

28 July 2016
[20–16]

Call for submissions – Proposal P1042

Low THC Hemp Seeds as Food

FSANZ has assessed a proposal prepared to develop a food regulatory measure to permit the sale of food derived from the seeds of low delta 9-tetrahydrocannabinol varieties of *Cannabis sativa* (low THC hemp), and has prepared a draft food regulatory measure. Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word ‘Submission’ and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 25 August 2016

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting documents

The following documents which informed the assessment of this Proposal are available on the FSANZ website at [P1042 - Low THC Hemp Seeds as Food](#).

Supporting Document 1	Dietary exposure assessment
Supporting Document 2	Cannabidiol hazard profile

Executive summary

Proposal P1042 – Low THC Hemp Seeds as Food was developed to consider a food regulatory measure to permit the sale of food derived from the seeds of low delta 9-tetrahydrocannabinol varieties of *Cannabis sativa* (*C. sativa*) (low THC hemp). The proposal was prepared following a request from the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum).

The Forum also requested that the following matters be considered as part of the proposal:

- the need to set a cannabidiol (CBD) limit to distinguish food from therapeutic goods, and include the respective acid precursors in any cannabinoid limits that are set
- policy advice relating to restricting the marketing and advertising of low THC hemp as a food, in particular, the following points are not in line with government policy:
 - use of the cannabis leaf or any representation that states, suggests or implies a link with illicit cannabis in any marketing or advertising of hemp seed food
 - food derived from hemp seed being advertised as having psychoactive effects
- advice from the International Narcotics Control Board and the European Union approach when setting a low THC limit in food.

Standard 1.1.1 – Structure of the Code and general provisions in the *Australia New Zealand Food Standards Code* (the Code) currently prohibits plants and fungi listed in Schedule 23 – Prohibited plants and fungi, from being sold as food or being used as an ingredient or component of a food for sale. Cannabis (all species) is listed in Schedule 23 as a prohibited plant.

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

Hemp seed oil is permitted to be sold as a food in New Zealand (under a New Zealand standard), but other hemp foods are currently subject to the prohibition in Standard 1.1.1.

FSANZ has previously approved draft variations to the Code in relation to two Applications (A1039 and A360)¹ seeking permission to sell industrial hemp as a food. However, both amendments to the Code were rejected by food regulation ministers². In rejecting the FSANZ approvals, ministers cited concerns that the use of low THC hemp in food may send a confused message to consumers about the acceptability and safety of cannabis; that there may be impacts on law enforcement (including effects on oral fluid drug testing and distinguishing between high and low THC varieties of cannabis); and that CBD content of low THC hemp seed foods should be considered in the context of increasing interest in its therapeutic properties. Ministers did not identify concerns relating to FSANZ's assessment that low THC hemp seed foods were safe for human consumption.

FSANZ is satisfied that low THC hemp seed foods are safe for consumption when they contain no more than the proposed maximum levels (MLs) of THC. FSANZ has also recognised that low THC hemp seed foods may provide a useful alternative dietary source of

¹[Application A360 – Use of Industrial Hemp as a Novel Food](#) and [Application A1039 - Low THC Hemp as a Food](#)

² A360 was rejected by the Food Regulation Australia and New Zealand Food Regulation Ministerial Council in 2002 and A1039 was rejected by the Australia and New Zealand Ministerial Forum on Food Regulation in 2015.

many nutrients and polyunsaturated fatty acids, particularly omega-3 fatty acids.

FSANZ has proposed a draft variation to Standard 1.4.4 – Prohibited and restricted plants and fungi that permits the sale of foods derived from the seeds of low THC varieties of *C. sativa*. Maximum levels of THC content that may be present in low THC hemp seed foods have been specified. Low THC hemp seeds may only be sold as a food if they are hulled and non-viable. Only seeds from low THC varieties of *C. sativa* could be used as a source for food and only naturally occurring THC may be present in low THC hemp seed foods.

The draft variation was made in accordance with the objectives in the FSANZ Act, and after consideration was given to the matters required by the Act in FSANZ's assessment of a proposal to amend the Code. FSANZ's previous risk assessments prepared for A360 and A1039 were prepared using the best available scientific evidence; they remain valid and support the current assessment. The previous risk assessments have not been reproduced in this Proposal; although an update of the dietary exposure included in A1039 has been prepared, using more recent nutrition survey data for Australian and New Zealand populations.

In response to the specific issues the Forum asked FSANZ to consider in this proposal, FSANZ:

- is not proposing a CBD limit in the Code for low THC hemp seed foods
 - although a limit for CBD has not been included in the draft variation, FSANZ has proposed additional drafting to make it clear the draft variation does not permit CBD (or other cannabinoids), including CBD extracted or derived from seeds of low THC *C. sativa*, to be a food for sale or used as an ingredient in a food for sale
- has proposed the maximum levels of THC that may be present in low THC hemp seed foods be drafted as 'total THC', which is defined as the total amount of THC and the acid precursor delta 9-tetrahydrocannabinolic acid (THC-A)
- is not proposing additional labelling or advertising requirements in the Code for low THC hemp seed foods, primarily because no relevant available scientific evidence that can be used as the basis of risk analysis to apply such measures, has been identified
- considers the advice from the International Narcotics Control Board does not impact on the assessment of this proposal.

1 Introduction

1.1 The Proposal

This proposal seeks to develop a food regulatory measure to permit the sale of food derived from the seeds of low delta 9-tetrahydrocannabinol varieties of *Cannabis sativa* (low THC hemp).

1.2 The current Standard

The *Australia New Zealand Food Standards Code* (the Code) prohibits all species of cannabis from being sold as food or being used as an ingredient or component of a food. Standard 1.1.1 – Structure of the Code and general provisions states a food for sale must not be, and must not have as an ingredient or component, a prohibited plant (subsections 1.1.1—10(5)(a) and 1.1.1—10(6)(e)). Cannabis (all cannabis species) is listed in Schedule 23 – Prohibited plants and fungi as a prohibited plant.

The prohibition includes a part or derivative of the cannabis species or a substance derived from that plant, part or derivative (refer to definition of prohibited plant or species – paragraph 1.1.2—3³).

Standard 1.4.4 – Prohibited and restricted plants and fungi provides exceptions to the prohibitions in Standard 1.1.1. However there are currently no exceptions for cannabis species.

The sale of hempseed oil as a food is permitted by the *New Zealand Food (Safety) Regulations 2002*. This permission is an exception to the prohibition on all cannabis species in the Code and applies only to hempseed oil. The permission is scheduled to expire on 30 October 2017. Other hemp food products are not permitted in New Zealand and remain subject to the prohibition in the Code.

1.3 Reasons for preparing the Proposal

The Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) has requested FSANZ develop a proposal on how, if it was considered appropriate, low THC hemp could be legally designated as a food. FSANZ has interpreted this request to be a request for developing a food regulatory measure to permit the sale of foods containing the seeds, or substances extracted or derived from the seeds of low THC hemp. The *Food Standards Australia New Zealand Act 1991* (FSANZ Act) does not permit FSANZ to develop or vary a standard to designate a product or a substance as a food.

