

Supporting document 1

Potential regulatory measures relating to marketing of hemp foods – Application A1039

Low THC Hemp as a Food

Executive summary

In December 2013, the Council of Australian Governments Legislative and Governance Forum on Food Regulation (the Forum) requested Food Standards Australia New Zealand (FSANZ) to investigate and provide advice on a number of issues as part of the review of FSANZ's decision to approve a draft variation to the Code to permit the sale of foods derived from hemp seeds (Application A1039). This supporting document provides additional detail to that presented in FSANZ's Review Report on issues relating to the marketing of hemp foods.

FSANZ has identified possible 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. However, consideration of these measures remains subject to the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) and administrative law. In developing or reviewing food regulatory measures and variations of such measures, FSANZ must comply with the FSANZ Act requirements and take into account all relevant considerations. FSANZ has evaluated these potential measures against the statutory requirements FSANZ must take into account in its decision making.

Based on this evaluation, 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.

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1 Introduction

As part of the review of Application A1039, the Forum asked FSANZ to investigate two main issues in relation to the marketing of hemp foods. These issues are listed below:

- The feasibility of prohibiting the use of hemp leaf images in any advertising relating to low THC hemp food products.
- The type of appropriate regulatory measures for the marketing of low THC hemp foods that would reduce the risk of consumers perceiving that low THC hemp food products contain cannabis.

2 Marketing of hemp food products

In response to the above issues, FSANZ initially identified potential regulatory measures that may be introduced in the Code to address them. These potential measures were identified in the context of the objectives and other matters in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) that FSANZ must take into account when developing regulatory measures. FSANZ then evaluated these potential measures against the FSANZ Act requirements and the evidence base, to determine the feasibility of FSANZ introducing these measures.

Table 1 includes 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 Act¹).

Consideration of these measures, in the context of amending the Code, remains subject to the FSANZ Act and administrative law. It is important to note that FSANZ could be subject to legal action in the event of any perceived irregularities in the assessment and decision making process for A1039, including its review. The FSANZ Act prescribes specific objectives for FSANZ when reviewing measures and variations, including when assessing an application to amend the Code. The matters prescribed by the FSANZ Act for assessing applications also remain relevant in a review of an application.

FSANZ considers that these legal requirements present some constraints for FSANZ in relation to introducing the type of measures identified in Table 1. FSANZ has addressed these legal requirements in its assessment of A1039, particularly in the Approval Report. Table 2 identifies the relevant considerations and provides commentary on the impact of these on each potential measure identified in Table 1.

Table 3 provides an overall evaluation of the feasibility of the potential measures identified in Table 1, taking into account legal requirements. This is not an exhaustive evaluation. It is intended only to provide information for the Forum on possible Code regulatory measures, the statutory requirements under which FSANZ decisions must be made and other non-Code regulatory measures that could be applied if low THC hemp foods were to be approved for sale and consumption in Australia and New Zealand.

¹ 'matters that may be included in standards and variations of standards'

FSANZ has also identified potential measures that could be explored in the context of other relevant legislation in Australia and New Zealand. For example, industrial hemp legislation in Australia could be amended to include prohibitions on the making of representations that state or imply psychoactive effects can be experienced from consuming hemp foods (or using hemp products in general). Similar prohibitions exist in New Zealand² and Canadian industrial hemp legislation and therefore apply to all hemp products, rather than being limited to hemp food products only.

It is important to note, as FSANZ identified in its assessment of A1039, that existing legislation (such as misuse of drugs and the Poisons Standard 2013) would require amendment before hemp foods with even small amounts of THC could be approved for human consumption (in addition to the draft variation approved by FSANZ). This may provide further opportunity for consideration of additional measures to address concerns in an alternative context to the Code.

3 Conclusion

Based on the evaluation provided in this supporting document, and particularly taking account of the statutory requirements under which FSANZ decisions must be made, 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.

