

16 December 2014
[26–14]

Review – Application A1039

Low THC Hemp as a Food

On 14 December 2012, the Australia and New Zealand Ministerial Forum on Food Regulation¹ (Forum) asked FSANZ to review its decision in relation to draft variations to Standard 1.4.4 – Prohibited and Restricted Plants and Fungi arising from Application A1039.

FSANZ was required to review the decision by 5 December 2014.

FSANZ has reviewed its decision and re-affirmed the approval of the variation to Standard 1.4.4 on 4 December 2014.

¹ convening as the Australia and New Zealand Food Regulation Ministerial Council

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Supporting documents

The following documents used to inform the review are available on the FSANZ website:
<http://www.foodstandards.gov.au/code/applications/Pages/applicationa1039lowt4708.aspx>

SD1 Potential regulatory measures relating to marketing of hemp foods (at Review)

Executive summary

On 14 December 2012, the Australia and New Zealand Ministerial Forum on Food Regulation (Forum) (convening as the Australia and New Zealand Food Regulation Ministerial Council) requested a review of the FSANZ Board's decision to approve a variation to Standard 1.4.4 to permit the sale of foods derived from the seeds of low THC hemp.

The grounds for the review were that the draft Standard:

- does not protect public health and safety; and
- is difficult to enforce or comply with in both practical or resource terms.

Matters addressed in the review

Forum issue	Summary of FSANZ'S response
Public health and safety	
<p>Impact on drug reduction strategies – the Forum was concerned that the availability of hemp foods may contribute to a public perception that low levels of cannabis are acceptable and safe to consume.</p> <p>The Forum also asked FSANZ to investigate the following matters relating to the marketing of hemp foods:</p> <ul style="list-style-type: none"> • Feasibility of prohibiting the use of hemp leaf images in any advertising relating to hemp foods • Type of appropriate regulatory measures for the marketing of hemp foods that would reduce the risk of consumers perceiving that hemp food products contain cannabis • Whether the literature provides any evidence demonstrating that the use of hemp in food products has led to an increase in the demand for illicit cannabis products. 	<p>FSANZ has not identified any scientific studies investigating the effect of hemp in food products on consumer perceptions and demand for illicit cannabis products. However, FSANZ received feedback from international jurisdictions in which hemp foods are permitted indicating that this concern did not appear to be well-founded.</p> <p>FSANZ identified possible regulatory measures that may be introduced in the Code (or other legislation) to prohibit the use of cannabis leaf images in advertising and to reduce the risk of consumers believing that foods derived from hemp seeds can produce psychoactive effects.</p> <p>FSANZ evaluated these possible measures in the context of the statutory requirements under which FSANZ decisions must be made (including FSANZ Act and administrative law requirements). FSANZ does not consider there is sufficient evidence for FSANZ to include additional controls in the approved variation to address the marketing of hemp foods.</p> <p>FSANZ did not identify any scientific studies investigating the impact of hemp in food products on demand for illicit cannabis products.</p>
<p>Roadside drug testing – impact of hemp foods</p>	<p>No additional evidence has become available since FSANZ's Approval Report. At Approval, FSANZ extrapolated the results of an unpublished study which suggested it is unlikely that consumption of hemp foods will trigger a positive result for an oral fluid drug test when the Australian Standard (AS/NZS 4308-2008) cut-off levels are utilised. However, this evidence is not definitive, and this issue remains uncertain.</p>

