offspring of gestational exposure to cannabinoids do not form a consistent pattern. There are reports of increased tremors and startles and alterations in the sleep cycle of neonates whose mothers who had regularly used cannabis during pregnancy (Fried et al. 1987). There have also been reports of alterations in sleep cycles in neonates of cannabis-exposed mothers (Scher et al. 1988). Cannabis-exposed children aged 9 months have also been reported to achieve slightly lower mental test scores than non-exposed children (Richardson et al., 1995), but this effect had disappeared by age 19 months. In other studies, no difference in sleep habits or psychomotor activities could be found (Tennes et al. 1985). There was also no effect on neuro-behaviour assessments found in 3-day old neonates (Dreher et al. 1994, 1997).

A longitudinal study by Fried et al. (1995, 1997) revealed small but significant variations in the verbal abilities and memory of cannabis-exposed children. At the age of 9 to 12 years, the ability to speak and spell did not differ from the unexposed group. At the conclusion of the study, the prenatally-exposed children were not found to differ significantly in neurobehavioural parameters from non-exposed children.

Genotoxicity and carcinogenicity

While there is some evidence of mutagenicity due to cannabis smoke, THC itself is not mutagenic in the Ames test (Zimmerman et al, 1978). There is some evidence that THC can interfere with the normal cell cycle (Zimmerman & McClean, 1973) and can also decrease the synthesis of DNA, RNA and protein (Blevins & Regan, 1976). There is also some evidence that THC can disrupt microtubule formation (Tahir & Zimmerman, 1992) but the evidence regarding the possible induction of chromosome aberrations is inconclusive. Joergensen et al, (1991) found no increase in the incidence of sister-chromatid exchanges (SCE) in lymphocytes of uses of cannabis compared to tobacco smokers.

The carcinogenicity of THC was examined in rats and mice in a study conducted by the US National Toxicology Program (NTP, 1996). Very high dose levels (125, 250 and 500 mg/kg/day) were used. There was evidence of thyroid hyperplasia in both male and female mice at all dose levels.

Epidemiological studies

There have been a number of studies involving retrospective analysis of cannabis users in order to examine potential adverse effects of THC. Most of these studies are considered to suffer from methodological problems and cannot be relied upon to provide a definitive conclusion, particularly with regard to low dose exposure.
A recent review by Hall & Solowij (1998) suggests that cannabis use results in dependency, subtle impairments in attention and memory, and possible impairment of cognitive skills in adolescents and adults. Struve et al (1998) have examined EEG changes in men who have used cannabis for 15-24 years and suggest that long-term exposure may be associated with slowed cognitive processing.

Threshold for toxicity effects

The most sensitive parameter for cannabinoid toxicity in animals seems to be the effect on reproductive hormone levels. In rats, changes in luteinising hormone and follicle stimulating hormone were noted at THC oral dose levels of 0.1 mg/kg, although no dose-response relationship was evident.

PSYCHOTROPIC EFFECTS

The acute effects of cannabis use include features such as mild euphoria, relaxation, increased sociability, heightened sensory perception and increased appetite. At high dose levels, effects can include perceptual changes, depersonalisation, panic, loss of a sense of time, sensation of high anxiety, tension and confusion (Mathew et al., 1993).

A number of studies have examined the acute effects of cannabis on the central nervous system and behaviour but such studies generally do not examine dose-response effects. Block et al (1992) have confirmed earlier finding that cannabis can affect memory in various ways, such as free recall of previous learned items, associative processes and psychomotor performance. These effects are considered modest.

Studies have also shown that cannabis use consistently increases the consumption of food although cannabis has not shown consistent effects on the users' subjective reports of appetite (Mattes et al. 1994). Cannabis also appears to increase the perceived rate of the passage of time. There are now a number of studies that show that cannabis impairs psychomotor performance in tasks such as handwriting and tests of motor coordination (Solowij et al. 1991).

Dose-response relationships

While there have some attempts to relate blood levels of THC with behavioural changes, this relationship is complicated by the wide individual variability observed. This individual variability may be related to dose, mode of administration, physiological and pharmacological differences and prior drug experiences of the subject.