² Misuse of Drugs (Industrial Hemp) Regulations 2006

Table 1: Possible Code regulatory measures for marketing/advertising of hemp foods

FSANZ Act section number	Section permits a Standard or variation of a Standard relating to -	Possible Code regulatory measure
s 16(1)(d)	any information about food including labelling, promotion and advertising	Prohibit hemp (cannabis) leaf images in advertising and on labels
		Prohibit use of specified terms and illustrations on the label and in advertising, for example the terms 'cannabis' and 'marijuana', cannabis leaf illustration.
		A general prohibition on suggesting, on a label or in advertising, that the food can produce psychoactive effects, either express or implied.
		Prohibit referencing or implying presence of any controlled substance
		Prescribe requirement for a statement to be on the label and in advertising, indicating the food is not an illicit drug and/or does not have psychoactive properties
s 16(1)(k)	restrictions on the premises at which, and the persons by whom, particular food may be sold or otherwise supplied	Limit the premises at which foods derived from hemp seeds can be sold or supplied
		Limit the persons by whom foods derived from hemp seeds can be sold or supplied
s 16(1)(l)	restrictions on the publications that may contain advertisements for particular food	Limit the publications that can contain advertisements for foods derived from hemp seeds
<p>FSANZ notes that the potential measure of prohibiting free promotional gifts in association with sale of foods derived from hemp seeds, such as plastic hemp (cannabis) leaves, is not a matter that may be included in a Standard or variation of a standard. This is noted for information purposes and is not considered appropriate for further consideration in the context of measures that FSANZ may introduce in the Code.</p>		

Table 2: Objectives FSANZ must take into account when reviewing a food regulatory measure

FSANZ Act section number	Detail of requirement	Notes
s18(1)	Objectives of FSANZ in developing or reviewing food regulatory measures and variations of food regulatory measures³	
s 18(1)(a)	Protection of public health and safety	<p>FSANZ's risk assessment concluded the consumption of foods derived from hemp seeds (at proposed MLs for THC) would not pose any public health and safety concerns. Concerns relating to representations on foods derived from hemp seeds have centred on the potential for representations to contribute to a public perception that low levels of (illicit) cannabis are acceptable and safe to consume.</p> <p>FSANZ has previously considered that imposing regulation on a food (in the Code) for the purposes of reducing the risk of harm from illegal drugs is outside the scope of matters that can be included in food regulatory measures made under the FSANZ Act. Measures to regulate representations of foods derived from hemp seeds are therefore not considered relevant to this objective.</p>
s 18(1)(b)	The provision of adequate information relating to food to enable consumers to make informed choices	Regulatory measures to prohibit the use of cannabis leaf images in labelling and advertising and to reduce the risk of consumers believing that foods derived from hemp seeds can produce psychoactive effects are not considered relevant to this objective as they prohibit rather than prescribe information for consumers.
s 18(1)(c)	The prevention of misleading or deceptive conduct	<p>Regulatory measures to prohibit the use of cannabis leaf images in advertising and labelling and to prohibit representations that reduce the risk of consumers believing that foods derived from hemp seeds can produce psychoactive effects would be relevant to this objective. A regulatory measure to prescribe a statement to be on the label and in advertising of foods derived from hemp seeds indicating the food is not an illicit drug and/or does not have psychoactive properties may be relevant to this objective</p> <p>In the Approval Report for Application A1039, FSANZ considered that as hemp is a variety of cannabis, the representation of a cannabis leaf on a hemp food label would be a truthful representation of the plant source of the product.</p>

³ the three objectives stated in subsection 18(1) are listed in order of priority in accordance with the FSANZ Act