The Forum requested that the following matters be considered as part of the proposal:

- the need to set a cannabidiol (CBD) limit to distinguish food from therapeutic goods, and include the respective acid precursors in any cannabinoid limits that are set
- policy advice relating to restricting the marketing and advertising of low THC hemp as a food, in particular, the following points are not in line with government policy:
- use of the cannabis leaf or any representation that states, suggests or implies a link

³ Prohibited plant or fungus means:

- (a) a plant or fungus listed in Schedule 23; or
- (b) a part or a derivative of such a plant or fungus; or
- (c) a substance derived from a plant, fungus, part or derivative referred to in paragraph (a) or (b).

- with illicit cannabis in any marketing or advertising of hemp seed food
- food derived from hemp seed being advertised as having psychoactive effects
- advice from the International Narcotics Control Board and the European Union approach when setting a low THC limit in food.

1.4 Background

1.4.1 Properties of hemp

C. sativa is well known as a source of the psychoactive phytocannabinoid, THC. In recent times, there has also been increasing interest in the therapeutic potential of other phytocannabinoids present in *C. sativa*, including cannabidiol (CBD). CBD appears to lack any significant intoxicating effects.

Varieties of *C. sativa* that contain levels of THC that are considered to be psychoactive, are known by various names, including marijuana. The THC level in these varieties of *C. sativa* varies from 3% to more than 15%, which is mostly in the form of non-psychoactive delta 9-tetrahydrocannabinolic acid (THC-A). Heating the plant material to 160°C or more converts the THC-A to the psychoactive THC. A slower, more gradual conversion occurs at room temperature. The levels of the other phytocannabinoids in these varieties are very low, typically <0.2%.

Varieties of *C. sativa* that contain no THC, or very low levels of THC, are commonly referred to as hemp, industrial hemp or industrial cannabis. Hemp does not have any psychoactive properties. The level of THC in hemp typically varies from zero to 0.5% (in the leaf and flowering head of the plant). There are corresponding higher levels of CBD (approximately 3.5%) and cannabidiolic acid (CBD-A) (approximately 10.5%) in hemp. There are currently no established regulatory limits on the CBD content of low THC hemp crops.

The fibrous part of the hemp plant has typically been used for industrial purposes, such as textiles, fibres (rope, nets and sacks), paper and building materials. The seed is the main part of the hemp plant used as a source of food. Shelled seeds, also known as hulled seeds, have the outer hull or coating of the seed removed. Cannabinoids are not synthesised within the hemp seed. However, traces of THC and CBD contamination of the seed may occur due to residual contamination of the outside of the seed coat, even under good agricultural/manufacturing practice. Rigorous cleaning methods, including washing, sieving and shelling, may help reduce or remove any cannabinoid contamination of seeds.

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

1.4.2 Applications to permit the sale of low THC hemp seed foods

There have been two applications to FSANZ to permit the sale of foods derived from hemp (Application A360 – Use of Industrial Hemp as a Novel Food⁴ and Application A1039 – Low THC Hemp as a Food⁵).

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<http://www.foodstandards.gov.au/code/applications/Pages/applicationa360hempasanovelfood/Default.aspx>

⁵ <http://www.foodstandards.gov.au/code/applications/Pages/applicationa1039lowt4708.aspx>.

Application A360 was received in 1998. FSANZ did not identify any safety concerns arising from the consumption of low THC hemp seed foods, subject to proposed maximum levels (MLs) of THC being established. FSANZ recommended amending the Code to remove the total prohibition on cannabis species and to set MLs for THC that would be permitted in specified low THC hemp seed foods.

However, in 2002, Ministers rejected FSANZ's proposed amendments to the Code. There was concern that the availability of low THC hemp seed foods may send a confused message to consumers about the acceptability and safety of illicit cannabis and pose problems for drug enforcement agencies.

FSANZ received an application from Dr Andrew Katelaris MD on 4 December 2009 (A1039), seeking approval for the use of the seed and seed products of *C. sativa* with low levels of THC as food.

FSANZ agreed to accept A1039 recognising that an assessment could take into consideration a number of developments since the assessment of A360, including the increased uptake of low THC hemp seed foods internationally and the development of industrial hemp licensing arrangements in Australia and New Zealand. The results of an updated risk assessment reflected the earlier assessment conducted for A360. FSANZ again proposed to amend the Code to permit the sale of low THC hemp seed foods, subject to MLs of THC being established.

The approval for A1039 was made in accordance with the FSANZ objectives in the FSANZ Act and also having regard to other matters required by the Act in developing food regulatory measures. FSANZ gave regard to concerns raised by stakeholders (including law enforcement issues), the outcomes of consultations with international jurisdictions where low THC hemp seed foods are legally available, an evaluation of potential impacts on stakeholders, and the outcomes of an economic analysis of benefits and costs.

However, in 2015, Ministers rejected the proposed amendments to the Code to permit the sale of low THC hemp seed foods resulting from A1039. The Forum noted that FSANZ found that foods containing the seeds or seed products of low THC hemp do not present any safety concerns as food. However, ongoing concerns were raised by some Forum Members relating to law enforcement issues, CBD levels and the potential marketing of low THC hemp in food.

The Forum agreed that further work be undertaken investigating information gaps that could help address the above concerns and requested that the Food Regulation Standing Committee (FRSC) conduct this work. At its March 2016 teleconference meeting, the Forum noted the outcomes of the FRSC investigations. Members noted that there was no formal proposal to permit low THC hemp as a food and so they agreed to task FSANZ to begin work on developing a proposal. FSANZ would follow the legislated process including a risk analysis and stakeholder consultation.

1.5 Procedure for assessment

The Proposal is being assessed under the General Procedure of the FSANZ Act.

2 Summary of the assessment

The previous assessments FSANZ conducted for Applications A360 and A1039 are publicly available. FSANZ's assessments, using the best available scientific evidence, determined that low THC hemp seed foods were safe for human consumption, subject to proposed MLs of THC being established. FSANZ's previous risk assessments remain valid and support the current assessment. The previously established tolerable daily intake (TDI) of 6 µg THC per kg body weight (bw) remains valid and has been used for the updated dietary exposure assessment (section 2.1).

FSANZ has not reproduced the previous risk assessments⁶ as part of the assessment of this proposal; although an update of the dietary exposure included in A1039 has been prepared, using more recent nutrition survey data for Australian and New Zealand populations (Supporting Document 1 (SD1)).

In addition, FSANZ's assessment of this proposal addresses the matters the Forum requested FSANZ investigate (section 2.2). The updated dietary modelling and the matters the Forum asked FSANZ to investigate are assessed below.

2.1 Dietary exposure update

Chronic dietary exposure to THC was previously estimated as part of the risk assessment in Applications A360 and A1039. The purpose of the estimates was to calculate potential exposure to THC assuming proposed MLs for THC for low THC hemp seed foods. For the purposes of assessing the current Proposal, the previous dietary exposure estimates for Australia and New Zealand were updated to incorporate more current national nutrition survey data. Dietary exposure estimates were compared to the TDI for THC of 6 µg/kg bw.

2.1.1 Risk assessment

Risk Assessment Question:

Will new national nutrition survey data have an impact on previous estimates of dietary exposure to THC from low THC hemp seed foods?