Following oral administration, the systemic bioavailability of THC is typically 5-10%, but could be up to 20% if contained in a lipophilic carrier such as a fat or oil. This is typically somewhat lower than that found via inhalation which is in the range 10-30% (Lindgren et al. 1981). After oral administration of 15-20 mg THC, peak plasma levels of approximately 5 ng/ml are generally reached after 1-3 hours.
The onset of subjective psychotropic effects occurs 30-90 minutes after the dose and persists for approximately 6 hours due to a continued absorption from the gut. To achieve psychotropic effects following oral exposure, higher dose would be required than after inhalation exposure due to slower intestinal absorption of THC.

A recent study by Harder & Rietbrock (1997) confirmed that both dose and dosing interval are determinants of the duration of the psychotropic effects of THC. Following inhalation of cannabis smoke, estimated to contain 9 mg THC, the duration of the psychotropic effect was approximately 45 minutes and further doses at one hourly intervals were required to maintain the maximal effect. Using cannabis with a low THC content (1 mg), smoking at intervals of 2 hours and 1 hour did not provoke a psychotropic response. However, it was stated that dosing at 30 minute intervals may lead to a short term moderate response.

Threshold for THC-related effects

The number of studies available which might be used as a basis to establish a threshold for psychotropic effects is limited since the majority of studies conducted with THC are concerned with gaining a better understanding of THC-related effects rather than determining the threshold for such effects. Given the somewhat subjective nature of psychotropic effects, it can also be difficult to distinguish an effect attributable to THC from a placebo effect.

There are, however, a number of studies that have examined the therapeutic applications of THC where unintended effects have been reported in relation to the dose. THC is used therapeutically as an anti-emetic agent for individuals undergoing cancer chemotherapy, as a muscle relaxant for individuals with multiple sclerosis, cerebral palsy and spinal cord injuries and as an appetite stimulant for individuals with AIDS-related diseases or as a general analgesic in a variety of medical conditions.

In a study by Lucas & Laszlo (1980), the effect of THC as an anti-emetic in cancer chemotherapy patients was examined at oral dose levels of 15 mg/m^3 body surface (equivalent to 24 mg/person) every 6 hrs and at 5 mg/m^3 body surface (equivalent to 8 mg/person) every 4 hrs. Of the nine patients who had received the high dose, three had severe psychological reactions. Patients who received the low dose had no serious side effects but 15 complained of being sleepier than usual and 30 complained of a dry mouth.

In a study by Pedro and Ellenberger (1981), the effect of THC on patients with spasticity was tested following oral dose levels of 0, 5 or 10 mg/person. Side effects related to the psychotropic effects of THC were minimal. Of the nine patients, two patients reported feeling 'high', one after the 10 mg dose and one after the placebo. In a similar study by Brenneisen et al (1996), the effect of THC was again tested on two patients with spasticity. One patient received an oral dose of 10 mg/day for 4 days while the other received an oral dose of 15 mg/day for 4 days.

On a self-rating mood and concentration ability scale, the first patient did not notice any significant differences while the second patient experienced some reversible deterioration.

In a study by Chesher et al. (1990), the effect of oral THC (in capsules and dissolved in sesame oil) on human mood and skills performance was conducted at dose levels of 0, 5, 10, 15 and 20 mg/person (0, 78, 155, 233 or 310 μg/kg) on groups of 16 male and female students (bodyweights 58-84 kg; median 64.5 kg). The performance measures included standing steadiness, hand-eye coordination, reaction time, a numbers test and a self-reported intoxication scale. The subjects completed the test battery at 1.3, 2.3, 3.3 and 4.3 hrs after consumption of the THC. The results indicated a linear dose-response relationship between THC and performance measures at the first three times. At 4.3 hrs, the slope was not significantly different from zero. On the self-reporting intoxication scale, the lowest dose level (5 mg) was not distinguishable from placebo, although there was a dose-related effect reported at other dose levels. The effects observed appeared to return to baseline after approximately 4 hrs. This study concludes that an effect on skill performance can occur at an oral dose of 5 mg/young adult (equivalent to 60 μg/kg for the highest weight individual in the study).

