MODERNIZING THE INDUSTRIAL HEMP REGIME

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EXECUTIVE SUMMARY

- The CHTA represents the Canadian industrial hemp industry. The Canadian industrial hemp industry is relatively young, but strong. It has grown significantly since the introduction of the regulatory regime in 1998 and Canada is now the largest exporter of industrial hemp worldwide. It is estimated that by 2020, exports of Canadian hemp products will total at least $142 million.

- Canadian industrial hemp contains less than 0.3% tetrahydrocannabinol ("**THC**") and other non-psychoactive cannabinoids, including cannabidiol ("**CBD**") and cannabinol ("**CBN**"). These non-psychoactive cannabinoids have a number of therapeutic uses and, when harvested from industrial hemp, exist in the absence of THC and display superior medicinal properties compared to synthetic cannabinoids.

- The existing regulatory regime for industrial hemp only permits the harvest, sale and processing of viable and non-viable seeds (with Health Canada permits) and plant stalks (as a non-controlled substance). It does not permit the harvest, sale or processing of other plant parts, such as leaves and flowers. This material is rich in non-psychoactive cannabinoids. As a result, the Canadian industrial hemp industry is missing out on a very lucrative market and Canadians are missing out on potentially useful therapeutic, natural health products and foods made from low-THC *Cannabis*.

- The availability of naturally-sourced non-psychoactive cannabinoids in industrial hemp, coupled with the global demand for these non-psychoactive cannabinoids for use in therapeutic products, natural health products and foods is a tremendous opportunity for Canadian hemp farmers. A field of hemp is estimated to produce over 12 kg CBD per hectare.

- Despite the absence of THC in industrial hemp, and the widespread recognition that CBD and CBN are neither psychoactive nor addictive, these non-psychoactive cannabinoids in industrial hemp are included in Schedule II to the *Controlled Drugs and Substances Act* (the "**CDSA**"). There is no basis in science or policy for the continued inclusion of these cannabinoids on Schedule II, particularly where they exist in the absence of THC. Indeed a number of other jurisdictions are currently considering reform to the regulation of these non-psychoactive cannabinoids to permit their use in therapeutic products, natural health products and foods.

- Given the above, the CHTA seeks the following regulatory reform:

    - Amend Schedule II to the CDSA to:

        - carve out "industrial hemp" from the definition of *Cannabis*; or

        - carve out non-psychoactive cannabinoids in, or from, Cannabis containing less than 0.3% THC; and

    - Amend the Industrial Hemp Regulations to allow for the harvest, sale and processing of whole plants.

- The CHTA is not advocating for deregulation of industry and welcomes Health Canada's continued oversight to ensure no misuse or illicit traffic of controlled substances through the industrial hemp regime.

MODERNIZING THE INDUSTRIAL HEMP REGIME

INTRODUCTION

The Canadian Hemp Trade Alliance ("**CHTA**") was established in 2003 as a national organization to represent Canada's industrial hemp industry. The CHTA promotes Canadian industrial hemp and hemp products globally, disseminates information and coordinates research. It currently has over 360 members, including farmers, processors, manufacturers, researchers, entrepreneurs and marketers.

The industrial hemp plant, *Cannabis sativa* L., is the same species as marijuana, although hemp and marijuana have important differences in genetic make-up, and in particular, the genes for cannabinoid production. Marijuana contains major genes that allow for the production of THC while hemp does not. In addition, hemp tends to contain higher levels of other cannabinoids, particularly those that are non-psychoactive. In Canada, *Cannabis sativa* plants that contain more than 0.3% THC are deemed to be marijuana and those containing 0.3% or less THC are classified as hemp.

Hemp is currently grown in Canada for grain and fibre. It is produced under permits issued by Health Canada pursuant to which seed and grain can be sold and transformed. The remaining plant parts (other than stalks) cannot currently be harvested or sold under Canadian law.

However, these remaining plant parts (and in particular, the leaves and modified leaves surrounding the seed (bracts)) contain non-psychoactive cannabinoids which have been identified and are currently being studied for a number of therapeutic uses.

The growing body of evidence supporting the therapeutic use of non-psychoactive cannabinoids is motivating re-evaluation of the way the *Cannabis* plant is regulated in a number of other global jurisdictions. Regulators are making way for the processing of non-psychoactive cannabinoids for therapeutic uses.

The continued listing of the non-psychoactive cannabinoids with potential therapeutic use on Schedule II of the CDSA has no basis in either science or policy. By way of example; it is widely understood that CBD has no psychoactivity and is not addictive, and there is a growing body of clinical research demonstrating its potential therapeutic uses.