Forum issue	Summary of FSANZ'S response
Impact on enforcement	
<p>Distinguishing between hemp and illicit cannabis –the Forum asked FSANZ to investigate:</p> <ul style="list-style-type: none"> The feasibility of prohibiting trade and consumption of whole hemp seeds, noting that consideration should be given to the feasibility of only permitting the trade and consumption of ground hemp seeds and whole hemp seeds that have been hulled and roasted 	<p>The variation approved by FSANZ sets out clear requirements that seeds must be hulled and non-viable before they can be offered for sale as foods or as ingredients in foods (in addition to maximum permitted levels of THC that are also prescribed). This would preclude the legal consumption of whole hemp seeds.</p> <p>Roasting of seeds, in addition to these requirements, does not appear to be necessary and may limit the variety of hemp food products that could be marketed, in addition to impacting on the nutritional profile of some hemp food products.</p>
<ul style="list-style-type: none"> In the context that low THC hemp oil is already commercially available in Australia for purposes other than human consumption, how that currently does or does not create difficulties for law enforcement agencies, marketing or workplace occupational health and safety drug testing. 	<p>Existing industrial hemp legislation in Australia and New Zealand should be sufficient to prevent the illegal trade in cannabis seeds. If additional controls on the trade of whole hemp seeds are considered necessary by other stakeholders, it may be appropriate for industrial hemp legislation to be amended to incorporate these controls.</p> <p>FSANZ received feedback from police, a hemp licensing authority and a forensic analytical laboratory indicating that non-food uses of hempseed oil has not created any issues for these agencies.</p>
<p>Consistency with international drug control conventions</p>	<p>FSANZ considers this issue to be outside of the considerations that FSANZ is able to take into account when developing food regulatory measures. FSANZ notes that hemp foods are permitted to be sold in a number of international jurisdictions that are also signatories to UN conventions on narcotic drugs.</p>
<p>Consistency with domestic legislation</p>	<p>The FSANZ assessment noted that the consumption of delta-9 tetrahydrocannabinol (THC) is prohibited in other legislation in Australian states and territories and in other Australian and New Zealand legislation. This legislation would require amendment before hemp foods with quantifiable amounts of THC could be approved for human consumption (in addition to the variation to Standard 1.4.4 approved by FSANZ).</p> <p>Consideration of potential amendments to other relevant legislation may provide an opportunity to address some of the concerns raised by the Forum and other stakeholders in an alternative context to the Code.</p>

The FSANZ Board has re-affirmed its approval of the variation to Standard 1.4.4 to permit the sale of hulled and non-viable hemp seeds as foods and of foods derived from the seeds of hemp, subject to maximum levels of THC.

1 Introduction

On 14 December 2012, the Forum requested a review of the FSANZ Board's decision to approve a 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 hemp, resulting from Application A1039.

FSANZ approved the sale of foods derived from the seeds of low THC hemp, subject to maximum limits (MLs) of THC permitted to be present in such foods and provided that hemp seeds are hulled and non-viable when sold as food or added to food.

FSANZ was required to review the decision by 5 December 2014.

2 Grounds for review

The Forum requested that FSANZ review its decision to approve the draft variation arising from Application A1039 on the grounds that the draft standard:

- did not protect public health and safety; and
- was difficult to enforce or comply with in both practical or resource terms.

The Forum noted in its original review request that it would seek advice from the Standing Council on Police and Emergency Management (SCPEM) with regard to law enforcement issues and from the Food Regulation Standing Committee (FRSC) with regard to potential issues related to the marketing of food containing low THC hemp. The advice from both these sources was provided to FSANZ and, in light of this advice, the Forum asked for additional issues to be considered as part of the FSANZ review. These additional issues were related to the issues raised in the original review request of 14 December 2012.

FSANZ has grouped the grounds for review and the additional issues into topic areas, rather presenting them in the chronological order in which they were received by FSANZ. These topic areas are noted in section 4 below, along with FSANZ's response.

3 Background

FSANZ received an Application from Dr Andrew Katelaris MD on 4 December 2009, seeking approval for the use of the seed and seed products of *Cannabis sativa* (*C. sativa*) with low levels of delta 9-tetrahydrocannabinol (THC) as food. Standard 1.4.4 – Prohibited and Restricted Plants and Fungi in the *Australia New Zealand Food Standards Code* (the Code) prohibits all species of cannabis from being added to food or sold as food in Australia and New Zealand. The Application was accepted for assessment on the basis that:

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that warranted the variation of a food regulatory measure.

C. sativa is well known as a source of the psychoactive substance, THC. Varieties of *C. sativa* that contain levels of THC that are considered to be psychoactive, are known by various names, including marijuana. Varieties of *C. sativa* that contain no, or very low levels of THC, are commonly referred to as hemp, industrial hemp or industrial cannabis. Hemp has typically been used for industrial purposes, such as textiles, fibres, paper, building materials (fibrous parts of plant) and also as a food source (seeds). Hemp does not have any psychoactive properties and is permitted to be cultivated (under licence) in New Zealand and most Australian states and territories. The level of THC in hemp typically varies from zero to 0.5%, while the THC level in cannabis used as a drug varies from 3–15%.

The seeds are the main part of the hemp plant used as a source of food. Hemp seeds, and even marijuana seeds, do not contain any THC. However, the seeds of *C. sativa* plants are wrapped in specialised leaves called the calyx. The calyx can produce THC, and can therefore cause some contamination of the outside of the seed coat. Rigorous cleaning methods, including washing, sieving and shelling, can reduce or remove any THC contamination of seeds. Shelled seeds, also known as hulled seeds, have the outer hull or coating of the seed removed. It is considered unlikely that consumption of residual THC that may be present on hemp seeds will be at a level where psychoactive effects could occur. In this report, low THC varieties of *C. sativa* will be referred to as hemp (including reference to the seeds and foods produced from the seeds).

