Name	Proposed Changes to the Misuse of Drugs (Industrial Hemp) Regulations 2006, and regulations under the Food Act 2014
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Thank you for the opportunity to comment and make recommendations on the "Proposed Changes to the Misuse of Drugs (Industrial Hemp) Regulations 2006, and Regulations under the Food Act 2014" document. "The Document"

We welcome your discussion document, following the 'yes' vote by the Food Ministers in April 2017.

The following are our comments and recommendations on "the document" as a national trade association, whose objectives are:

- To ensure Government legislation and compliance issues are necessary, workable and industry friendly;
- Removing industrial hemp from the prohibited botanicals list.
- Ensuring Government regulations remain pertinent and up to date.
- Ensure the public is properly and reliably informed regarding industrial hemp developments, technology and produce.
- Encourage environmentally friendly and ethical bioregional developments.
- Acknowledge NZHIA has no interest in the recreational cannabis debate, except where it may impede industry development.
- Supporting the industry to be able to make and market hemp products from all parts of the iHemp plant (2016)

We recommend a Keep it Simple approach, which requires a change in mind set by the regulator, rather than adding more words to our regulations. Many of the items raised in the discussion document are already suitably covered by the existing legislation.

Keep it Simple Strategy

- Amend the Food Act 2014 or regulations 2015, to include the food code variation 1.4.4; this will define and authorise hemp seed food products for human consumption.
- Under the hemp regulations, the above amendment will allow the industry to produce and sell "hemp products" into the human hemp seed food market, these hemp products are adequately defined as "hemp food products' in the Food Act, so no further work is required

Introduction

Above all we would like to stress and encourage MPI and the MOH to keep it simple.

This was a theme throughout the original consultation on the iHemp regulations. We know this because we were part of the interagency working group who developed the regulations. The senior government officials on this working group were eager to follow the lead from Industry, as it was understood that the industry would be tasked with realising the potential of hemp, and therefore needed to be enabled.

These senior officials were making decisions based on the accepted fact that we were working with a low THC arable crop, which did not need to be managed as a controlled drug. In August 2006, the Misuse of Drugs Regulations 1977 were amended to acknowledge that licences for the cultivation, processing and distribution of industrial hemp as an agricultural crop could now be issued under the iHemp Regulations.

Medicines Control (MC) must acknowledge that we are not a 'pseudo drug' industry. The iHemp Regulations allow licences to be issued to grow a low THC arable crop, which can then be made into a wide range of hemp products. The scope of end uses is purposefully not restricted in the regulations, as they were created to enable an industry to develop and use non-drug iHemp cannabis in all manner of useful hemp products. MC should get over their confusion: we are not an illicit industry; there is adequate control in the IHemp Regulations and associated legislation depending on the end use (i.e. as a food complying with the Food Act and Food Code)

The industry accept that the hemp regulations are our guiding legislation, independent from MODA.
Industrial hemp has been clearly defined as low THC, which differentiates us from other forms of Cannabis. The iHemp Regulations permit licences to be issued to grow low THC iHemp as an arable crop, not a controlled drug.

This is in accordance with the UN Single Convention on Narcotic Drugs 1961, Article 28

Article 28
CONTROL OF CANNABIS

1. If a Party permits the cultivation of the cannabis plant for the production of cannabis or cannabis resin, it shall apply thereto the system of controls as provided in article 23 respecting the control of the opium poppy.
2. This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fibre and seed) or horticultural purposes.
3. The Parties shall adopt such measures as may be necessary to prevent the misuse of, and illicit traffic in, the leaves of the cannabis plant.

Importantly 28-2 exempts cannabis grown for "industrial purposes (fiber and seed) or horticultural purposes." And 28-3 also clarifies the leaf material, which in the case of iHemp (grown under our iHemp Regs) would similarly be exempt as there is no "misuse" nor "illicit traffic in" the leaves when made into hemp products.

From our point of view the iHemp regulations allow the licensed cultivation of iHemp, which enables us to make hemp products and create a new industry for Aotearoa, New Zealand - and we simply want to get on with it.

In the spirit of not raising complications where none exist, we make the following comments and recommendations based on the questions raised in your discussion document. We hope you can see the wisdom in our approach, since it reduces the need for the extra work and words outlined in the discussion document.

In the past we have worked well with Government officials and enjoyed their positive support and we look forward to continuing this for a long time to come.

But with all due respect, you have missed the point and ignored the feedback received at the MPI stakeholder consultation in September 2017.

