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Approval report – Proposal P1042

Low THC Hemp Seeds as Food

Food Standards Australia New Zealand (FSANZ) has prepared and assessed a proposal 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*.

On 28 July 2016, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 39 submissions.

FSANZ approved the draft variation on 9 March 2017. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 22 March 2017.

This Report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

Table of contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION	4
1.1 THE PROPOSAL	4
1.2 THE CURRENT STANDARD	4
1.3 REASONS FOR PREPARING THE PROPOSAL.....	4
1.4 PROCEDURE FOR ASSESSMENT	5
2 SUMMARY OF THE FINDINGS	5
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS	5
2.1.1 <i>Including a CBD limit in low THC hemp seed foods in the Code</i>	5
2.1.2 <i>Cannabinoid acid precursors</i>	6
2.1.3 <i>Labelling and advertising</i>	7
2.2.1 <i>Dietary exposure update assessment</i>	8
2.2.2 <i>Conclusion</i>	9
2.3 CONSIDERATION OF MATTERS RAISED BY THE FORUM.....	9
2.3.1 <i>Including a CBD limit in the Code</i>	9
2.3.2 <i>Cannabinoid acid precursors</i>	13
2.3.3 <i>Labelling and advertising</i>	14
2.3.4 <i>International Narcotics Control Board advice</i>	17
2.3.5 <i>Other issues</i>	17
2.4 RISK COMMUNICATION.....	18
2.4.1 <i>Consultation</i>	18
2.5 DECISION	19
2.6 FSANZ ACT ASSESSMENT REQUIREMENTS	19
2.6.1 <i>Section 59</i>	19
2.6.2 <i>Subsection 18(1)</i>	21
2.6.3 <i>Subsection 18(2) considerations</i>	22
3 TRANSITIONAL ARRANGEMENTS	23
ANNEX 1: SUMMARY OF ISSUES RAISED IN SUBMISSIONS	25
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>	40
ATTACHMENT B – EXPLANATORY STATEMENT	44
ATTACHMENT C – DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE (CALL FOR SUBMISSIONS)</i>	47

Supporting documents

The [following documents](#)¹ which informed the assessment of this Proposal are available on the FSANZ website:

- SD 1 Dietary exposure assessment (at Approval)
- SD 2 Cannabidiol hazard profile

¹ <http://www.foodstandards.gov.au/code/proposals/Pages/P1042LowTHChemp.aspx>

Executive summary

Proposal P1042 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* (low THC hemp). Low THC hemp contains no THC or very low levels of THC (the psychoactive component of cannabis) and has no psychoactive properties. The Proposal was prepared following a request from the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum).

The Forum requested that the following matters be considered when assessing the Proposal:

- whether a cannabidiol (CBD) limit should be set to distinguish food from therapeutic goods, and whether acid precursors should be included in any cannabinoid limits that are set
- policy advice provided by the Forum that the following 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.

The sale of foods derived from hemp is currently prohibited by the *Australia New Zealand Food Standards Code*. However, hemp seed oil is permitted to be sold as a food in New Zealand (under New Zealand legislation).

The FSANZ assessment of P1042 has updated previous assessments, including the dietary assessments FSANZ conducted for Applications [A360 – Use of Industrial Hemp as a Novel Food](#)² and [A1039 – Low THC Hemp as a Food](#)³. In addition, FSANZ's assessment of this Proposal addressed the matters requested by the Forum.

FSANZ concludes that low THC hemp seed foods are safe for consumption when they contain no more than specified maximum levels (MLs) of THC (including its acid precursor delta 9-tetrahydrocannabinolic acid). FSANZ has also recognised that low THC hemp seed foods may provide a useful alternative dietary source of nutrients and polyunsaturated fatty acids, particularly omega-3 fatty acids.

FSANZ has approved a draft variation to Standard 1.4.4 – Prohibited and restricted plants and fungi to permit 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. Whole low THC hemp seeds are not permitted for retail sale as food or an ingredient in a food for sale unless they are hulled and non-viable. Foods or food ingredients derived from low THC hemp seeds will be subject to certain labelling and advertising restrictions. Only seeds from low THC varieties of *C. sativa* can be used as a source for food and only naturally occurring THC (and other cannabinoids) may be present in low THC hemp seed foods.

² <http://www.foodstandards.gov.au/code/applications/Pages/applicationa360hempasanovelfood/Default.aspx>

³ <http://www.foodstandards.gov.au/code/applications/Pages/applicationa1039lowt4708.aspx>

For the reasons outlined in this report, the approved draft variation differs from the draft variation on which submissions were called. The main differences are that the approved draft variation now incorporates labelling and advertising restrictions for low THC hemp seed foods, including prohibitions on the use of certain terms and images and on making nutrition content and health claims about CBD; and that a ML for CBD content in foods has been specified.

FSANZ considers the advice from the International Narcotics Control Board does not impact on the assessment of this Proposal.

The commencement date for the approved draft variation is six months after the date of gazettal.

1 Introduction

1.1 The Proposal

This Proposal sought 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 (paragraphs 1.1.1—10(5)(a) and 1.1.1—10(6)(e)).

Cannabis (all cannabis species) is listed as a prohibited plant in Schedule 23 – Prohibited plants and fungi. 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—3⁴).

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 hemp seed oil as a food is permitted by the *New Zealand Food (Safety) Regulations 2002* (regulation 26). This permission operates as an exception to the prohibition in the Code on all cannabis species and applies only to hemp seed oil. The regulation and the permission it provides are 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 Code⁵.

Internationally, many jurisdictions, including Canada, Germany, United Kingdom, The Netherlands, Belgium, Switzerland and Austria permit the sale of low THC hemp seed foods (including hemp seed oils).

1.3 Reasons for preparing the Proposal

In March 2016, FSANZ received a request from the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) to develop a proposal on how, if it was considered appropriate, low THC hemp could be legally designated as a food. FSANZ interpreted the Forum's request as being a request to develop a food regulatory measure to permit the sale of foods containing the seeds, or products extracted or derived from the seeds of low THC hemp.

⁴ 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).

⁵ Hemp seed oil produced in New Zealand cannot be exported to Australia under the Trans-Tasman Mutual Recognition Agreement because it is prohibited by Customs and other legislation in Australia.

The Forum requested that FSANZ consider the following matters:

- the need to set a cannabidiol (CBD) limit to distinguish food from therapeutic goods, and to include the respective acid precursors in any cannabinoid limits that are set
- policy advice provided by the Forum, relating to restricting the marketing and advertising of low THC hemp as a food, in particular, that the following 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.

1.4 Procedure for assessment

The Proposal was assessed under the General Procedure.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ sought submissions on the draft variation to the Code (and associated assessment summary) between 28 July 2016 and 25 August 2016. A detailed summary of issues raised in submissions and FSANZ's response is at Annex 1. Comments on specific issues are as follows and the risk management response is addressed in section 2.3.

2.1.1 Including a CBD limit in low THC hemp seed foods in the Code

2.1.1.1 Government

Most government submitters supported the views of the Forum regarding setting a limit for CBD to help distinguish between foods and therapeutic goods (including potential for self-medication). A CBD limit in the Code was also viewed as a means of limiting the cultivation of hemp crops bred specifically for extraction and fortification of foods with CBD.

A joint submission from the New Zealand Ministry for Primary Industries and Ministry of Health noted that FSANZ had proposed MLs for THC, despite there being no risk of psychoactive effects (based on the low levels of THC present in low THC hemp seed foods). As such, they were of the view that, similarly, limits should be set for CBD (although there is no risk of therapeutic effects being achieved with the low levels of CBD present in low THC hemp seed foods).

In response to this view, FSANZ notes that the Tolerable Daily Intake (TDI) for THC was established as part of the assessment of Applications A360 and A1039. The TDI was established on the basis of protecting against adverse effects on skill performance (e.g. hand-eye coordination and reaction time), which were observed at lower levels than that observed for psychoactive effects. MLs for THC were therefore set on the basis of the TDI, rather than on the consideration of psychoactive effects.

The Ministries also noted that in New Zealand, CBD (and THC) are class B1 controlled drugs under the *Misuse of Drugs Act 1975*. This means that no amount of CBD (or THC) is acceptable in food, unless that legislation is amended. As a controlled drug, an exemption would have to be made in legislation to allow for the low levels that may be present in hemp seed foods, should this proposal be approved. New Zealand advised that this would be problematic for CBD without an upper limit in the Code.

2.1.1.2 Non-government

Non-government submitters were of the view that a CBD limit was not required for the reasons that FSANZ had outlined in its assessment summary, together with a number of other reasons including:

- there was no apparent need for a CBD limit if low THC hemp seed foods were not fortified (as per the draft variation) and if the seeds were processed under good agricultural/manufacturing processes, so as to be free of contamination
- establishing a CBD limit could create compliance costs for the industry, which were not necessary, unless they are underpinned by public health and safety concerns
- with regards to the future development of high CBD hemp crops, such crops have been developed at large costs to plant breeders and, as such, breeders were highly protective of such seed stock for uses other than food.

In addition, one industry submitter suggested that FSANZ did not have the legal authority to include additional text in the draft variation to guard against fortification with CBD, especially given that FSANZ had stated in the assessment summary that CBD was not a concern in terms of public health and safety. FSANZ notes that the FSANZ Act clearly authorises FSANZ to develop standards that set compositional requirements for food, including in relation to fortification and contaminants: see section 16 of the FSANZ Act.

2.1.2 Cannabinoid acid precursors

In the assessment summary, FSANZ noted that some of the acid precursor to THC and delta 9-tetrahydrocannabinolic acid (THC-A) present in low THC hemp seed foods may be converted to THC (even at room temperatures). As such, FSANZ determined that the proposed MLs for THC should take into account the THC-A content. FSANZ considered two potential options for achieving this (section 2.3.2.1).

The vast majority of submitters who commented on this aspect agreed with FSANZ's approach to taking into account THC-A in proposed MLs for THC.

However, several industry submitters questioned the need for any THC limits, noting that industrial hemp food products come from low THC industrial hemp crops grown under licence. As such, THC content is not a concern from a food safety point of view and THC limits create more compliance costs in the form of THC testing, which adds no value to the industry or the consumer. In this context, THC and THC-A levels are irrelevant as they would not be present in industrial hemp in quantities that would warrant any control measures. However, FSANZ notes the MLs for THC included in the draft variation were set on the basis of protecting against consumers reaching the TDI for THC established during previous FSANZ assessments.

2.1.3 Labelling and advertising

During the assessment of this Proposal and assessments of A360 and A1039, concerns were raised by stakeholders that certain representations (such as the cannabis leaf) that might be used in the labelling and advertising of low THC hemp seed foods could suggest that the food has psychoactive properties. There were also concerns that consumers could become more accepting of illicit cannabis and this could undermine attempts to reduce its illegal use.

2.1.3.1 Government

Most government submitters expressed a strong preference for specific labelling requirements to be included in the Code for low THC hemp seed foods, along the lines of the policy advice provided to FSANZ by the Forum.

In particular, government agencies highlighted the potential for consumers to receive mixed messages about the acceptability of illicit cannabis; to make an incorrect association between low THC hemp seed foods and illicit cannabis; or to assume the food had psychoactive effects, if certain images and terms are used on labels and advertising for low THC hemp seed foods. These submissions asked for further consideration to be given to prohibitions on the use of the cannabis leaf image and the word 'Cannabis' on labels and associated advertising; and on any representations that state, suggest or imply a link with illicit cannabis or psychoactive effects.