The international drug control treaties to which Canada is a party only require protection against misuse and illicit traffic in the leaves and flower parts of the *Cannabis* plant. These treaties do not prohibit the cultivation of *Cannabis* for commercial or therapeutic purposes, as long as adequate protections against misuse and diversion are in place. Furthermore, any such restrictions are subject to the country's constitutional principles and the basic concepts of its legal system. The CDSA provides for the making of regulations to enable the use of controlled substances for therapeutic applications, and amendments can be made to the CDSA Schedules where doing so is in the public interest.

Canada has been a world leader in hemp production, and is the largest exporter of hemp products. However, competitors in the US, Europe, Australia and other countries could dominate this new and potentially very lucrative market because governments in those countries are amending regulatory regimes to allow for the harvest, sale and processing of non-psychoactive cannabinoids. Doing the same in Canada would bring great financial benefit to Canadian industry, amounting to potential revenues of several hundred million dollars to the industry from a multi-billion dollar CBD market.

The CHTA appreciates the opportunity to make these submissions, and to work with the Government to amend the regulatory regime for industrial hemp. The CHTA supports continued regulatory oversight of the Canadian industrial hemp industry, while allowing for whole plant use for the harvest, sale and processing of non-psychoactive cannabinoids. In this way the industry can continue to be a global leader in the cultivation and exportation of industrial hemp.

THE CANADIAN INDUSTRIAL HEMP INDUSTRY

Commercial hemp has been successfully cultivated in Canada since the introduction of the *Industrial Hemp Regulations* (the "**Regulations**") in 1998. The creation of the regulatory regime for industrial hemp was largely motivated by economic factors, i.e. the cultivation of industrial hemp as a potential source of jobs and income in the Canadian agricultural and industrial sectors.[1] In addition, there was an increased need to develop alternative sources of fibre.

In response to these needs, and following Health Canada's determination that industrial hemp could be successfully grown in Canada as something separate from marijuana, the Regulations were created and a new Canadian industry was born.[2]

Hemp is an important and growing part of the Canadian agriculture industry. High margins for producers have attracted many new growers, and licensed acres have grown by over 20% per year for the last five years, reaching approximately 84,000 acres in 2015. While still small relative to other more established commodities, this is impressive growth for a crop introduced to Canadian farmers less than 20 years ago.

Exports of Canadian hemp products have grown by almost 50% per year in the last five years to reach exports of $110 million in 2015. Canada is currently one of the largest exporters of industrial hemp. If exports grow at the same rate as seeded acres (lower than the current rate of growth), by 2020 the value of total exports of hemp products will be at least $142 million.[3]

Canadian-grown hemp stalk, fibre and seeds have been used in the manufacture of hundreds of products, including construction material, animal bedding, paper, rope, furniture, textiles, clothing, food, and personal care items. We are now seeing similar demand for new uses of this plant, which call for the opening of a new, regulated market.

As demonstrated by the impressive growth in hemp production and exports, Canadian farmers have an excellent capacity to adopt new crops and expand production in response to growing demand. A new market opportunity arising from the use of Canadian industrial hemp as a source of non-psychoactive cannabinoids can be readily captured by Canadian producers.

THE CANADIAN INDUSTRIAL HEMP REGULATIONS (the "Regulations")

The Regulations were enacted pursuant to section 55 of the CDSA.[4] The CDSA and its Regulations provide a framework for the control of substances that can alter mental processes and that may cause harm to an individual or to society when diverted to an illicit market.[5] The Regulations thus permit the legal production and processing of hemp for commercial purposes while providing compliance and enforcement mechanisms to prevent diversion of *Cannabis* to the illicit drug market.

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[1] As stated in the Regulatory Impact Analysis Statement that accompanied the introduction of the Regulations in 1998: Recently, there has been renewed interest in the cultivation of industrial hemp. It has been suggested that this may provide an alternative crop for some regions of Canada. The introduction of industrial hemp may thus translate into new jobs in agriculture, industry, research and retail.

[2] http://www.hc-sc.gc.ca/hc-ps/substancontrol/hemp-chanvre/about-apropos/faq/index-eng.php.

[3] Based on annual growth of 20 per cent for each hemp product component from 2014 actual values, hemp fiber exports grow by 9.5 per cent per year and are quite small.

[4] Section 55 of the CDSA enables the making of regulations to (among other things) enable the use of controlled substances for medical, scientific and industrial applications. As explained by the Supreme Court of Canada in *R. v. Smith* [2015] 2 S.C.R.: "In recognition of the fact that controlled substances may have beneficial uses, the CDSA empowers the government to create exemptions by regulation for medical, scientific or industrial purposes (s. 55).

