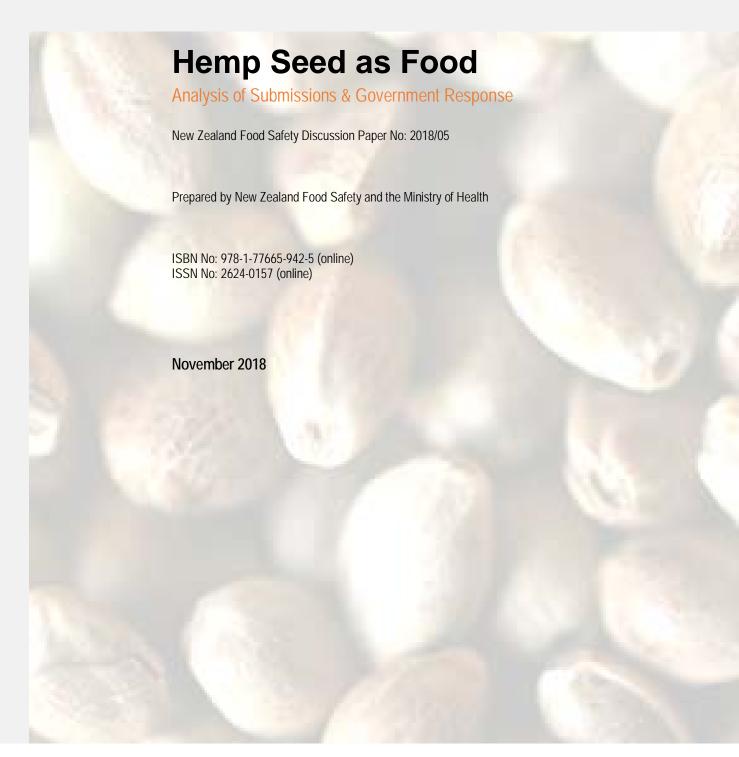


New Zealand Food Safety

Haumaru Kai Aotearoa



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1 Executive summary

This document is a summary of the responses that emerged from the consultation on *Proposed changes* to the Misuse of Drugs (Industrial Hemp) Regulations 2006 and regulations under the Food Act 2014.

Consultation period:

10 May - 20 June 2018

64 submissions received from:

Growers, businesses, consumers and industry groups.

The discussion paper can be found online at MPI's website¹.

Views on food

Respondents were strongly in favour of hemp seed and hemp seed food products. Many comments requested that more of the plant be accessible and with less or no regulation.

Views on Industrial Hemp regulations

Some respondents, while supportive of the Food Code amendment, felt that the regulations were adequate and needed no revision. Feedback suggests that certain regulations are being read in isolation and that clearer guidance specific to the industry is required.

Views on hemp licensing

Some respondents supported making no amendment to the activities hemp licence holders can undertake. However, several respondents requested more guidance material. Respondents were also strongly in favour of the ability to have multiple properties per licence, although some disagreed with paying an additional fee for this facility. It is important to note that licensing changes would require a cost analysis and regulatory changes.

In addition to responding to the questions in the discussion document, many submissions provided views that went beyond the scope of this consultation. Many writers wanted to share their views on medicinal cannabis, New Zealand's environment, economy and political processes.

Given the volume of information received and the breadth of views expressed in the responses, and in the interests of clarity, this document does not include every response received for each question. This work stream is focussed on folding hemp seed as food into New Zealand's domestic law and addressing some practical aspects of the regulations for the hemp sector.

Submitters who are interested in medicinal cannabis can find out more at the Ministry of Health's website.²

Two submissions were provided by representative industry groups. Their advice is appreciated and some of the original proposals have been amended to reflect their concerns.

New Zealand Food & Grocery Council (NZFGC)

"NZFGC is strongly supportive of most of the proposed amendments that will deliver application and implementation of provisions relating to the production, supply, use and sale of hemp as food. In one area (Part Four – licensing) we suggest some rethinking would be valuable but we would not want this to delay the process of amendment."

Government response

The Ministries acknowledge NZFGC's concerns, especially in relation to the operational aspects of the licensing system. Guidance regarding Food Act requirements will be made available.

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¹ https://www.mpi.govt.nz/news-and-resources/consultations/proposed-changes-to-the-misuse-of-drugs-industrial-hemp-regulations-2006-and-regulations-under-the-food-act-2014/

https://www.health.govt.nz/our-work/regulation-health-and-disability-system/medicines-control/medicinal-cannabis

The New Zealand Hemp Industries Association Inc. (NZHIA)

"The NZHIA do not agree with the amendments proposed by the Ministry of Health to the Hemp Regulations. They are unnecessary and restrict and remove existing personal rights and liberties of hemp licence holders under the Hemp Regulations to the detriment of both the hemp industry and the public health."