The review required was to change Misuse of Drugs Act 1975 (MODA) and remove iHemp from the definition of controlled drugs. This must happen for an industry to develop, as then all other issues can be resolved by the iHemp regulations.

The discussion document creates more problems than it solves in its fit for purpose review (see part 4.)

We feel you have failed to comprehend the objects, definition and permission of the iHemp Regulations which are currently very "fit for purpose" as they enable our industry to develop.

This situation will change if you start making these unnecessary amendments to the iHemp regulations. We will strongly dispute these changes as they lack reason and logic and are not fact and evidence based.

We are not being licensed to grow a drug crop, in fact we are doing the exact opposite, producing a low THC iHemp crop - which should be embraced as a new primary industry. The current attitude of MOH is to control us, as if we were growing opium, as in Article 23 of the UN Convention, when clearly article 28 should be used.

Article 23 may be relevant for the medicinal cannabis scheme, but it is wholly inappropriate for iHemp cannabis which has no value in the illicit market and cannot be misused.

The attitude of MOH is a disservice to the people involved in building the industry, and does not respect the considerable investment in time and money~~,~~ that people have made over many years in the iHemp industry. The continued stifling of the industry by MOH is unacceptable, and we believe no other industry would put up with being treated like this.

We have a bad law, in the Misuse of Drugs Act 1975 and it should be a priority to remove iHemp (in all its forms, seed, leaf, roots, and stems) from its control, since iHemp has insufficient levels of THC to be treated as a controlled drug.

Some of the recommendations in the document wish to amend the Objective and Definitions of the iHemp regulations, we view these as significant changes which should only be made with the approval of the select committee and should not be taken lightly as industry will oppose them with all the means available to us.

<u>2.2 Summary of Proposal</u>

2.2 SUMMARY OF PROPOSALS

The proposals in this document provide for:

- consistency between the Food Standards Code to allow low-THC hemp seed as food and the Industrial Hemp Regulations;
- regulations under the Food Act 2014 to declare low-THC hemp seed to be a food; and
- greater flexibility around licensing to possess, cultivate and trade in low-THC hemp.

NZHIA Executive comment

The first two have been signalled to industry since April 2017, the third one is in line with the "Object" of the 2006 Industrial Hemp Regulations (iHemp Reg's) - to enable the industry. This is commendable and if it was taken seriously by the Government if would mean a great deal to industry.

The current attitude of Medicines Control is to restrict and try and control the emerging industry, as if it were working with a high THC controlled drug. This is not enabling the industry and is not the intent of the regulations, nor is it required - if MC accept we are growing, under licence, a low THC arable crop.

Creating problems where none exist will stifle the development of our industry. This is completely unacceptable for New Zealand given the potential economic, environment and social benefits of an enabled iHemp industry.

2.3.1 Cost recovery

Noted as 'not in scope', but signals that it may occur in the next two years. In the document you note "This potentially limits the changes that can be made to the licencing process*"* … we would like to know what this actually means?

Executive comment – the licence cost

We would like the Ministry of Health to start charging us $500 as per the regulation.

Currently their invoice is for $511, this sends mixed messages to the industry about the government's approach to legislation.

Let's get an enabling industry underway before you consider justifying an increase in licence cost.

What additional value is offered to justify an increase in cost? see section 6.3

2.3.2 Medicinal Cannabis/hemp

We have agreed that we will put to one side, for the moment, the use of iHemp as a cannabis medicine – as this topic will be covered by the Medicinal Cannabis Scheme and amendments to Misuse of Drugs Act 1975 (MODA) and Medicines Act 1984.

However, it should be noted that we are interested in revenue, streams from all parts of iHemp, including the use of hemp products, supplied to people and organisations involved in the production of medicinal cannabis products.

Only iHemp can produce "hemp products" and all hemp products will need to comply with the relevant legislation, for their particular end use - in this case the Medicines Act and MODA.

3.2 Application for Low - THC Cannabis Sativa Hemp Seed as food

It should be noted that the original application was submitted in December 1998, A360 – Use of Industrial Hemp as a Novel Food.

A second application from industry was submitted in 2009, A1039 - Low THC Hemp as a Food, when this failed, the Forum asked their officials to come up with a proposal.

P1042 – Low THC Hemp Seeds as Food was drafted on 28 July 2016, the variation to the food code was not changed after consultation, and the proposal received a 'yes' vote from the Food Ministers' Forum on 27 April 2017.

The Food Ministers wanted this to happen within 6 months of being gazetted, and with the support of the Australian federal government this happened in Australia in November 2017. However, MPI signalled that this would take 12-18 months in New Zealand.