A government submitter also suggested FSANZ prescribe the name 'hemp' as the only permitted term to refer to the hemp seed or hemp seed derived product/ingredient. The type of hemp product would need to be qualified e.g. hemp seed, hemp seed oil, hemp seed flour, hemp seed protein. FSANZ has noted products available overseas almost exclusively use the name 'hemp' on the labels and has previously observed that low THC hemp seed oils available as foods in New Zealand use the name 'Hempseed Oil'. The use of a prescribed name does not address submitter concerns about certain representations causing consumers to make an incorrect association with illicit cannabis.

In response to the suggestion by FSANZ that alternative legislation (to the Code) could be amended by the relevant jurisdiction(s), government submitters held the strong view that the Code was the most appropriate mechanism for regulating the advertising and labelling of low THC hemp seed foods, as it would ensure a consistent approach across all Australian jurisdictions and New Zealand. In addition, the Code would likely be the most obvious reference point for businesses wishing to sell low THC hemp seed food products, compared with other regulation (such as industrial hemp legislation).

2.1.3.2 Non-government

Apart from one private submitter, no private or industry submitters (including the Dietitians Association of Australia) identified a need for any further labelling restrictions or requirements.

Submissions received from industry and private submitters reflected many of the comments made in response to the call for submissions during the assessment of A1039. Submitters noted the intended target market for hemp seed foods was mainly health conscious consumers and, as such, the majority of the marketing strategies overseas focused very much on the nutritional quality of low THC hemp seed foods, including it being a very good dietary source of many nutrients and polyunsaturated fatty acids. Submitters noted that it would make no business sense to make any associations between low THC hemp seed foods and illicit cannabis, including its psychoactive effects and use of the cannabis leaf image.

Some non-government submitters opposed the introduction of additional labelling requirements/restrictions in the Code for low THC hemp seed foods, suggesting labelling is adequately controlled by existing regulations. Other non-government submitters were silent on the issue of additional requirements/restrictions. One non-government submitter was of the view that additional, appropriate labelling should be supported, including the use of the prescribed name 'hemp' and a prohibition on the use of the cannabis leaf image.

In its submission, the Industrial Hemp Association of Victoria advised that it continued to recommend to its commercial members that they avoid presenting their product with labelling that displays an image of the hemp leaf. The Association also asks that members, when joining or renewing their membership, acknowledge that the Association does not support recreational or medicinal cannabis.

2.2 Risk assessment

The FSANZ approach to the assessment of this proposal was to provide updates on previous FSANZ assessments for Applications [A360 – Use of Industrial Hemp as a Novel Food](#)⁶ and [A1039 – Low THC Hemp as a Food](#)⁷. In particular, an update of the dietary exposure assessment included in A1039 was prepared, including an assessment of both THC and CBD in low THC hemp seed foods, using more recent nutrition survey data for Australian and New Zealand populations (section 2.2.1 and Supporting Document 1 (SD1)).

In addition, FSANZ's assessment of this Proposal considered the matters the Forum requested FSANZ to investigate (section 2.3) and had regard to the submissions and comments received following the call for submissions.

2.2.1 Dietary exposure update assessment

The updated dietary exposure assessment presented at SD1, using the most recent available food consumption data and unpublished analytical data provided by the New South Wales Department of Health (NSW Health), confirmed that no Australian and New Zealand population groups examined would exceed the TDI of 6 micrograms (μg) per kg body weight (bw)⁸ for THC at the mean and 90th percentile of estimated dietary exposure. Dietary exposure estimates ranged between 5–26% of the TDI for the Australian and New Zealand populations. Dietary exposure estimates were based on conservative assumptions and are therefore likely to be overestimates.

Estimates of dietary exposure to CBD indicated that consumption of low THC hemp seed foods (at the levels indicated in Table 3 in SD1) would not result in any Australian and New Zealand population groups assessed reaching the Lowest Oral Human Therapeutic Dose (LOHTD) for CBD of 2 mg/kg bw/day at the mean and 90th percentile of exposure⁹. The maximum estimate of dietary exposure to CBD was <1% of the LOHTD, making even more conservative assumptions than those made for THC exposure. 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.

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

⁶ <http://www.foodstandards.gov.au/code/applications/Pages/applicationa360hempasanovelfood/Default.aspx>

⁷ <http://www.foodstandards.gov.au/code/applications/Pages/applicationa1039lowt4708.aspx>.

⁸ The previously established TDI of 6 $\mu\text{g}/\text{kg}$ bw THC also remains valid.

⁹ The LOHTD was considered to be the applicable measure, in the absence of a health-based guidance value such as the TDI. More detail on how FSANZ estimated the LOHTD is provided in SD2.

2.2.2 Conclusion

FSANZ's previous dietary exposure 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. The updated assessment indicated the MLs for THC previously proposed by FSANZ are consistent with protecting consumers against exceeding the TDI for THC. Therefore, FSANZ 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.

The dietary exposure estimates for CBD, based on analytical data available on the levels found in a range of foods indicated that 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. In addition, FSANZ did not identify any reports of adverse effects attributable to CBD in the published scientific literature.

FSANZ also noted the outcome of previous assessments that indicated that low THC hemp seed foods may provide a useful alternative dietary source of nutrients including polyunsaturated fatty acids, particularly omega-3 fatty acids.

2.3 Consideration of matters raised by the Forum

2.3.1 Including a CBD limit in the Code

The Forum requested FSANZ consider setting a limit in the Code for CBD 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.

This recent interest in the use of CBD for therapeutic purposes has stimulated the development of cultivars high in CBD. The information available on the levels in leaves and the levels in hemp seed products which may arise from the use of these cultivars is limited and no information could be identified in peer reviewed literature. Cultivars with up to 20% CBD in their leaves have been reported on the internet¹⁰, but no information from peer-reviewed sources could be located by FSANZ. The levels of CBD found in the flowering parts of hemp varieties permitted to be cultivated in New Zealand range from 0.5% to 3%¹¹. The differential between CBD levels in standard cultivars and high CBD cultivars would need to be many orders of magnitude higher to give rise to foods in the concentration range which would be similar to therapeutic levels.

The maximum CBD level recorded in the analytical survey of hemp seed oil products was 23 mg/kg (Table 3, SD2). This is approximately 33 µg/ml based on a specific gravity of 0.703 (the value for olive oil). High CBD hemp oil products¹² obtained from high CBD cultivars have been identified from websites. The levels claimed for some CBD oils on the web are 85 mg cannabinoids/ml i.e. three orders of magnitude, or one thousand times, higher than those measured in the analytical survey. While consumption of these high CBD products could result in an intake similar to a daily therapeutic dose, these high values could not have been obtained from the seed, based on the consideration of the levels in the plants. The levels refer to whole plant cannabinoids and they are also referred to as Hemp Extract Oils.

FSANZ considers there is no risk of therapeutic levels resulting from the consumption of foods compliant with the Code i.e. non-fortified foods derived from low THC hemp seeds.

¹⁰ <http://www.cbdseeds.com/blog/top-3-cbd-rich-strains/>

¹¹ Seed supplier data sheets provided to FSANZ

¹² E.g. <https://www.cwhemp.com/all-charlottes-web-cannabinoid-hemp-cbd-supplements/everyday-extract-oils>.

Even if future development results in higher CBD levels than 20% of the flowering parts these could still not produce foods with levels of CBD approaching a therapeutic level. This takes into consideration:

- CBD levels in strains which are currently cultivated domestically¹³
- CBD levels found in hemp seed oils obtained from such strains (analytical survey information)
- the differential between the CBD levels in normal and high CBD cultivars (maximum 40 fold difference)
- the manifold difference in the estimated dietary exposure levels and those which would reach the LOHTD (section 2.2.1).

As noted in SD2, no adverse health effects attributable to CBD were located by FSANZ in the published literature. Therefore a CBD limit was not required to protect public health and safety.

FSANZ also considered the possibility of seeds being harvested from plants grown for CBD production. The levels of CBD decrease in the plant when the plant flowers and produces seeds, thus there would be no incentive for growers to use such plants for hemp seed oil production.

FSANZ notes that a CBD limit in the Code that is not established to protect public health and safety may be an arbitrary value. The basis of setting a CBD limit in this case would need to take account of the levels of CBD expected to be present in foods derived from low THC hemp crops which are produced using good manufacturing processes, without adversely impacting licensed hemp growers and food manufacturers in relation to CBD levels that are naturally present in low THC hemp crops. The analytical survey of hemp food products conducted by NSW has provided data on the levels of CBD detected in a range of hemp food products (unpublished, refer to section 4 of SD1).

FSANZ understood the Forum wanted to ensure that CBD-fortified products could not be sold as food, should low THC hemp seed foods be permitted for sale in Australia and New Zealand. Part of the Forum's concern also related 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. CBD-fortified products are sometimes marketed side-by-side with low THC hemp seed food products. A CBD limit in the Code has been viewed by government stakeholders as a means of distinguishing between low THC hemp seed foods and other hemp based products (such as CBD-fortified products) purported to have a therapeutic effect.

Discussions with an intergovernmental advisory group (IGAG), set up by FSANZ to inform the assessment of this Proposal, and in submissions and communications from individual jurisdictions also identified potential benefits of establishing a CBD limit in the Code:

- to provide a fixed reference point for jurisdictions to set exceptions/exemptions in relevant drug control legislation (noting that legislation other than the Code would need to be amended should the sale of low THC hemp seed foods be legalised). FSANZ notes the inclusion of a CBD limit in the Code is not a pre-requisite for other legislation to be amended.

¹³ Information was available on cultivars grown for hemp in New Zealand. Data on Australian crops were not found but it has been assumed that the New Zealand values are representative of hemp which has not been bred for high CBD levels

- to provide some protection against the current availability and future development of hemp crops that contain higher levels of CBD (noting that CBD limits are not currently prescribed in industrial hemp cultivation legislation). FSANZ's evaluation indicates, for reasons elaborated earlier, that the possibility of the development of high-CBD cultivars does not itself create a risk associated with the consumption of foods derived from low THC hemp seeds that would require managing by setting a CBD limit in the Code.
- to provide a necessary tool for enforcing the standard to determine if a hemp oil product has been fortified. This point is addressed in section 2.3.1.1.
- to protect against consumers self-medicating and stopping their use of appropriate medication. This point is addressed in section 2.3.1.1.

2.3.1.1 Risk management

Consideration of need for a maximum limit

FSANZ did not propose a CBD limit in the draft variation in the call for submissions. However, after having regard to all relevant considerations, including the views of governments, FSANZ has decided to amend the proposed draft variation to include a ML for CBD. This decision has given weight to the significant concerns expressed by government stakeholders in relation to enforcement of the draft variation. FSANZ notes the following reasons are in keeping with the approach taken in the call for submissions. The reasons against imposing a limit are:

- As outlined in section 2.3.1, including a CBD limit in the Code is not necessary to protect public health and safety.
- The FSANZ Act does not provide authority for FSANZ to develop or vary a standard for the purposes of designating a product or substance to be a therapeutic good. Standards set under the FSANZ Act do not and cannot determine whether a product is a food or a therapeutic good.
- Hemp seeds do not produce cannabinoids, so cannabinoids will only be present in very small amounts on the seeds as a result of contamination with the cannabinoid-producing parts of the plant. The approved draft variation only permits the seeds of low THC hemp to be sold as food or used as ingredients. Prohibiting other parts of the plant being used as a source of food and the fortification of hemp seed products with cannabinoids ensures that levels of CBD will be much lower than therapeutic levels, without needing to set a limit for CBD in the Code.