A previous Application to FSANZ, Application A360, requested the approval of industrial hemp as a food. A360 was progressed as a novel food application. During the assessment of A360, FSANZ did not identify any safety concerns arising from the potential consumption of hemp foods. FSANZ recommended removing the total prohibition on *Cannabis* species in the Standard and the introduction of MLs for THC in specified hemp foods.

However, in May 2002, the then Ministerial Council rejected the FSANZ recommendation for A360. The Ministerial Council was concerned that the use of hemp in food may send a confused message to consumers about the acceptability and safety of cannabis. The Ministerial Council also highlighted concerns about law enforcement, particularly potential issues relating to distinguishing between high and low THC varieties of cannabis. The Ministerial Council considered that the total prohibition on all *Cannabis* species in the Code should remain.

FSANZ agreed to accept Application A1039 after it was recognised that an assessment could take into account a number of developments since the assessment of A360, including the increased uptake of hemp foods internationally and the development of industrial hemp licensing arrangements in Australia and New Zealand.

FSANZ's assessment of A1039 expanded and updated the previous assessment conducted for A360. FSANZ's risk assessment concluded that low THC hemp foods were safe for consumption when they contained no more than the specified MLs of THC. FSANZ also recognised that foods derived from hemp seeds might provide a useful alternative dietary source of many nutrients and polyunsaturated fatty acids, particularly omega-3 fatty acids.

FSANZ approved a variation to Standard 1.4.4 that permits the sale of foods derived from the seeds of low THC varieties of *C. sativa*. Requirements for MLs of THC that may be present in hemp foods have been specified. Hemp seeds may only be sold if they are non-viable. The approved variation also makes it clear that only low THC varieties of *C. sativa* can be used as a source for food and that only naturally-occurring THC may be present in hemp-based food.

The approval was made in accordance with the FSANZ objectives in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). A risk assessment was conducted by FSANZ to address public health and safety. FSANZ also had regard to other matters, as required by the FSANZ Act, during its assessment of applications to amend the Code. These other matters included concerns raised by stakeholders, consultation with international jurisdictions in which hemp foods are legally available (including Canada and some European countries), and an evaluation of the potential impacts on stakeholders.

A number of concerns were expressed by stakeholders regarding the potential impacts that the legal availability of hemp foods may have on drug testing (particularly oral fluid testing), the effects on drug reduction strategies and law enforcement activities relating to illicit drug use. The FSANZ assessment concluded that the consumption of hemp foods was unlikely to adversely impact on urine drug testing.

FSANZ also examined the concerns that were raised regarding the possible adverse impact of consumption of hemp foods on oral fluid drug testing. There was limited evidence on this subject. FSANZ extrapolated the results of high THC inhalation and consumption (cookies) on oral fluid testing to predict the potential impact of the consumption of hemp foods at the MLs of THC proposed by FSANZ (ESR, unpublished). The extrapolation suggested that this concern was unlikely to eventuate; however this evidence is suggestive, not definitive.

FSANZ considered the requirement in the approved variation to Standard 1.4.4 for hemp seeds to be hulled and non-viable would mitigate the concerns of law enforcement agencies relating to the possession of illicit cannabis seeds.

FSANZ conducted an economic analysis to support the assessment. Obtaining accurate and relevant data on benefits and costs was difficult and the economic consideration of options was based largely on qualitative considerations. The economic analysis noted the approved variation provides moderate benefits to industry and consumers while seeking to minimise the potential costs to government and law enforcement agencies that may arise from hemp food permissions. However, whether the approval of the draft variation is likely to result in an overall positive net benefit to the community depends on how likely it is that it will cause complications and costs to law enforcement activities related to illicit drugs, and the magnitude of those costs, if they do exist.

FSANZ considered some matters raised by stakeholders to be outside of the matters that FSANZ could take into consideration when developing a food regulatory measure. FSANZ acknowledged these matters in the Approval Report and suggested they may be more appropriately considered by Ministers in a broader policy context. Whilst FSANZ acknowledges the importance of these matters, they go beyond FSANZ's authority and, instead, sit with governments responsible for administering the relevant legislation.

