

Supporting Document 6

International Hemp Regulations

Summary

This supporting document has been prepared from completed questionnaires received from various countries and jurisdictions plus additional information from other sources. The information presented can be split into 3 distinct geographical areas: New Zealand; North America; Europe.

The sale and consumption of hemp foods is permitted in all countries/jurisdictions reported on. The requirements relating to production of industrial hemp and THC content in food however varies considerably from very explicit and specific(e.g Canada) to less rigorous (e.g Ireland).

Where explicit controls do exist this is generally through a licensing system covering obtaining seeds for planting to end of processing hemp products.

The THC content in food is generally controlled via using low hemp cultivars, with some regions also setting THC limits in foods. Only Canada has specific detailed requirements regarding how to render and confirm seeds as non-viable. For other regions the lack of rules around viability seems to be a result of exemption of seeds from misuse of drug type regulations. The reasons for these exemptions were not explicit in the information reviewed but are likely to be due to the common understanding that the seeds do not contain THC.

With regard to the potential for positive drug tests for THC resulting from the consumption of hemp foods containing low THC values, the feedback from the questionnaires was either there was no evidence of issues or no information was available. Some responders made reference to research carried out on consumption of hemp foods and analysis of blood and urine for THC content. The overall conclusion was that consumption of food containing low levels of THC did not interfere with such tests. No information was provided on saliva drug testing and consumption of foods containing THC.

Similarly the feedback did not indicate any issues or major concerns regarding the permission to allow low levels of THC in foods and an increase in illicit drug use. However although the USA does have regulations to allow the cultivation of industrial hemp, including food use, obtaining licences has been difficult, if not impossible, due to the USA government concerns about the message it may give to the general public regarding illicit cannabis use.

Several countries, including New Zealand, have legislation in place which prohibits any reference to psychoactive activity appearing in any advertisement associated with hemp products.

Table 1 – Summary of regulatory approach to hemp foods

Country	New Zealand	Canada	USA*	UK	Netherlands	Italy	Austria	Belgium	Germany	Cyprus	Ireland
Hemp food allowed	Hemp oil only	yes	yes	yes – case by case	yes	yes	yes	yes – case-by-case	yes	yes	yes
THC limits in food	No limit defined	No more than 10ug/g	Zero	Case by case	no	Expected to be zero	Expected to be such that exposure does not exceed 1-2 ug/kg bw/day	10mg/kg – oil from seed 5 mg/kg – seed and flour 0.2 mg/kg other foods and drinks	Recommendations:5 µg/kg – beverages 5000 µg/kg oil 150 µg/kg other foods	Expected to be zero	Expected to be zero
Licence system for growing	yes	yes	yes	yes	no	Hemp production not allowed	yes	unclear	Information not provided	Information not provided	no
Seed control for production	Yes – expectation is for plants to yield no more than 0.35% THC	Yes – expectation is for plants to yield no more than 0.3% THC	yes	yes –EU regulations: must present in the Common seed catalogue	yes – EU regulations :must present in the Common seed catalogue	Not applicable no hemp production allowed	yes	yes	Information not provided	Information not provided	yes – EU regulations :must present in the Common seed catalogue
Unhulled seed allowed	no	yes	No information	Exempt from UK Misuse Drugs Act	yes	Work in progress	no	no	Information not provided	Information not provided	yes
Hulled seed allowed	no	yes	No information	Exempt from UK Misuse Drugs Act	yes	Work in progress	yes	unclear	Information not provided	Information not provided	yes

Table 1 – Continued

Country	New Zealand	Canada	USA*	UK	Netherlands	Italy	Austria	Belgium	Germany	Cyprus	Ireland
Viable seed specific controls	yes	yes	No information	Exempt from UK Misuse of Drugs Act	No controls	No information	no	no	Information not provided	Information not provided	no
Aware of any drug testing issues?	No information	No information	No information	No information – UK requires proof of task impairment before testing	no	No information	No evidence of issues	no	no	no	Not aware
Issues with associated illicit cannabis use	No information	No evidence available	No information	No information	no	No information	No information	no	no	no	Not aware
Any marketing issues i.e association with illicit cannabis use?	Reference to psychoactive activity is prohibited in any advertisement associated with hemp products.	Reference to psychoactive activity is prohibited in any advertisement associated with hemp products.	No information	No information	no	No information	No information	Some suppliers focus on cannabis aspect	no	no	Not aware

Summaries of individual country, states or jurisdictions approach to hemp foods

New Zealand

The Misuse of Drugs (Industrial Hemp) Regulations 2006 enables the cultivation and distribution of industrial hemp under a licensing regime that ensures other forms of cannabis are not cultivated and distributed under the guise of industrial hemp.