Government response

A number of changes have been made in response to NZHIA's submission. The Ministries acknowledge that the NZHIA, and 12 submissions specifically indicating their support for NZHIA, are opposed in principle to amending the Industrial Hemp Regulations. They have neither agreed, nor disagreed, but have requested that all proposals be withdrawn. The analysis assigns this position to a category of opinion of 'oppose in principle', which has been noted and considered.

2 Acronyms and abbreviations

The following is a list of commonly used acronyms and abbreviations in the summary of submissions.

Acronym/abbreviation	Meaning
CBD	Cannabidiol
Food Code	Australia New Zealand Food Standards Code
FSANZ	Food Standards Australia New Zealand
Industrial Hemp Regulations	Misuse of Drugs (Industrial Hemp) Regulations 2006
MPI	Ministry for Primary Industries
NP	National Programme
NZHIA	New Zealand Hemp Industries Association Inc.
THC	Tetrahydrocannabinol
The Forum	Australia and New Zealand Ministerial Forum on
	Food Regulation
The Ministries	The Ministry of Health and the Ministry for
	Primary Industries

3 Summary and analysis of submissions

3.1 PROPOSED AMENDMENTS TO FOOD REGULATIONS

3.1.1 Proposal: make a regulation declaring hemp food products covered by the amendment to Standard 1.4.4 to be 'food' for the purpose of section 9 of the Food Act 2014.

In April 2017, the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) approved an amendment to Food Standard 1.4.4 for the sale of low-THC hemp seed food products.

Because the definition of food in the Food Act does not include any substance that is a medicine, controlled drug or psychoactive substance, hemp seed food products must be declared a food by Order in Council under section 393 of the Food Act 2014.

Thirty-six submissions supported this proposal and only one submission opposed. Many submitters commented on the diverse range of foods that can be made with hemp: protein powder, flour, breads, milk, ice cream, cheese and smoothies. Submissions from growers, businesses and consumers indicated their support for introducing hemp into New Zealand food supply.

"Hemp seed foods are a nutritious and harmless addition to our diets that I would like to see in every home."

"I fully support the intent of making consumption as food in relation to industrial hemp in NZ...It is important that the changes in any regulation do not restrict or hinder the use of any food as a food."

"Hemp foods should encompass hemp food products from not only the hemp seeds but also the rest of the plant."

It is important that prospective hemp food businesses are aware that <u>The Food Standards Code</u> extends beyond Standard 1.4.4. It specifies what nutrition, health and related claims can be made about food products, and regulates special purpose foods such as infant formula and infant food.

An Order in Council has been made to action this proposal.

3.1.2 Proposal: revoke regulation 157 of the Food Regulations 2015 once hemp seed food products are declared to be food.

The sale of hemp seed oil has been permitted in New Zealand for many years (under regulation 157).

Regulation 157 will now no longer be required as hemp seed oil is covered by the amended Standard 1.4.4 of the joint Food Standards Code.

Thirty-three submissions supported this proposal and only one submission opposed.

Regulation 157 will be repealed at the same time that amendments to Standard 1.4.4 are adopted and commenced in New Zealand.

3.2 PROPOSED AMENDMENTS TO THE MISUSE OF DRUGS (INDUSTRIAL HEMP) REGULATIONS 2006

3.2.1 Proposal: modify the Object of the Regulations to clarify that therapeutic products are not included in the Industrial Hemp Regulations and to include hemp seed as food.

The Object of the Regulations (the Object) currently states – The object of these regulations is to enable the cultivation and distribution of industrial hemp under a licensing regulation that ensures that other forms of cannabis are not cultivated and distributed under the guise of industrial hemp.

The purpose of amending the Object of the Regulations is to provide clarity about the requirements that must be met by those who cultivate and produce products from hemp plants. The current wording has been interpreted by some to mean that the <u>only</u> requirements that have to be met, regardless of the product produced, are those set out in the Misuse of Drugs (Industrial Hemp) Regulations 2006 (Industrial Hemp Regulations). The Industrial Hemp Regulations do not operate in isolation from other regulations and industrial hemp products will need to meet any additional requirements in the sector in which the product will be marketed.

There was mixed feedback on this proposal. Eleven agreed and five disagreed. The New Zealand Hemp Industries Association Inc. (NZHIA) did not support amending the Object. It argued that the regulations work well to allow production of hemp products, whilst recognising that when used in a particular market they will have to comply with the requirements of those markets.