Conclusion - There are few studies available upon which to examine the low-level effects of THC in humans or to determine a dose level at which no effects are observed. In relation to psychotropic effects, the studies available indicate most individuals require a minimum oral dose of 10 mg THC per person and the majority require an oral dose of 15-20 mg per person to experience a psychotropic effect. In relation to skills performance, an oral dose that produces a minimal effect is approximately 5 mg/person (equivalent to 60 μg/kg) for young adults. There were no self-reported mood effects at this dose level.

CONCLUSION

There is limited data available to assess the potential adverse health effects of orally administered THC in humans, particularly at the low dose levels. Much of the data available relates to exposure by inhalation. In experimental animals, the parameters most sensitive to orally administered THC appear to be changes to the endocrine hormones. The significance to humans of these observed changes in animals is unclear since a dose-response was generally not demonstrated. In oral studies in humans, either no effect or only transitory effects were observed.

In relation to psychotropic effects, the studies available indicate most individuals require a minimum oral dose of 10 mg THC per person and the majority require an oral dose of 15-20 mg per person to experience a psychotropic effect.

The most sensitive effects observed in humans seem to be related to skill performance following oral administration. On the basis of the data available, it was not possible to establish a level at which no effects were observed, however, the lowest-observed-effect level (LOEL) was 5 mg/person, equivalent in this study to a dose level of 60 μg/kg bw. The effects seen at this dose level were minimal and reversible. There were no psychotropic effects observed at this dose level. In order to take account of the possible variability in response in the human population, an uncertainty factor of 10 should be applied to the LOEL from this study in order to derive an overall tolerable daily intake for the human population. Thus, an estimate of the overall tolerable daily intake for the human population is 6 μg/kg bw.

It is evident that there is considerable individual variation in relation to the potential effects of THC. Some of the factors that may moderate the effects of THC include:

i. the development of tolerance following regular exposure;
ii. the density of cannabinoid receptors in the brain (known to be low in children);
iii. interaction with other cannabis ingredients such as cannabidiol (CBD); and
iv. the slow metabolism of THC and potential for cumulative effects.

The matrix in which the THC is consumed will also influence the level of absorption, with the highest absorption from an oil product.

On the basis of the data available, there is no evidence of adverse health effects in humans at low levels of THC exposure and a tolerable daily intake of 6 μg/kg bw can be established. If the products from low THC hemp plants are used as food, the level of THC in the final products should be such that the dietary intake of THC is no greater than 6 μg/kg bw.

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ATTACHMENT 6

DIETARY EXPOSURE REPORT

A dietary exposure assessment was undertaken to ensure that the proposed maximum permitted levels of δ–9-delta tetrahyrocannabinol (THC) within foods containing hemp would not lead to dietary exposures greater than 6 μg/kg bw, the tolerable daily intake (TDI) for the human population (see Safety Assessment report – Attachment 5). Dietary modelling integrates food consumption data with food chemical levels to estimate dietary exposure.

Food consumption data

Individual records of 24-hour recall food consumption data.
The Authority used the DIAMOND computer program in the dietary modelling process. The food consumption data used for the dietary modelling were derived from the 1995 National Nutrition Survey (NNS) of Australia, for people aged 2 years and over (13858 respondents), and the 1997 New Zealand NNS, surveying people 15 years and over (4636 respondents). DIAMOND provides access to the individual dietary records from the NNSs, which were both derived from a 24-hour food recall methodology, including records of individual body weights. The use of DIAMOND to access individual dietary records gives more information about the distribution of the individual dietary exposure estimates than is possible using point estimates of population food consumption.

However, it should be noted that the range of food consumption figures reported in 24-hour recall surveys will tend to be far greater than that reported in 7-day surveys or food frequency surveys because these two survey methods report on dietary patterns averaged over a number of days or months respectively. For staple foods that are frequently consumed, there may be little difference between the range of consumption reported over 24 hours and that averaged over a longer time period. However, for occasionally consumed foods the range of food consumption reported from 24-hour recall data will be much greater than that from surveys that reported over a long period of time. A collaborative study undertaken by the Institute of European Food Studies (IEFS 1998) to assess the influence of survey duration on reported food consumption shows very clearly that as the duration of the surveys increases, the number of consumers of each food item increases but mean consumption for consumers only (eaters) decreases when averaged over the number of days in the survey. However, for staple foods, such as bread, the change is much less marked than that for occasionally consumed foods, such as pizza. The amount of food consumed by all respondents does not change over time.