[5] See for example: http://www.hc-sc.gc.ca/ahc-asc/legislation/acts-reg-lois/acts-reg-lois/faq-ncr-rss-eng.php.

MODERNIZING THE INDUSTRIAL HEMP REGIME

"Industrial hemp" is defined in the Regulations as the plants and plant parts of the genera *Cannabis* with leaves and flowering heads containing no more than 0.3% THC and a maximum level of 10 ppm for THC residues in products derived from hemp grain. Determination of THC levels is based on plant samples prepared following a strict protocol adopted by Health Canada.

Among other things, the Regulations control the import, export, cultivation, processing and advertising of industrial hemp through a system of registration, licencing, permit and authorization and Health Canada oversight of the industry. The activities regulated by the Regulations are as follows:

	Import Export	Possession	Production	Sale Provision	Transport Sending Delivering
"industrial hemp" stalks, seeds and derivatives	√	√*	√	√*	√*
sprouts, leaves, flowers, bracts	X	√	√	X	√
derivative or product made from sprouts, leaves, flowers, bracts	X	√	X	X	√
derivative of seed, viable grain or non-viable grain (or product made therefrom) containing +10µg/g THC	X	√	√	X	√
* to the extent necessary to conduct the licensed activity					

The Regulations require disposal of the leaves and flowering heads of industrial hemp by retting or otherwise rendering them into a condition such that they cannot be used for any purpose not permitted under the CDSA.

THE CANNABINOIDS PRESENT IN INDUSTRIAL HEMP

The *Cannabis sativa* plant is highly complex, with hundreds of chemical constituents, including over 80 cannabinoids,[6] a unique set of compounds secreted in trichomes found primarily on the bracts surrounding the flower or seed. It is generally understood that cannabinoids imitate endocannabinoids (compounds made naturally by the human body) and in this way, have a host of potential therapeutic uses.[7]

THC, CBD and CBN

The most abundant (and talked-about) cannabinoids in *Cannabis sativa* are THC, cannabidiol ("**CBD**") and cannabinol ("**CBN**").[8] One of the main differences between hemp and marijuana is the cannabinoid profiles, or more specifically, the ratios of THC and CBD.[9]

[6] Etienne P. M. de Meijer, et. Al., *The Inheritance of Chemical Phenotype in Cannabis sativa L.,* 163 Genetics 335, 335 (Jan. 1, 2003), available at http://www.genetics.org/content/163/1/335.full.pdf+html.

[7] See, for example, the HC Cannabinoid Information Document (http://www.hc-sc.gc.ca/dhp-mps/marihuana/med/infoprof-eng.php). The CHTA acknowledges that the HC Cannabinoid Information Document does not express conclusions from Health Canada about the appropriate use of cannabinoids for medical purposes, and is not an endorsement of the use of cannabinoids by Health Canada.

[8] HC Cannabinoid Information Document, section 1.1.1.

Cannabinoid Concentrations

Marijuana typically contains THC concentrations of 3-15% (or higher) while hemp typically contains less than 1% (and in Canada, less than 0.3%). A level of about 1% THC is considered the threshold for *Cannabis* to have a psychoactive effect or an intoxicating potential.[10]

Hemp generally has more CBD than marijuana, and can often reach 6% in the leaves and bracts, as analyzed according to Health Canada guidelines. RPC Science and Engineering, in its capacity as an approved testing lab for THC monitoring, notes that Canadian hemp samples generally contain between 1 and 5% CBD. A field of hemp is estimated to produce over 12 kg CBD per hectare. Of particular interest, researchers have documented that naturally-sourced CBD displays superior medicinal properties compared to synthetic CBD.[11]

CBN is not a naturally-occurring substance, but instead exists by the degradation of THC in plant material upon exposure to UV light, heat, oxygen and poor storage conditions.[12] Given its origin as a degradation artefact of THC, and given the very low levels of THC in industrial hemp, the percentage of CBN in industrial hemp is trace or undetectable. According to RPC Science and Engineering, Canadian industrial hemp contains less than 0.05% CBN.