The updated dietary exposure assessment presented in this Proposal at SD1 confirms that, using the most up-to-date available food consumption data and unpublished analytical data provided by the New South Wales Department of Health (NSW Health), no Australian and New Zealand population groups examined would exceed the TDI for THC at the mean and 90th percentile of estimated dietary exposure. Dietary exposure estimates ranged between 5-26% of the TDI of 6 µg/kg bw for the Australian and New Zealand populations.

Estimated dietary exposure to THC reported here is lower than that reported previously, most likely due to changes in food consumption patterns in the more recent nutrition surveys and the replacement of dairy milks with non-dairy beverage consumption as a more realistic proxy for hemp seed based non-dairy beverage consumption. Dietary exposure estimates are based on conservative assumptions and therefore likely to be overestimates.

More detail on the dietary exposure assessment is provided in SD1.

⁶ Supporting Document 1 of A1039 Approval Report:
<http://www.foodstandards.gov.au/code/applications/pages/applicationa1039lowt4708.aspx>

2.1.2 Risk management and conclusion

The updated dietary exposure assessment indicates the MLs for THC previously proposed by FSANZ are consistent with protecting consumers against exceeding the TDI for THC. Therefore, FSANZ has maintained the proposed MLs for THC in low THC hemp seed foods developed during the assessment of A360 and affirmed in the assessment of A1039. See section 2.3 for further discussion on the definition of THC, in the context of including reference to delta 9-tetrahydrocannabinolic acid (THC-A), the precursor acid of THC.

2.2 CBD limit

The Forum asked FSANZ to consider setting a limit for CBD in low THC hemp seed foods in the Code, to help distinguish between foods and therapeutic goods. There is increasing interest in the therapeutic properties of CBD, with a large number of clinical trials investigating the effect of CBD on a range of conditions (including schizophrenia, epilepsy, chronic pain and anxiety). FRSC research identified a small number of CBD-fortified products (available internationally and online) that may provide a therapeutic dose, including pressed seed hemp oil that is fortified with CBD extract (concentrated extracts from other parts of the hemp plant). These CBD-fortified products are not legally available in Australia and New Zealand at present.

The request from the Forum is related to differentiating food and therapeutic goods, rather than setting a limit based on safety (such as the MLs for THC that FSANZ has proposed for low THC hemp seed foods). FSANZ has conducted an estimate of dietary exposure to CBD from low THC hemp seed foods and determined there is no risk to public health and safety (section 2.2.1). Section 2.2.2 includes discussion of the issues associated with establishing a CBD limit in the Code.

2.2.1 Exposure to CBD from low THC hemp seed foods

2.2.1.1 Risk assessment

Risk Assessment Question:

Is there a risk to public health and safety from exposure to CBD resulting from the consumption of low THC hemp seed foods?

Dietary exposure assessments were undertaken for CBD in low THC hemp seed foods, using unpublished analytical data provided by NSW Health. Based on 'worst case' conservative assumptions, estimated dietary exposure to CBD for consumers of low THC hemp seed foods was <1% of the lowest oral human therapeutic dose (LOHTD) of 120 mg/day estimated by FSANZ. More detail on how FSANZ estimated the LOHTD is provided in SD2. The amount of low THC hemp seed foods that would need to be consumed to reach the LOHTD for CBD is many orders of magnitude higher than is realistically possible. For example, 5 kg/day of hemp seed oil or 24 kg/day of hemp seeds would need to be consumed to reach the LOHTD. More detail on the dietary exposure estimate for CBD is included in SD1.

2.2.1.2 Risk management

The dietary exposure estimates for CBD indicate that a CBD limit in the Code is not necessary to protect public health and safety because the amount of low THC hemp seed foods that would need to be consumed to reach a therapeutic dose is many orders of magnitude higher than is realistically possible. Therefore, MLs for CBD would not serve a risk management purpose in relation to protecting public health and safety.

2.2.2 CBD limit in Code

FSANZ understands, in the event of low THC hemp seed foods being permitted for sale in Australia and New Zealand, the Forum wants to ensure that CBD-fortified products cannot be sold as food. The Forum has asked FSANZ to investigate establishing a CBD limit in the Code as a means of achieving a clear delineation between low THC hemp seed foods and hemp based products that are intended to achieve a therapeutic effect, such as CBD-fortified products.

FSANZ established an intergovernmental advisory group in order to gain a better understanding of the Forum's concern and to obtain views on the potential benefits of establishing a CBD limit in the Code. FSANZ's discussion with the intergovernmental advisory group identified the Forum's concern relates to the potential for CBD-fortified products to be misused by consumers seeking to self-medicate for serious medical conditions such as epilepsy and to stop taking their prescribed medications. Although CBD-fortified products are not legally available in Australia and New Zealand, they are marketed internationally, sometimes side-by-side with low THC hemp seed food products (online).

Based on the views of the advisory group and other discussions FSANZ has conducted with stakeholders and consideration of FSANZ and other legislation, FSANZ has identified a number of issues associated with establishing a CBD limit in the Code in the context of differentiating between food and therapeutic goods. These issues are identified and discussed below.

2.2.2.1 Issues associated with establishing a CBD limit in Code

Differentiating foods from therapeutic goods

The FSANZ Act does not permit FSANZ to develop or vary a standard to designate a product or substance a therapeutic good. Standards set under the FSANZ Act do not determine whether a product is a food or a therapeutic good. This is determined by provisions in the FSANZ Act and the *Therapeutic Goods Act 1989*. Establishing a CBD limit that is not based on evidence of needing to protect public health and safety may be a decision that is open to legal challenge, although the likelihood of legal challenge is not known.

The draft variation prepared for A1039, and affirmed in the assessment of this proposal, would not permit the sale of CBD-fortified products as foods. CBD-fortified products contain added CBD that is sourced from parts of the cannabis plant that produce CBD (not the seeds). Only foods derived from low THC hemp seeds would be permitted under the FSANZ draft variation, which is drafted as an exception to the overarching prohibition on all cannabis species in the Code. Any substance derived from another part of the cannabis plant would not be permitted to be added to, or sold as food, and would still be subject to the overarching prohibition on all cannabis species. However, in order to remove doubt, FSANZ has included additional text to make it clear the draft variation does not permit CBD, including CBD extracted or derived from seeds of low THC *C. sativa*, to be a food for sale or used as an ingredient in a food for sale. The additional text in the draft variation refers to 'cannabinoids', rather than just CBD (which is one type of cannabinoid). Although CBD is of particular interest at present, there are a variety of other cannabinoids that may be naturally present in low THC hemp seed foods and may be of interest in future.

The draft variation would permit the natural presence of cannabinoids in low THC hemp seed foods due to contamination during processing. THC content would be limited to the MLs included in the draft variation. CBD and other cannabinoid content would not be restricted by specific MLs in the Code due to the lack of safety concern associated with exposure to these cannabinoids at the levels present in low THC hemp seed foods.

A review of products available online indicates that CBD-fortified products are packaged and marketed in a significantly different manner to low THC hemp seed foods, such that they would not be easily mistaken for foods. They are typically presented as premium products and are clearly labelled to contain CBD. The majority of products are 'oil drops' and tinctures supplied in small dropper bottles, whilst others are sold in capsule form. A number of products are labelled as dietary supplements.