FSANZ advises, in response to the other issues mentioned in section 2.3.1, that:

- A requirement in the approved draft variation that only foods derived from the seeds of low THC hemp may be sold or used as ingredients, together with a requirement that only cannabinoids that are naturally present in or on the seeds can be in low THC hemp foods, act to ensure that low THC hemp foods cannot contain therapeutic CBD levels.
- Despite concerns expressed by governments in relation to public health and safety, in the context of potential self-medication by consumers, FSANZ considers the availability of low THC hemp seed foods does not give rise to real concerns about a risk of misuse to self-medicate in substitution for CBD products. The quantity of low THC hemp seed foods required to be consumed to reach a therapeutic dose of CBD is orders of magnitude greater than would be realistically possible.

- As noted by non-government submitters, a CBD limit in the Code could impose additional compliance costs that are not required to protect public health and safety in terms of food.
- In relation to claims about CBD content, Standard 1.2.7 – Nutrition, health and related claims prohibits claims of a therapeutic nature. In addition, the inclusion in the approved draft variation of a specific prohibition on nutrition content and health claims about CBD restricts the potential for products to be marketed based on the presence of CBD; thereby reducing the likelihood of misuse by consumers seeking to self-medicate or being misled by claims about CBD (see 2.3.3.5 below).

FSANZ proposed amendments to prohibit the fortification of low THC hemp seed foods with CBD (and other cannabinoids) and to prohibit claims being made about CBD content and communicated these proposed changes to government stakeholders. However, despite the above considerations, governments have expressed strong concern about determining compliance for products that contain CBD at levels higher than expected in food products. Governments have noted that products cannot be analysed to determine whether CBD is naturally present or whether CBD has been added to the product; and that without a limit, or ML, for CBD specified in the Code it will therefore not be possible to determine compliance with the provision in the draft variation (that low THC hemp seed foods not be fortified with CBD).

FSANZ must develop food regulatory measures that are enforceable. FSANZ has given weight to government concerns about determining compliance and has agreed to establish a ML for CBD.

Factors considered in setting a maximum level

As noted above, a ML for CBD in hemp seed foods is not required to protect public health and safety. Foods would need to contain very high levels of CBD for consumers to reach therapeutic values, estimated to be 186 mg/kg for hemp seed 'milk'; 3560 mg/kg for hemp seed oils; 7385 mg/kg for hemp seed protein powders; 4604 mg/kg for hemp seeds and 475 mg/kg for hemp seed flour, based on a high (97.5th percentile) consumer. As noted in the dietary modelling evaluation and section 2.2.1 these levels are much higher than would be found in non-fortified foods, so FSANZ has not used these levels as the basis for setting a ML for CBD. Rather, the ML has been established on the basis of levels which are achievable in unfortified low THC hemp seed products. FSANZ has considered the information available on levels analysed in the survey of low THC hemp seed foods commissioned by NSW Health (unpublished, refer to section 4 of SD1). The survey included analysis of 45 hemp seed samples, 73 non-encapsulated oil samples and 55 flour samples. No hemp seed 'milk' samples were available for analysis.

There are three factors relevant to this consideration of MLs

1. Application of the ML for total cannabinoids, CBD or CBD plus CBD-A (CBD's precursor). Insufficient information is available on the total cannabinoid levels in the products surveyed. The survey report only lists levels for CBD, CBD-A, THC and THC-A but refers to the inclusion of some other cannabinoids in the CBD value. It would therefore be inappropriate to set a value for total cannabinoids because that would require an analysis of all cannabinoids present in a range of products. Whilst CBD-A levels are present, and are higher than CBD, it is not necessary to include CBD-A in the ML. The purpose of setting a ML is to ensure enforceability and CBD itself can serve as the measure of natural occurrence.

2. Foods to which a ML should apply. Fortified hemp seed oils and milk are available online. Hemp seed itself is not likely to be fortified. Whilst CBD levels vary in different food types (Table 5 of SD1), FSANZ proposes to set a single ML for all foods as this would simplify enforceability, and would not require an assessment of achievability for the different food types (particularly for hemp seed 'milk' where no samples were available for analysis). Exceedances of the ML in any food would be a clear indication that CBD had been added to it.
3. The ML numerical value. In the NSW survey hemp seed oils had the highest CBD levels (up to a maximum of 23 mg/kg). CBD levels will vary depending on factors such as cultivars, growing, harvest and processing conditions and the survey was not designed to assess these factors or variability. In order to account for the probable greater variation in the broader hemp seed food supply than seen in a survey of only 73 oil samples, a value which is approximately three-fold the highest value seen in the survey (i.e. 75 mg/kg) is proposed as the ML. This ML will be applied to all foods for sale, not just to low THC hemp seed foods.

The approved draft variation includes a ML for CBD content in foods for sale of 75 mg/kg. FSANZ notes that this level is well below a level which would give rise to therapeutic effects for high consumers of foods containing CBD and is applied in order to address concerns raised about the enforceability of the prohibition on fortification with CBD.

2.3.2 Cannabinoid acid precursors

The Forum requested that FSANZ 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. Although a ML for CBD will be set, it is not necessary to include CBD precursors since the purpose of this ML is to verify that a food has not been fortified and this does not require analysis of both CBD and its precursor (section 2.3.1.1). However we have given consideration to precursors of THC.

Both THC and its acid precursor, THC-A, can be present in low THC hemp seed foods, due to contamination during processing. FSANZ considered whether the MLs for THC set in previous assessments needed to be amended to take into account THC-A.

THC-A is not psychoactive, but is converted to THC quickly at sufficient temperature (160°C), with slower, more gradual conversion at room temperature. Certain analytical methods for THC and THC-A include a heating step. This may promote the conversion of THC-A to THC, which may result in a higher level of the active form of THC being present in the analysed sample than may have initially been present in the low THC hemp seed food.

2.3.2.1 Risk management

FSANZ considered two options for ensuring that proposed MLs for THC take into account the THC-A content. The first option involved maintaining previously proposed MLs for THC in low THC hemp seeds and seed products. However, the MLs would apply to *total* THC, defined as the combined amount of THC and THC-A. This option would address any uncertainties around rates of conversion at different temperatures or during analysis of samples.

The second option involved deriving separate MLs for THC and THC-A in low THC hemp seed foods. Separate MLs for each type of low THC hemp seed food would need to be below the MLs for THC proposed by FSANZ so that estimated dietary exposure to the total amount of THC plus THC-A did not exceed the TDI. However, FSANZ noted that establishing separate MLs for THC and THC-A would be subject to two areas of uncertainty.

Firstly, based on unpublished survey data from NSW Health, there does not appear to be a relationship between the THC and THC-A content of low THC hemp seed foods. Secondly, the rate of conversion of THC-A to THC in low THC hemp seed foods is variable, depending on different lengths of storage and heating.

Either option would achieve the same risk management outcome of ensuring that consumers do not exceed the TDI. However FSANZ determined that MLs for total THC in low THC hemp seed foods, where total THC is the combined amount of THC and THC-A, is the more appropriate option as it is subject to less uncertainty.

FSANZ has established a ML for CBD in foods for sale in the approved draft variation. However, the acid precursor of CBD, CBD-A, has not been included in this ML for the reasons outlined in section 2.3.1.1.

2.3.3 Labelling and advertising

The Forum requested FSANZ consider policy advice relating to restricting 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.

FSANZ discussed the Forum's request regarding marketing and advertising restrictions with the IGAG. The IGAG held the view that labelling and advertising issues were of critical importance to the Forum in its consideration of whether or not to permit low THC hemp seed foods. This view is reflected in many of the government submissions (section 2.1.3.1).

In the context of labelling and advertising, FSANZ has also considered the concerns raised in relation to setting a limit in the Code for CBD as a means of distinguishing between foods and therapeutic goods; and the potential for CBD-fortified products to be misused by consumers seeking to self-medicate (as discussed in section 2.3.1).

2.3.3.1 Review of the scientific literature

In its assessment of A1039, FSANZ conducted a review of the scientific literature to identify if any studies had been published on whether consumers believed that hemp products could have psychoactive effects and whether the labelling or advertising of such products had any effect on this belief. FSANZ updated this literature search in June 2016. No relevant studies were identified in either literature search.

FSANZ also reviewed the scientific literature for evidence that certain labelling and/or advertising of hemp seed foods caused consumers to link such foods with illicit cannabis and to make consumers see illicit cannabis as being more acceptable. Once again, no relevant literature was identified.

2.3.3.2 International jurisdictions

FSANZ, as part of its assessment of A1039, sought information from overseas regulatory agencies relating to the marketing and advertising of low THC hemp seed foods. 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.¹⁴

Most international jurisdictions responded that they were not aware of any problems in relation to low THC hemp seed foods being marketed in such a way as to suggest they may have psychoactive properties. However, Belgium noted that while producers do market the nutritional qualities of hemp foods, some products had been marketed with large images of a cannabis leaf on the label. They suggested that this may be viewed as making a connection with illicit cannabis use.

2.3.3.3 Existing standards

There are currently a number of existing standards that would apply to the labelling and advertising of low THC hemp seed foods.

Standard 1.2.2 – Information requirements – food identification, requires that a name or description of a food sufficient to indicate the true nature of the food is provided (where there is no prescribed name for the food in the Code).

Standard 1.2.4 – Information requirements – statement of ingredients requires ingredients in a food to be declared in the statement of ingredients by either the common name of the ingredient or a name that describes the true nature of the ingredient (or a generic name if there is one specified in the Code).

Voluntary nutrition content claims and health claims in the labelling and advertising of food are regulated by Standard 1.2.7. Nutrition content claims are claims about the presence or absence of certain nutrients or substances in a food. Standard 1.2.7 contains conditions for making nutrition content claims. The standard also includes conditions for making 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. The provisions regarding preapproval or self-substantiation would apply to any health claims linking low THC hemp seed foods with health effects including psychoactive properties.

In addition, Standard 1.2.7 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).

Further to the above mentioned standards, there are other 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 seed and seed products 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).

¹⁴ Note that in New Zealand, under the *Misuse of Drugs (Industrial Hemp) Regulations 2006*, hemp products may not be advertised to have psychoactive effects. See Section 2.3.3.4.

2.3.3.4 Other relevant legislation

In New Zealand, under the *Misuse of Drugs (Industrial Hemp) Regulations 2006*, hemp products may not be advertised to have psychoactive effects, whereby the definition of 'advertisement' covers any words, whether written, printed, or spoken, and any pictorial representation or design, used or appearing to be used to promote the sale of, or to stimulate interest in hemp or hemp products.

Consumer protection legislation in Australia and New Zealand covers misleading and deceptive labelling and advertising. Enforcement action could be taken should there be cases of substantive misrepresentation in the labelling and advertising of low THC hemp seed foods.

2.3.3.5 Risk management

The existing regulatory measures in the Code and other relevant legislation for the labelling and advertising of food as outlined in sections 2.3.3.3 and 2.3.3.4 will apply to low THC hemp seed foods.