3.5 What does this mean for industry?

> If you currently grow hemp under a licence with the MOH for industrial purposes nothing will change. If you decide to grow hemp seed for sale you will need to grow hemp under a licence from MOH and register your business with MPI to operate under a National Programme.

Executive comment

What additional MOH licence are you referring to here?

We currently grow iHemp under a general licence, which allows us to make hemp products in whole or in part from the iHemp crop. We dispute the need for an additional MOH licence to grow seed for sale.

Hemp seed is grown for two main reasons: as a sowing seed or as a grain if sold for processing.

"The document" makes reference to the need for a licensed grower to operate under a National Programme. We dispute this: as arable farmers producing grain for processing we do not have to comply with the National Programme. Arable farmers do not need to have a food safety program registered with MPI, although the food

people we sell to will need to comply with this. It is not common practice in the production of other arable crops, and so it should not be part of the process to grow hemp seed for human consumption.

Part two – Proposed amendments to food regulations

4.1 Proposed amendment to Food Regulations 2015

We accept that an amendment to Section 9 of the Food Act 2014~~,~~ is required to declare hemp seed as food, that is, permitted by Standard 1.4.4-6 to be a "food" for the purposes of the Food Act 2014.

4.2 Revocation of Regulation

We agree that regulation 157 is no longer required. Hemp seed oil will be covered as a hemp seed food, as per the variation to the food code 1.4.4, which in New Zealand will be included in the Food Act 2014, via an amendment to the Food Regulations 2015. This is good housekeeping and does not affect the industry.

Executive comment

We envisage that the required amendment to the Food Regulations 2015~~,~~ can be as simple as Regulation 157. The latter allowed hemp seed oil for human consumption in New Zealand to become part of the Food Code.

QUESTION 1
We accept the need for the proposed changes, a simple 'one liner' acknowledging the Food Code variation 1.4.4 thereby allowing hemp seed in all its forms for human consumption needs to be added to the Food Regulations 2015. We encourage you to expand the variation and align the food act with the UN single convention by: • Allowing hemp teas and flour from the leaves and tops of the plant to be used as a human food • Clarifying that crushed and powdered hemp seeds are available for retail sale along with hulled seed • Allowing hemp sprouts to be a human food • Allowing whole hemp seed By widening the definition of hemp food products in the NZ Food Regulations you can allow a wider range of hemp foods for human consumption and add significant economic opportunities from the high value nutritional products from other parts of the plant.

Part Three: Proposed amendments to the Misuse of Drugs (Industrial Hemp) Regulations 2006

5.1 Proposed Changes

Our feedback on the proposed changes to the interpretation section, as summarised in 5.1, will be handled under each of the relevant headings in 'the Document".

We will not be commenting on them individually here, suffice to say that there is not "confusion" with certain definitions, there are simply "differences of opinion".

As it is not the Ministry of Health's role to define or direct industry, there will always be differences of opinion, which, if required, should be decided upon by the courts.

We do not think that adding more definitions and headings are required, as the iHemp Regulations are sufficiently clear to be able to accommodate the addition of hemp seed foods. The latter are covered for the purposes of the iHemp regulations as a "hemp product." And in this instance, the associated legislation requiring compliance is detailed in The Food Code, variation 4.1.1. In New Zealand's case, this is enacted via the Food Regulations 2015, under the Food Act 2014.

5.2 Regulation 3: Object

We strenuously dispute the need to change the Objective.

You propose to modify the Objective, to clarify that therapeutic products are not included in the industrial hemp regulations and to include hemp seed food.

The regulations "Enable" the industry, they do not restrict the industry and so there is no need for a definite list of what can or can't be made in to hemp products. This would be impossible to do as markets develop and consumer demand evolves, so there is no point in creating a limiting list, which is of no benefit to industry nor to the Government.

The regulations work well to allow the production of hemp products, whilst knowing that when used in a particular market they will have to comply with the requirements of those markets, thereby ensuring that safe, low THC industrial hemp is fit for purpose in those industries.

iHemp has a potential use in the medicines market, and our farmers should be able to produce suitable crops for all the markets available. If in the case of a medicine, or therapeutic end use, it will then have to comply with the Medicinal Cannabis Scheme and Medicines Act.

The objective is clear: it is explaining the role of the regulations, to enable an industry to develop "under a licensing regime that ensures other forms of cannabis are not cultivated and distributed under the guise of industrial hemp."

There is no place in this objective to reduce and/or limit the industry: this destroys the concept of "enablement" and goes against the spirit and outcomes envisaged when the regulations were developed. Please remember - we worked with the interagency group on the development of these regulations, and we were at the table when all of these issues and end uses were discussed.