A licence is required to cultivate industrial hemp. Hemp means cannabis plant, seed or fruit. The licence details the exact activities which can be undertaken, by whom and where. Each individual along the supply chain needs to be named on the licence. In addition the licence lists which cultivars can be grown.

The licence requires various records to be kept including source, type and amount of seed, how much is planted, how much is harvested and explanation for discrepancy between numbers planted and yield. The licence is issued for 1 year but can be extended up to a maximum of 3 years.

Only hemp seed oil is permitted for human consumption as a food in New Zealand. Hemp seed oil can be produced in New Zealand providing it is derived from cannabis seed from plants that are grown in New Zealand under a licence issued by the Director-General of the Ministry of Health. For imported hemp seed oil to be allowed as a food it must first be tested by an analyst working in a laboratory approved under the Misuse of Drugs Act 1975, if the THC levels are acceptable it is authorised for sale and use.

No information was found on whether there is a limit for THC content in hemp oil approved for food use.

As hemp seeds can only be supplied under licence to another individual who has a valid licence the viability of hemp seeds has not been addressed under New Zealand legislation.

The Ministry of Health have issued Guidelines for the sampling of industrial Hemp for Testing. The objective of this testing is to ensure hemp plants have a THC content of less than 0.35%. Transport of samples for testing to an authorised laboratory is at the discretion of the grower/licence holder but needs to be fast and secure.

Under the Misuse of Drugs regulations any reference to psychoactive activity must not appear in any advertisement associated with hemp products, including oils.

North America

Canada

Canada allows the sale and consumption of hemp foods.

A licence is required to possess hemp seed or grain to conduct the following activities: cultivate, process (pressing for oil, rendering hemp seed/grain non-viable), import, export, sell and provide.

The THC concentration is controlled via an approved seed list. Having a list of permitted varieties ensures the level of THC does not exceed 0.3%. Also licenced individuals must have the crop tested to verify this.

The import of viable hemp seeds requires an import permit. The importation, exportation or wholesale sale of a hemp seed or grain derivative or a product made from that derivative is outside the legislation if:

- 1) the derivative or product was not made from whole industrial hemp plants. or
- 2) a representative sample from each lot/batch of the derivative or product being imported or export, or sold at wholesale, has been found to contain 10ug/g THC or less when tested at a competent laboratory using the prescribed analytical procedures.

Non-viable hemp seeds are also exempt but derivatives of non-viable seeds are **NOT**.

Health Canada has prepared an Industrial Hemp Technical Manual – Standard Operating Procedures for Sampling, Testing and Processing Methodology. This manual covers the following:

- Basic analytical procedure for determining THC level in industrial hemp
- Procedure for field sampling of industrial hemp stands
- Method for sample handling and preparation
- Basic method for determination of THC in hempseed oil
- Sampling of non-viable cannabis seed for viability testing
- Viability testing of non-viable cannabis seed
- Approved methods for rendering cannabis seeds non-viable
- Accreditation and qualification requirements for laboratories and for sampling and testing personnel
- Analytical performance standards

Non-viable grain is defined as intact viable grain which has been rendered non-viable using methods set-out in the Industrial Hemp Technical Manual and have been shown to be incapable of germination.

Approved methods for making seed non-viable are:

Steam heat: The use of steam for rendering seed or grain non-viable requires that the seed lot be homogenous and that all parts of the seed lot be subjected uniformly and continuously to steam heat for a minimum of 15 minutes. Due to the insulating properties of seed, care must be taken to assure that the entire lot is exposed to live steam (steam under pressure). If subsequent testing shows that the lot is not 100% non-viable, the process must be repeated.