FSANZ did not propose any additional regulatory measures in the Code for the labelling and advertising of low THC hemp seed foods in the call for submissions. This was primarily because no relevant available scientific evidence that could be used as the basis of risk analysis to apply such measures had been identified.

After having regard to all relevant considerations, including the views of governments, FSANZ has decided to amend the proposed draft variation. In the absence of scientific evidence on which to assess risk, FSANZ adopted a more conservative approach and has given weight to the views and advice of government, including agencies responsible for drug reduction and related harm minimisation strategies in Australia and New Zealand. This advice highlighted the prevalent illicit drug culture in Australia and New Zealand, its impacts, and the need to avoid any perception or confusion, either intended or implied, between low THC hemp seed foods and the acceptability of illicit cannabis.

FSANZ notes that some non-government submitters identified that avoiding linkages with illicit cannabis is important from a business perspective. Although there was minimal support from these submitters for introducing specific labelling restrictions, it is evident that avoiding linkages with illicit cannabis is a concern that is not restricted to governments.

The approved draft variation now includes provisions to prohibit the following representations on the labelling and advertising of low THC hemp seed foods:

- an image or representation of any part of the *C. sativa* plant (including the leaf), except for the seed
- the words 'cannabis', 'marijuana' or words of similar meaning.

In addition, the food must not be labelled or otherwise presented for sale in a form which expressly or by implication suggests that it has a psychoactive effect.

In response to issues raised by the Forum in relation to CBD, the approved draft variation includes a prohibition on making nutrition content and health claims about CBD (see section 2.3.1.1). However, voluntary nutrition content and health claims relating to other properties of food in low THC hemp (such as protein and omega fatty acid profiles) are permitted and will need to meet the requirements of Standard 1.2.7.

2.3.4 International Narcotics Control Board advice

The Forum requested FSANZ consider advice from the International Narcotics Control Board (INCB) and the European Union (EU) approach when setting a low THC limit in food. Advice received from the INCB indicated that matters related to cannabis are addressed in the 1961 Single Convention on Narcotic Drugs (the Single Convention).

Advice from the INCB notes the Single Convention distinguishes between the cultivation of the cannabis plant for the production of cannabis¹⁵ or cannabis resin, and the cultivation of the plant exclusively for industrial purposes. Cultivation for the production of cannabis and cannabis resin is subject to strict control measures in the Single Convention. The Single Convention does not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seeds) or horticultural purposes. The ICNB advised that these are excluded from the measures of control as these 'cannabis by-products' do not have psychoactive properties. Despite this exclusion, parties to the Convention are required to adopt measures as necessary to prevent the misuse of and illicit traffic in the leaves of the cannabis plant. Based on this advice from the INCB, FSANZ concluded that there were no measures in the Single Convention that would preclude FSANZ from developing a regulatory measure in the Code to permit low THC hemp seed foods, particularly noting other legislation in Australia and New Zealand prevents the misuse of and illicit traffic in the leaves and other parts of the cannabis plant.

The Forum had asked FSANZ to investigate setting a low THC limit in food giving consideration to the EU approach. The INCB advice referred to the [EU limit](#)¹⁶ of 0.2% THC. However, this limit relates to hemp crops. Australia and New Zealand have existing legislation that sets strict controls on the cultivation of hemp domestically; crops are subject to regular testing of THC levels, and must be under 0.3-1%, depending on the jurisdiction. FSANZ determined that the EU limit advised by INCB was of no relevance to FSANZ's consideration of THC limits for low THC hemp seed foods. As such, it had no impact on previous FSANZ conclusions or on the assessment of this Proposal.

2.3.5 Other issues

2.3.5.1 Total THC maximum levels for final food products

FSANZ proposed that, in line with the Forum's request, acid precursors be included in the limits set for THC. We have not identified a need for limits for CBD or its precursors.

FSANZ proposed that the best option for including acid precursors in the limits set for THC would be by adopting the MLs it has derived for THC to 'total THC', which is defined as the total amount of THC and the acid precursor delta 9-tetrahydrocannabinolic acid (THC-A). Whilst there was support for this approach (see section 2.1.2), some government submitters also suggested that FSANZ consider including an additional ML for total THC for final foods manufactured from one or more hemp seed ingredients. The Victorian Government submission noted this may be necessary to satisfy existing or amended state and territory legislation for the control of drugs and poisons.

¹⁵ In the Single Convention, 'Cannabis' means the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated.

¹⁶ Council Regulation (EC) No 1782/2003:

<http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32003R1782&from=en>

FSANZ noted it would be difficult and complex to develop appropriate MLs for final foods, as it is not possible to anticipate the variety of final foods that may ultimately contain low THC hemp seed ingredients and the concentration of low THC hemp seed ingredients in these foods. In addition, MLs for other contaminants in the Code are subject to similar analytical considerations in relation to levels in final food products i.e. the proportion of ingoing ingredients in final food products may need to be determined in order to determine the proportion of the ML to apply to final food products.

2.3.5.2 Definition of low THC *C. sativa* in draft variation

FSANZ included a definition of 'low THC *Cannabis sativa*' in the approved draft variation. The definition references a level of 1% THC in the leaves and flowering heads of the plant. In the drafting for A1039, the level referenced was 0.5%, and this is still the level referenced in SD5 to A1039. However, following advice received from NSW that 0.5% was unsuitable as it was lower than the allowance for THC levels in hemp crops cultivated in some Australian jurisdictions (which is 1%), the 0.5% level was amended to 1% in the CFS.

The New Zealand Government submission noted that the New Zealand *Misuse of Drugs (Industrial Hemp) Regulations 2006* allows for a THC limit of only 0.35%. This means that cannabis with more than 0.35% would not be considered hemp in New Zealand. There is concern that this may create conflict between the Code and the NZ regulations, and confusion in New Zealand for growers of hemp and persons processing hemp seed.

FSANZ has included a definition of 'low THC *Cannabis sativa*' to ensure that seeds for food use are sourced only from low THC hemp varieties and not from illicit cannabis. This was a concern raised by stakeholders during the assessment of A1039. FSANZ considers a definition is warranted on this basis.

FSANZ considered whether separate definitions could be included for Australia (no more than 1% THC) and New Zealand (no more than 0.35% THC) or whether the definition in the Code could refer to THC levels prescribed in industrial hemp regulations in Australian jurisdictions and New Zealand. However, FSANZ considered this would mean the Code would contain different requirements for the same products, across different jurisdictions and that this is not appropriate for the Code. For this reason, FSANZ has maintained the 1% THC level in the definition of low THC *C. sativa* in the approved draft variation. FSANZ notes that the relevant intergovernmental agreements and related food legislation provide, and are, the means for jurisdictions to vary requirements of the Code as applied by their laws, if they wish. Regulation 26 of the New Zealand (*Food*) *Safety Regulations 2002 (NZ)* and the exemption from Standard 1.4.4 that it provides for hemp seed oil in New Zealand is a case in point.

The New Zealand Government also noted that the limit set in New Zealand regulations referred to THC measured on a dry matter basis, and questioned whether the analysis of THC on a dry matter basis was standard practice in Australia. FSANZ understands this is the case in Australian jurisdictions that permit the cultivation of hemp.

2.4 Risk communication

2.4.1 Consultation

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

FSANZ communicated widely on this Proposal. The call for submissions attracted significant interest from the media, the hemp industry, consumers and government stakeholders.

The call for submissions was notified via the Notification Circular, media release and through FSANZ's social media portals and its newsletter, Food Standards News. Subscribers and interested parties were also notified. The hemp seeds consumer web page was updated.

FSANZ sought submissions on the draft variation to the Code (and associated assessment summary) focusing on the matters the Forum asked FSANZ to investigate) between 28 July 2016 and 25 August 2016.

Thirty-nine submissions were received in response to the CFS. All comments were valued and contributed to the rigour of the assessment. The issues raised in four late comments received after the closing date for receipt of submissions reflected issues raised in other submissions, and were therefore considered as part of the overall assessment of the Proposal. Of the 39 submissions received, 29 submitters indicated their support of FSANZ's proposed approach, four submitters did not support the draft variation, and the remainder gave no specific indication either way.

Annex 1 contains a summary of issues raised in submissions and how FSANZ responded to them, with cross references to appropriate sections of the report, supporting documents or draft variation, as relevant.

2.5 Decision

The draft variation as proposed following assessment was approved with amendments and is at Attachment A. The variation takes effect six months after the date of gazettal.

The related explanatory statement is at Attachment B. This is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

The draft variation on which submissions were sought is at Attachment C.

2.6 FSANZ Act assessment requirements

2.6.1 Section 59

2.6.1.1 Consideration of costs and benefits

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 to the community, government or industry that would arise from that variation.

The Office of Best Practice Regulation (OBPR) assessed that the proposed change to the Code would be likely to have no more than minor regulatory impacts on business, community organisations or individuals. Therefore, a Regulation Impact Statement (RIS) was not required to be prepared (OBPR reference 20932).

FSANZ conducted an economic or cost benefit analysis as part of the assessment of A1039. This concluded the variation would provide moderate benefits to industry and consumers. FSANZ considers this economic analysis remains valid for this proposal, noting low THC hemp seed foods have remained subject to the Code's prohibition since the rejection of A1039. The restrictions that ensure the sale of non-viable seeds only were developed to minimise potential costs to government and law enforcement agencies that might arise from low THC hemp seed food permissions.

Whether the variation is 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 the variation would result in complications and costs to law enforcement activities related to illicit drugs (notwithstanding the requirement that only non-viable seeds be sold), and the magnitude of any such costs. The FSANZ economic analysis is available as SD2 to the Approval Report for A1039¹⁷.

The restrictions imposed on labelling and advertising may impose minor costs on some New Zealand hemp seed oil manufacturers that may be required to re-label their products. The establishment of a ML for CBD may also impose minor costs on some New Zealand hemp seed oil manufacturers, although FSANZ considers the ML has been established at a high enough level to counter any impact on current hemp seed oil products in New Zealand. These restrictions may also place conditions on products imported into domestic markets that are not imposed by overseas food standards. However, FSANZ notes that at present, low THC hemp seed food products are not permitted to be sold in the domestic market and that overall, the approved draft variation will provide a market opportunity that does not currently exist for these food products in Australia and New Zealand. Potential impacts of inconsistencies with international food standards are discussed in more detail below (section 2.6.3).

2.6.1.2 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 remove the prohibition in the Code for the sale of low THC hemp seed foods.

In relation to restrictions on labelling and advertising and the CBD content of low THC hemp seed foods included in the approved draft variation, FSANZ notes there are alternative measures available, including other laws, existing standards and the development of codes of practice/conduct. However, after having regard to all relevant considerations, including the views of governments, FSANZ has agreed to introduce explicit labelling and advertising restrictions and a ML for CBD in the approved draft variation. These restrictions reflect that weight has been given to the views and advice of government, including agencies responsible for drug reduction and related harm minimisation strategies in Australia and New Zealand - agencies that have highlighted concerns relating to the prevalent illicit drug culture in Australia and New Zealand – and food enforcement agencies.

2.6.1.3 Any relevant New Zealand standards

Standard 1.4.4 is a joint Standard and is applied in New Zealand by New Zealand food laws.