FSANZ understands that CBD-fortified products are not permitted to be sold in Australia and New Zealand. If CBD-fortified products were permitted in the future FSANZ understands that these products, like other medicinal cannabis products, would only be available in Australia and New Zealand via prescription from specialist medical practitioners and potentially only after Ministerial permission is granted. This restricted access should address the potential for consumers seeking to self-medicate with these products.

Reference point for amending other legislation

In addition to the main concern of the Forum, FSANZ's discussion with the advisory group identified two potential benefits of establishing a CBD limit in the Code. The first potential benefit is that a CBD limit in the Code may provide a consistent reference point for jurisdictions to set exceptions/exemptions in relevant drug control legislation. Consumption of CBD is not permitted in Australia and New Zealand, except for therapeutic use under special circumstances (medicinal cannabis). In order for the consumption of the low levels of CBD that may be present in low THC hemp seed foods to be legalised, legislation other than the Code will need to be amended.

FSANZ notes a CBD limit in the Code may provide a reference point for levels to be set in jurisdictions' drug control legislation, so that a consistent approach could be taken across each jurisdiction in Australia and New Zealand. However, a CBD limit in the Code is not a prerequisite for these amendments to other legislation to be made.

With respect to a consistent approach across jurisdictions, particularly in relation to CBD levels, jurisdictions could develop model provisions that could be incorporated in a co-ordinated and consistent fashion. Jurisdictions are currently investigating other legislation that may need to be amended to enable the legal consumption of low THC hemp seed foods should FSANZ's draft variation be approved.

Protect against higher CBD hemp crops

The second potential benefit of a CBD limit in the Code is that it may provide some protection against the future development of hemp crops that contain higher levels of CBD (noting CBD limits are not currently proscribed in industrial hemp cultivation legislation). FSANZ notes that hemp regulations already control the cultivation of hemp crops in Australia and New Zealand. If controls on the CBD content of hemp crops are considered necessary, hemp legislation may be a more appropriate place to set controls on the levels of cannabinoids permitted to be present in hemp crops. FSANZ considers a CBD limit for hemp seed foods is not the most appropriate way of controlling CBD content of hemp crops.

International consistency

International jurisdictions have not set CBD limits for hemp foods (or for hemp cultivation). A CBD limit in the Code may present a trade barrier and impose additional compliance costs that are not required in other markets.

2.2.3 Conclusion

FSANZ must take into account a number of factors in developing or varying regulatory

measures. After consideration of all relevant factors, FSANZ has decided not to propose a CBD limit in the Code for low THC hemp seed foods for the following reasons:

- A CBD limit in the Code is not necessary to protect public health and safety because the CBD content of low THC hemp seed foods is not the limiting factor in protecting public safety for these foods.
- If FSANZ establishes a CBD limit in the Code in order to differentiate between foods and therapeutic goods, and therefore not based on evidence of needing to protect public health and safety, this may be a decision that is open to legal challenge. Standards set under the FSANZ Act do not determine whether a product is a food or a therapeutic good. This is determined by provisions in the FSANZ Act and the *Therapeutic Goods Act 1989*.
- FSANZ's draft variation would not permit the fortification of low THC hemp seed foods with CBD. FSANZ has introduced additional clarification to ensure the draft variation does not permit CBD (or other cannabinoids), including CBD extracted or derived from seeds of low THC *C. sativa*, to be a food for sale or used as an ingredient in a food for sale.
- A CBD limit in the Code is not a requirement for other legislation to be amended. If low THC hemp seed foods are permitted for sale in Australia and New Zealand, other legislation (other than the Code) will need to be amended to permit the consumption of low levels of CBD (and THC) that may be present in these foods. This will need to occur irrespective of whether or not a CBD limit is established in the Code.
- A CBD limit in the Code may not be the most appropriate method of protecting against the development of hemp crops with higher CBD levels in the future. Industrial hemp legislation in Australia and New Zealand would appear to be a more appropriate method of controlling cannabinoid levels in hemp crops; an approach that is currently taken to address THC levels in domestic hemp crop cultivation.
- A CBD limit in the Code may present a trade barrier and impose additional compliance costs that are not required in international markets. International jurisdictions have not set CBD limits for hemp foods.

2.3 Cannabinoid acid precursors

The Forum asked FSANZ to include the respective acid precursors in any cannabinoid limits that are set. Only THC and CBD were identified by the Forum as cannabinoids that may require limits in the Code. Noting FSANZ's conclusion in section 2.2.3 relating to CBD, the only MLs FSANZ is proposing for hemp seed foods apply to THC. FSANZ has therefore considered whether the MLs for THC set in previous assessments need to be amended to take into account THC-A (the precursor acid of THC).

2.3.1 Risk assessment

Risk Assessment Question:

Will levels of THC-A present in low THC hemp seed foods impact on the MLs FSANZ has proposed for THC in the assessment of previous applications?

Delta 9-tetrahydrocannabinolic acid (THC-A) is not psychoactive, but is converted to THC quickly at sufficient temperature (160°C), with slower, more gradual conversion at room temperature. Both THC and THC-A can be present in low THC hemp seed foods as a result

of contamination during processing. If the food is stored for a significant amount of time, or perhaps more importantly, is heated by the consumer, some of the THC-A may be converted to THC. The presence of THC-A in low THC hemp seed foods may result in consumers having a greater potential to exceed the TDI for THC.

2.3.2 Risk management

FSANZ considers the MLs for THC in low THC hemp seed foods need to be set such that estimated dietary exposures to THC do not exceed the TDI for THC. Noting that THC-A can be converted to THC, the MLs should be set so that the THC-A content is considered. The rate of conversion of THC-A to THC may vary for different low THC hemp seed foods. Conversion will be much faster for foods that are heated, either during processing or by consumers after purchase. Products that are heated during processing may not present a significant issue in relation to determining if they are compliant with MLs (were they to be established) because there may already have been a significant conversion of THC-A to THC prior to analysis and the MLs would apply to food for sale.

However the conversion of THC-A to THC may be more of a concern for products that are heated by consumers prior to consumption, so that the THC-A content of a low THC hemp seed food may need to be taken into account.

FSANZ also notes that some analytical methods for detecting THC and THC-A in low THC hemp seed foods include a heating step of samples. Therefore, it is possible that some analytical detection methods may also convert some THC-A to THC, resulting in detection of higher levels of THC than may have initially been present in the original sample. MLs for THC will need to account for the variability and uncertainty in THC/THC-A levels and conversion rates.

FSANZ has considered two potential options for incorporating THC-A into MLs for THC. These options are discussed below.

Total THC MLs

This option would maintain the previously proposed MLs for THC in low THC hemp seeds (5 mg/kg), hemp seed oil (10 mg/kg), processed hemp seed products (5 mg/kg) and hemp seed based beverages (0.2 mg/kg). However, the MLs would be for total THC, defined as the combined amount of THC and THC-A. This option would mitigate any potential uncertainty relating to levels of THC and THC-A in low THC hemp seed foods and rates of conversion of THC-A to THC. If the total level of THC-A and THC in a food is below the ML for total THC, any conversion of THC-A to THC would not result in a level of THC that is greater than the ML and would be protective of consumers.