4 Summary of the findings

4.1 Public health and safety

4.1.1 Impacts on drug reduction strategies

4.1.1.1 Forum concern

The Forum was concerned that the use of low THC hemp in food may undermine drug reduction strategies by contributing to a public perception that low levels of cannabis are acceptable and safe to consume. After receiving advice from FRSC, the Forum requested FSANZ investigate a number of issues related to this concern:

- the feasibility of prohibiting use of hemp leaf images in marketing hemp food products
- the type of appropriate regulatory measures for marketing hemp foods that would reduce the risk of consumers 'perceiving low THC hemp food products contain cannabis'²
- whether the literature provides any evidence demonstrating the use of hemp in food has led to an increase in the demand for illicit cannabis products.

² FSANZ has interpreted this reference to low THC hemp food products containing cannabis to refer to the potential for consumers to perceive that consumption of hemp foods could produce psychoactive effects.

4.1.1.2 FSANZ response

FSANZ had previously indicated during the assessment of A1039 that the concern that the use of hemp foods may result in consumers being more accepting of illicit cannabis use is outside of the normal scope of considerations that FSANZ can take into account in developing a food regulatory measure. Therefore, FSANZ's decision at Approval did not address this concern. In response to the Forum's review request, FSANZ has investigated the specific issues relating to this concern (see the three dot points above), rather than the general concern about acceptance of cannabis. More information on these specific issues is provided below. However, in relation to the general concern, FSANZ notes that it has not identified any scientific studies investigating the effect of hemp in food products on consumer perceptions and demand for illicit cannabis products. In addition, FSANZ notes the feedback received from international jurisdictions in which hemp foods are permitted indicated that this general concern about consumer perceptions and acceptance of cannabis use associated with the use of hemp in foods did not appear to be well-founded (see Approval Report).

In response to the Forum's request that FSANZ investigate the marketing issues identified in the first two dot points above, FSANZ has identified examples of the type of regulatory measures (in the Code) that could be used to prohibit the use of cannabis leaf images in advertising and to reduce the risk of consumers believing that foods derived from hemp seeds can produce psychoactive effects (in accordance with relevant parts of subsection 16(1) of the FSANZ Act³). Supporting document 1 includes a detailed discussion of these examples. However, a brief summary is provided below.

Possible Code regulatory measures include prohibitions on food labels and advertising relating to images of the cannabis leaf, specific terms (e.g. 'cannabis' and 'marijuana') and any suggestion that consuming hemp foods can produce psychoactive effects. Compulsory requirements for labelling or advertising could be introduced to state that hemp foods are not an illicit drug and/or do not have psychoactive properties. Restrictions could also be placed on the premises at which hemp foods can be sold or supplied, or to whom hemp foods could be sold. Limits could also be placed on the type of publications that can contain advertisements for hemp foods. Table 1 of SD1 lists these examples and the relevant sections of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) from which these examples are derived.

FSANZ considered these possible measures in the context of the FSANZ Act objectives (section 18 of the FSANZ Act) and considerations (section 29 of the FSANZ Act) that FSANZ must take into account when reviewing a food regulatory measure. FSANZ also highlighted measures in other contexts (outside of the Code) that currently exist or that could be considered by other stakeholders. For example, consumer law in Australia and New Zealand covers misleading and deceptive labelling and advertising. FSANZ discussed the issue of misleading representation with the Australian Competition and Consumer Commission (ACCC) and the New Zealand Commerce Commission, with both agencies agreeing that enforcement action could be taken under their respective legislation in cases of misrepresentation. Similar advice was received by the Forum from the ACCC (through FRSC). Table 2 of SD1 provides detail on these considerations.

Finally, FSANZ evaluated the feasibility of the potential measures, taking into account the legal requirements relating to FSANZ's consideration of these measures, in the context of amending the Code, remains subject to the FSANZ Act and administrative law. In developing or reviewing food regulatory measures and variations of such measures, FSANZ must comply with the FSANZ Act and take into account all relevant considerations.

³ 'matters that may be included in standards and variations of standards'

These legal requirements mean that FSANZ is constrained in introducing the type of measures identified above. For example, FSANZ must base its decisions on the best available scientific evidence. A number of the potential measures are not supported by scientific evidence. FSANZ's evaluation is provided in more detail in Table 3 of SD1.

FSANZ has not introduced any of the potential measures identified above in the approved variation. FSANZ has not identified evidence on which it could base additional labelling and/or advertising or supply requirements in the Code for hemp foods.