THC Concentration Levels

The data outlining THC concentrations of foods that were provided with the application consisted of ranges of THC concentration levels in a variety of products. The data were not adequate to derive meaningful median THC concentration levels to use in the dietary modelling.

Therefore, the proposed maximum levels (MLs) were used as the levels of THC in hemp containing foods for the dietary models.

Proposed MLs

Proposed MLs for various commodities containing hemp were derived by estimating a maximum concentration of THC in each commodity that would not result in consumers exceeding the TDI for THC, assuming consumption at the 95th percentile level. The highest 95th percentile consumption figure from the 1995 NNS in each commodity group was taken, for example, the 95th percentile consumption of olive oil was the highest of all potential salad oils considered. The maximum concentration of THC for each commodity group that would not result in exposure above the TDI was estimated. These calculations assume that the entire commodity contains THC and that it is the only product consumed. An exception was made for wheat flour, where it was considered unrealistic to assume that 100% of the commodity contained hemp; therefore 10% of the 95th percentile consumption of wheat flour was used. The equation used for these calculations is as follows:

$$\text{Maximum concentration (mg/kg)} = \frac{\text{TDI (mg/d)}}{\text{Consumption (kg)}}$$

The consumption figures used in the calculations and the results are shown in Table 1.

Table 1: Calculations for derivation of proposed MLs for THC in various food groups

Commodity	Source of consumption figures	Age	95th Percentile Food Consumption (kg)	Resulting maximum concentration (mg/kg)
Hemp oils	Olive oil	2 – 12	0.016	10.22
		20+	0.028	16.07
Hemp seed	Mustard seed	2 – 12	0.007	24.56
		20+	0.013	33.58
Hemp tea, brewed	Black tea, brewed	2 – 12	0.615	0.27
		20+	1.776	0.25
Hemp-based beverage	Mammalian milk	2 – 12	1.461	0.12
		20+	1.558	0.29
Hemp flour	10% Wheat flour	2 – 12	0.021	8.1
		20+	0.024	18.5

Note: The TDI in mg/d for adults aged 20 years and above is 0.45 mg/d (based on a mean body weight of 75 kg and TDI of 6 μg/kg bw/day), and for children aged 2-12 years is 0.168 mg/d (mean body weight of 28 kg).

Proposed MLs have been derived from the worst case scenario presented in Table 1, usually from the maximum concentration for children aged 2-12 years old, by use of the convention of rounding down to the nearest 1, 2, 5 or 10 mg/kg figure.

From the above table, the proposed ML for hemp oil is 10 mg/kg. From the above Table, the proposed ML for hemp seed alone would be 20 mg/kg, however, the ML for hemp flour is lower (8 mg/kg for children).

As hemp flour is a product of hemp seed and the major food, the data from hemp flour was used and proposed ML rounded down to 5 mg/kg, and applied to both hemp seed and hemp flour.

For hemp-based beverages, although the maximum concentration would be 0.1 mg/kg, it was concluded that 0.2 mg/kg would be appropriate because it is very unlikely that hemp-based beverages would replace all mammalian milk consumption. In other countries, hemp-based beverages are sold in 125 ml containers and it is therefore unlikely that it would be consumed in the large quantities that have been reported in the 1995 NNS for milk (1.4-1.6L).

Derivation of the proposed MLs were done using Australian food consumption data only. It was assumed that the consumption of the food groups in New Zealand were similar.

In summary, the proposed MLs are as follows:

- Hemp seed and hemp flour 5 mg/kg
- Hemp oil 10 mg/kg
- Hemp-based non-dairy beverages 0.2 mg/kg
- Other foods 0.2 mg/kg

THC dietary exposure estimate

To assess if exposure to a diet containing THC at the proposed MLs posed a public health and safety risk, a dietary exposure estimate was undertaken. Foods likely to contain hemp that were considered for inclusion in the modelling are as follows:

Hemp seeds can be used to make muesli bars and baked goods, as well as being eaten by themselves. Hemp seeds were not a part of the Australian or New Zealand diet when the NNSs were conducted, and therefore consumption data from the 1995 and 1997 NNSs for seeds that could be used similarly to hemp seeds were included in the modelling (poppy seeds, sesame seeds, sunflower seeds and mustard seeds). A THC level of 5 mg/kg in hemp seeds was used.