People who currently work for the MOH are saying things like "it was only ever intended for textiles and animal feed", but are making it up as they go along. They are incorrect, and are unaware of the history behind the

regulations. This needs to change so that they are able to correctly interpret the legislation, and thus can properly enable the industry.

This does great disservice to the senior officials who formulated the regulations, to the industry which is trying hard to work within the regulations, and to the New Zealand and international consumers, who are missing out on the hemp products we can supply.

The Objective cannot be changed to acknowledge food, as this is sufficiently achieved in the amendment at 4.1 above. Similarly for medicine – this will be covered by the Medicinal Cannabis Scheme and its subsequent review in two years.

The 2006 Object should remain, it is clear and concise and explains the need for the regulations. This could be expressed as enabling an industry to develop whilst making sure high THC cannabis products are not marketed as Low THC industrial hemp.

We believe that the other controls and words that you wish to add, will dilute this meaning, rendering it meaningless. More words add no value to the object, and it is inappropriate to consider using the objective to limit the emerging market. Telling us we can't do things when you have not clearly thought them out is not relevant to the industrial hemp industry. This industry will continue to change and evolve until hemp is finally treated as just another arable crop.

Changing the Object would make the regulations less fit for purpose, and potentially adds further confusion. This creates uncertainty and stifles the industry.

Executive comment

We strenuously do not support this recommendation, adding or excluding products is not the role of the objective.

Changes to the regulations should be meaningful and in line with the current objective.

The regulations can resolve all issues when read and applied in the spirit and intent of the objective. Suitable control of hemp products can be achieved when sector-specific legislation is applied to the production of goods in that sector's market.

Fundamental changes to the Objective is outside the scope of this review, and should be made via the Select Committee, and involve all of the issues raised by industry which have been ignored in this document.

<u>5.3 Interpretation of Cannabis</u>

The industry has always accepted that when officials use the term "Cannabis Sativa" it covers all the genus of the cannabis plant.

You have mentioned that Industry wants to include other species of cannabis. You may be referring to *cannabis indica* and *cannabis ruderalis* which are considered on a taxonomic level to be separate from c*annabis sativa*.

From a house-keeping point of view, amending the definition for cannabis to include all forms of the genus cannabis would be a better definition than stipulating Cannabis Sativa, however this may lead to a conflict with the food variation which also refers to "Cannabis Sativa".

The real point raised with stakeholders at an MPI meeting in September 2017 - which seems to have been missed by the writers of this document - is the need to differentiate between low THC industrial hemp cannabis and high THC marijuana cannabis.

This is critical, and if time was spent on clarifying the difference between these two types of cannabis, a lot of the problems arising in interpretation would be resolved and amendments to legislation could be made more effectively.

Executive Recommendation:

We have a definition for industrial hemp, as per the regulations, so by default everything else should be treated as a controlled drug – *that is, marijuana cannabis*.

If iHemp was completely removed from being treated as a controlled drug (due to its definition of THC content – since it does not contain any psychoactive qualities), then the hemp regulations would be fit for purpose and our industry could be enabled with the support of the government.

QUESTION 2
We would be in favour of a change to the interpretation of "cannabis" in the iHemp Regulations. It could read "Cannabis Sativa is a generic term for any plant of the genus cannabis." This would clear up any confusion regarding any potential sub species of cannabis, as they would all be included under the generic term Cannabis Sativa, which avoids a conflict with the Food Code.

5.4 Interpretation of Director-General

We accept that the proposal would future-proof the regulations, allowing the administration of the regulations to be handled by another Ministry, such as MPI who are a more natural fit to administer our arable industry.

Executive Recommendation:

We would further recommend that removing industrial hemp from control of the Misuse of Drugs would allow the relevant attorney general to not only administer the regulations, but to make all the decisions affecting the industry, without having to burden the Ministry of Health on matters that relate to our arable industry.

5.5 Interpretation of Hemp Food Product 5.5

We dispute the need for a definition of a hemp food product. This sets an unrealistic precedent - will you be following this with a hemp building product? (that meets the Building Act/Code) or a hemp fuel product? or a hemp textile product? when these markets are developed…?

The hemp regulations allow licensed farmers to grow low THC industrial hemp, and **only low THC industrial hemp** can be used to produce **hemp products**.

The regulations are not the correct arena to define the end uses for these hemp products - there are too many to include, and more definitions will lead to differences in opinion, causing confusion and uncertainty.