As outlined in section 1.2, the New Zealand *Food (Safety) Regulations 2002* include a provision that exempts the sale of hempseed oil as a food in New Zealand from the requirements of Standard 1.4.4 (as applied). The exemption is scheduled to expire on 30 October 2017.

As noted in section 2.3.3.4, in the New Zealand *Misuse of Drugs (Industrial Hemp) Regulations 2006*, hemp products may not be advertised to have psychoactive effects.

2.6.1.4 Any other relevant matters

Other relevant matters are considered below.

¹⁷ <http://www.foodstandards.gov.au/code/applications/pages/applicationa1039lowt4708.aspx>

Matters raised by the Forum and by submitters

As explained above, FSANZ had regard to, as one of a number of relevant matters, the policy advice provided by the Forum relating to restricting marketing and advertising of low THC hemp as a food. This matter is considered at section 2.3.3 above.

Other matters raised by the Forum (and by submitters) included: whether changes to legislation (including non-food related laws) would also be required before the sale of food derived from the seeds of low THC hemp could occur; the extent of any such changes; and the implications, if any, for roadside drug testing. As stated in the A1039 Review Report, FSANZ considers such matters to be outside of the matters that FSANZ could take into consideration when developing a food regulatory measure. Whilst FSANZ acknowledges the importance of these matters, they are more ones for the governments responsible for administering the relevant legislation. In this regard, FSANZ understands that Forum members have agreed that each jurisdiction would undertake an extensive audit of their respective legislation to determine any relevant amendments that will be required to complement the draft variation if endorsed by the Forum and gazetted in the Code. At the request of government stakeholders FSANZ has agreed to incorporate a delayed commencement date for the approved draft variation. This will provide regulators with the opportunity to implement changes to other legislation that will be required if the approved draft variation is agreed by the Forum. The commencement date will be six months after the approved draft variation is gazetted in the Code.

FSANZ also understands that the Forum will separately consider the results of a research project being undertaken by the Food Regulation Standing Committee to investigate the impact of consumption of low THC hemp seed foods on random roadside drug testing programs. These results were not considered by FSANZ in its assessment of this Proposal.

2.6.2 Subsection 18(1)

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

2.6.2.1 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 summarised in section 2.2 (and in SD1 of the [A1039 Approval Report](#)¹⁸).

2.6.2.2 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 current provisions in 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 relevant to this objective (section 2.3.3).

2.6.2.3 The prevention of misleading or deceptive conduct

FSANZ 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 and potential for consumers to be misled by claims about CBD.

¹⁸ <http://www.foodstandards.gov.au/code/applications/pages/applicationa1039lowt4708.aspx>

As outlined in section 2.3.3.5, FSANZ has decided to impose restrictions relating to the labelling and advertising of low-THC hemp seed foods. These measures are relevant to this objective.

2.6.3 Subsection 18(2) considerations

FSANZ also had regard to:

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

FSANZ considered the best available scientific evidence as it related to the safety of consumption of low THC hemp seed foods. In particular, FSANZ included updated food consumption data in the risk assessments for THC and CBD (section 2.2) in relation to the consumption of low THC hemp seed foods; and amended the definition of THC for the purpose of the MLs (section 2.3.2).

FSANZ also reviewed the scientific literature for evidence to support the application of restrictions to the labelling and advertising of low THC hemp seed foods. FSANZ did not identify any available scientific evidence for or against restrictions, but did have regard to stakeholder views and government policy in relation to the acceptability of illicit cannabis use, as outlined in section 2.3.3.

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

Low THC hemp seed foods are permitted for sale in some countries. The MLs for THC content of low THC hemp seed foods that are included in the approved draft variation are consistent with levels that are set in other countries (where specified) and are achievable.

In terms of CBD, no international organisations or other countries have set limits on the CBD content of low THC hemp seed foods. The establishment of a CBD limit in the Code may impose additional compliance costs that are not required in international markets. However, as noted in section 2.3.1.1 FSANZ has decided to establish a ML for CBD in the approved draft variation. The ML has been established on the basis that it is not expected to be onerous on food manufacturers because it includes an uncertainty factor above the maximum CBD content detected in an analytical survey of hemp seed food products.

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. These regulations are not **food standards** per se and apply more broadly to any hemp products. FSANZ is not aware of any other country that has specific restrictions relating to representations on hemp foods.

Most other countries consulted by FSANZ that permit the sale of low THC hemp seed foods (including hemp seed oils) advised that they were not aware of any problems in relation to low THC hemp seed foods being marketed in such a way as to suggest they may have psychoactive properties. Belgium noted that while producers do market the nutritional qualities of hemp foods, some products had been marketed with large images of a cannabis leaf on the label. They suggested that this may be viewed as making a connection with illicit cannabis use.

Developing measures in the Code to regulate representations on foods derived from low THC hemp seeds may be inconsistent with food standards in other jurisdictions.

However, the restrictions included in the approved draft variation may be consistent with observed marketing practices for hemp food products internationally. FSANZ has noted products available overseas almost exclusively use the name hemp on the labels; non-government submitters have highlighted that the majority of marketing strategies for hemp foods overseas focused very much on the nutritional quality of low THC hemp seed foods rather than attempting to make linkages with illicit cannabis (section 2.1.3.2).

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

There are potential benefits to the food industry in permitting low THC hemp seed foods. The extent of the overall benefit to the food industry would depend on the profitability of the production of low THC hemp seed foods domestically and internationally.

The permission would open up domestic and export markets for foods derived from hemp seed. Anecdotal evidence suggests that there is increasing demand overseas for low THC hemp seed foods, especially from consumers interested in the health benefits of the seeds, oil and protein. The introduction of labelling and advertising restrictions in the approved draft variation may impose conditions, for products imported into Australia and New Zealand, which are not required by international food standards. However, FSANZ notes that other Code requirements must also be met by imported foods (including nutrition information panels on food labels) and the approved draft variation restrictions are likely to be one of a number of aspects that may need to be addressed by food companies exporting products to Australia and New Zealand. In addition, as noted in the section above, international marketing of hemp food products appears, anecdotally, to be focussed on nutritional quality rather than attempting to make linkages with illicit cannabis.

A more general permission to sell low THC hemp seed foods in Australia and New Zealand as in the draft proposed variation could serve to permit trans-Tasman trade in these products, subject to amendments to other legislation (e.g. customs legislation).

- **the promotion of fair trading in food**

No issues were identified.

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

There are no policy guidelines relevant to this Proposal. FSANZ has had regard to the policy advice provided by the Forum (section 2.3).

3 Transitional arrangements

The commencement date of the approved draft variation will be six months after the date of gazettal. This will enable Australian and New Zealand regulators a period of time in which to amend relevant legislation that will be required to support the approved draft variation in respective jurisdictions (section 2.6.1.4).

Regulation 26 of the *New Zealand (Food) Safety Regulations 2002* exempts hemp seed oil from the application of Standard 1.4.4 in New Zealand. The regulation provides that hemp seed oil that meets certain conditions can be sold as a food in New Zealand irrespective of any restrictions contained in Standard 1.4.4. New Zealand authorities have advised that they intend to repeal regulation 26 which would remove the Standard 1.4.4 exemption for hemp seed oil. FSANZ has not included a stock-in-trade provision in the approved variation for hemp seed oil sold as a food in New Zealand.

The timing of the expiry or revocation of regulation 26 is a matter for the New Zealand Government and any stock-in-trade provisions, if considered required by New Zealand authorities, can be incorporated in the relevant New Zealand legislation at the time of any repeal.

Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)