Separate THC and THC-A MLs

This option would result in separate MLs for THC and for THC-A in low THC hemp seed foods. The MLs would need to take into account the potential for THC-A to be converted to THC, particularly for products that can be stored for a long period of time or are intended to be heated by consumers after purchase. Separate MLs for each type of low THC hemp seed food would need to be below the MLs for THC previously proposed by FSANZ so that estimated dietary exposure to total THC did not exceed the TDI. Therefore, separate THC and THC-A MLs would achieve the same risk management outcome as total THC MLs (THC + THC-A).

Establishing separate MLs for THC and THC-A would be subject to two areas of current uncertainty. Firstly, based on the unpublished survey data FSANZ obtained from NSW Health, there does not appear to be a consistent relationship between THC and THC-A

content in low THC hemp seed foods. Secondly, FSANZ notes the rate of conversion of THC-A to THC in low THC hemp seed foods is not certain and will vary depending on different lengths of storage and heating.

2.3.3 Conclusion

FSANZ notes that the two options discussed above would achieve the same risk management outcome of ensuring consumers do not exceed the TDI for THC. However, establishing separate MLs for THC and THC-A appears to be subject to greater uncertainty than establishing MLs for total THC (THC + THC-A). FSANZ considers MLs for total THC is an appropriate risk management measure to account for levels of THC and THC-A in low THC hemp seed foods. Therefore, FSANZ's draft variation proposes MLs for total THC in low THC hemp seed foods, where total THC is the combined amount of THC and THC-A.

2.4 Labelling and advertising

During the assessment of A360 and A1039, concerns were raised by stakeholders that representations (including labelling and advertising) associated with low THC hemp seed foods could suggest psychoactive properties (relating to consumption of those foods). There were also concerns that certain labelling and advertising of low THC hemp seed foods may result in consumers being more accepting of illicit cannabis and could undermine attempts to reduce the illegal use of cannabis.

The Forum requested that when preparing this proposal, FSANZ consider policy advice relating to restricting the marketing and advertising of low THC hemp as a food. The Forum stated that in particular, the following points are not in line with government policy:

- use of the cannabis leaf or any representation that states, suggests or implies a link with illicit cannabis in any marketing or advertising of hemp seed food
- food derived from hemp seed being advertised as having psychoactive effects.

2.4.1 Risk assessment

As outlined in FSANZ's assessment of A360 and A1039, low THC hemp seed foods meeting the proposed ML for total THC content will not induce psychoactive effects. During consideration of A1039 FSANZ conducted a review of the scientific literature to ascertain whether any studies had been published on consumers' perceptions of hemp products, particularly whether consumers believe that hemp products would have psychoactive effects and whether the labelling or advertising of hemp products (including words, pictures and symbols) has any effect on this belief. FSANZ updated this literature search in June 2016. No relevant articles were identified in either literature search.

FSANZ has also reviewed the scientific literature for evidence that the labelling and/or advertising of hemp seed foods causes consumers to link hemp seed foods with illicit cannabis, and further to this, to make illicit cannabis seem more acceptable. Once again, no relevant articles were identified.

During consideration of A1039, FSANZ liaised with overseas regulatory agencies in regions where low THC hemp seed foods are permitted, to ascertain whether they had experienced any problems in relation to these foods being marketed in such a way as to suggest they may have psychoactive properties. Most respondents indicated they were not aware of such problems in their respective countries. However, Belgium noted that while producers do market the nutritional qualities of hemp foods, some products have been marketed with large images of a cannabis leaf on the label and suggested that this may be viewed as making a connection with illicit cannabis use.

Some submitters to the A1039 Call for Submissions noted that consumers could be misled if the cannabis leaf was used in relation to hemp foods, as this is the image the population associates with drugs. A beer product from the UK bearing a cannabis leaf on the label was noted by one submitter as an example of the potential marketing of hemp food products that may occur. Some submitters (including hemp industry submitters) considered that some controls over the labelling of hemp foods (particularly use of the leaf and any reference promoting hemp food as being psychoactive) could be beneficial.

Other submitters to the A1039 Call for Submissions noted that the intended target market for hemp foods is health conscious consumers, including people with intolerances and allergies to other food products; and that the marketing of the majority of hemp foods overseas focuses on the nutritional profile of hemp, rather than attempts to make connections with drug-like effects. Submitters suggested that consumers would respond negatively to any suggestion of THC contamination or psychoactive properties of hemp foods. Submitters noted that if anything, manufacturers may choose to focus on the lack of THC content or psychoactive effects when marketing such foods.

2.4.2 Risk management

In considering potential risk management measures relating to the labelling and advertising of low THC hemp seed foods, existing standards need to be taken into account. There are currently a number of regulatory measures in place that would apply to the labelling and advertising of low THC hemp seed foods. These measures are outlined in the sections below.

2.4.2.1 Identification of food and ingredients

For most packaged food, a name or description of the food sufficient to indicate the true nature of the food must be provided on the label (where there is no prescribed name for the food in the Code) (Standard 1.2.2 – Information requirements – food identification).

The ingredients of a food must be declared in the statement of ingredients of most packaged foods by either a name by which the ingredient is most commonly known or a name that describes the true nature of the ingredient (or a generic name if there is one specified in the Code) (Standard 1.2.4 – Information requirements – statement of ingredients).

For foods derived from hemp seeds or containing ingredients derived from hemp seeds, product and ingredient names that may be considered acceptable under these standards include 'Hemp' and 'Low THC cannabis'. FSANZ has previously observed that low THC hemp seed oils available as foods in New Zealand use the name 'Hempseed Oil'.

2.4.2.2 Nutrition content claims and health claims

Nutrition content claims and health claims in the labelling and advertising of food are regulated by Standard 1.2.7 – Nutrition, health and related claims. This standard includes conditions for claims about the nutrition content of food (nutrition content claim), for example, claims in relation to polyunsaturated fatty acids, monounsaturated fatty acids and the omega fatty acid content of foods. The standard also includes conditions for claims about the relationship between a food or property of a food, and a health effect (a health claim), including when these claims are stated, suggested or implied. Health claims must either be preapproved (listed in the Code) or self-substantiated according to detailed requirements set out in the Code. These provisions would apply to health claims linking low THC hemp seed foods with psychoactive properties.

Standard 1.2.7 also prohibits claims of a therapeutic nature, i.e. claims that refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition. Claims must

also not compare a food with a good that is represented to be for therapeutic use or likely to be taken to be for therapeutic use (section 1.2.7—8).

2.4.2.3 Other standards and legislation

In addition to the standards outlined above, there are other generic labelling provisions in Part 1.2 – Labelling and other information requirements of the Code that would apply to low THC hemp seed foods and foods containing low THC hemp seeds as an ingredient, when sold for retail sale. These requirements include:

- date marking (Standard 1.2.5)
- requirement for a nutrition information panel (Standard 1.2.8)
- percentage labelling (Standard 1.2.10).