In the case of "hemp products" being used to produce "hemp food products' there is a clear path to the Food Act, and back to the Food Code. The FSANZ Food Code has already clearly defined hemp food products, and all the compliance is contained in the food legislation. (Also in other legislation such as the Fair Trading Act, Advertising Standards Act etc.)

This makes sense as the hemp regulations allow the production of hemp products. Separate legislation, depending on the market in which the hemp products are to be used, will govern the specific requirements to ensure goods are suitable for their specific markets.

There is no need for a definition of Hemp Food Product, nor hulled hemp seed, nor whole hemp seed. These are sufficiently detailed and controlled in the food variation 1.4.4-6.

For the purposes of the iHemp regulations, hulled hemp seeds are clearly a hemp product, since they are processed (removing the shell from the seed) and are no longer viable, so can no longer be considered simply as seeds. As a hemp product, Section 67 of the regulations under "permissions"- allows the public to be in possession of hulled hemp seed.

With regard to whole hemp seed - again we do not need a definition in the iHemp Regulations, as MODA (another piece of legislation with which the hemp industry must comply) defines cannabis seed as a Class C Drug – so currently anyone processing, or in possession of, whole hemp seed would require a licence.

Executive Recommendation:

All the outcomes you have required in 5.1 Proposed Changes, and this section 5.5, are already covered in the iHemp regulations, and so no further action is required.

As part of your 'fit for purpose' review, removing cannabis seed from MODA would automatically make them 'hemp products', which would be useful for industry, as the seed stores best when it is in its shell.

This would allow the public to keep whole seeds as foods and would be in line with the United Nations Single Convention 1961, Article 28-2. *This Convention shall not apply to the cultivation of the cannabis plant exclusively for industrial purposes (fiber and seed) or horticultural purposes.*

5.5.3 Rationale

We dispute that CBD has "always been a drug under Schedule 2 of the Misuse of Drugs Act": this was introduced without any consultation in September 2017. We note that the reference to CBD - added in haste in 2017 ~~last year~~ - is going to be reversed as part of the work being done on the Medicinal Cannabis Scheme.

In August 2011 CBD was introduced as a prescription medicine along with THC in the Medicines Regulations 1984.

At a meeting with Medicines Control on 3rd May 2018, the issue of CBD as a controlled drug/prescription medicine and the effect this would have on naturally occurring CBD in other hemp products, was discussed.

The senior officials present confirmed that this would only be an issue if the hemp products were being used as a medicine, and would not affect the use of hemp products being used in other ways such as human and/or animal foods.

CBD in foods is specifically coved by the food variation. Other CBD restrictions are not required in the iHemp regulations, cannabinoids other than THC are irrelevant as they are not psychoactive. *It is totally impractical to redraft the regulations every time a new cannabinoid becomes popular, so why start here?*

Naturally occurring CBD does not require control in the iHemp regulations. Against our advice limits are included in the food variation, but for the purposes of the iHemp Regulations CBD Limits are irrelevant, we are only concerned with THC levels. CBD limits in the Food Variation, are specifically for hemp food products, and should not be used as justification to add more words and interpretations into the iHemp Regulations. Therefore, restrictions other than for the controlled drug THC, are not required.

Executive Recommendation

Hemp food products are adequately defined in the Food Variation. The iHemp regulations do not need further definitions when sector-specific legislation clearly defines how hemp products are applied in that sector.

The iHemp regulations are a licensing regime, the "responsible people" need to comply with the regulations for industrial hemp products, which are then used in other sectors with their unique requirements.

The responsible person holding the iHemp licence should not be expected to know all the other sector- specific legislation as in many cases this will not be relevant to them.

5.6 Interpretation of Hemp Product

We oppose the amendment to the definition of "hemp product" : the distinction between hemp products and therapeutic products will be made clear by the Medicinal Cannabis Scheme.

It should be noted that all products, derived in whole or in part from industrial hemp become hemp products. And the general provision in section 67 applies and no licence is required to be in possession of hemp products.

We agree that therapeutic products require a different production, testing and monitoring regime, but if they are derived from iHemp, then they are hemp products, grown under an industrial hemp licence. *This is an important point, as our iHemp farmers and growers may wish to grow to the specification of a medicinal cannabis product manufacturer or supplier.*

Clearly the industrial hemp can be grown under a general licence and the manufacturer/supplier is the correct person to have to comply with the Medicinal Cannabis Scheme. Part of the setup of the scheme will be to define suitable safety and quality standards, for the necessary compliance.