Hemp oil is a product that would be mainly used as a salad oil. An approach similar to that used for hemp seeds was used for hemp oil, where oils with similar uses were included in the modelling. The oils modelled were rapeseed oil, soybean oil, cotton seed oil, safflower oil, sesame seed oil, sunflower seed oil and olive oil. A THC level of 10 mg/kg in hemp oil was used.

Hemp flour can be made in one of two ways. Whole hemp seeds can be ground into flour, whereby the flour would have a similar THC concentration as the hemp seed (assuming no destruction of the THC due to processing). Alternatively, the husk can be removed from the seed, and the hulled seed can be ground into flour. The THC concentration would be lower using this process. In the model, a THC level of 5 mg/kg in flour, which is the same as the proposed ML for seed, was used.

Hemp based non-dairy milk is made from soaking hemp seeds in liquid. A THC level of 0.2 mg/kg was used for this beverage.

Other hemp containing food groups were identified, as they were either available overseas as a hemp product, or likely to be produced containing hemp (Grotenhermen, Jarus & Lohmeyer, 1998). For example, h*emp tofu* is another product made from hemp. Also, h*emp tea* is made from soaking hemp leaves in liquid. Although the above calculation suggests an ML of 0.2 mg/kg is suitable for hemp-based tea as consumed, no information was available to propose an ML for dried hemp leaves used for preparation of hemp-based tea. As these foods are minor uses for hemp, their contribution to the total diet would be minimal. Their inclusion in the modelling would have very little impact on estimated dietary exposures to THC.

Another product that may contain hemp is beer. This product was not included in the dietary modelling for THC because the process that is involved in the brewing of beer is believed to destroy the THC.

Table 2 contains the THC concentrations for the various commodities used in the modelling.

Table 2: THC Concentrations used in dietary modelling for various food groups

Food	Proposed ML (mg/kg)
Flour	5
Hemp-based non-dairy milk	0.2
Seeds	5
Oils	10

It was not considered realistic to assume 100% of commodities in the model are hemp products exclusively, for the following reasons:

- hemp flour needs to be mixed with other flour for baking. Consumers would not bake all products containing flour with hemp flour (i.e. cakes, bread, pasta etc.);
- it would be difficult to consume hemp seeds exclusively as part of a bar for example. Muesli bars can contain around 3-10 % of hemp seeds; and
- hemp-based non-dairy milk is a very sweet product, a property that could make it difficult to consume in the same quantity as cow's milk.

Ten percent of the food products (except hemp-based non-dairy milk, see below) have been identified as potentially containing hemp (Grotenhermen, Jarus & Lohmeyer, 1998). Therefore, an adjustment factor of 10% was used in the model to represent the amount of the mainstream commodity (oils, seed, flour) that would be likely to be replaced by hemp containing products. From the 1995 NNS it was estimated that approximately 3% of milk consumers drink soy beverages. In estimating the dietary exposure to THC it was assumed that consumption of hemp-based beverages would be similar to that of soy beverages, therefore an adjustment factor of 3% was given to mammalian milk consumption.

Modelling was conducted using data derived from the 1995 Australian NNS for all consumers aged 2 years and above and the 1997 New Zealand NNS for all consumers aged 15 and above. Other population sub groups were modelling, including 2-12 years (Australia only) to represent children. This age group are more vulnerable to exceeding a TDI due to their large food consumption compared to their small body weight. A second age group of 13 to 19 years of age (15-19 years for New Zealand) was used to represent teenagers.

This age group can also eat large quantities of foods per kilogram of body weight. Lastly, adults aged 20 years and over were considered (Table 3).

Table 3: Population sample details for THC dietary modelling for Australia and New Zealand

Population	Group Description	Number of Respondents	Number of Consumers	Consumers as a % all Respondents	Mean body Weight (kg)
Australia	2 years & above	13858	13819	99.7	67
	2 – 12 years	2079	2079	100	28
	13 – 19 years	1063	1058	99.5	63
	20+ years	10716	10682	99.7	75
New Zealand	15 years & above	4636	4624	99.7	71
	15-19 years	297	296	99.7	65
	20+ years	4339	4328	99.7	71

Results

Dietary exposure estimates for median consumers and 95th percentile THC consumers are displayed below in Table 4 as µg THC/kg bw/d and as a percentage of the TDI.