In light of the feedback, this proposal has been withdrawn. The Ministries will support the industry through improved guidance about the additional requirements hemp products must meet when entering food or other markets beyond paper and fibre.

3.2.2 Question: Is there any specific reason to change the interpretation of cannabis to the genus cannabis, given seeds can only be from *Cannabis sativa*?

The discussion document sought views on this question.

The Industrial Hemp Regulations currently define Cannabis as the species Cannabis sativa.

In total, twelve respondents supported a change, five were against. Some respondents in favour of retaining the current definition were concerned that a broader definition would confuse consumers about the difference between hemp and psychoactive Cannabis. However, other submissions focused on the potential for industry and trade expansion if hemp was not restricted to *Cannabis sativa*.

"We believe under current law, allowing only low THC Sativa (hemp) is crucial to distinguishing between Industrial hemp and recreational marijuana."

"The THC content of any sub-species of cannabis can be bred down to the stipulated levels for "hemp". Sub-species include C. sativa, C. chinensis, C. ruderalis, C. indica, and C. afganica, all of which can be used for non-drug purposes (with sativa and chinensis having strong traditions of industrial use)."

"The restriction to one Cannabis cultivar (Cannabis Sativa) will continue to place restrictions on the development of the NZ hemp industry. If regulation uses specific THC measurement for each cultivar it will allow the industry to diversify its seed development, give growers confidence to expand the current low THC Cannabis breeds and find the crop most suited to their growing environments and market demands."

Given the issues raised, it was determined that further research and analysis is merited before changes are made.

3.2.3 Proposal: widen the definition to the Director-General of the organisation that administers the regulations.

The current Industrial Hemp Regulations specify that the Director-General is the Director-General of Health. There was strong support from respondents to widen the definition of 'Director-General'. Fifteen submissions supported a wider definition, and no submissions were against.

This change provides for future changes within government agencies and it enables another government agency to administer the regulations on behalf of the Ministry of Health. The proposed change and consequential amendments throughout the Regulations, where employees of the Ministry of Health are specified, have been made.

3.2.4 Proposal: add a definition for hemp food products consistent with the Food Standards Code.

Nine submissions agreed, ten disagreed. Opposing submitters indicated that a definition is not required in the Industrial Hemp Regulations as this already exists in food legislation.

Further to this, some submissions commented on expanding the definition of hemp food products to other parts of the plant (i.e. leaves) and not just the seed.

"We agree to the adding of a definition that..." is in line with Food Standards Code 1.4.4-6..." We don't, however, agree with the need for extra detail in the Industrial Hemp Regulations, as it is already covered by the Food Standards Code."

"I believe that the food issue should be treated separately to the fit for purpose review, as the food is a priority and can be achieved without tweaking the iHemp Regulations."

The following definition for hemp food product has been added to the industrial hemp regulations:

Hemp seed food product means a hemp seed food product declared to be a food by regualtions under the Food Act 2014.

Adding this definition allowed the drafting of changes to the permissions in regulation 67 (activities that do not require a licence), that are necessary to allow hemp seed food products, to be done in the clearest way possible.

The application that led to the 2017 decision by the Forum did not include a proposal for use of leaves and other parts of the plant. Consequently, only hemp seeds were assessed and approved as food. A separate application to FSANZ would be required to expand the definition of hemp food products to include other parts of the plant.

3.2.5 Proposal: amend the definition of hemp product to make the distinction between a hemp product and a therapeutic product clear.

The current definition of a hemp product is "a product of a kind that is derived, in whole or in part, from industrial hemp". Submissions were divided on this proposal, eleven were in support and seven were against.

"The current regs ENABLE the Industry as Intended and do not restrict the Industry, they were set up and worded this way to allow for a growing Industry as is the case with all Industries, Hemp is no different and should be treated as such."

"We also agree with all other new and existing interpretations under the 2006 Regulations."

It has been determined that a change to the definition in order to make the distinction between a hemp product and a therapeutic product clear is not necessary, as the law is clear.

However, the definition of 'hemp product' has been amended to include a hemp seed food product. This change allowed the drafting of amendments to regulation 67 (the activities that do not require a licence), that are necessary to enable hemp seed food products, to be done in the clearest way possible.

A separate regulatory pathway is being developed for medicinal cannabis products and the definition of hemp product will be reviewed again as part of the development of that scheme. In the interim, guidance can be developed to provide clarity between a hemp product, a therapeutic product, and a raw material that requires a licence.

3.2.6 Proposal: add a definition for hulled seeds consistent with the Food Standards Code which states hulled seeds means seeds from which the outer coat or hull of seeds has

been removed. Add a definition for whole seeds which are seeds that have not had the outer coat removed.