It seems logical that the Medicinal Cannabis Scheme would be incorporated under the Medicines Act 1981. The Medicines Act will then define a "medical cannabis product."

Any higher THC products, would need to be grown under a separate licence, authorised by MODA 1975 and the 1977 regulations, via the Misuse of Drugs (Medicinal Cannabis) Amendment bill – this will be the pathway for high THC therapeutic products to be made available to the medicinal cannabis industry. Low THC iHemp, would

be available via the iHemp regulations, as a hemp product and both would need to be produced to the required standards.

The iHemp industry is therefore ready to supply, hemp product into this market when it is created under the Misuse of Drugs (Medicinal Cannabis) Amendment bill. Any licensed medicinal cannabis product supplier will need to ensure that the iHemp they are using meets the safety and quality standards set up by the scheme.

5.7 Interpretation of Hulled Seeds and Whole Seeds

We disagree with the need for a definition of hulled seeds or whole seeds in the iHemp Regulations, as discussed previously, both these terms are suitably defined in the accompanying legislation, being Food Act 2014, adopting the food variation 1.4.4-6 (definition of hulled seed) and Misuse of Drugs Act 1975 (classification of whole seed).

We do not want to get into the situation, where the iHemp regulations need to be amended every time some associated piece of legislation gets updated.

Industrial hemp components (seed, fiber, roots, leaf) will ultimately be used in a massive range of industries, and for those that have specific legislation, regulations, codes etc, then these are the appropriate places to define how iHemp works in these sectors (food, medicines etc.).

Adding a definition of hulled seed or whole seeds adds nothing to the iHemp regulations and is unnecessary. It brings into the iHemp regulations a reference to CBD which is irrelevant - it is a red herring, since it should not be considered a controlled drug.

These additional definitions serve no useful purpose from Industry's point of view; they only add confusion, and do not encourage proper referral to other relevant legislation.

The regulations cannot accommodate everything. The duplication of information covered in other legislation would soon overwhelm the regulations and lead to conflicts with the relevant industry sector legislation.

This would add more problems to an already overwhelmed regulator, who would not only be responsible for the issuing of licences to grow iHemp and make hemp products, but they would then need to be familiar with all the associated legislation for the wide range of end uses.

Medicine and food are today's topics, but are you prepared to discuss building codes, supplements, veterinary medicines etc? The short answer is no, these other sectors and end uses have their own compliance frameworks, which do not have to be duplicated in the iHemp Regulations.

Executive Recommendation

Change MODA to remove whole hemp seed as per the United Nations Single Convention on Narcotic Drugs 1961 (see Article 28 on page 1). This would be in alignment with England, Canada and Europe, all of whom allow the public access to whole hemp seeds.

5.8 Interpretation of THC

The food variation which is being adopted includes a provision that in the case of foods THC and THC-A should be combined together. This relates specifically to hemp seed food products and may not be correctly applied to all hemp products.

The NZHIA is not in favour of letting a specific treatment with regard to 'hemp seed food products' to control the more general definition of 'hemp products'. In the future other sectors and end users might separately identify THC and THC A, and so the iHemp regulations should be kept general, with specific treatment made in the legislation for that particular end use/industry sector.

QUESTION 3
We do not agree with the proposed change for the reason given above

Part 4 – 6 Proposed Amendments to Licensing

Since 2006, Industry has also gained 'new knowledge and experience in working with the Regulations" and we would like to work with the Ministry of Health to ensure the Regulations remain "fit for purpose" and the appropriate level of regulatory oversight is applied to hemp licences.

"The document" has outlined several areas of interest and to this list we would like to add the other issues repeatedly raised by industry over the last 10 years , which relate to clarifying interpretations, keeping the regulations workable, the role of the responsible person, and the application form and guidance documents that contain questions which are not supported by the Regulations – See Section 6.1.4 – Question 5. These issues are currently being worked through in a series of meetings with senior Ministry of Health Officials.

Executive Recommendation

We encourage MPI to become part of these meeting as they are part of the "fit for purpose" review. We are happy to supply you with the details on the workability issues and interpretations which we are reviewing with the Ministry of Health. Please let us know a suitable Senior MPI person to include in these meetings.

This fit for purpose review~~,~~ ignores most of the points raised in the September 2017~~,~~ stakeholder meeting. This has clearly been a missed opportunity and has resulted in MPI raising only the points which MOH want to include. These actions will further restrict the hemp regulations and will continue to disable the industry.