FSANZ Act section number	Detail of requirement	Notes
		<p>Some submitters to Application A1039 noted that consumers could be misled if the cannabis leaf was used in relation to hemp foods, as this is the image the public associates with drugs.</p> <p>A beer product from the UK bearing a cannabis leaf on the label was noted by one submitter as an example of the potential marketing of hemp food products that may occur. Some submitters (including hemp industry submitters) considered that some controls over the labelling of hemp foods (particularly use of the leaf and any reference promoting hemp food as being psychoactive) could be beneficial.</p> <p>The application of current requirements for the naming of foods and ingredients of foods would need to be considered if specific regulatory measures for the representation of foods derived from hemp seeds were to be included in the Code.</p> <p>Standard 1.2.2 – Food Identification Requirements, 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).</p> <p>Standard 1.2.4 – Labelling of Ingredients requires ingredients to be declared in the statement of ingredients by either the common name of the ingredient or a name that describes the true nature of the ingredient. For foods containing hemp as an ingredient, product and ingredient names that may be considered acceptable under these Standards include ‘Hemp’, ‘Low THC Hemp’. In New Zealand, hemp seed oils observed by FSANZ used the name ‘Hempseed Oil’.</p>
s 18(2)	Matters that FSANZ must have regard to when reviewing food regulatory measures:	
s 18(2)(a)	The need for standards to be based on risk analysis using the best available scientific evidence	<p>FSANZ has conducted a review of the scientific literature to ascertain whether any studies have been published on consumers’ perceptions of hemp products, particularly whether consumers believe that foods derived from hemp seeds would have psychoactive effects and whether the labelling of foods derived from hemp seeds (including words, pictures and symbols) has any effect on this belief. No relevant articles were identified in the literature search (see section 4.2 above).</p> <p>FSANZ has been informed by New Zealand regulatory agencies that they have not had any issues associated with the labelling and representation of hempseed oils brought to their attention.</p>

FSANZ Act section number	Detail of requirement	Notes
		<p>During consideration of A1039, FSANZ liaised with overseas regulatory agencies in regions where hemp food products are permitted, to ascertain whether they had experienced any problems in relation to hemp foods being marketed in such a way as to suggest they may have psychoactive properties. Most respondents indicated they were not aware of such problems in their respective countries. However, Belgium noted that while producers do market the nutritional qualities of hemp foods, some products have been marketed with large images of a cannabis leaf on the label and suggested that this may be viewed as making a connection with illicit cannabis use.</p> <p>There is therefore no available scientific evidence that FSANZ is aware of, that can be used as the basis of risk analysis to support the development of regulatory measures that prohibit the use of cannabis leaf images in advertising or labelling or to prohibit representations that reduce the risk of consumers believing that foods derived from hemp seeds can produce psychoactive effects.</p>
s 18(2)(b)	The promotion of consistency between domestic and international food standards	From an international perspective, the Canadian Industrial Hemp Regulations and the New Zealand Misuse of Drugs (Industrial hemp) Regulations 2006 include prohibitions related to advertising industrial hemp, its derivatives or any product made from those derivatives that imply it is psychoactive. FSANZ notes this regulation is not a food standard and is not aware of any other country that has specific restrictions relating to representations on hemp foods. FSANZ therefore considers that development of regulatory measures in the Code to regulate representations on foods derived from hemp seeds may be inconsistent with other international food standards.
s 18(2)(c)	the desirability of an efficient and internationally competitive food industry	Regulatory measures to prohibit the use of cannabis leaf images in advertising or labelling and to prohibit representations that reduce the risk of consumers believing that foods derived from hemp seeds can produce psychoactive may have a negative impact on the efficiency or international competitiveness of the food industry, if such measures are not required internationally. However, FSANZ acknowledges that the majority of the hemp food industry internationally promotes products as healthy foods and does not attempt to make links with illicit cannabis. The Australian and New Zealand hemp industry has also suggested a similar approach to marketing of hemp foods would be followed in the local market. Therefore, such a requirement may not have a significant effect on international competitiveness.

FSANZ Act section number	Detail of requirement	Notes
s 18(2)(d)	the promotion of fair trading in food	No issues have been identified by FSANZ to date.
s 18(s)(e)	any written policy guidelines formulated by the Ministerial Council ⁴	There are no relevant policy guidelines
Other relevant considerations		
s 29(2)(a) assessment criteria	whether costs that would arise from a food regulatory measure developed or varied as a result of the proposal outweighed the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure	<p>FSANZ investigated the possible benefits and costs to all parties impacted by the recommendation to permit the sale of hemp foods during the assessment of A1039. The economic analysis noted that approval of the draft 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.</p> <p>FSANZ did not identify evidence to indicate that approval of hemp foods, in accordance with the draft variation, would result in consumers being misled or more accepting of illicit cannabis use. FSANZ therefore did not include this as a cost.</p> <p>Some hemp industry stakeholders have indicated the potential economic benefits for Australian industry are likely to be more substantial than presented in the FSANZ assessment to date.</p> <p>There may be additional costs for New Zealand hemp seed oil industry if labelling requirements in addition to current requirements are introduced. This may necessitate the development of a regulatory impact statement to determine whether additional controls provide a net benefit to the community.</p>
s 29(2)(b) assessment criteria	whether other measures (available to the Authority or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the application	<p>Consumer law</p> <p>FSANZ previously noted that consumer protection legislation in Australia and New Zealand covers misleading and deceptive labelling and advertising. Many submitters suggested that existing consumer protection legislation is sufficient to cover potential labelling of hemp foods that may be misleading. FSANZ discussed the issue of misleading representation with the Australian Competition and Consumer Commission and the New Zealand Commerce Commission.</p>