In New Zealand, under the *Misuse of Drugs (Industrial Hemp) Regulations 2006*, hemp products may not be advertised to have psychoactive effects.

FSANZ notes that consumer protection legislation in Australia and New Zealand covers misleading and deceptive labelling and advertising. During the assessment of A1039, FSANZ discussed the issue of misleading representation with the Australian Competition and Consumer Commission and the New Zealand Commerce Commission. They concurred that enforcement action could be used in the case of substantive misrepresentation.

From an international perspective, the Canadian Industrial Hemp Regulations include a requirement that no person can advertise industrial hemp, its derivatives or any product made from those derivatives to imply that it is psychoactive. FSANZ is not aware of any other country that has specific restrictions relating to representations on hemp foods.

It is important to note, as FSANZ identified in its assessment of A1039, that existing legislation (such as misuse of drugs) would require amendment before low THC hemp seed foods with even small amounts of THC could be approved for human consumption (in addition to the draft variation approved by FSANZ). This may provide an opportunity for consideration of additional measures to address concerns other than in the Code. Additionally, jurisdictions have the option of amending their existing food laws or enacting new laws to impose requirements over and above those in the Code in relation to low THC hemp seed foods. FSANZ notes that a model set of regulations could be agreed and then issued by jurisdictions to impose certain restrictions or prohibitions.

2.4.3 Conclusion

FSANZ must take into account a number of matters in developing or varying regulatory measures. Policy advice from the Forum is only one of those matters which must be weighed against all relevant matters. After considering all relevant matters, FSANZ does not propose additional regulatory measures in the Code for the labelling and advertising of low THC hemp seed foods and foods containing hemp seeds as an ingredient, for the following reasons:

- FSANZ has not identified any risks of a safety nature that require additional labelling requirements.
- FSANZ has not identified any available scientific evidence that that can be used as the basis of risk analysis (as required by the FSANZ Act) to apply additional measures relating to consumer perception and links to illicit cannabis (no evidence of risk has been identified).
- Low THC hemp does not have psychoactive properties and consumer protection regulation will apply to false or misleading representations (implied and express) that

low THC hemp seed foods are psychoactive.

- The existing regulations for labelling and advertising of food will apply to low THC hemp seed foods and foods containing hemp seeds as an ingredient, including Standard 1.2.7, which will apply to health claims regarding the psychoactive properties of low THC hemp seed foods.
- FSANZ considers that imposing regulation on a food to reduce the risk of harm from illegal drugs is outside the scope of matters that can be included in food regulation measures made under the FSANZ Act (previously highlighted in FSANZ's assessment of A1039).
- Alternative legislation (to the Code) could be amended by the relevant jurisdiction(s) to impose requirements over and above those in the Code. This would not be subject to the limitations imposed by the FSANZ Act.
- Development of regulatory measures in the Code to regulate representations on foods derived from hemp seeds would be inconsistent with other international food standards.

2.5 International Narcotics Control Board advice

The Forum requested FSANZ consider advice from the International Narcotics Control Board (INCB) and the European Union approach when setting a low THC limit in food. The INCB was asked by FRSC for advice in relation to whether the sale of hemp seed foods (with low levels of THC) would be compliant with United Nations conventions on narcotic drugs. The INCB advice does not preclude development of a regulatory measure in the Code to permit low THC hemp seed foods.

The INCB advice referred to the European Union limit of 0.2% THC in hemp crops, which the Forum has asked FSANZ to investigate in the context of setting a low THC limit in food. FSANZ notes the limit referred to in the INCB advice relates to hemp crop only⁷. The European Union has not developed THC limits for hemp seed foods.

Australia and New Zealand have existing legislation that sets strict controls on the cultivation of hemp domestically. Hemp can only be cultivated in Australia and New Zealand under strict licensing arrangements and crops are subject to regular testing of THC levels.

FSANZ therefore considers the EU limit referred to in the INCB advice is not of relevance to FSANZ's consideration of THC limits for low THC hemp seed foods and therefore does not impact on previous FSANZ conclusions or on the assessment of this Proposal.

2.6 Risk communication

2.6.1 Consultation

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by this Proposal and the effects of regulatory options. While not all comments may be taken on board during the process, they are all valued and contribute to the rigour of our assessment.

⁷ Council Regulation (EC) No 1782/2003:
<http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32003R1782&from=en>

All calls for submissions are notified through the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News. Anyone who is an interested party or who makes a submission will be notified at each stage of the assessment.

If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Australia and New Zealand Ministerial Forum on Food Regulation. If the decision is not subject to a request for a review, stakeholders will be notified of the gazettal of the variation to the Code.

FSANZ has updated its fact sheet about hemp on the FSANZ website.

FSANZ also established an intergovernmental advisory group to assist with assessing the proposal through the provision of advice on the issues highlighted in the Forum request and has consulted with experts at the Therapeutic Goods Administration and Department of Health in Australia and the Ministry of Health in New Zealand. The expertise and assistance of those consulted is acknowledged.

2.6.2 World Trade Organization (WTO)

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

There are no internationally consistent approaches to the regulation of hemp foods. Some countries have no restrictions on the sale of hemp foods, some have established MLs for THC and others do not permit the sale of hemp foods that have detectable levels of THC⁸. Amending the Code to permit the addition to food or sale as food of low THC hemp seeds and seed products is unlikely to have a significant effect on international trade. A number of countries permit the sale of hemp foods and a permission to allow the sale of low THC hemp seed foods in Australia and New Zealand would provide a liberalisation of trade opportunities.

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

2.7 FSANZ Act assessment requirements

2.7.1 Section 59

When assessing this Proposal and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

2.7.1.1 Cost benefit analysis

Paragraph 59(2)(a) of the FSANZ Act requires FSANZ to have regard to whether the costs that would arise from the proposed draft variation outweigh the direct or indirect benefits of that variation.

The Office of Best Practice Regulation (OBPR) assessment is that the proposed change appears likely to have no more than minor regulatory impacts on business, community

⁸ See SD5 of A1039 Approval Report:
<http://www.foodstandards.gov.au/code/applications/pages/applicationa1039lowt4708.aspx>

organisations or individuals, so a Regulation Impact Statement (RIS) is not required to be prepared (OBPR reference 20932).

FSANZ conducted an economic analysis as part of the assessment of A1039. This concluded the approved variation would provide moderate benefits to industry and consumers. The restrictions on selling only non-viable seeds were developed to minimise potential costs to government and law enforcement agencies that might arise from low THC hemp seed food permissions. Whether the approved variation was likely to result in an overall positive net benefit to the community would depend on the uptake and profitability of the production and marketing of low THC hemp seed foods on the one hand and on the other, whether it would cause complications and costs to law enforcement activities related to illicit drugs, and the magnitude of those costs if they did exist. The FSANZ economic analysis is available as SD2 to the Approval Report for A1039⁹.

2.7.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Proposal to permit the sale of low THC hemp seed foods.

2.7.1.3 Any relevant New Zealand standards

The New Zealand Food (Safety) Regulations 2002 include a provision to permit the sale of hempseed oil as a food in New Zealand. The permission is scheduled to expire on 30 October 2017. As noted above, in the *Misuse of Drugs (Industrial Hemp) Regulations 2006*, hemp products may not be advertised to have psychoactive effects.