Annex 1: Summary of issues raised in submissions

Issue	Raised by	FSANZ response (including any amendments to drafting)
CBD limit in Code		
<p>Suggests that there is no need to set limits for CBD (or THC or THC-A), provided the low THC hemp seed products are unfortified and free of contamination.</p>	Private	Noted. FSANZ has decided to include a ML for CBD in the Code for foods for sale, giving weight to government concerns about enforceability of the approved draft variation (see Section 2.3.1).
<p>Mind altering substances are tolerated in foods and beverages (e.g. gamma-hydroxybutyrate – GHB in wine) without any labelling requirements or limits being set (although GHB is a Class B prohibited substance in the <i>Misuse of Drugs Act 1975</i>).</p>	Private	Noted. FSANZ has decided to include a ML for CBD in the Code for foods for sale as noted above.
<p>Supports FSANZ’s decision not to impose a CBD limit in the Code, for the reasons FSANZ gave in its assessment report.</p>	Hempstore Aotearoa New Zealand Hemp Industries Association (NZ Hemp Industries)	Noted. FSANZ has decided to include a ML for CBD in the Code for foods for sale as noted above.
<ul style="list-style-type: none"> • Considers that, from an agricultural industry perspective, the FSANZ proposal falls well short of what is required to bring Australia and New Zealand in line with global developments in the hemp industry. • Disagrees with FSANZ regarding excluding cannabinoids from being extracted or derived from low THC hemp. Hemp foods and hemp products derived from Industrial Hemp can be both a health supplement and a food ingredient. • The non-drug constituents of low THC hemp (including many cannabinoids, flavonoids, and terpenes) can be utilised and have nutraceutical value which is of interest to the general public and Agri-food industry. 	NZ Hemp Industries New Zealand Hemp Brokers Hemptastic	<p>Noted. FSANZ has decided to include a ML for CBD in the Code foods for sale as noted above.</p> <p>The approved variation addresses only the sale of low THC hemp seed and seed products as food. The Code does not regulate dietary supplements. The sale of dietary supplements in New Zealand is subject to specific legislation. In Australia, dietary supplements are regulated either as foods (and therefore must be compliant with the Code) or therapeutic goods (and therefore subject to the requirements of the <i>Therapeutic Goods Act, 1989</i>). FSANZ is not expressly excluding cannabinoids from being extracted or derived from low THC hemp. The fortification of foods with cannabinoids will not be permitted by the approved draft variation. The sale of CBD-fortified (or other cannabinoid fortified) products for oral consumption as food will not be permitted and may be subject to other legislation in Australia and New Zealand. For example, the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)) in Australia and the <i>Misuse of Drugs Act (MoDA) 1975</i> in New Zealand.</p> <p>In order for cannabinoids to be utilised for their nutraceutical value, amendments to respective drug legislation (and not the Code) would likely be required.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Notes that there is no CBD in the hulled seed. In addition, high CBD strains of seed have been bred at immense cost to the plant breeders. For this reason breeders are highly protective of their seed stock and the possibility of CBD finding its way into foods is extremely unlikely.</p>	<p>New South Wales Industrial Hemp Association Incorporated (NSW Industrial Hemp)</p>	<p>FSANZ has noted there are products available online derived from high CBD cultivars which are being sold as foods. Our analysis indicates such foods are derived by fortification of hemp seed oil or by use of other parts of the hemp plant. FSANZ has decided to include a ML for CBD in the Code for foods for sale as noted above.</p>
<p>Supports FSANZ's position in relation to CBD limits.</p>	<p>New Zealand Food and Grocery Council (NZFGC)</p>	<p>Noted. FSANZ has decided to include a ML for CBD in the Code for foods for sale as noted above.</p>
<ul style="list-style-type: none"> • Notes anecdotal reports of crops with high levels of CBD internationally. Products from these crops could be imported as foods and used as therapeutic products. Therefore, a ML of CBD would be useful to differentiate low THC hemp seed food from therapeutic cannabis products. • Recommends that FSANZ gives this issue more consideration. 	<p>Victorian Department of Health and Human Services and the Victorian Department of Economic Development, Jobs, Transport and Resources (Vic Govt)</p>	<p>Noted. FSANZ has decided to include a ML for CBD in the Code for foods for sale as noted above. The approved draft variation includes a prohibition on the making of nutrition content and health claims for CBD, which will restrict the potential for food products to be marketed on the basis of CBD (section 2.3.1).</p>
<ul style="list-style-type: none"> • Notes that currently, THC hemp cultivars produce very little CBD, but it is possible to breed high CBD hemp cultivars and this situation would need to be managed if it occurred in future. The legislation which regulates cultivation of low THC hemp crops in each jurisdiction provides a mechanism that could be used to manage CBD levels in low THC hemp crops, should this prove necessary. • However, an alternative approach would be needed to manage products from hemp cultivars that may be bred and grown overseas to produce high CBD products that may be beyond the remit of both the Code and jurisdictions' hemp cultivation regulations. 	<p>New South Wales Food Authority (NSWFA) Victorian Department of Health and Human Services and the Victorian Department of Economic Development, Jobs, Transport and Resources (Vic Govt)</p>	<p>Noted. FSANZ has decided to include a ML for CBD in the Code for foods for sale as noted above.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<ul style="list-style-type: none"> Notes that in New Zealand, cannabinoids are class B1 controlled drugs under the <i>Misuse of Drugs Act (MoDA) 1975</i>. This means that no amount of CBD, THC etc. is acceptable in food, unless the legislation is amended¹⁹. New Zealand's preference is to set a limit for CBD in the Code, irrespective of whether it is reclassified from a controlled drug to a prescription medicine (this is currently under consideration) for the following reasons: <ol style="list-style-type: none"> A limit will legitimise and set a standard for the very low levels of CBD that may be present (due to contamination). Whilst there is no risk to public health in the low levels of CBD that could be present, the low levels can only be assured by setting a limit for CBD. If CBD remains a controlled drug (in New Zealand) then an exemption will have to be made in legislation to allow for the low levels proposed in hemp seed foods. This will be difficult without an upper limit in the Code. If CBD is reclassified as a prescription medicine in New Zealand, it can be in food only as long as the concentration of the CBD is not greater than 10ppm – above this it is a prescription medicine. While a higher maximum limit could be specified for CBD in the prescription medicine schedule, 10ppm would seem to be an obvious upper limit to choose (it is noted that the maximum level found in some hemp seed oils tested was above this level). 	<p>New Zealand Ministry of Health and Ministry for Primary Industries (NZ MoH, NZ MPI)</p>	<p>Noted. FSANZ has decided to include a ML for CBD in the Code for foods for sale as noted above. In response to particular issues raised in this submission, FSANZ notes the following (in number order):</p> <ol style="list-style-type: none"> A CBD limit in the Code is not a requirement or prerequisite to achieve legislative consistency between jurisdictions. Based on survey information provided to FSANZ the level of CBD in low THC hemp seed foods is significantly lower than levels required for therapeutic doses (see section 2.2). A CBD limit in the Code is not a requirement for other drug legislation to be amended. FSANZ notes that low THC hempseed oil has been available in New Zealand for a number of years without a limit in the Code (or New Zealand food regulations) or an exemption in New Zealand drug legislation, noting that THC is also a controlled drug. The survey information provided to FSANZ indicates some hemp seed oils have higher CBD levels than that proposed by MPI (10ppm). This is addressed in section 2.3.1. FSANZ has decided to include a ML for CBD in the Code for foods for sale as noted above. FSANZ has decided to include a ML for CBD in the Code for foods for sale as noted above. The FSANZ approved draft variation does not permit fortification. In addition, low THC hemp seed food products can only be sourced from the seeds of low THC <i>C. sativa</i>. The likelihood of low THC hemp seed foods being fortified with CBD is unclear. A review of products available online indicates 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.

¹⁹ In Australia, CBD is classified as a prescription medicine in preparations for therapeutic use except when containing more than 2% of other cannabinoids found in cannabis.

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>5. Naturally occurring contamination of hemp seed foods by CBD will not have a therapeutic effect; likewise naturally occurring contamination by THC will not cause a psychoactive effect either, yet FSANZ is setting a limit for THC.</p> <p>6. Fortification of a food product with CBD is not permitted by the drafting. However, if fortification is suspected, it would be difficult to prove and take action without a CBD limit.</p> <p>7. It is possible that the CBD could be extracted from a fortified food product in a more concentrated form, such that products that appear to be suitable can be high in CBD.</p> <p>8. People are likely to attempt to use hemp seed products medicinally (i.e. hemp seed oil by buccal administration). An oil product extracted from hemp seeds and stalks has been used for legitimate therapeutic purposes (prescribed by a medical practitioner) by this route in New Zealand due to the absence of pharmaceutical grade CBD product.</p> <p>9. CBD is known to interact with prescription medicines, particularly those used in epilepsy. Without a CBD limit, a common and incorrect message is sent that CBD, unlike THC is harmless.</p>		<p>8. As above. In addition, the approved draft variation includes a prohibition on the making of nutrition content and health claims for CBD, which will restrict the potential for food products to be marketed on the basis of CBD (section 2.3.1).</p> <p>9. Noted. However levels present in non-fortified hemp seed food are considerably below levels which are used therapeutically. See also the response for issue 8 above.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<ul style="list-style-type: none"> • Considers that a limit for CBD be imposed (e.g. 50 mg/kg) to ensure the food is distinguished from a therapeutic good. • Although hemp seed oil does not contain CBD or THC, some hemp seed oils are claimed and advertised to do so. These are in fact hemp oil which is an extraction of the cannabis plant. Some are mixtures of seed and hemp oil and have cannabinoids added. • The terms hemp oil and hemp seed oil have been used interchangeably. Hemp seed oil should not be used to describe products that contain hemp oil or have been adulterated with cannabinoids not present in hemp seed oil. 	Department of Health (Cwth)	<p>Noted. FSANZ has decided to include a ML for CBD in the Code for foods for sale as noted above.</p> <p>In addition, the approved draft variation permits only the <u>seeds</u> sourced from low THC hemp to be used to produce foods and ingredients. Hemp oil which includes an extraction from other parts of the cannabis plant will not be permitted to be sold as food in Australia and New Zealand.</p> <p>The approved draft variation also permits the natural presence of cannabinoids in low THC hemp seed foods due to contamination during processing; fortification of the seed and seed products with cannabinoids is not permitted.</p> <p>The approved draft variation also includes a prohibition on the making of nutrition content and health claims for CBD, which will restrict the potential for food products to be marketed on the basis of CBD (section 2.3.1).</p> <p>There are a number of existing standards in the Code and other legislation (including consumer protection legislation) that cover misleading and deceptive labelling, for example, in cases where the term 'hemp seed oil' has been incorrectly used to describe products that contain hemp oil.</p>
<p>Late comment: CBD limits have not identified issues that warrant the continued prohibition of low THC hemp.</p>	Dept of Primary Industries, Parks, Water & Environment Tasmania	Noted. FSANZ has decided to include a ML for CBD in the Code for foods for sale as noted above.
Cannabinoid acid precursors		
<p>Supports the drafting, such that the ML for total THC includes THC-A. This approach addresses 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.</p>	Hempstore Aotearoa NZ MoH and NZ MPI NZFGC Department of Health (Cwth)	Noted. FSANZ notes that some of the acid precursor THC-A present in low THC hemp seed foods may be converted to THC (even at room temperatures). As such, FSANZ has decided that the proposed MLs for THC should take into account the THC-A content (see section 2.3.2)

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Does not support the need for any THC limits [for THC or its precursor].</p> <ul style="list-style-type: none"> Industrial hemp food products come from crops grown under licence, from certified low THC seeds. THC content is not a concern from a food safety point of view. THC limits create more compliance costs in the form of THC testing which adds no value to the industry or the consumer. <p>Therefore, THC and THC-A levels are irrelevant as they are not present in industrial hemp in quantities that would warrant control measures.</p>	<p>NZ Hemp Industries Hemptastic</p>	<p>Noted. The proposed MLs for THC in low THC hemp seed foods are protective of public health and safety. MLs have been set on the basis of the TDI. This is the amount of THC that can be ingested daily over a lifetime of daily consumption without appreciable health risks. The TDI is based on the lowest observed levels of THC that may have an impact on skill performance (not psychoactive effects). FSANZ's dietary exposure estimates that high consumers of hemp foods will not exceed the TDI, even if the foods contain THC at the MLs established by FSANZ.</p> <p>The MLs for THC in low THC hemp seed foods will be consistent across Australia (including the states and territories) and New Zealand as they will be included in the Code. The MLs are also comparable with international regulatory limits for hemp seed foods (where these have been set) and would not be trade-restrictive.</p> <p>The establishment of MLs for low THC hemp seeds and three main categories of hemp seed foods will therefore provide additional assurance to consumers of the safety of all low THC hemp seed foods available for sale in Australia and New Zealand.</p>
Labelling and advertising		
<p>Concern that hemp leaf images or other links to illicit hemp may be used to label or market hemp food; this will contribute towards normalising the (illicit) cannabis culture.</p> <p>Mixed messages regarding the acceptability and safety of cannabis use might reduce or ruin public health messages about the harmful effects of cannabis (drug) usage.</p> <p>FSANZ is asked to give more regard to the policy advice provided by the Forum and, in particular, further consideration to how the use of the cannabis leaf image/other representations implying links to illicit cannabis may be prohibited on low THC hemp foods.</p>	<p>Vic Govt NSWFA and New South Wales Ministry of Health NZ MoH and NZ MPI Western Australia Police Department of Health (Cwth)</p>	<p>Noted. Section 2.3.3 addresses labelling and advertising issues in detail, including FSANZ's decision to amend the draft variation to include specific labelling and advertising restrictions for low THC hemp seed foods.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Other suggested changes to the drafting:</p> <ul style="list-style-type: none"> • prohibit the word <i>Cannabis</i>' • prohibit references to illicit cannabis • use Reg 62 of the <i>Misuse of Drugs (Industrial Hemp) Regulations 2006</i> as a starting point. <p>It is not feasible to restrict advertising through Australian Consumer Law; the Code is the most appropriate place to restrict advertising. However, it is important that ACCC guidelines are met (no inference to psychoactive content or benefits) and to ensure that no health claims are used unless substantiated and FSANZ approved.</p> <p>Stringent, additional regulatory measures are absolutely necessary to prevent this situation developing to the detriment of the community; particularly young people.</p>		
<p>The word "Hemp" only should be used on labelling (not Cannabis or Marijuana).</p> <p>Prescribe the name 'hemp' and qualify the type of hemp, e.g. hemp seed, hemp seed oil, hemp seed flour, hemp seed protein etc.</p>	<p>Safe2eat – Food Industry Consultants NZ MoH and NZ MPI</p>	<p>Noted. See above and section 2.3.3.5 of the report. FSANZ notes that a prescribed name does not address submitter concerns about certain representations causing consumers to make an incorrect association with illicit cannabis.</p> <p>In terms of qualifying the type of hemp, FSANZ is of the view that it is unlikely that hemp foods would be hidden in an ingredient list under a generic term such as 'vegetable oil', rather than being fully qualified. Hemp seed foods are likely to be considered a premium product, and as such, it is considered likely that food manufacturers wishing to add hemp seed foods as an ingredient in another food would wish to alert consumers to this fact, and use it as a major selling point.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<ul style="list-style-type: none"> • Is of the view that there is no need for additional requirements regarding labelling in the Code. Labelling is adequately controlled by existing regulations. Consumer protection legislation in Australia and New Zealand covers misleading and deceptive labelling and advertising and this is the best protection against misleading advertising. In New Zealand, there is section 61 of the <i>Misuse of Drugs Act, Industrial Hemp Regulations 2006.</i> • Notes that overseas, hemp health benefits are its major selling points. It is incongruous for companies to send mixed messages that detract from health benefits of hemp seed. Drug inferences strongly detract from this message. This is key to Australian and New Zealand governments accepting that the general public is mature in its understanding of hemp plant benefits, and is ready for hemp food. • A private submitter suggested the calculated marketing of hemp foods to include the hemp leaf as a marketing device could quite possibly be negatively misconstrued by the bulk of a likely conservative and health conscious target market. • There is no market or monetary advantage in associating hemp product with illicit drugs. • The submitter has no trust that any substantive market exists for a product which is sold on drug associations and yet has no drug content. • Use of the leaf as a marketing device should be left to industry to determine the value thereof. 	<p>Private Agri Fibre Industries NZ Hemp Industries NZ Hemp Brokers Hemptastic NSW Industrial Hemp Association Inc NZFGC Industrial Hemp Association – Victoria</p>	<p>Noted. However, for the reasons outlined in this report, FSANZ has amended the draft variation to include restrictions on the labelling and advertising of low THC hemp seed foods. Refer to section 2.3.3.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<ul style="list-style-type: none"> • Suggests that a direct analogy can be made with poppy seeds. Consumers are not warned that poppy seeds may contain opiates and nor do they purchase poppy seeds believing them to be able to provide an opiate benefit. • Argues that publicly funded anti-drug efforts might in actual fact have the opposite effect on impressionable, young people, more so than any leaf representation would. • Associating the hemp leaf image with health food might well be an effective deterrent to youngsters who want to cultivate a rebellious, devil may care image. • In terms of the potential for mixed messages, note that Australia is a signatory of the UN Single Convention on Narcotic Drugs. The Single Convention specifically excludes the seeds in Article 28. Thus it draws a line between the illicit use of drugs and the industrial use of hemp seeds. The use of hemp seeds is considered internationally as wholly separate and distinct from illicit drug use, and there is no concern in other countries that provision of hemp food will send a mixed message to consumers on the acceptability and safety of cannabis, and in particular foster its illicit use. • The Industrial Hemp Association – Victoria continues to recommend to its commercial members that they avoid presenting their product with labelling that displays the hemp leaf and asks that members acknowledge that the Association does not support recreational or medicinal cannabis. 		