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)

FSANZ Act section number	Detail of requirement	Notes
		<p>They agreed that enforcement action could be used in the case of misrepresentation. Additional measures in the Code could be taken in response to possible misrepresentations made on hemp food products. However, as noted above, a decision to include this type of regulatory measure in the Code would be subject to the legal requirements FSANZ must have regard to in reviewing food regulatory measures.</p> <p>Food Acts</p> <p>Jurisdictions have provisions in their food legislation which prohibit misleading conduct. For example, Section 18 of the NSW Food Act prohibits misleading conduct in relation to food. This includes engaging in conduct that: is misleading or deceptive or is likely to mislead or deceive in relation to the advertising, packaging or labelling of food intended for sale or the sale of food; or causes food to be advertised, packaged or labelled in a way that falsely describes the food.</p> <p>Some jurisdictions make it an offence to refer to a prescribed or proscribed substance in an advertisement (eg, subregulation 292(4) of the Health (Drugs and Poisons Regulations 1996 (SA), section 24 of the <i>Controlled Substances Act 1984</i> (SA), section 36ZG of the <i>Drug Misuse and Trafficking Act 1985</i> (NSW)). In New Zealand, under the Misuse of Drugs (Industrial Hemp) Regulations 2006, hemp products may not be advertised to have psychoactive effects. FSANZ has not investigated the scope and application of such provisions in the context of other legislation.</p> <p>Jurisdictions also have the option of amending their existing laws or enacting new laws to apply certain regulatory measures e.g. an express prohibition on the use of hemp (cannabis) leaf images or the terms ‘cannabis’ and ‘marijuana’ on food labels and in advertising of food products.</p> <p>Section 141 of the NSW Food Act also permits the making of regulations that contain provisions that are in addition to, or in substitution for, one or more of the Code’s provisions. That is, jurisdictions would appear to have the option of making their own regulations to impose requirements over and above those in the Code in relation to hemp food products.</p> <p>Industry guidance or code of practice</p> <p>The option of a non-regulatory approach such as a guideline or voluntary code of practice developed by industry could also be considered.</p>

FSANZ Act section number	Detail of requirement	Notes
		Some submitters noted that the intended target market for hemp foods is health conscious consumers, including people with intolerances and allergies to other food products; and that the marketing of the majority of hemp foods overseas focuses on the nutritional profile of hemp, rather than attempts to make connections with drug like effects. Submitters suggested that consumers would respond negatively to any suggestion of THC contamination or psychoactive properties of hemp foods. Submitters noted that if anything, manufacturers may choose to focus on the lack of THC content or psychoactive effects when marketing hemp foods.
s 29(2)(c) assessment criteria	any relevant New Zealand standards	The New Zealand Food (Safety) Regulations 2002 include a provision to permit the sale of hemp seed oil as a food in New Zealand. As noted above, in the Misuse of Drugs (Industrial Hemp) Regulations 2006, hemp products may not be advertised to have psychoactive effects.