Psychoactive Properties

It is well known that THC is the cannabinoid in *Cannabis* that is responsible for the plant's psychoactive effects. It is also well known that CBD has no psychotropic properties, and CBN has little if any. As set out in Health Canada's May 2013 Addendum to the *Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids* (February 2013 version) (the "**HC Cannabinoid Information Document**"): THC is responsible for most of the psychotropic effects of cannabis; CBD and CBN have little, if any, psychotropic properties.[13] Throughout the HC Cannabinoid Information Document, CBD in particular is classified as a non-psychotropic cannabinoid.[14]

CBD has very low affinity for both CB_1 and CB_2 receptors, and this is thought to explain its lack of psychotropic activity. In addition to lacking psychoactivity, CBD may also counteract the psychoactive effects of THC. As articulated by Dr. Steven Laviolette in the attached paper:

> … whereas THC has been repeatedly demonstrated, in both clinical and pre-clinical research studies to possess psychoactive effects in the mammalian brain, emerging evidence demonstrates that CBD can block the effects of THC both in terms of central nervous system side effects, and at the pharmacological level.[15]

There is also preclinical and clinical data demonstrating that CBD may be useful as an intervention for addictive behaviors.[16]

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[9] Shannon L. Datwyler & George D. Weiblen, *Genetic Variation in Hemp and Marihuana (Cannabis sativa L.) According to Amplified fragment Length Polymorphisms*, J. Forensic Sci. Vol. 51 No. 2, 371, 271 (March 2006), available at http://geo.cbs.umn.eduDatwyler&Weiblen2006.pdf.
[10] Hemp as Agricultural Commodity at p. 2.
[11] https://www.endoca.com/blog/cbd-extract-vs-synthetic-cbd/
[12] Cannabinol Position Paper, Maya R. Chaddah at p. 1, attached at Appendix "A".
[13] HC Cannabinoid Information Document, section 1.1.1.
[14] See for example, section 2.1.
[15] CBD Position Paper, Evidence for the Safety and Clinical Efficacy of Cannabidiol, Steven R. Laviolette at p. 1, attached at Appendix "B".
[16] http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4444130/pdf/sart-9-2015-033.pdf.

Potential Therapeutic Uses

There is a growing body of evidence supporting the potential therapeutic uses of the non-psychoactive cannabinoids found in *Cannabis*. The evidence supporting the therapeutic uses of CBD is more advanced than that relating to the uses of CBN or other non-psychoactive cannabinoids.

According to Dr. Laviolette, there is now "compelling" clinical and pre-clinical evidence of the powerful therapeutic applications of CBD in the treatment of a number of disorders. This is also echoed by Health Canada in the HC Cannabinoid Information Document:

> Cannabidiol (CBD) … affects the activity of a significant number of other targets including ion channels, receptors, and enzymes. Results from pre-clinical studies suggest **CBD has anti-inflammatory, analgesic, anti-nausea, anti-emetic, anti-psychotic, anti-ischemic, anxiolytic, and anti-epileptiform effects**.
>
> …
>
> Much of what is known about the beneficial properties of the non-psychotropic cannabinoids (e.g. CBD, THCV) is derived from in vitro and animal studies and few, if any, clinical studies of these substances exist. However, the results from these in vitro and animal studies point to **potential therapeutic indications such as psychosis, epilepsy, anxiety, sleep disturbances, neurodegeneration, cerebral and myocardial ischemia, inflammation, pain and immune responses, emesis, food intake, type-1 diabetes, liver disease, osteogenesis, and cancer**.[17] [emphasis added]

Of note, Health Canada has approved, SATIVEX® a pharmaceutical product containing THC and CBD for use as an adjunctive treatment for symptomatic relief of spasticity in adult patients with multiple sclerosis.[18] We are unaware of any CBD-only product available in Canada.

The common pharmacological characteristics attributed to CBN are as a sedative, antibiotic, anti-convulsant and anti-inflammatory. Preclinical studies have discovered roles for CBN in analgesia, treatment of psoriasis, bone formation, facture healing, multidrug resistance, inhibition of antibiotic resistant *Staphylococcus aureus* and immune regulation.[19]

The CHTA is not advocating for any specific use of CBD or CBN, recognizing that more research and clinical studies are likely needed before the approval of therapeutic products, natural health products or foods containing these cannabinoids. However, the CHTA acknowledges that CBD (and to a similar extent CBN) presents much potential for therapeutic uses, particularly in the absence of THC, and wants its members to be in a position to take advantage of the growing market for these naturally-sourced, non-psychoactive cannabinoids in Canada and elsewhere.