The current Industrial Hemp Regulations do not differentiate between hulled and whole seeds, meaning that a licence is required to possess or trade in both forms of the seed.

The proposed amendment to the Food Standards Code distinguishes between hulled and whole seeds. This distinction also needs to be reflected in the Industrial Hemp Regulations. This enables non-viable, hulled hemp seeds or hemp seed food products to be freely possessed or traded, without a licence.

A hemp product is a product that is <u>derived</u> from industrial hemp plants. A hemp product is <u>not</u> a raw material, it is processed and no longer recognisable as the original seed, leaf or stalk. Hulled seeds are not likely to fit the current definition of hemp products because they are not derived from seeds, but are still seeds themselves. Even if these seeds are not viable, or are crushed, they are still seeds. This is consistent with the Food Standards Code definition that a seed includes part of a seed.

Eleven submissions agreed and five disagreed. There is a view among these submitters that hulled hemp seeds are a hemp product, and under the current Industrial Hemp Regulations, a licence is not required to possess or trade in hemp products.

A few submissions also stated that the definition (as defined in the amendment to the Food Standards Code) should allow for hemp seeds that are still whole but processed to make them non-viable. For example, toasted/flavoured whole hemp seeds.

A definition of hulled hemp seeds is needed to distinguish between whole seeds (with the seed coat on) which will require a licence for import, export, sale and possession, and hulled hemp seeds which will not need a licence.

The following definition of 'hulled hemp seeds' has been added to the regulations:

Hulled hemp seeds means hemp seeds-

- a) from which the outer coat or hull of the seeds has been removed; and
- **b)** that are not able to germinate.
- 3.2.7 Proposal: amend the definition of THC to mean the total amount of delta 9-tetrahydrocannabinol and delta 9-tetrahydrocannabinolic acid.

The definition for THC is tetrahydrocannabinol in the Industrial Hemp Regulations and does not include references to other aspects of THC, such as tetrahydocannabinolic acid (THC-A).

The definition for hemp seed and its food products (as defined in the Food Standards Code) refers to total THC, which is inconsistent with the current Industrial Hemp Regulations definition.

Food Code THC levels				Industrial Hemp Regulations THC levels		
(a) the seeds :			(a) Plants with a THC content that is:			
	(i)	are seeds of low THC Cannabis sativa; and	(i (i	generally below 0.35%; and is not above 0.5%.		
	(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.				

Twelve submissions agreed and four disagreed. One submission stated that the current definition should remain as is because the Industrial Hemp Regulations should be kept general and not make specific reference to hemp seeds and its food products. Another submission argued that most or all of their approved Industrial Hemp varieties would not meet the requirements under the proposed definition.

The following definition of 'THC content' has been added to the Industrial Hemp Regulations. This change makes the regulations as consistent as possible with the Food Standards Code to avoid confusion for the industry.

THC content, in relation to a hemp plant, means the content of delta 9-tetrahydrocannabinol and delta 9-tetrahydrocannabinolic acid of the plant expressed as a percentage of the dry weight of the plant.

3.3 PROPOSED AMENDMENTS TO LICENSING

3.3.1 Proposal: add the importing and exporting of whole hemp seeds as an approved activity.

While importing and exporting of whole hemp seeds have never been specifically listed as an 'activity' in the Industrial Hemp Regulations, under current law, licences are required for these activities under the Misuse of Drugs Regulations 1977.

"Regulation 7 needs to be changed to include the importing and exporting of registered cultivars. As described in 6.1.2 in the proposed changes document."

Fifteen submissions agreed and four disagreed.

While this proposal was supported, Regulation 7 has been re-examined and it was determined that current arrangements are sufficiently enabling for the industry. This proposal has been withdrawn.

3.3.2 Question: Do you agree to allow for the application to include a provision for an applicant to include all approved cultivars?

The discussion document raised this as a question.

Respondents strongly supported this question, with 18 comments in support and no comments against. Some submissions noted that people applying for hemp licences may not know what cultivar they will be growing, or the cultivar they wish to grow may change over time. One respondent was concerned that there should be no additional charge for this ability.

Having considered the responses, the Ministries agree that the guidance material accompanying the new regulations will explain how the activities section of the application works. This can be addressed without amending the Regulations.

3.3.3 Proposal: to retain the current flexibility to specify only one activity or to list more licensable activities.

The Regulations currently allow flexibility for an applicant to specify only one or some activities or to list all licensable activities.