Infra-red cooking process: This is accomplished by first tempering the seed to a moisture content of 13 to 14 %. The seed is then heated using natural gas generated infra-red energy of a wavelength of 1.8 to 3.2 microns. The seed must be heated to a minimum temperature of 110 degrees Celsius. The seed flow rate must be set to assure that the time of cooking includes heating time from ambient to treatment temperature, and that treatment time is sufficient to result in non-viable seed. If subsequent testing shows that the lot is not 100% non-viable, the process must be repeated.

The Regulations also require that persons who possess seed or viable grain for the purpose of rendering it non-viable shall have it tested for viability at a laboratory that is designated as an accredited laboratory under section 14 of the Canada Agricultural Products Act and keep

records to demonstrate that the rendering process was successful. It is the responsibility of the processor, not the supplier of the grain or the recipient of the oil or meal to assure that testing is done after treatment. Accredited laboratories must also have authorization to possess industrial hemp grain or seed.

After it has been proven that the seeds are non-viable, the whole seeds are exempt from the regulations and unrestricted sale and provision is permitted. However if a derivative (e.g shampoo) is made from the non-viable seed a licence to produce the derivative is needed unless the starting derivative or products contains 10 mcg/g THC or less and the product is not modified to increase the THC level.

Viability testing of cannabis seed must be conducted on all lots of non-viable cannabis seed using a method extracted from the International Rules for Seed Testing (ISTA 1996). For the lot to be considered non-viable there must be 0% normal seedlings and a maximum of 5% abnormal seedlings. Laboratories conducting this testing must be authorized by the Minister and accredited for seed testing by the Canadian Food Inspection Agency, or by the International Seed Testing Association.

The response to questions around human drug testing and how the legal availability of hemp seeds has impacted on illicit cannabis use was “No information available”.

Similarly no information was provided on compliance and enforcement of hemp foods.

United States of America (information obtained from various sources, no questionnaire response)

Any item which contains any quantity of THC is a schedule 1 drug under the US Controlled Substances Act (CSA) unless the Drug Enforcement Administration (DEA) has exempted the item from control or listed it in another schedule based on FDA-approved medical use. Hemp products which are exempt are those which are considered by DEA not to result in THC entering the human body e.g paper, rope, clothing, animal feed mixtures, soaps and shampoos.

Growing industrial hemp in the US is not strictly illegal, however it requires a permit granted by DEA which has proven difficult to obtain.

The US does allow the import of foods (e.g oil and seeds) which has been derived from hemp but it has a zero tolerance on THC levels and the seeds must be non-viable. Certification to these effects is required.

A 2010 report “Hemp as an Agricultural Commodity”, prepared for the US Congress concluded “The main obstacles facing the potential market are US government drug policies and DEA concerns about ramifications of the US commercial hemp production. These concerns are that commercial cultivation could increase the likelihood of covert production of high THC-marijuana, significantly complicating the DEA’s surveillance and enforcement activities and send the wrong message to the American public concerning the government’s position on drugs.”

European Union

EU laws do allow the marketing of hemp products and also the cultivation of industrial hemp. However whether these activities actually occur in individual countries and if they do, the

specific rules around them are decided on a case-by-case basis at a member state level (see individual EU country reports).

Hemp products produced in the EU can only be grown from varieties listed in the Common catalogue of varieties of agricultural plant species (http://ec.europa.eu/food/plant/propagation/catalogues/index_en.htm).

In 2009 the EU regulations were amended to indicate that the maximum content of THC allowed in hemp plants must be lower than 0.2%.

EU Regulations on General Food Law, which covers food during manufacture, preparation or treatment, recognises "...any product being extracted from or made on the basis of hemp can be considered as narcotic drugs in the meaning of the United Nations Convention on Narcotic Drugs (1961) and the United Nations Convention of psychotic substances (1971). According to Article 2(g) of Regulation (EC) N° 178/2002 (General Food Law), narcotic or psychotropic substances covered by the aforesaid conventions should not be considered as "food" and consequently, they should not be allowed to be incorporated into the food during manufacture, preparation or treatment. Member States are responsible for enforcing food law. That is, how food law is enforced is at the discretion of individual Member States. See sections for individual EU countries for information (when provided) on approaches taken by individual member states.