We struggle to understand the reasons why MC continues to be unhelpful and restricting, when the iHemp regulations clearly create a situation which would allow them to enable our industry. This attitude has become noticeably more unhelpful in the last 9 years, resulting in a situation where the NZHIA has little faith in the ability of MC to administer the iHemp regulations, drawing on the spirit and intentions for which they were written.

We note the MC officials are callous in their dealings with the industry, many times lacking the courtesy to respond, and seeming to be unable or unwilling to support the development of the industry.

The workability issues can, for the main part, be handled by agreeing on the interpretation of the iHemp Regulations; these are simply things like requiring our licences to be securely kept (Section 29 of the regulations). Pharmacies and other business display their licences. We are very proud of our iHemp licences and believe that it would be appropriate to display our licences in a similar way (hanging on the office wall should be accepted as a "secure place").

If an interpretation cannot be agreed upon, or the intent is unclear, then a change to the regulations maybe required. Such amendments should be based on reason and logic and be supported by a fact and evidence-based approach.

Most of the recommended changes to the iHemp Regulations made in this document *do not* meet that criteria, and will, if adopted, diminish the effectiveness of the iHemp regulations. This is clearly unacceptable to Industry.

6.1 Regulation 7 – General Licence

It is very clear to NZHIA members that importing and exporting industrial hemp is a major part of the business plan. And is essential if we are going to realise the full economic potential of the industry.

There is a framework that allows us to import and export industrial hemp, via a controlled drug import/export licence, issued by the Ministry of Health. Industrial hemp seed has an import health standard for both sowing and processing seed, including biosecurity issues. Exports of industrial hemp that meet the legal requirements of the receiving country, and can be legally produced in New Zealand, should be able to be exported under the current framework.

Although we can import and export, we agree that the activities in section 7 are very New Zealand-orientated, and we would support adding two words "or overseas" after the word New Zealand, in section 7 (1) (a) and (c)

We disagree with adding "whole hemp seeds": there is no need to limit the import or export of industrial hemp to just 'whole seeds', since farmers are interested in the revenue streams from all parts of the industrial hemp plant, as allowed under the current legislation.

Hulled hemp seeds (as discussed above) are already a hemp product, so the usual raw food import and export requirements apply to this product.

We do not understand your reference in 6.1.2 Proposal …. Exempting "some hemp products from requiring a licence…" Surely if they are hemp products there is no licence required, as per Section 67 of the Regulations, "Permission".

6.1.3 Hulled hemp seeds are a hemp product and are non-viable, so do not need a licence currently. Medicines Control may have a different opinion on this, which is currently being disputed with the Ombudsman. Due to the acceptance of the food variation, their point of view becomes irrelevant, unless they want to be in conflict with the ANZFSA Food Minsters and obstruct a new industry for New Zealand.

QUESTION 4
We do not agree with the proposal or rationale, presented in "the Document" for the reasons given above. That said we have no objection to adding the words "or overseas" in to Regulation 7 (1) (a) and (c) as above.

6.1.4 General discussion point one (general licences)

The Document discusses the confusion around listing the cultivars on the licence, this is caused by a poorly worded question on the application form, Q 6.2 "Specify the approved cultivars proposed to be licenced for"

At the time of application, many people would not know what varieties they will be able to obtain, so it is logical that they would list all approved varieties, so having a button/option to select all approved varieties would save time.

A similar logic applies to Q 6.4 "who and where will seeds be obtained from" many applicants will not know which supplier they will end up using, so the answer on the application becomes "any suitably licensed hemp seed supplier" - which makes this question redundant and irrelevant, and it should therefore be removed from the application.

QUESTION 5
This is a workability issue related to the application form, it never required a change to Regulation 7, which is clear in that~~,~~ you can only grow the varieties issued on your licence. Medicines Control~~,~~ might change the wording on the licence, to "all approved varieties", but again this does not need a change to the iHemp Regulations.

QUESTION 5 Additional - Changes to the Application – A Workability issue
In addition to the above, the application should remove all questions not relevant to the licencing process and not in the regulations, these include: • Q 3.5 "is the premises within 5 km of a school…." this is a red herring and is not in the regulations 13(2c). It adds nothing to the application process, since a quick google search will show the regulator where the location is. The requirement is for a safe location, so why does this question on school add anything to the definition of 'safe'. You are still able to obtain a licence if within 5km of a residential zone providing the location is safe. • Q 7.2, "visible from the road"- this should be covered off in Q) 3.6 plan and should be included in the guidance notes. In time this will become irrelevant, and should not be identified as a problem, as it will be discussed in terms of the "safe location." <u>Declaration</u> • Line 3 – Am entitled to use the land, this is covered in Q7.1 • Line 4 – This should be changed to being familiar with the iHemp Regulations 2006 • Line 5 – the reference to police checks for all individuals over 17 years old, who work or reside on the site is not in the regulations and is not relevant, this is the sort of excessive compliance that will put farmers off getting involved in the industry.