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[17] HC Cannabinoid Information Document, section 2.1. See too: Aizpurua-Olaizola et al., *Evolution of the Cannabinoid and Terpene Content during Growth of Cannabis sativa Plants from Different Chemotypes*, Journal of Natural Products, October 23, 2015; The Supreme Court of Canada decision in R. v. Smith (2 S.C.R. 602) at paragraph 7(1): "The active compounds of the cannabis plant, such as THC and cannabidiol, have established medical benefits and their therapeutic effect is generally accepted…".

[18] See Sativex® Product Monograph: http://www.ukcia.org/research/SativexMonograph.pdf

[19] Izzo, AI, Borrelli, F., Capasso, R., Di, Marzo V, Mechoulam R. Non-psychotropic plant cannabinoids: new therapeutic opportunities from an ancient herb. Trends Pharmacol. Sci. 2009;30:515-527.

THE REGULATION OF CBD AND CBN IN CANADA

As set out above, the CDSA and its regulations provide a framework for the control of substances that can alter mental processes and that may produce harm to an individual or to society when diverted to an illicit market, including *Cannabis*.[20] Schedule II to the CDSA contains "cannabis, its preparations and derivatives" and a list of substances that are included in the definition. This list includes marijuana, CBD, CBN and THC.

Canada regulates "controlled substances" in accordance with its obligations pursuant to international treaties. Pursuant to these, Canada is required to implement measures to prevent the misuse of, and illicit traffic in (among other things) the leaves and flower parts of the *Cannabis* plant. These obligations do not prohibit the cultivation of *Cannabis* for commercial or therapeutic purposes.[21]

The 1961 UN Single Convention on Narcotic Drugs recognizes that the medical use of narcotic drugs continues to be indispensable for the relief of pain and suffering and that adequate provision must be made to ensure the availability of narcotic drugs for such purposes. This Convention requires signatories to ensure the availability of such drugs for such purposes. It also requires signatories to control against abuse by (among other things) preventing the misuse of, and illicit traffic in, the leaves of the *Cannabis* plant. *Cannabis* (cannabis and cannabis resin, and extracts and tinctures of cannabis) were included in Schedules I (substances considered addictive and harmful) and IV (substances with "particularly dangerous properties"). With regard to Schedule IV narcotics in particular, Article 2, 5 (b) of the Convention says:

> A Party shall, if in its opinion the prevailing conditions in its country render it the most appropriate means of protecting the public health and welfare, prohibit the production, manufacture, export and import of, trade in, possession or use of any such drug except for the amounts which may be necessary for medical and scientific research only…

The 1971 UN Convention on Psychotropic Substances specifically permitted the use of marijuana for limited medical purposes by duly authorized persons.

The 1988 Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances required countries to take measures to prohibit the cultivation, production, possession and trafficking of psychoactive substances, and the cultivation and possession of *Cannabis* for personal use.

It is important to note that none of the conventions require countries to make drug use *per se* a criminal offence. The treaties do not require countries to 'prohibit' any of the classified substances in themselves. Rather, the treaties establish a system of strict legal control of the production and supply of controlled drugs for medical and scientific purposes, as well as introducing sanctions aimed at combating the illicit production and distribution of these same substances for other purposes.

Canadian courts have confirmed the scope of these international treaties and specifically that they permit Canada to create regimes for the therapeutic use of the *Cannabis* plant. Indeed, the Canadian

[20] See for example: http://www.hc-sc.gc.ca/ahc-asc/legislation/acts-reg-lois/acts-reg-lois/faq-ncr-rss-eng.php.

[21] See, for example the Regulatory Impact Analysis Statement that accompanied the introduction of the Regulations in 1998: Internationally, *Cannabis* falls under the United Nations' *Single Convention on Narcotic Drugs, 1961* which Canada has signed and ratified. The Convention requires measures to prevent the misuse of, and illicit traffic in, the leaves of the *Cannabis* plant. However it does not prohibit the cultivation of industrial hemp for commercial purposes.

Marihuana Medical Access Regulations (the "**MMAR**") and subsequently the *Marihuana for Medical Purposes Regulations* (the "**MMPR**") established such a regime.

Canadian courts have further confirmed that any regime that allows for the therapeutic use of a controlled substance (like the *Cannabis* plant) must comply with constitutional principles. As noted by the Ontario Court of Appeal in *R. v. Parker*:

> [147] … The 1988 Convention requires states to prohibit possession, purchase and cultivation of marijuana for personal use, subject to the country's "constitutional principles and the basic concepts of its legal system". It is self-evident that if under our Constitution, namely s. 7 of the Charter, the prohibition of possession and cultivation of marijuana for medical purposes is unconstitutional, it would be open to Parliament to enact such an exemption and still comply with its treaty obligations…Prohibiting possession or cultivation of marijuana for personal medical use does nothing to enhance the state's interest in fulfilling its international obligations.
>
> …
>
> [149] … The Convention therefore, is not a prohibition against all possession or distribution. As article 3(2) states, the Convention must be read subject to Canada's constitutional principles and it is up to Canada to "adopt such measures, AS MAY BE NECESSARY" [court emphasis] to criminalize the possession of marijuana. The respondent / Crown, on these facts and based on any of the tests of the principles of fundamental justice, has not demonstrated the necessity of a legislative enactment so broad as to prevent therapeutic use of this non-manufactured grown plant product.