In response to the third dot point above, FSANZ conducted a literature search to investigate whether it provides any evidence demonstrating that the use of hemp in food products has led to an increase in the demand for illicit cannabis products. The search was conducted in Scopus, EconLit, Food Science Source, FSTA, Medline, SocINDEX, JSTOR, and Business Source Complete. The search terms used included 'hemp', as well as terms related to consumer perceptions such as 'perception', 'acceptability' and 'marketing', and 'food' to find items relating to hemp food products.

The literature search found no relevant results. In total, the searches conducted obtained 1,164 citations. The citations were screened based on title, or (where the content of the article was ambiguous based on the title alone) the abstract and/or full text were also screened. The types of articles that were represented in the citations obtained were predominantly articles from trade journals describing new hemp food products; profiling hemp food businesses or hemp farmers; or detailing changes in regulations about the growing of hemp or sale of hemp as a food product. There were also a number of articles on alternative uses for hemp (such as in building insulation), research on the effect of hemp ingestion on THC levels in the human body, the use of cannabis as a drug (but not in connection with low-THC hemp products).

4.1.2 Roadside drug testing

4.1.2.1 Forum concern

The Forum highlighted the concern of law enforcement agencies that the use of low THC hemp in foods may interfere with the results of roadside drug testing (in Australia), which utilises oral fluid testing to detect the presence of THC. Roadside oral fluid testing is a major part of the strategy to reduce drug driving in some Australian states. The Forum noted that evidence from a peer-reviewed study would be necessary in order to determine the impact of low THC hemp foods on roadside drug testing.

4.1.2.2 FSANZ response

FSANZ included commentary in its Approval Report on an unpublished study by the New Zealand Institute of Scientific Research (ESR). The ESR study investigated THC residues in oral fluids following smoking high THC cannabis cigarettes and consuming cookies containing high levels of THC. Using the data from this study, FSANZ estimated the levels of THC residues likely to be found in oral fluids after consuming hemp foods. This extrapolation suggested that it was unlikely that consumption of hemp foods would trigger a positive result for an oral fluid drug test when the Australian Standard (AS/NZS 4308-2008) cut-off levels were utilised. However, there was still a lack of peer-reviewed scientific evidence on which to provide certainty about the potential impact (or lack of) of hemp food consumption on oral fluid testing results. More detailed discussion of this issue was included in the FSANZ Approval Report (section 4.5.2 and SD3).

FSANZ is not aware of any new evidence to confirm whether the consumption of hemp foods is likely to interfere with oral fluid drug testing. FSANZ liaised with the hemp industry to determine the level of interest in funding a scientific study to investigate this issue. However, the industry did not wish to commit significant funds to a study that in its view was only one of a number of issues the Forum was likely to take into account in making a decision.

4.2 Impacts on enforcement

4.2.1 Distinguishing between hemp and illicit cannabis

4.2.1.1 Forum concern

The Forum's initial review request highlighted the concern that it might be difficult for law enforcement agencies to distinguish between high and low THC varieties of cannabis and that this potential burden on these agencies had not been included in FSANZ's assessment.

After receiving advice from the SCPEM, the Forum also asked FSANZ to investigate two additional issues as part of the review:

- The feasibility of prohibiting trade and consumption of whole hemp seeds, noting that consideration should be given to the feasibility of only permitting the trade and consumption of ground hemp seeds and whole hemp seeds that have been hulled and roasted.
- In the context that low THC hemp oil is already commercially available in Australia for purposes other than human consumption, how that currently does or does not create difficulties for law enforcement agencies, marketing or workplace occupational health and safety drug testing.

4.2.1.2 FSANZ response

As noted in section 3 above, at Approval, FSANZ considered the requirement in the approved variation for hemp seeds to be hulled and non-viable would mitigate concerns of law enforcement agencies about the possession of illicit cannabis seeds, and therefore, the need to distinguish between hemp and illicit cannabis seeds.

The variation approved by FSANZ sets out clear requirements that seeds must be hulled and non-viable before they can be offered for sale as foods or as ingredients in foods (in addition to having maximum permitted levels of THC). This would preclude the legal consumption of whole hemp seeds.

It does not appear that roasting to distinguish between the seeds of different cannabis varieties is necessary if the seeds are already de-hulled. The Queensland *Drugs Misuse Act 1986* provides a definition of 'denatured' for seed harvested from industrial cannabis plants. It 'means that the seed will not grow because it has been cracked, de-hulled, heated, or treated in another way that prevents growth'. This definition implies that de-hulling or roasting (heated) and not necessarily both, is required to denature hemp seeds. FSANZ has concluded that including a requirement that hemp seeds must also be roasted (in addition to being hulled and non-viable) is not required in the approved variation.