6.1.5 General discussion point one (general licences)

Regulation (7) (1) activities allowed under a general licence. And (8) research and breeding activities.

We are not sure why you picked this section to comment on as "the Document" does not seem to raise any issues and therefore concludes the regulations are flexible enough and no change is required.

As nothing has changed we are interested to see how the "new guidance material accompanying the new regulations will explain how the activities section of the application work."

QUESTION 6
We agree there is no need to change 7 (1), but we are interested to see the guidance material and provide feedback on this document, in the same way we have reviewed the registers and other MOH documents, in advance of the much anticipated IT platform - which has now been in development for quite some time.

QUESTION 6 Additional – Change to Regulation (8)
We would support a change to regulation 8 (1) to allow processing, as this is part of the method to decide if a new variety is fit for use in a particular industry. Cultivars are bred for specific end uses; these will need to be tested and this may require them to be processed.

6.2 Regulation 9 – Individuals who are eligible to Hold Licences

Regulation 9 (f) and (g) do not repeat each other, as one relates to the licence holder complying with the obligations imposed under the regulations (f) and the second one relates to undertaking the activities on the licence (g).

Since the activities can vary from licence to licence then it is important to ensure that individuals have the expertise and resources to comply with the regulations and to undertake the activities sought.

We further note that Regulation 10 includes the same information for body corporates and partnerships (g) and (h), we must remain consistent.

No amendment is necessary for either regulation 9 nor 10 as they are not duplicated and deal with two separate areas. Having access to the expertise and resources to 1) comply with the obligations under the regulations and 2) undertake the activities on the licence.

Executive recommends

We disagree that this drafting amendment is necessary as the regulations are not duplicated for the reasons given above.

As with gun licences, convictions over 10 years old do not disqualify you from holding a licence. Growing hemp is not as dangerous as using a gun, so we would recommend a similar approach with regard to convictions would be suitable for the iHemp industry.

New licencees could build on the current 3 year approach, and then be allowed to apply for a renewal of licence with a 10 year period.

The licence should also include a credit card size version. This would cover the responsible person when transporting iHemp. Currently transport companies are exempt from holding a licence, but from time to time it is necessary for licencees to move iHemp product from fields to processors etc. Should we be pulled over by the police at this time, a driver's licence sized iHemp licence would confirm that we are authorised to be in possession of, and are responsible for the iHemp.

6.3 Regulations relating to locations stated on licences

Section 15 says the general licence should be $500, we would like Medicines Control to charge this as per the regulations, not $511 - as this sends mixed messages to the industry about MC's approach to the iHemp regulations.

Clarity should be given in the application guidance notes on refunds, an application should be pre-screened before an invoice is sent, to ensure all the basics are covered and nothing obvious (likely to stop a licence being issued) has been highlighted.

QUESTION 7
Having more than one property per licence – this makes sense from a workability approach, as storage, cleaning etc. may need to be done at other locations, rather than on the farm where the iHemp has been grown. Incurring additional fees to add a property to your current licence – it does not cost much to search a location on google maps, so we do not accept that this would justify an increase in cost (see 2.3.1) Suggestions for a different approach: Allow multiple locations at no extra cost

6.4 Regulation 67 - Permission

We disagree with the need to make any changes to regulation 67. Hulled hemp seed is a hemp product under the iHemp regulations. And hemp food products as defined in the Food Code variation 1.4.4 are also hemp products so there is no need to amend regulation 67 Permission. This is not a consequential amendment as it is not required. Even if you introduce a definition for hemp food products in the iHemp regulations it will relate to a hemp product already covered in Regulation 67.

Regulation 67 related to permission is clear, people who do not hold a licence do not commit an offence if they possess, use or trade in hemp products. When the food variation allows hemp food products, the regulations will naturally cover this, as a hemp product, for the reasons given throughout this consultation document.

This proposal will confuse the Permission by making a specific reference to hempseed foods, when the general approach of hemp products already covers what the permission sets out to achieve.

New and innovative products will be developed in the future and are covered adequately by the hemp regulations and any other legislative frameworks for their end use.

We do not want the situation to arise where each new product has to be acknowledged in the iHemp regulations. This is not the role of the regulations – the latter were created to issue licences and enable the industry, not disable it with unnecessary definitions and duplications of other legislative requirements.