The Supreme Court of Canada in *R. v. Smith* considered the exemption created in the MMAR and subsequently the MMPR allowing for the possession of dried marijuana. The Supreme Court of Canada characterized the issue before it as follows: whether restricting medical access to marihuana to dried marihuana violates section 7 of the Charter.[22] In answering this question, the SCC concluded that the object of the restriction to dried marihuana is the protection of health and safety. The SCC then states: the prohibition on non-dried medical marihuana undermines the health and safety of medical marihuana users by diminishing the quality of their medical care. The effects of the prohibition contradict its objective, rendering it arbitrary.

Similarly, the restriction on CBD from industrial hemp undermines the health and safety of potential users by restricting access to CBD to only synthetically-sourced CBD or CBD that also contains THC.

CBD IN OTHER JURISDICTIONS

The lack of psychoactivity associated with CBD, combined with its potential therapeutic uses, has led to suggested reform in a number of other jurisdictions. These reforms are aimed at opening a market for CBD and CBD-based products. Some of these recent developments are discussed below.

The United States

Four bills have recently been introduced by the United States Congress, all of which have now been referred to special committees. The adoption of any of these bills could make the United States, a country that grows far less industrial hemp than Canada, a world leader in the legalization and regulation of CBD.

[22] Section 7 of the Charter provides: "Everyone has the right to life, liberty and security of the parson and the right not to be deprived thereof except in accordance with the principles of fundamental justice".

This would provide a tremendous opportunity for Canadian industrial hemp farmers if they were permitted to harvest, sale and process the whole plant; an opportunity that would otherwise be lost to foreign competitors.

The *Industrial Hemp Farming Act of 2015*[23] proposes to remove industrial hemp from *the Controlled Substances Act of 1970* ("**CSA**") by amending the definition of "marijuana" contained therein to specifically exclude industrial hemp. This Act proposes to define industrial hemp in the same way as Canada.

The *Compassionate Access, Research Expansion & Respect States Act of 2015*[24] proposes to remove CBD from the CSA by clarifying that the term "marijuana" does not include "cannabidiol," and by further defining "cannabidiol" as meaning "the substance cannabidiol, as derived from marijuana or the synthetic formulation, that contains not greater than 0.3 percent delta-9-tetrahydrocannabinol on a dry weight basis", i.e. CBD from industrial hemp.

The *Charlotte's Web Medical Access Act of 2015*[25] and *Therapeutic Hemp Medical Access Act of 2015*[26] propose to amend the CSA to exclude CBD and CBD-rich plants from the definition of "marijuana," and from treatment as a controlled substance under such Act. The Act also seeks to exempt CBD or CBD-rich plants from the *Federal Food, Drug, and Cosmetic Ac*t.

In addition to the above-noted proposed bills, in December 2015, the United States Drug Enforcement Administration eased some of the regulatory requirements imposed by the CSA for those who are conducting FDA-approved clinical trials on CBD. These modifications are aimed at "streamlin[ing] the research process regarding CBD's possible medicinal value and help foster ongoing scientific studies". [27]

The European Union

Currently, hemp products produced in the EU can only be grown from varieties listed in the common catalogue of varieties of agricultural plant species.[28] Europe has adopted a system under which the varieties found in this catalogue are subsidized. The European Commission has adopted 0.3 percent as the acceptable content of THC in industrial hemp. Beyond that, each individual member state may set a lower accepted percentage.