Issue	Raised by	FSANZ response (including any amendments to drafting)
<ul style="list-style-type: none"> • Considers that the proposal to not allow depictions of the hemp plant is arbitrary, onerous and should be rejected. • Depicting the ingredients provides immediate recognition. • Proposed restrictions could present trade barriers and additional compliance costs – to importers of hemp seed foods as well. • Is of the view that consumers would respond negatively to any suggestion of THC contamination or psychoactive properties. • Notes that as low THC foods are not psychoactive, there is other legislation (consumer protection legislation) that will prevent psychoactive claims being made. • Considers that further controls in the Code are not warranted. 	Hempstore Aotearoa	Noted. See FSANZ's response above.
International Narcotics Control Board advice		
Agrees that the EU limit referred to in the INCB advice is not relevant to FSANZ's consideration.	Hempstore Aotearoa NZ Hemp Industries NZ MoH and NZ MPI Department of Health (Cwth)	Noted. See section 2.3.4.
Other issues		
Total THC MLs for final food products Suggests that FSANZ considers including an additional ML for total THC for final foods derived or manufactured from one or more hemp seed ingredients. Inclusion of this upper level may be necessary to satisfy existing or amended state and territory legislation for the control of drugs and poisons.	Vic Govt	<p>Noted. FSANZ considers it would likely be difficult and complex to develop appropriate MLs for final foods, as it is not possible to anticipate the variety of final foods that may ultimately contain low THC hemp seed ingredients. In cases where there was no ML for a specific mixed food, then the ML for the ingoing ingredient would apply (e.g. 5 mg/kg for seeds).</p> <p>FSANZ notes that the approach used to apply MLs to mixed foods is the same as that used for other contaminants specified in the Code. As such, this would not be a new issue for jurisdictions.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Definition of low THC <i>C. sativa</i> in draft variation:</p> <ul style="list-style-type: none"> • Is concerned about the definition of ‘low THC <i>C. sativa</i>’ in 1.4.4—6(6) of the draft and, in particular, notes that <i>C. sativa</i> containing more than 0.5% THC would not be considered industrial hemp in New Zealand, despite the definition in the Code. This may create confusion for New Zealand producers and may be a similar issue for Australian jurisdictions that do not have an allowance of 1% THC in industrial hemp plants. • In New Zealand, industrial hemp is defined as <i>C. sativa</i> that generally contains below 0.35% THC and not more than 0.5% THC in the leaves and flowering heads of the plant. 	<p>NZ MoH and NZ MPI</p>	<p>Noted. See section 2.3.5.2 for discussion of this issue.</p>
<p>Hulled versus non-viable</p> <p>Disagrees with the wording in the drafting around being ‘hulled and non-viable’. This could be interpreted that manufacturers need to hull the seed (in effect sterilizing them as non-viable) and then do further treatment to confirm them as non-viable. This may involve another processing step which is unwarranted and adds a further cost to the industry and consumer.</p>	<p>NZ Hemp Industries Hemptastic</p>	<p>Noted. In assessing A1039, FSANZ received information from the industrial hemp industry that hulled seeds are non-viable. However, this has not been confirmed authoritatively. The approved draft variation will require that the processing conditions used will hull all seeds <i>as well as</i> rendering the seeds non-viable. How manufacturers meet the requirements of ‘hulled and non-viable seeds’ is up to them and their processes. FSANZ notes the submission that the extra steps could add cost but considers this is warranted in order to address enforcement issues.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Additional text around CBD</p> <p>Noted that ‘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 <i>C. sativa</i>, to be a food for sale or used as an ingredient in a food for sale.’ However, the submitter does not believe that FSANZ has the legal ability to include such additional text, especially as CBD is not a concern for public safety.</p>	Hemp Foods Australia	Noted. See section 2.3.1.1 for discussion of this issue.
<p>Impact on other regulations</p> <p>Notes that this submission may impact upon other Acts and Regulations and subordinate legislation. Therefore recommends that FSANZ consults with state and territory government medicines and poisons areas on this issue.</p>	Private	Noted. In March 2016, the Forum acknowledged that there is a range of Commonwealth, New Zealand and state and territory legislation that currently prohibits the sale of low THC hemp as a food. Other such legislation would have to be amended before low THC hemp could be sold as a food. Therefore, members agreed that each jurisdiction would undertake an extensive audit of their respective legislation to determine any relevant amendments that will be required to complement the draft variation if it is gazetted in the Code.
<p>Clear definitions required.</p> <p>Suggests that clear definitions be provided for:</p> <ul style="list-style-type: none"> • what are foods derived from hemp seeds • which hemp products can be used or not used • what foods can have hemp products added to them and what percentage (as this would be a factor in diluting the already low-THC present) • what is a maximum recommended daily intake of low THC hemp from all sources. 	Private	<p>Noted. The approved draft variation includes definitions for <i>low THC C. sativa</i>, <i>seeds</i>, <i>seeds of low THC C. sativa</i>, <i>hulled seeds</i>, <i>non-viable seeds</i>, and <i>total THC</i>.</p> <p>FSANZ does not consider it is necessary to further describe what are foods derived from hemp seeds; and which hemp products can be used or not used – as these points are adequately covered by the approved draft variation.</p> <p>In addition, FSANZ does not consider it necessary or appropriate to specify or mandate in the Code which specific foods can have hemp products added to them.</p> <p>‘Recommended daily intakes’ refer to the number of ‘standard serves’ people should consume from the five core food groups (i.e. vegetables and legumes, fruit etc.) each day, for a nutritious and balanced diet. Consumers and health professionals can determine how low THC hemp seed foods fit within the context of recommended daily intakes. It is not appropriate for FSANZ to set a maximum recommended daily intake for low THC hemp.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Natural whole hempseeds should be allowed</p> <ul style="list-style-type: none"> • Notes that the variation only considers hulled hemp seed foods. It ignores whole hemp seeds, sprouted foods and the numerous food and beverage products obtainable from other parts of the low THC industrial hemp plant being utilized and marketed globally. • Argues that hulled seeds do not retain the same degree of freshness and it is not possible to use hemp sprouts for food purposes. • Requests that this requirement include a review date, similar to the hempseed oil review in October 2017 in New Zealand. 	<p>Hempstore Aotearoa NZ Hemp Industries</p>	<p>Noted. The approved draft variation will allow unhulled and viable low THC hemp seeds to be used to produce hemp seed food products, being oil, beverage and any other product that is extracted or derived from the hemp seeds (such as flour and protein powder).</p> <p>The requirement that hemp seeds that are sold as food at retail or used as ingredients in food for sale at retail be hulled and non-viable was a strong preference for law enforcement agencies to ensure that hemp seeds and the seeds of illicit cannabis could be distinguished in the event of a consumer possessing whole seeds (which would be illegal).</p> <p>It is not normal practice for FSANZ to propose review dates. Should there be a reason for a subsequent review of this standard this can be accomplished by the standard processes for amending the Code (by an application or a Proposal).</p>
<p>Commencement date.</p> <p>Suggests that the commencement date of any new standard be set with regard to the legislative amendments that jurisdictions will be required to make to permit the use of low THC hemp seed as food.</p>	<p>Vic Govt</p>	<p>Noted. The approved draft variation will commence six months after the date of gazettal. FSANZ recognises that other legislation in Australia and New Zealand will require amendment before low THC hemp seed foods are legally permitted to be sold and consumed, despite gazettal in the Code. This legislation and its amendment or otherwise is a matter for others.</p>
<p>Industry assistance</p> <p>Offers to develop a code of practice within 12 months of approval and gazetting to ensure marketing focuses on the health benefits; and world best practice with seed handling/ washing to minimise levels of surface THC.</p> <p>Offers expert advice in relation to current Australian hemp production etc.</p>	<p>Agri Fibre Industries Vitahemp Australian Industrial Hemp Alliance</p>	<p>Noted. FSANZ notes offers of assistance made by the hemp industry in relation to developing a Code of Practice, quality assurance programs and obtaining expert advice. FSANZ notes that FSANZ has included labelling and advertising restrictions in the approved draft variation, which may negate the need for a Code of Practice to address this aspect. The other aspects that may be addressed in a Code of Practice are likely to be best developed with the support of other government agencies responsible for enforcement of the Code and other relevant legislation.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Offers to work with the Australian Government to develop an industry based quality assurance regime to manage the safe handling and testing of hemp food inputs thereby ensuring only low THC products enter the food marketing system.</p>		
<p>Schedule 23 changes</p> <ul style="list-style-type: none"> • Requests a change in Schedule 23 – Prohibited plants and fungi – to make an exception for Low THC industrial hemp grown under licence. Adding this exception to the word ‘cannabis’ will remove low THC hemp foods from inclusion in Schedule 23. • Hemp seed and products have negligible THC content and they should not be controlled as if they come from a drug crop. 	<p>NZ Hemp Industries</p>	<p>Noted. However, for the reasons outlined in this report, FSANZ considers the approved draft variation to be the appropriate mechanism to provide a partial exception to the Code’s prohibition on all cannabis species being sold as food or used as an ingredient in food.</p>
<p>Hemp web page</p> <p>Recommends that FSANZ include a webpage to provide consumers with information about hemp foods to allay concerns regarding psychoactive properties relating to the consumption of those foods.</p>	<p>Dietitians Association of Australia</p>	<p>Noted. FSANZ has an existing webpage on its website that provides the general public with information about hemp seeds as food, including previous consideration of applications to permit foods derived from hemp, and the status of this Proposal. This webpage will be updated as appropriate at the completion of P1042.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Drafting issues Seeks confirmation that if seeds are used to produce foods where the seeds are not whole in the food – e.g. oil, flour or crushed to make a beverage (1.4.4—6(2)), then the seeds can be unhulled.</p> <ul style="list-style-type: none"> • Notes that in section 1.4.4—6(2)(c) there are other hemp seed foods such as flours and protein powder. The term ‘substance that is extracted’ is not correct terminology for these foods. This is because extracted substances could be taken to be a novel or nutritive substance (and presumably require separate permission in the Code). Suggests deleting the words ‘extracted or’, so that it reads: ‘any other substance that is derived from’ • Has concerns around the use of the term ‘substance’ in 1.4.4—6(2)(c) and suggests that it would be more correct to use the term ‘food’. • Suggests that in 1.4.4—6(3), the word ‘product’ be clarified to read ‘seed product’ and as per above, the words ‘extracted or’ again be deleted. 	<p>NZ MoH and NZ MPI</p>	<ol style="list-style-type: none"> 1. Noted. The drafting allows unhulled and viable low THC hemp seeds to be used to produce hemp seed food products, being oil, beverage and any other substance that is extracted or derived from the hemp seeds. Hemp seeds that are sold as food at retail or used as ingredients in food for sale at retail must be hulled and non-viable. 2. FSANZ considers the use of the term ‘extracted from’ (1.4.4—6(2)(c)) is appropriate and consistent with other provisions in the Code, including other subsections of the approved draft variation and Standard 1.4.4. Separate provisions for nutritive substances and novel foods will apply (if relevant) to substances extracted or derived from seeds of low THC <i>C. sativa</i>. 3. Paragraph 1.4.4—6(2)(c) in the approved variation refers to ‘product’ to reflect the type of products intended to be captured by this provision (e.g. low THC hemp seed flour and protein powder). The use of the word ‘food’ instead of ‘substance’ may present unnecessary confusion for lay users. 4. The word ‘product’ in 1.4.4—6(3) clearly relates only to 1.4.4—6(2) and is therefore not required to be repeated in 1.4.4—6(3). See comments at dot point 2 in relation to words ‘extracted or’.
<p>Expressed interest in outcome, set out the Canadian situation and identified the market opportunities which could arise from the approval of this Proposal.</p>	<p>Canadian Government</p>	<p>Noted</p>