2.7.1.4 Any other relevant matters

The Forum asked FSANZ to take policy advice relating to restricting marketing and advertising into account in the assessment of this Proposal. As detailed in section 2.4, FSANZ has had regard to this policy advice, in the context of the range of other matters that FSANZ must also take into account when developing or varying food regulatory measures.

The results of a research project being undertaken by FRSC to investigate the impact of consumption of low THC hemp seed foods on random roadside drug testing programs will not be available until later in 2016. This issue will be considered separately by the Forum and has not been addressed by FSANZ in its assessment of P1042.

In addition, Forum members have acknowledged that there is a range of Commonwealth, New Zealand and State and Territory legislation that currently prohibits the sale of low THC hemp seed foods. Such legislation would need to be amended, in addition to any variation to the Code, before low THC hemp seed foods could be legally sold. The Forum has agreed that each jurisdiction will therefore undertake an extensive audit of their respective legislation.

Other relevant matters are considered below.

2.7.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

⁹ <http://www.foodstandards.gov.au/code/applications/pages/applicationa1039lowt4708.aspx>

2.7.2.1 Protection of public health and safety

FSANZ's risk assessment concluded that the consumption of low THC hemp seed foods would not pose any public health and safety concerns where the total THC content is below the proposed MLs, as detailed in section 2.1 and in SD1 of the A1039 Approval Report¹⁰.

FSANZ considers that imposing regulation on a food (in the Code) for the purposes of reducing the risk of harm from illegal drugs is outside the scope of matters that can be included in food regulatory measures made under the FSANZ Act. Measures to regulate representations of low THC hemp seed foods are therefore not considered relevant to this objective.

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

The labelling of low THC hemp seed foods would be subject to the current provisions of the Code, including the requirement to include hemp seeds and ingredients derived from hemp seeds in the list of ingredients. It was not considered necessary to apply additional labelling requirements (section 2.4).

2.7.2.3 The prevention of misleading or deceptive conduct

FSANZ has considered this objective in relation to the representation of foods derived from low THC hemp seeds or foods that contain these foods as an ingredient, and their possible association with illicit cannabis (section 2.4). FSANZ concluded that no further risk management measures are required in the Code.

As part of its assessment of A1039, FSANZ investigated potential regulatory measures that could be used to prohibit the use of cannabis leaf images in advertising and to reduce the risk of consumers believing that low THC hemp seed foods can produce psychoactive effects. In a literature search conducted for A1039 and updated in 2016, FSANZ did not identify any available scientific evidence to warrant the inclusion of additional regulatory measures (section 2.4).

2.7.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has considered the best available scientific evidence as it relates to the safety of consumption of low THC hemp seed foods. In particular, FSANZ has included updated food consumption data in the risk assessments for THC (section 2.1) and CBD (section 2.2) from consumption of low THC hemp seed foods; and the definition of THC to which the proposed MLs apply (section 2.3).

FSANZ has also reviewed the scientific literature for evidence to apply additional measures for the labelling and advertising of low THC hemp seed foods, as outlined in section 2.4.

- the promotion of consistency between domestic and international food standards

Low THC hemp seed foods are permitted for sale in some countries but not in others. There are no international food standards for low THC hemp seed foods. The MLs for THC content

¹⁰ <http://www.foodstandards.gov.au/code/applications/pages/applicationa1039lowt4708.aspx>

of low THC hemp seed foods that are included in the draft variation are consistent with levels that are set in other countries (where applicable) and are achievable. No international jurisdictions have set limits on the CBD content of low THC hemp seed foods. The establishment of a CBD limit in the Code may present a trade barrier and impose additional compliance costs that are not required in international markets.

The Canadian Industrial Hemp Regulations and the New Zealand *Misuse of Drugs (Industrial hemp) Regulations 2006* include prohibitions relating to advertising industrial hemp, its derivatives or any product made from those derivatives that imply it is psychoactive. FSANZ notes these regulations are not **food standards** and is not aware of any other country that has specific restrictions relating to representations on hemp foods.

FSANZ therefore considers that developing regulatory measures in the Code to establish a CBD limit and to regulate representations on low THC hemp seed foods may be inconsistent with other international food standards.

- the desirability of an efficient and internationally competitive food industry

There are potential benefits to industry in permitting low THC hemp seed foods and the permission would open up domestic and export markets for foods derived from hemp seed. A more general permission to sell low THC hemp seed foods in Australia and New Zealand could serve to enhance trans-Tasman trade in these products.

- the promotion of fair trading in food

No issues have been identified.

- any written policy guidelines formulated by the Forum on Food Regulation

There are no policy guidelines relevant to this proposal. FSANZ notes policy advice has been provided by the Forum, which FSANZ has taken into account in its assessment of this Proposal (section 2.4).

2.8 Preferred approach

FSANZ has prepared a draft variation to the Code to permit the sale of low THC hemp seed foods, subject to MLs of THC, based on the following reasons:

- Low THC hemp seed foods have been assessed as safe for human consumption at the recommended maximum levels of THC content.
- The draft variation provides a net benefit to the affected parties.
- No other measures would be more effective at achieving this outcome.

3 Draft variation

The draft variation to the revised Code is at Attachment A and is intended to take effect on gazettal. The draft variation requires low THC hemp seeds sold as food or ingredients in food for sale to be hulled and non-viable unless they are being sold for use in the manufacture of other foods derived from hemp seed. This clarifies the drafting of FSANZ's previous approval of Application A1039. Food manufacturers may need to use unhulled low THC hemp seeds in the manufacture of seed products (such as oil, beverages, flour etc.). The draft variation at Attachment A includes clarification that the seeds used to produce these seed products may be unhulled and viable. FSANZ notes that food manufacturers will need to meet hemp licencing requirements in order to be permitted to possess and process unhulled and/or viable seed. Unhulled and viable seeds would not be permitted to be sold as food or ingredients in food for sale to consumers.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

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



Food Standards (Proposal P1042 – Low THC Hemp Seeds as Food) Variation

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

Dated [To be completed by Standards Management Officer]

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

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Proposal P1042 – Low THC Hemp Seeds as Food) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] **Standard 1.4.4** is varied by inserting after section 1.4.4—5

1.4.4—6 **Exception relating to *Cannabis sativa* seeds and seed products**

- (1) *Cannabis sativa* seeds may be a food for sale or used as an ingredient in a food for sale if:
 - (a) the seeds:
 - (i) are seeds of low THC *Cannabis sativa*; and
 - (ii) contain not more than 5 mg/kg of total THC; and
 - (iii) if the food is for retail sale – are non-viable and hulled; and
 - (b) the only cannabinoids in or on the seeds are naturally present.
- (2) Subject to subsection (3), all or any of the following seed products may be a food for sale or used as an ingredient in a food for sale:
 - (a) oil extracted from seeds of low THC *Cannabis sativa* if the oil contains not more than 10 mg/kg of total THC;
 - (b) a beverage derived from seeds of low THC *Cannabis sativa* if the beverage contains not more than 0.2 mg/kg of total THC;
 - (c) any other substance that is extracted or derived from seeds of low THC *Cannabis sativa* and contains not more than 5 mg/kg of total THC.
- (3) The only cannabinoids in the product must be those that were naturally present in or on the seeds from which the product was extracted or derived.
- (4) In subsection (2) –
seeds of low THC *Cannabis sativa* includes viable and unhulled seeds.
- (5) In this section –
hulled seeds means seeds from which the outer coat or hull of seeds has been removed.
low THC *Cannabis sativa* has the meaning given by subsection (6).
non-viable seeds means seeds that are not able to germinate.
seeds includes a part of a seed.
total THC means the total amount of delta 9-tetrahydrocannabinol and delta 9-tetrahydrocannabinolic acid.
- (6) *Cannabis sativa* is low THC *Cannabis sativa* if the leaves and flowering heads of the *Cannabis sativa* do not contain more than 1% delta 9-tetrahydrocannabinol.