The regulations as they currently stand create a grey area for European hemp farmers: there appears to be no restriction on which parts of industrial hemp plants may be used, or which parts must be discarded. This grey area allows for many emerging companies to commercialize products that are CBD-based.[29]

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[23] https://www.congress.gov/bill/114th-congress/senate-bill/134 and https://www.congress.gov/bill/114th-congress/house-bill/525

[24] https://www.congress.gov/bill/114th-congress/senate-bill/683

[25] https://www.congress.gov/bill/114th-congress/house-bill/1635

[26] https://www.congress.gov/bill/114th-congress/senate-bill/1333

[27] http://www.dea.gov/divisions/hq/2015/hq122315.shtml. As stated by the DEA in its news release: Marijuana is a Schedule I controlled substance because of the presence of tetrahydrocannabinol (THC), marijuana's psychoactive ingredient. Because CBD contains less than 1 percent THC and has shown some potential medicinal value, there is great interest in studying it for medical applications. Currently, CBD is a Schedule I controlled substance as defined under the CSA. Though the FDA approves drugs for medical use in the United States, the DEA regulates the handling of all controlled substances, including those being used by researchers to conduct studies.

[28] http://ec.europa.eu/food/plant/plant_propagation_material/plant_variety_catalogues_databases/search/public/index.cfm?event=SearchVariety&ctl_type=A&species_id=240&variety_name=&listed_in=0&show_current=on&show_deleted=

[29] See for example: https://kanavape.com/

In addition, CBD has recently been designated as an orphan medicinal product under Regulation No 141/2000 of the European Parliament and Council.[30]

Australia

In Australia, a legislative amendment recently came into effect, placing CBD on Schedule 4 (prescription medicines) to the Standard for the Uniform Scheduling of Medicines and Poisons.[31] In addition, this amendment created an exemption to the entry for THC on Schedule 9 (prohibited substances), which effectively removes CBD from this schedule, altogether.[32]

In its interim decision regarding these amendments, the Australian government acknowledged the therapeutic uses and safety of CBD, as well as a desire for a CBD market to see the light in Australia. [33] The decision states that "there is low risk of misuse or abuse as cannabidiol does not possess psychoactive properties".

THE PROPOSAL FOR REFORM

In light of the above, the CHTA is advocating for expansion of the current regulatory regime for industrial hemp to permit use of the whole plant for harvest, sale and processing non-psychoactive cannabinoids.

For greater clarity, the CHTA is not advocating for deregulation of the industrial hemp industry. The CHTA is concerned about the impact of diversion of industrial hemp to the illegal market on the reputation of the Canadian industrial hemp industry, and wants to ensure that any regulatory amendments sufficiently protect against any such diversion. The CHTA is proud of the fact that to-date, there have been no violations of the THC concentration limit by any Canadian industrial hemp producer, and no findings of marijuana being cultivated by licensed industrial hemp producers.

Amendments to Schedule II of the CDSA

As set out above, the CDSA and its regulations are intended to provide a framework for the control of substances *that can alter mental processes* and that may produce harm to an individual or to society when diverted to an illicit market. As also set out above, it is now recognized that CBD and CBN are non-psychoactive and not addictive.

There are at least two ways that Schedule II can be amended to reflect the well-recognized fact that CBD and CBN are not psychoactive and have potential therapeutic uses, in a sufficiently narrow way to alleviate concerns about illicit use of the *Cannabis* plant as follows:

i. Carve out industrial hemp (as defined in the Regulations) from the definition of *Cannabis*; or

ii. Amend the definitions of CBD (item 1(3)) and CBN item 1(4)) to specify that the restricted substances do not include CBD or CBN in or from *Cannabis* containing less than 0.3% THC.

[30] http://ec.europa.eu/health/documents/community-register/2015/20150728132623/dec_132623_en.pdf
[31] CBD's entry on Schedule 4 states: CANNABIDIOL in preparations for therapeutic use containing 2 per cent or less of other cannabinoids found in cannabis.
[32] Schedule 9 refers to controlled drugs which have therapeutic uses, but high potential for abuse. CBD is mentioned in the Schedule 8 entry for the drug nabiximols. However, nabiximols is defined as containing a range of cannabinoids including a mixture of both THC and CBD. The listing of CBD on Schedule 4 (Controlled Drugs) is due to its presence in Nabiximols, a drug that contains several cannabinoids.
[33] https://www.tga.gov.au/book/interim-decisions-matters-referred-expert-advisory-committee-acms-out-session-november-2014

These suggested amendments are in-line with those being contemplated by Canada's major trading partners, particularly the U.S.

The required amendments can be made pursuant to section 60 of the CDSA which allows the Governor in Council to, by order, amend any of the Schedules by adding to them or deleting from them, any item or portion of an item where the amendments is deemed necessary in the public interest.

Amendments to the Regulations

As set out above, the Regulations do not allow for the import or sale of whole plants, or the import, sale or production of any derivative or any product made from a derivative of the whole plant. Accordingly, sections 2 and 3 of the Regulations will need to be amended.