The majority of respondents who commented on this proposal were supportive of making no amendment, with 17 in support and three against. One respondent believed an amendment was necessary in order to include importing and exporting as approved activities.

"We recommend that the default in the application form provides for all activities."

"Having had to apply for both General and Breeders licences, and duplicating most of the answers and doubling the cost, I think this proposal is just a revenue generating exercise."

It has been determined that no amendment is required.

3.3.4 Proposal: to merge 9(f) and (g) together – requirements of licence holders.

Regulation 9(g) requires the licence holder to have a higher level of expertise and resources "to undertake the activities" compared to the requirements in 9(f) "to comply with the obligations". In practice, 9(f) is the standard that needs to be met, rather than 9(g).

Whilst these are similar, the Ministries view 9(f) and 9(g) as being quite different and the proposal to revoke 9(g) will better reflect the criteria taken into account in considering licence applications.

The majority of submissions did not comment on this proposal. There were five respondents in favour of this amendment and two against.

This amendment has been made.

3.3.5 Question: What are your thoughts on having more than one property per licence?

The discussion document raised this as a question.

There was strong support from respondents for this question, with 22 submissions in favour and one submission supportive if the change would reduce duplication. No submissions opposed this question. One respondent suggested:

"A system (public or private) should be developed to geographically represent where hemp crops are being grown so as not to cause confusion."

Several respondents requested licences for a longer term than three years or driver's licence style portable licences.

There was less support for charging an additional fee for licences with more than one property. Overall, nine submissions agreed to an additional fee and six supported an additional fee so long as it was a small increase (for example, of between \$20 and \$50). Five respondents opposed any increase to the licence fee.

"Only if properties added to license later rather than multiple properties on original license."

"There is a need to recover costs of visits /inspection of sites so additional charging is acceptable but must not be excessive."

"An additional fee per site (eg \$50), is still much better and tidier than needing another licence."

The responses to these questions have been informative. Further analysis will need to be completed before this change can be made, noting that this change does not require amendment to the regulations.

3.3.6 Proposal: to make an amendment so that a person who does not hold a hemp licence does not commit an offence if they possess, use or trade in non-viable, hulled hemp seeds or hemp seed food products.

Submitters supported the intent of this proposal that a licence is not required to possess, use or trade in hulled hemp seed or hemp seed food products. Some submitters thought a licence is not needed currently.

Eleven submissions agreed and one disagreed.

This amendment is essential to enact the Food Standards Code and has been made.

Appendix 1: List of submitters

David Bedggood

Adam Shand Ken Greaves
Angela van Zyl Kristy Robinson

Anna Dobson Larry's Creek Farm (Sarah and Aaron Silcock)

Beefy Green Nutritional Hemp (Brendon Lisa Barrington

McIntosh & Brad Lake)

Louis Murphy-Harris

Ben Hawker

Lyndall Fuller

Breadman Organic Bakery (Cassandra & John Booth)

Maria Lempriere

Cees Hekelaar Mason La Trobe

Christopher Aldridge

Matthew Brajkovich

Midlands (Lisa Ree)

Dana Mignon

New Zealand Food & Grocery Council (Carole

Dave Brown Inkster)

David Bedggood

New Zealand Hemp Brokers (Chris Woodney)

David MacClement

New Zealand Hemp Industries Association Inc.

David Whyte (Richard Barge & Donald Mcintosh)

Donald James Mcintosh OrganicAg (Bill Quinn)

Eben Wilson Peter Wadham
Em's Power Cookies (Emily Miazga) Polly Brownlee

Emele Faifua Regan Ross
Emma Barr Rhys Harris

Emma Nelson Snugtech (Simon White)

Frans Theewis Stephen Mawer

Functional Whole Foods NZ (David Musgrave) Suzanne Beer

Hamish White TeRana Porter
Hemp Connect (Werner Schulze) The Health Shop (Orléa Rayne)

Hemp Earth (Richard Hawker)

Tikapa Organics (Atkins Whanau)

Viv Barr

Hemp Farm (Sean Doyle & Dave Jordan) Tom Welch

Hemptastic Ltd (Richard Barge) Wailife (Bari Samadi)

Herbal Remedease (Stacey & Neal King) World Foods NZ (Tom Moore)

Tierbal Remedease (Stacey & Neal Ring) World Foods NZ (Tolli Moore)

Hikurangi Group (Manu Caddie)

Zeb Horrell

Hukatere Hemp (Charlene Mayes)

Hune Tahere
Isaac Gumbrell

Kakariki Hemp Processing (Andrew Bell)

Hemp Unlimited Aotearoa (Steve Burnett)

Kate McFlinn
Kelly Screen