Within the EU foods containing hemp products are allowed in several countries including UK, Germany, Austria, Finland, Italy but not in others e.g France, Greece and Spain. This is despite France and Spain allowing industrial hemp production for other purposes and Italy not allowing commercial hemp production for any purpose.

United Kingdom

In the UK the use of hemp in food is considered on a case-by-case basis. Factors considered include the amount of hemp present in the final product, the extent of use and anticipated intake.

Cannabis is controlled under the Misuse of Drugs Act 1971 (MDA). However when separated from the plant the following are exempt: mature stalk or any such plant; fibre produced from mature stalk of any such plant and seed of any plant.

Although the MDA in general prohibits the cultivation of any plant of the cannabis genus it does have "other special purposes" which is used to allow the commercial cultivation of industrial hemp fibre and pressing the seed for oil. Interestingly no mention of other food forms is mentioned (UK Home Office, Low THC Cannabis (Industrial Hemp) Licensing Factsheet- Mar 2011 V 1.0).

The UK Home Office is responsible for issuing licences to cultivate and possess industrial hemp. As part of the licence granting procedure a commercial end use needs to be defined. Records need to be kept of locations, planting, seed types (only those in the EU common seed catalogue can be used) and crop yields.

The UK take a "light touch regime" approach to industrial hemp cultivation which means for the vast majority of applications they do not expect to undertake a site or compliance visit.

Previously industrial hemp had to be screened and planted in locations away from schools, public rights of way or vehicular access. These rules have now been relaxed and a more performance based approach taken. The requirement is now to site the crop sensitively.

Industrial Hemp growers can claim a subsidy from the government for growing the crop, however this does not seem to apply if the crop is grown solely for food.

The UK response questionnaire did not provide any information with regard to association with use of illicit cannabis or driving drug levels, however the following was sourced from other sources.

In October 2001 the UK Home Secretary requested the Advisory Council on the Misuse of Drugs to review the classification of cannabis preparations. The Council's report considered "Does cannabis use lead to other drug use?". Their conclusion was "It is not possible to state, with certainty, whether or not cannabis use predisposes to dependence on Class A drugs such as heroin or crack cocaine. Nevertheless the risks (if any) are small and less than those associated with the use of tobacco and alcohol."

UK driving laws (Road Traffic Act 1988) states that it is an offence to drive whilst unfit through drugs. The police are empowered to test for drugs. Before a bodily fluid test is carried out, firstly there has to be evidence of impairment. Physical tests such as pupil size and appearance; walking and balance tests are initially performed at the road side. If the police suspect impairment then at a police station the individual is examined by a trained medical examiner who may take a blood test.

The Netherlands

Food containing hemp is allowed to be sold and consumed in The Netherlands.

The Dutch do not have any specific laws governing hemp in food, therefore EU laws and regulations are followed. The information provided indicates there are no maximum levels for THC in food for the Netherlands, no licencing requirements, no import restrictions and no THC based controls on the seed.

The seeds from Cannabis plants are exempt from the Dutch Opium Act.

No information was provided on THC drug testing in relation to food or effect of the availability of hemp foods on the illicit cannabis use. No issues were noted regarding the promotion of drug-like effects as part of the marketing of hemp foods.

Italy

Italy allows hemp based foods. The THC level is currently expected to be zero but this may be revised in the future.

Local health authorities, fraud squad and import authorities have the responsibility for checking the THC level in food. At the border the checks are carried out on the documentation plus sampling and analysis may be performed.

Currently the Italian authorities are finalising procedures around the availability of whole hemp seeds but no details were provided.

The communication stated that hemp production is not allowed in Italy.

Austria

Austria permits the sale and consumption of hemp containing foods. There are no Austrian specific legal requirements for hemp foods, therefore EU laws and regulations are followed. There is an Austrian Narcotics Drugs Decree which covers hemp varieties; this Decree excludes inflorescences and infructescences of cannabis plants.

Based on the European General Food Law Regulation (EC) 178/2002 requirement that food has to be safe, the Austrian expectation is that the THC content in foods must not exceed 1-2 ug/kg bw/day. The communication also mentioned specific product guidance values but no further information was provided.