Table 4: Estimated dietary exposures to THC for potential consumers of foods containing hemp and various age groups for Australia and New Zealand

Population	Group Description	Median exposure µg/kg bw/d (% TDI)	95th %tile exposure µg/kg bw/d (% TDI)
Australia	2 years and above	0.8 (13.0)	2.7 (44.4)
	2 – 12 years	1.9 (31.0)	4.4 (72.7)
	13 – 19 years	1.0 (16.6)	2.6 (43.7)
	20+ years	0.7 (11.2)	1.7 (28.7)
New Zealand	15 years and above	0.7 (11.3)	1.9 (31.9)
	15-19 years	1.0 (16.0)	2.9 (47.8)
	20+ years	0.7 (11.1)	1.8 (30.5)

Discussion

The results, shown in Table 4, illustrate that it is likely that no consumers in Australia or New Zealand, for the total population, or in sub population groups, for both median consumers, and consumers of THC at the 95th percentile, are at risk of exceeding the TDI for THC. The major contributors to THC exposures for Australian consumers 2 years and above were hemp flour (91%) and hemp-based non-dairy beverage (6%). For New Zealand consumers (15 years and over) the major contributors were hemp flour (90%) and hemp-based non-dairy beverage (7%).

It should be noted that dietary exposures are likely to be overestimated, due to a number of reasons:

- there is the conservative assumption that 10% (and 3% for milk) of all foods consumed from the food groups will contain hemp;
- the models assume that all of the 10% (3% for hemp-based beverages) contains the THC at the proposed maximum levels. The actual THC levels resulting in the food should be lower than the ML; and
- 24-hour recall food consumption data tends to overestimate habitual consumption of a given commodity, leading to higher estimates of potential dietary exposure than would be the case over a long period of time.

Conclusion of the dietary exposure report

Proposed MLs for various commodities containing hemp were derived by estimating a maximum concentration of THC in the commodity that would not result in consumers exceeding the TDI for THC, assuming consumption at the 95th percentile level. The proposed MLs were then used for the dietary exposure assessment to ensure that they would not lead to a total dietary exposure greater than the TDI.

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 Australia and New Zealand. The exposures obtained are likely to be an overestimate because THC levels were assumed to be at the proposed ML and it is unlikely that the proportion of foods containing hemp would be as high as that assumed (10% for all foods groups considered except mammalian milk at 3%).

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Institute of European Food Studies (IEFS), 1998, *The effect of survey duration on the estimation of food chemical intakes, Report Number 3*, IEFS, Ireland.

ATTACHMENT 7

SUMMARY OF THE PUBLIC SUBMISSIONS
APPLICATION A360 - USE OF HEMP PRODUCTS AS FOOD

Australian Hemp Products

- Hemp seed is a traditional and well-accepted food and nutritional source throughout many countries of the world.
- There is a demand in Australia for hemp seed products.
- There is a need for a nutritional source of omega-3 and omega-6 fatty acids.
- There is a market potential in Asia, USA and Europe.

Brumby's Bakeries Ltd

- Support the application to allow the use of hemp products as foods.
- Nutrition properties of hempseed compare favourably with soy, flax etc.
- Trial bakes proved excellent in the areas of characteristics, consistency and taste of the finished product.

Country Hemp, Montville, Qld

- Support the application to allow the use of hemp products as foods.

Dietitians Association of Australia

- DAA Food Standards Advisory Committee requires further information on hempseed's nutritional value and benefits before it can comment.

Food Technology Association of Victoria

- No objection to hempseed oil as, with GMP, the hempseed oil should contain no THC.
- Hempseed requires a provision to ensure negligible THC.
- Suggest removal of prohibition on Cannabis use in food but provide maximum permitted levels of THC.

Health Department of Western Australia

- WA Food Advisory Committee does not support the application for the following reasons:
  - administrative and enforcement of standards: there are significant logistical difficulties to permit low THC containing *Cannabis* while prohibiting all other forms of the same species;
  - not in the interests of public health and safety: marketing which emphasised the presence of Cannabis may influence public opinion on the acceptability of psychoactive marijuana in society and undermine the government's anti-drug program; and
  - interference with drug assays in prosecution against illicit use of Marijuana: the possibility of positive THC urine tests from consumption of hemp foods.