Attachment B – Explanatory Statement

1. Authority

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

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P1042 to develop a food regulatory measure to permit seeds of low delta 9-tetrahydrocannabinol (low THC) varieties of *Cannabis sativa*, and certain products derived from those seeds, to be a food for sale or used as an ingredient in a food for sale.

The Authority considered the Proposal in accordance with Division 2 of Part 3 and has prepared a draft variation to Standard 1.4.4.

2. Purpose and operation

The Code currently prohibits Cannabis from being sold as food or included as an ingredient or component of a food for sale. Section 1.1.2—3(2) of Standard 1.1.2 and section S23—2 of Schedule 23 provide that all Cannabis species (hemp, marijuana) and substances derived from Cannabis species are a prohibited plant for the purposes of the Code. Subsections 1.1.1—10(5) and (6) provide that a prohibited plant cannot be a food for sale, or be an ingredient or component in a food for sale, unless expressly permitted by another provision of the Code. There is no such express permission for Cannabis in the Code.

The Authority has prepared a draft variation to Standard 1.4.4 to permit certain types of seeds and seed products from *Cannabis species* (spp.) to be sold as a food or used as an ingredient in a food provided that certain conditions are met. These conditions will include a requirement that only seeds sourced from low level THC varieties of *Cannabis sativa* may be used to produce foods and food ingredients. The delta 9-tetrahydrocannabinol and the delta 9-tetrahydrocannabinolic acid present in these seeds and seed products must be present at no more than specified maximum levels. Delta 9-tetrahydrocannabinol, delta 9-tetrahydrocannabinolic acid and any other cannabinoids present in these seeds and seed products must be naturally present.

The draft variation does not provide permission for cannabidiol or other cannabinoids that have been extracted or derived from seeds of low THC *Cannabis sativa* to be themselves a food for sale or used as an ingredient in a food for sale.

The draft variation makes clear that cannabinoids may be present in or on seed and the seed products that will be permitted to be sold as food or used as an ingredient in a food for sale. The requirement is that these cannabinoids be present by natural occurrence only. While the seeds of the Cannabis plant do not produce cannabinoids, in nature they come into contact with those parts of the plant that do. As a result, cannabinoids (including cannabidiol) can be naturally present at low levels in seed foods even under good agricultural and manufacturing practice. The draft variation will allow this presence by natural occurrence. Fortification of the seed and seed products with cannabinoids will not be permitted.

The draft variation will require seeds that are offered for sale to consumers as foods or for use as ingredients in foods to be non-viable and hulled. The proposed amendments to Standard 1.4.4 will not preclude food manufacturers from using seeds that are viable and not hulled in the manufacture of foods, subject to industrial hemp licensing arrangements and any other applicable laws.

3. Documents incorporated by reference

The variation does not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1042 will include one round of public consultation.

A Regulation Impact Statement (RIS) was not required because the draft variation is likely to have no more than minor regulatory impacts on business, community organisations or individuals.

5. Statement of compatibility with human rights

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

6. Variation

Item [1] inserts a new section 1.4.4—6 into Standard 1.4.4.

The proposed section will provide a permission for the purposes of paragraphs 1.1.1—10(5)(a) and 1.1.1—10(6)(e) of the Code to permit certain seeds and seed products from low THC varieties of *Cannabis sativa* to be sold as food or added to food.

Proposed subsection 1.4.4—6(1) provides that *Cannabis sativa* seeds may be a food for sale or used as an ingredient in a food for sale only if each of the following conditions is met.

- The seeds are of a *Cannabis sativa* plant, the leaves and flowering heads of which contain no more than 1% delta 9-tetrahydrocannabinol.
- The total combined amount of delta 9-tetrahydrocannabinol and delta 9-tetrahydrocannabinolic acid in the seeds does not exceed 5 mg per kg of seeds.
- The delta 9-tetrahydrocannabinol, delta 9-tetrahydrocannabinolic acid and any other cannabinoids present in the seeds are naturally occurring in or on the seeds.
- If for retail sale – the seeds are non-viable and hulled (that is, the outer coat has been removed).

Proposed subsection 1.4.4—6(2) provides a permission for three specific types of products derived from seeds of low THC varieties of *Cannabis sativa*.

Paragraph 1.4.4—6(2)(a) and subsection 1.4.4—6(3) will permit oil extracted from the seeds of low THC *Cannabis sativa* to be a food for sale or used as an ingredient in a food for sale if: the total combined amount of delta 9-tetrahydrocannabinol and delta 9-tetrahydrocannabinolic acid in the oil does not exceed 5 mg per kg of oil; and the only cannabinoids present in the oil are those that were naturally present in or on the seeds from which the oil was extracted.

Paragraph 1.4.4—6(2)(b) and subsection 1.4.4—6(3) will permit a beverage derived from the seed of low THC *Cannabis sativa* to be a food for sale or used as an ingredient in a food for

sale if: the total combined amount of delta 9-tetrahydrocannabinol and delta 9-tetrahydrocannabinolic acid in the beverage does not exceed 0.2 mg per kg of the beverage; and the only cannabinoids present in the beverage are those that were naturally present in or on the seeds from which the beverage was derived.

Paragraph 1.4.4—6(2)(c) and subsection 1.4.4—6(3) will permit any other substance extracted or derived from the seed of low THC *Cannabis sativa* to be a food for sale or used as an ingredient in a food for sale if: the total combined amount of delta 9-tetrahydrocannabinol and delta 9-tetrahydrocannabinolic acid in the substance does not exceed 5 mg per kg of the substance; and the only cannabinoids present in the substance are those that were naturally present in or on the seeds from which the substance was extracted or derived.

Proposed subsection 1.4.4—6(3) will require that the only cannabinoids present in a product listed in subsection 1.4.4—6(2) must be those that were naturally present in or on the seeds from which the product was extracted or derived. The purpose of this requirement is to prevent the fortification of seed products with cannabinoids.

Proposed subsection 1.4.4—6(4) will provide that the seed products permitted by subsection 1.4.4—6(2) may be derived or extracted from hulled, unhulled, viable or non-viable seeds.

Proposed subsection 1.4.4—6(5) defines certain terms for the purposes of section 1.4.4—6.

Proposed subsection 1.4.4—6(6) defines the phrase 'low THC *Cannabis sativa*' for the purposes of section 1.4.4—6.