The communication mentioned a recent EFSA review regarding the use of hemp in animal feed. One of the outcomes of that review was a recommended provisional maximum tolerable intake (PMTDI) of 4 µg THC bodyweight for humans (for further information see SD1, Section 1.2, *EFSA Opinion*).

Austria has no direct experience with drug testing results but referred to a German study (published 2008) where students were fed hemp chocolate, granola bars etc which had quantifiable amounts of THC. Although large amounts were consumed and blood and urine samples were taken on an hourly basis no positive blood or urine results were obtained. Experiments involving considerable amounts of hemp tea produced similar results. The overall conclusion was that hemp-containing foodstuffs which meet German guidance values and consumed in normal amounts do not lead to blood concentrations associated with hallucinogenic effects or positive Cannabis results. No information was provided on saliva testing.

The Austrian Food Inspection Authorities are responsible for THC compliance in food. Hemp foods such as seeds, oil, butter, beer and chocolates are tested on a case by case-basis for THC content. Hemp tea is tested on a routine basis. In the last year the failure rate was approximately 1%. The information provided indicates that the expectation is for these foods not to contain THC. As the limit for THC in food mentioned previously in the correspondence from Austria is based on a bodyweight per day value which appears to then be extrapolated to a specific product value (also mentioned above) we assume the comparison of the test result is against the product specific value.

The THC content in field samples is tested by the accredited AGES- Competence Centre Veterinary Drugs and Hormones. They have had no reports of samples being outside the limits of 0.2% THC (about 50% had a maximum of 0.01 to 0.1% THC, the rest were between 0.1 and 0.18%).

Belgium

Belgium permits the sale and consumption of hemp foods. Prior to the food being available for sale, it must be granted an exemption from the Belgian food regulations. Exemptions are granted on a case-by-case basis. To date these include: tea based beverages; alcoholic beverages; oil; seeds; flour.

For those foods where exemptions are granted the level of THC needs to be provided on a batch basis and maximum levels must not exceed these values. These provisions also apply to imported foods containing THC.

Oil of seed: 10 mg/kg
Seed and flour of seed: 5 mg/kg
Other foods and drinks: 0.2 mg/kg

The above limits are based on evaluation in the previous hemp food application, A380,

carried out by FSANZ.

The Belgians are not aware of any issues associated with positive drug test results and availability of hemp foods. They use the batch testing for THC content to counteract the possibility of high THC products getting into the food chain. In addition, any hemp production needs to comply with EU regulations and laws on type of seed used.

The communication commented on issues around suppliers who use the hemp leaf motif with an aim of increasing market share of their products but no information on how/if this was addressed.

Germany

Germany allows the sale and consumption of hemp based foods. They do not have any specific regulations on hemp-containing foods, however the following recommendations for the maximum content of THC in foods exist:

5 µg/kg for non-alcoholic and alcoholic drinks

5000 µg/kg for edible oils

150 µg /kg for all other foods.

The response from Germany indicated they are not aware of any issues associated with positive drug test results and availability of hemp foods.

Cyprus

Similar to the Netherlands and Ireland, Cyprus do not have any specific hemp products in food regulations, therefore EU laws and regulations will apply with regard to seed. Similar to Ireland, the expectation seems to be that hemp based foods would have no detectable levels of THC.

No information was provided on THC drug testing in relation to food or the effect of the availability of hemp foods on illicit cannabis use.

Ireland

To date the presence of THC in hemp foods in Ireland has not been an issue and thus there is no specific regulation. The expectation is that hemp food would contain zero THC.

In the absence of specific country laws and regulations, growing of cannabis for industrial hemp production is governed by EU laws and regulations.

No information was available on THC drug testing in relation to food or effect of the availability of hemp foods on illicit cannabis use.

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Denmark (not included in summary table due to ambiguity)

The response from Denmark stated "...that foods or food ingredients from Cannabis sativa containing THC cannot be legally marketed in Denmark as food." However it then continues to state if substances derived from Cannabis sativa is added to foods for nutritional or physiological purpose it might need to be assessed by the Danish Veterinary and Food Administration. This latter comment indicates that providing the THC content is zero hemp based foods would be allowed in Denmark.

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