Advice from hemp industry stakeholders indicates that roasting of hemp seeds may adversely affect the potential number of hemp seed food products that may be produced and this would reduce the economic benefit for the hemp industry and limit consumer choice. For example, hulled (shelled) hemp seeds (also known as hemp hearts) are a popular hemp food product available overseas that may be adversely affected by roasting the seeds.

Roasting may also impact on the nutritional profile of hemp seeds, depending on the temperature the seeds are subjected to (lower temperatures having less impact).

Additional restrictions on the type of food products derived from low THC hemp seeds that may be marketed (e.g. by imposing roasting requirements and prohibiting trade in whole seeds), in accordance with FSANZ's draft variation, may limit the viability and competitiveness of the market in Australia and New Zealand, particularly given the variety of products available in international markets.

Existing industrial hemp legislation in Australia and New Zealand sets out licensing arrangements for the cultivation, trade, possession, processing and supply of industrial hemp (including seeds) and industrial hemp products. In addition, it is illegal to grow hemp without a licence and to possess hemp plants and parts of plants, which have not been processed, outside of the licence conditions. Only authorised persons are permitted to possess whole hemp seeds. This requirement would not be affected by a decision to approve hemp foods to be sold in Australia and New Zealand. Additional details on hemp regulations in Australia and New Zealand were provided as part of the FSANZ Approval Report (SD5). These current control measures appear to be sufficient to prevent the illegal trade in cannabis seeds.

If additional controls on the trade of whole hemp seeds are considered necessary for food production, it may be more appropriate for industrial hemp legislation to be amended to incorporate these controls. In New Zealand, the processing of industrial hemp into specified hemp products requires a licence under the Misuse of Drugs (Industrial Hemp) Act and related Regulations.

FSANZ has previously considered it unlikely that there would be value in attempting to present (traffic) seeds of high THC cannabis as hemp seeds. The approved variation includes the requirement that low THC hemp seeds must be hulled (which is expected to denature the seeds so they cannot be grown). In addition, seeds from all strains of cannabis, including high THC varieties used for drug use, do not contain THC. Any THC present on a cannabis seed is the result of contamination from other parts of the plant. Presenting seeds derived from non-hemp varieties as hemp for drug use would therefore not be an efficient or suitable method of obtaining THC. Furthermore, denaturing of hemp seeds ensures they are not viable (that is, de-hulling ensures the seeds will not germinate and produce hemp plants) so the presentation of non-hemp varieties as hemp for cultivation purposes also appears unlikely.

FSANZ requested feedback from police, hemp licensing authorities and analytical laboratories about whether non-food uses of hempseed oil has created any difficulties in the above contexts. FSANZ has received responses from only four of nine organisations contacted, after multiple attempts to elicit this information (responses provided by police agencies, a hemp licensing authority and an analytical laboratory). The responses indicated that no difficulties have been observed.

Some stakeholders have noted that if hemp foods were required to contain zero, or non-detectable THC, some of the potential enforcement issues could be mitigated, particularly in relation to roadside drug testing and consistency with international drug control conventions (section 4.2.2) and domestic legislation (section 4.2.3). However, FSANZ's assessment has not considered a zero THC tolerance is required for hemp foods. At present, the production of hemp foods is not able to guarantee zero THC content. In addition, FSANZ's risk assessment concluded that the consumption of hemp foods, containing no more than the MLs included in the approved variation, is safe.

FSANZ also notes that the ability to detect THC in hemp foods may depend on the analytical methodology used. Hempseed oil is permitted to be sold as a food in New Zealand, providing there is no detectable THC present in the oil. However, FSANZ understands that the limit of detection used when testing hempseed oil products in New Zealand is equivalent to the highest ML proposed by FSANZ (10 mg/kg). Therefore, although there may be some THC present in hempseed oil sold as food in New Zealand, the levels are lower than the level of detection (of THC) in the analytical methodology used; and for the purposes of the testing, is considered zero THC. FSANZ notes that some international jurisdictions also have a zero THC tolerance for hemp foods. However, FSANZ is not aware of the levels of detection used in these jurisdictions.

4.2.2 Consistency with international drug control conventions

4.2.2.1 Forum concern

The Forum has expressed concern that to permit the use of products from cannabis with a quantifiable level of THC would be inconsistent with the overarching restrictions that apply under the *Single Convention on Narcotic drugs, 1961* and the *Convention on Psychotropic Substances, 1971*, to which Australia and New Zealand are both signatories.