Table 3: Evaluation of possible Code regulatory measures for hemp food marketing

Possible regulatory measure for foods derived from hemp seeds	Comment/evaluation
Specifically prohibit hemp (cannabis) leaf images in advertising and on labels	<ul style="list-style-type: none"> • Relevant to FSANZ objective of prevention of misleading or deceptive conduct. • Limited/no available scientific evidence to support the imposition of this additional measure in the Code. • Hemp is a variety of cannabis, so presenting the cannabis leaf on a label or marketing material may not be a misrepresentation of the plant that hemp foods are sourced from. The draft variation approved by FSANZ permits only foods derived from hemp seed. It is not clear if hemp leaf would be interpreted by enforcement agencies as a misrepresentation of the part of the plant used as the source of hemp foods. • May not fully address concerns unless combined with other regulatory measures.
Prohibit use of specified terms and illustrations on the label and in advertising, for example the terms 'cannabis' and 'marijuana', cannabis leaf illustration	<ul style="list-style-type: none"> • May be relevant to FSANZ objective of prevention of misleading or deceptive conduct. • May not fully address concerns if certain terms or representations of concern were not prohibited (i.e. it may be difficult to define all terms which may be viewed as an association with illicit drug use). • The use of a term like 'marijuana' on the label or advertising of hemp food may be misleading because marijuana refers to high THC cannabis. Therefore, may not require specific prohibition of this type of term in the Code.
A general prohibition on suggesting, on a label or in advertising, that the food can produce psychoactive effects, either express or implied.	<ul style="list-style-type: none"> • Relevant to FSANZ objective of prevention of misleading or deceptive conduct. • Limited/no available scientific evidence to support the imposition of this additional measure in the Code. • Industrial hemp legislation in Canada and New Zealand includes this kind of general prohibition for hemp products. Industrial hemp legislation may be a more appropriate place for this type of prohibition in Australia. • Reference to psychoactive effects for hemp foods would be misleading because hemp foods do not have psychoactive properties. Misleading conduct would be addressed in consumer law and food acts.
Prohibit referencing or implying presence of any controlled substance	<ul style="list-style-type: none"> • Existing controls in other legislation may be a more appropriate avenue for this type of measure.

Possible regulatory measure for foods derived from hemp seeds	Comment/evaluation
Prescribe requirement for a statement to be on the label and in advertising, indicating the food is not an illicit drug and/or does not have psychoactive properties	<ul style="list-style-type: none"> • May be relevant to FSANZ objective of the prevention of misleading or deceptive conduct. • Limited/no available scientific evidence to support the imposition of this additional measure in the Code. • This may draw attention to the illicit use of cannabis, even though the intent is to make it clear that hemp foods do not have psychoactive properties. Does not appear a satisfactory measure. • FSANZ would need to consider evidence of effectiveness of such a statement if this was to be considered as a legitimate option.
Limit the premises at which foods derived from hemp seeds can be sold or supplied	<ul style="list-style-type: none"> • An example of this type of measure in the Code relates to the sale of foods for special medical purposes, which are intended for use under medical supervision. Hemp foods have a nutritional profile that would provide an effective alternative source of omega 3 fatty acids and other nutrients for the whole population. There is no apparent reason to limit the availability of hemp foods if approved for sale, and any such limitation may adversely affect the commercial benefit to industry from permitting the sale of foods derived from low THC hemp seeds. • Does not appear to be warranted, based on any of FSANZ's objectives (s 18 of the FSANZ Act). • May be difficult to implement.
Limit the persons by whom foods derived from hemp seeds can be sold or supplied	<ul style="list-style-type: none"> • An example of this type of measure in the Code relates to the sale of foods for special medical purposes, which are intended for use under medical supervision. Hemp foods have a nutritional profile that would provide an effective alternative source of omega 3 fatty acids and other nutrients for the whole population. There is no apparent reason to limit the availability of hemp foods if approved for sale. • Does not appear to be warranted, based on any of FSANZ's objectives (section 18 of the Act). • May be difficult to implement.
Limit the publications that can contain advertisements for foods derived from hemp seeds	<ul style="list-style-type: none"> • Does not appear to be warranted, based on any of FSANZ's objectives (s 18 of the FSANZ Act). • Hemp foods are marketed internationally as health foods, including use as an alternative food source for consumers who have food allergies and/or preferences for non-animal and other sources of foods. Limiting advertising to certain publications only would appear to be limiting information available to population groups that may benefit from the availability of hemp foods.
Prohibit free promotional gifts in association with sale of foods derived from hemp seeds, such as plastic hemp (cannabis) leaves	<ul style="list-style-type: none"> • Not a matter that may be included in a standard or variation of a standard – noted for information purposes only.