Attachment A – Approved 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 Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on a date 6 months after the date of gazettal.

Schedule

[1] Standard 1.2.7 is varied by inserting after section 1.2.7—4

Note Section 1.4.4—7 proscribes health claims and nutrition content claims in relation to cannabidiol in hemp food products.

[2] Standard 1.4.4 is varied by

[2.1] omitting the Note to section 1.4.4—2 and substituting

Note 1 In this Code (see sections 1.1.2—2 and 1.1.2—3):

claim means an express or implied statement, representation, design or information in relation to a food or a property of food which is not mandatory in this Code

coca bush means:

- (a) *Eurythroxylum coca*; or
- (b) a substance derived from *Eurythroxylum coca*.

health claim means a claim which states, suggests or implies that a food or a property of food has, or may have, a health effect

health effect means an effect on the human body, including an effect on one or more of the following:

- (a) a biochemical process or outcome;
- (b) a physiological process or outcome;
- (c) a functional process or outcome;
- (d) growth and development;
- (e) physical performance;
- (f) mental performance;
- (g) a disease, disorder or condition.

label, in relation to a food being sold, means any tag, brand, mark or statement in writing or any representation or design or descriptive matter that:

- (a) is attached to the food or is a part of or attached to its packaging; or
- (b) accompanies and is provided to the purchaser with the food; or
- (c) is displayed in connection with the food when it is sold.

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).

property of food means a component, ingredient, constituent or other feature of food.

restricted plant or fungus means:

- (a) a plant or fungus listed in Schedule 24; 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).

Note 2 Section 1.1.2—9 (Definition of **nutrition content claim**) provides as follows:

(1) In this Code:

nutrition content claim means a claim that:

- (a) is about:
 - (i) the presence or absence of any of the following:
 - (A) a biologically active substance;
 - (B) dietary fibre;
 - (C) energy;
 - (D) minerals;

- (E) potassium;
- (F) protein;
- (G) carbohydrate;
- (H) fat;
- (I) the components of any one of protein, carbohydrate or fat;
- (J) salt;
- (K) sodium;
- (L) vitamins; or
- (ii) glycaemic index or glycaemic load; and
- (b) does not refer to the presence or absence of alcohol; and
- (c) is not a health claim.

Note See also subsections 1.1.2—9(2) to (4), 2.6.2—5(4) and 2.10.2—8(3).

Note 3 Standard 1.2.7 prescribes requirements for making health claims and nutrition content claims.

[2.2] 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 product 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.

1.4.4—7 Restriction on claims and representations about foods that are or which contain hemp food products

- (1) This section applies to a food for sale that consists of, or has as an ingredient, a hemp food product.
- (2) The food for sale must not be labelled or otherwise presented for sale in a form which expressly or by implication suggests that the product has a psychoactive effect.
- (3) The label for the food for sale must not include:
 - (a) a nutrition content claim about cannabidiol; or
 - (b) a *health claim about cannabidiol; or
 - (c) an image or representation of any part of the *Cannabis sativa* plant (including the leaf of that plant) other than the seed; or
 - (d) the words 'cannabis', 'marijuana' or words of similar meaning.
- (4) The label for the food for sale may include the word 'hemp'.
- (5) In this section:

Hemp food product means *Cannabis sativa* seeds and/or a seed product that are permitted by section 1.4.4—6 to be a food for sale or used as an ingredient in a food for sale.

Psychoactive effect means:

- (a) stimulation or depression of a person's central nervous system, resulting in hallucinations or in a significant disturbance in, or significant change to, motor function, thinking, behaviour, perception, awareness or mood; or
- (b) causing a state of dependence, including physical or psychological addiction.

1.4.4—8 Level of cannabidiol in food for sale

Cannabidiol must not be present in any food for sale at a level greater than 75 mg/kg.

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.

The Authority 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 approved a draft variation of a standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

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

2. Purpose and operation

The Authority has prepared a draft variation to Standard 1.4.4 to permit certain types of seeds and seed products from *Cannabis* species to be sold as a food or used as an ingredient in a food provided that certain conditions are met.

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 the Proposal included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 28 July 2016 for a four-week consultation period.

A Regulation Impact Statement was not required because the proposed variation is likely to have only a minor regulatory impact 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] amends Standard 1.2.7 by inserting a Note after section 1.2.7—4. The Note provides a reference in Standard 1.2.7 to the prohibition imposed by subsection 1.4.4—7(3) on health claims and nutrition content claims in relation to cannabidiol in hemp food products.

Item [2.1] amends Standard 1.4.4 by omitting the Note to section 1.4.4—2 and substituting three new Notes. Note 1 provides a reference in Standard 1.4.4 to sections 1.1.2—2 and 1.1.2—3, which define certain terms used in Standard 1.4.4 including in new sections 1.4.4—6 and 1.4.4—7.

Note 2 provides a reference in Standard 1.4.4 to a definition in section 1.1.2—9 of the term ‘nutrition content claim’. Section 1.4.4—7 includes a reference to nutrition content claims made in relation to cannabidiol in hemp food products and foods that contain hemp food products as ingredients.

Note 3 provides a reference to Standard 1.2.7 and the requirements in that Standard for making health claims and nutrition content claims. Section 1.4.4—7 refers to health claims and nutrition content claims made in relation to cannabidiol in hemp food products and foods that contain hemp food products as ingredients.

Item [2.2] amends Standard 1.4.4 by inserting sections 1.4.4—6, 1.4.4—7 and 1.4.4—8 into the Standard.

Section 1.4.4—6 provides a permission for the purposes of paragraphs 1.1.1—10(5)(a) and 1.1.1—10(6)(e) of the Code to allow certain seeds and seed products from low THC varieties of *Cannabis sativa* to be sold as food or added to food.

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 only 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).

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

Paragraph 1.4.4—6(2)(a) permits 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 10 mg per kg of oil.

Paragraph 1.4.4—6(2)(b) permits a beverage derived 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 beverage does not exceed 0.2 mg per kg of the beverage.

Paragraph 1.4.4—6(2)(c) permits any other product that is extracted or derived 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 product does not exceed 5 mg per kg of the product.

Subsection 1.4.4—6(3) requires 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.

Subsection 1.4.4—6(4) provides 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.

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

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

Section 1.4.4—7 restricts how food for sale that consists of, or has as an ingredient, a hemp food product, may be packaged, labelled, advertised or sold.

Subsection 1.4.4—7(1) provides that section 1.4.4—7, and the restrictions imposed by it, apply only in relation to a food for sale that consists of, or has as an ingredient, a hemp food product. Subsection 1.4.4—7(5) defines the term 'hemp food product' for the purposes of subsection 1.4.4—7(1).

Subsection 1.4.4—7(2) provides that such a food for sale must not be labelled or otherwise presented for sale in a form which expressly or by implication suggests that the product has a psychoactive effect. Subsection 1.4.4—7(5) defines the term 'psychoactive effect' for the purposes of subsection 1.4.4—7(2).

Subsection 1.4.4—7(3) imposes restrictions in relation to the label for the food for sale.

Paragraph 1.4.4—7(3)(a) provides that the label must not include a nutrition content claim about cannabidiol.

Paragraph 1.4.4—7(3)(b) provides that the label must not include a health claim about cannabidiol.

Paragraph 1.4.4—7(3)(c) provides that the label must not include an image or representation of any part of the *Cannabis sativa* plant (including the leaf of that plant) other than the seed.

Paragraph 1.4.4—7(3)(d) provides that the label must not include the words 'cannabis', 'marijuana' or words of similar meaning.

Subsection 1.4.4—7(4) provides that, notwithstanding subsection 1.4.4—7(3), the label for the food for sale may include the word 'hemp'.

Subsection 1.4.4—7(5) defines certain terms for the purposes of section 1.4.4—7.

Section 1.4.4—8 provides that food for sale must not contain cannabidiol in excess of 75 mg/kg. The purpose of this requirement is to provide a compliance value to support the prohibition in section 1.4.4—6 on the fortification of seeds and products with cannabinoids and to ensure foods do not contain CBD at a level that would not be expected to be naturally present.

Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)



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.