4.2.2.2 FSANZ response

FSANZ's assessment of A1039, including this review, has not addressed this concern. FSANZ considers this concern is outside of the boundaries of the considerations that it can take into account when developing food regulatory measures. However, FSANZ notes that hemp foods are permitted to be sold in a number of international jurisdictions that are also signatories to UN conventions on narcotic drugs.

4.2.3 Consistency with domestic legislation

4.2.3.1 Forum concern

The Forum also expressed concern that the approved variation would put the Code in direct conflict with legislation in a number of states and territories and in New Zealand (which prohibit and/or restrict the use of THC and cannabis).

4.2.3.2 FSANZ response

The FSANZ assessment noted that the consumption of THC is prohibited in other legislation in Australian states and territories and in other Australian and New Zealand legislation (such as misuse of drugs legislation, the Poisons Standard 2013 and border control legislation). This legislation would require amendment before hemp foods with even small amounts of THC could be approved for human consumption (in addition to the variation to Standard 1.4.4 approved by FSANZ). FSANZ notes that consideration of potential amendments to other relevant legislation may provide an opportunity to address some of the concerns raised by the Forum and other stakeholders in an alternative context to the Code.

4.3 FSANZ Act assessment requirements

4.3.1 Section 29

4.3.1.1 Cost benefit analysis

FSANZ conducted an economic analysis as part of the assessment of A1039.

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

4.3.1.2 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 Application.

4.3.1.3 Any relevant New Zealand standards

Hempseed oil is permitted to be sold as a food in New Zealand and a more general permission for foods derived from hemp seed in Australia and New Zealand could serve to enhance trans-Tasman trade in these products. The sale of other hemp derived foods in New Zealand may be affected by other legislation, which is noted in section 4.2.3 above.

4.3.1.4 Any other relevant matters

A number of other matters were raised by submitters and the Forum during assessment of this Application. FSANZ has addressed some of these matters in making its decision. However, some fall outside of FSANZ's responsibilities under the FSANZ Act and have not been considered by FSANZ in reaching its decision.

4.3.2. Subsection 18(1)

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

4.3.2.1 Protection of public health and safety

FSANZ's risk assessment concluded that the consumption of foods derived from hemp seeds would not pose any public health and safety concerns where the THC content is below the MLs included in the approved variation.

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

Hemp ingredients would be required to be listed in the list of ingredients.

4.3.2.3 The prevention of misleading or deceptive conduct

FSANZ investigated potential regulatory measures that could be used to prohibit the use of cannabis leaf images in advertising and to reduce the risk of consumers believing that foods derived from hemp seeds can produce psychoactive effects. FSANZ did not consider there was sufficient evidence to warrant the inclusion of additional regulatory measures to those included in the approved variation.

4.3.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has considered the safety of hemp foods as described in SD1 at Approval. FSANZ has also considered the available scientific evidence relating to the potential effect of hemp food consumption on human drug testing and on consumer perceptions in relation to acceptability and safety of cannabis.

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

Hemp foods are permitted in some countries but not others. There are no international standards for hemp foods. The MLs for THC content of foods derived from low THC hemp that are included in the approved variation are consistent with levels that are set in other countries (where applicable) and are achievable.

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

There are potential benefits to industry in permitting hemp foods and the permission would open up domestic and export markets.

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

There are no issues to address.

- **any written policy guidelines formulated by the Ministerial Council⁴.**

There are no policy guidelines relevant to this application.

5 Decision

The FSANZ Board re-affirmed its approval of the variation to Standard 1.4.4 to permit the sale of hulled and non-viable hemp seeds as foods and of foods derived from the seeds of hemp, subject to maximum levels of THC. The variation takes effect on gazettal.

The variation is Attachment A. The explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

6 Transitional arrangements

FSANZ has reviewed the Code in order to improve its clarity and legal efficacy. This review was undertaken through Proposal P1025 – details of which are on the FSANZ website⁵. FSANZ released a draft revision of the Code for public comment in May 2013. The draft revision has changed the Code's structure and format. A further draft revision of the Code and call for submissions was released in July 2014.

The FSANZ Board approved the proposed changes to the Code in December 2014 and that decision has since been notified to Ministers.

⁴ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

⁵ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

If Ministers do not request a review of the Board's decision, the new Code is expected commence in March 2016 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to Chapters 1 and 2 of the current Code, including the variations at Attachment A, if not rejected by the Forum.