- Noted the recent attempt to import 'Hemp beer" from the UK into WA and that the marketing strategy relies on the use of a marijuana leaf on the label.

Hemp Store Aotearoa Ltd

- Support the application to allow the use of hemp products as foods.
- Manufacturer, wholesaler and retailer of hemp products and have imported hempseed chocolate, muesli bars, lollipops into New Zealand.
- New Zealand food regulations do not cover hemp seed or hempseed oils, but hempseed is a Class C controlled drug under the Misuse of Drugs Act 1975. Hempseed oil is not mentioned in the same legislation.
- There is uncertainty in the hemp industry as to the legal status of their products.
- A local hempseed and hempseed oil industry will create regional employment, reduce imports and create export revenue.
- Emphasises the nutritional benefits of hempseeds.

Supports establishing a maximum level for THC in hemp products.

Hemptastic New Zealand Ltd

- Support the application because hempseed is a source of essential fatty acids.

Human Services - Victoria

- No objection to progression of the application provided:
  - THC is absent or at levels which produce no pharmacological effect;
  - extraction of THC for drug use is not viable; and
  - residual levels of THC are consist with levels permitted in other countries;
  - hempseed products are safe for human consumption.

- In Victoria, low THC material is produced by imposing a requirement that plants are harvested before the seed is set.
- Agree that hemp seed oil has a favourable nutrient profile.
- Hempseed oil is technically legal since cold-pressing extraction has diminished its botanical origins and psychoactive substances (THC below the level of detection).
- Hempseed from low THC cultivars is indistinguishable from seed of high THC cultivars without genetic profiling. Overseas the problem is overcome by washing the seed and certification of the level of THC and its isomers in a product batch.
- *Cannabis* plants and seeds are still prohibited substances under other legislation.
- Questions were raised in relation to:
  - an entry in the Edible Oil Standard;
  - likelihood of reversion to high THC plants;
  - a sterilization requirement for hempseeds; and
  - sampling programs and methods of analysis for THC.

InforMed Systems Ltd

- Supports the application to allow the use of hemp products as foods.
- Notes the nutritionally favourable fatty acid profile of hemp oil.

- Considers it essential that the low THC plant be used and that the level of THC in the edible oil be restricted.
- Suggest a 10 mg/kg level for THC in oil but indicates that this could be higher if safe and if the industry could not comply with this low level.

New Zealand Hemp Industries Association Inc.

- Support the application.
- Believe option 5 in the preliminary assessment is the best option.

New Zealand Ministry of Health

- Notes that in New Zealand, under the Misuse of Drugs Act 1975 it is illegal to be in possession of hemp seed or hemp seed oil with detectable THC. Hemp seed oil may be imported into NZ provided it contains no detectable THC.
- A change to the Misuse of Drugs Act would be necessary to allow marketing of hemp seed or hemp seed oil in New Zealand.

Qld Department of Primary Industry (Qld Industrial Hemp Advisory Committee)

- Supports the proposal to permit the use of hemp seed and hemp seed oil in foods.
- Recommends removal of the entry for Cannabis spp. from the Table to clause (8) of Standard A12 and establishment of an appropriate threshold level for THC.
- The reasons for the QIHAC support include: (i) hemp is a valuable source of essential fatty acids; (ii) direct economic benefit as a result of the sale of hemp seed products; (iii) indirect economic benefit by providing impetus for the hemp fibre industry; (iv) conformity to other countries; (v) community acceptance of hemp as a food.
- Recommends that aspects such as quality standards and expiry date for hemp products be included on the packaging.
- Requests that a national standard for hemp seed production should be considered.

Tasmanian Hemp Company

- Support the application to allow the use of hemp products as foods.
- Re-enforce the nutritional benefits of hempseeds and hemp oil.
- Recommend a level of 50 ppm for hempseed oil.

The Triple M Company Ltd

- Supports the application to allow the use of hemp products as foods.
- Marijuana has a THC level in the range 5-15% which industrial hemp grown in Europe has a certified THC content of less than 0.3% THC.