Attachments

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

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



Food Standards (Application A1039 – Low THC Hemp as a Food) Variation

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

Dated [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 (*Application A1039 – Low THC Hemp as a Food*) Variation.

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

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

3 Commencement

These variations commence **on the date of gazettal**.

SCHEDULE

[1] Standard 1.4.4 is varied by

[1.1] omitting subclause 1(1) and substituting

“(1) Subject to clause 1A, a plant or fungus, or a part or a derivative of a plant or fungus, listed in Schedule 1, or any substance derived therefrom, must not be intentionally added to food or offered for sale as food.”

[1.2] inserting after clause 1 the following new clause

“1A Exception for certain *Cannabis sativa* seeds and certain *Cannabis sativa* seed products

(1) *Cannabis sativa* seeds may be added to food or offered for sale as food if the seeds –

- (a) are seeds of low THC *Cannabis sativa*; and
- (b) contain not more than 5 mg/kg delta 9-tetrahydrocannabinol which is naturally present; and
- (c) are non-viable seeds; and
- (d) are hulled seeds.

(2) All or any of the following seed products may be added to food or offered for sale as food –

- (a) oil extracted from seeds of low THC *Cannabis sativa* if the oil contains not more than 10 mg/kg delta 9-tetrahydrocannabinol and the delta 9-tetrahydrocannabinol is naturally present in the oil;
- (b) a beverage derived from seeds of low THC *Cannabis sativa* if the beverage contains not more than 0.2 mg/kg delta 9-tetrahydrocannabinol and the delta 9-tetrahydrocannabinol is naturally present in the beverage;
- (c) any other substance extracted or derived from seeds of low THC *Cannabis sativa* if the substance contains not more than 5 mg/kg delta 9-tetrahydrocannabinol and the delta 9-tetrahydrocannabinol is naturally present in the substance.

(3) In this clause –

hulled seed means a seed where the outer coat or hull of the seed is removed.

low THC *Cannabis sativa* has the meaning given by subclause (4).

non-viable seed means a seed that is not able to germinate.

seed includes a part of a seed.

(4) *Cannabis sativa* is low THC *Cannabis sativa* if the leaves and flowering heads of the *Cannabis sativa* do not contain more than 0.5% delta 9-tetrahydrocannabinol.”

Attachment B – Explanatory Statement

1. Authority

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

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1039 which seeks to approve the use of hemp seeds and hemp seed products as food. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation⁶, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft 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 *Legislative Instruments Act 2003*.

2. Purpose and operation

Currently, all Cannabis species (hemp, marijuana) and substances derived from Cannabis species are prohibited under Standard 1.4.4 from being intentionally added to food or sold as food. The Authority has approved an amendment to Standard 1.4.4 to permit the sale, as a food, including as an ingredient of a food, the seed and seed products from Cannabis species (spp.) with levels of delta 9-tetrahydrocannabinol (THC) as follows:

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

The amendment includes a requirement that only seeds sourced from low THC varieties of *Cannabis sativa* can be used to produce foods and food ingredients. Low THC *Cannabis sativa* means *Cannabis sativa*, the leaves and flowering heads of which contain no more than 0.5% THC. In addition, the THC present in these seeds and seed products sold as food, or included as an ingredient in food, must be naturally present.

⁶ convening as the Australia and New Zealand Food Regulation Ministerial Council

The requirements for seeds derived from low THC varieties of *Cannabis sativa* to be non-viable and hulled, apply to seeds offered for sale to consumers as foods and seeds used as ingredients in foods sold to consumers. However, the amendment to Standard 1.4.4 does not preclude food manufacturers from using seeds that are viable and not hulled in the manufacture of foods, subject to industrial hemp licensing arrangements and any other applicable laws, before the foods are sold to consumers.

3. Documents incorporated by reference

The variation does not incorporate any documents by reference.

4. Consultation

An initial round of public consultation preceded the assessment and preparation of a draft variation. This initial public comment period called for public comment on 15 March 2011 for a six week consultation period.

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1039 has included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 6 December 2011 for a ten-week consultation period.

A Regulation Impact Statement (RIS) was not required because of the deregulatory nature of the proposed variation to Standard 1.4.4.

5. 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

This item inserts a new clause 1A as an exception to Schedule 1 of Standard 1.4.4 – Prohibited Plants and Fungi, so as to permit the addition to food or sale as food of certain seeds and seed products from low THC varieties of *Cannabis sativa*. The permitted seeds and seed products can have a THC content no more than the maximum level set for specific food types and must be naturally present. Seeds must be non-viable and hulled (outer coat removed).