All the remaining safeguards already in place in the Regulations would be maintained according to the *status quo*, with extension to account for whole plant use and the harvest, sale and processing of non-psychoactive cannabinoids, as required. That is, regulation of industrial hemp is still required to ensure appropriate levels of THC.

The expansion of the regulatory regime for industrial hemp should not cause concerns that industrial hemp could benefit illicit marijuana production; any such concerns are completely unwarranted and unjustified. Marijuana is grown without pollination or seed set in order to increase the number of seed bracts and the amount of resin on those bracts, and thus obtain the highest possible concentration of THC. Growers of marijuana (medicinal or otherwise) would want to avoid cross-pollination with hemp plants at all costs to avoid the significant lowering of the THC content (and accordingly, the value) of the marijuana crop. Consequently, growers of illicit marijuana avoid hemp fields and a wide area surrounding them.

The required amendments to the Regulations can be made pursuant to section 55 of the CDSA which allows the Governor in Council to make regulations to (among other things) enable the use of controlled substances for therapeutic applications.

CONCLUSION

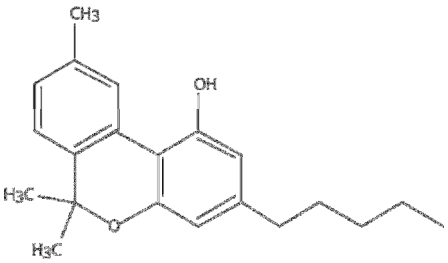
In conclusion, the CHTA once again thanks the Canadian Government for the opportunity to discuss these issues and to work together to create a regime for whole plant use to facilitate the harvest, sale and processing of non-psychoactive cannabinoids from industrial hemp.

We recognize that the Government will likely have additional questions and we welcome the opportunity to engage in a lasting and meaningful discussion.

Appendix A

CANNABINOL (CBN)

Maya R. Chaddah, Science Communications

	Key Points
Cannabinol (CBN)  	– *CBN results from the degradation of THC in fresh plant material upon exposure to UV light, heat, oxygen and poor storage conditions.* – *Industrial hemp contains undetectable to trace levels of CBN.* – *CBN is undetectable in hemp essential oils.* – *CBN weakly stimulates cannabinoid receptors CB1 and CB2.* – *There are no isomeric, physiologically-active forms of CBN.* – *CBN is not psychoactive: it does not increase heart rate, change perception, emotion, cognition or sociability.* – *CBN is not scheduled by the Convention on Psychotropic Substances.* – *CBN has many potential therapeutic applications.*

1. CANNABINOL (CBN) IN *CANNABIS SATIVA*

Cannabinol (CBN) has a long recorded history. First isolated in 1896 [1], CBN's chemical structure was not described until 1940 [2] when it was incorrectly believed to be the main psychotropic ingredient in *Cannabis sativa* – a role later attributed to Δ9-tetrahydrocannabinol (THC). CBN is now known to be among one of over 80 phytocannabinoids found in *Cannabis sativa* but it is not present in any appreciable amount. CBN is not a naturally-occurring substance, and instead exists **by the degradation of THC in fresh plant material upon exposure to UV light, heat, oxygen and poor storage conditions** [0, 4]. Taking advantage of this process, laboratory tests measure the ratio of CBN to THC to gauge the freshness of *Cannabis sativa*: higher quantities of CBN are a telltale sign of poor storage and older age of the plant material [0, 4, 5].

2. CANNABINOL (CBN) IN INDUSTRIAL HEMP

Industrial hemp is a tall-growing variety of the Cannabis plant bred specifically to conform to regulatory limits on THC content. These are defined by the Canadian Industrial Hemp Regulations (SOR 95/156) as "plants and plant parts of the genera Cannabis, the leaves and flowering heads of which do not contain more than 0.3% THC w/w and includes derivatives of such plants and plant parts" [6]. Health Canada contrasts the very low level of THC in industrial hemp with the 5% w/w THC often found in recreational *Cannabis sativa* [7].

The industry around non-textile based applications of hemp has been made possible by the varieties of hemp that conform to THC industrial standards. A newer and growing niche market for hemp is the extraction of essential oils from hemp influorescences for flavour and fragrance additives. In a two-year field trial by Bertoli et al., 10 hemp-type cultivars were assessed for the production of biomass and essential oils. Of note, **CBN was undetectable in the essentials oils derived from all 10 cultivars** [8].

Given its provenance as a degradation artefact of THC, and the very low levels of THC in industrial hemp, **the percentage of CBN in industrial hemp is placed at undetectable to trace levels.** The UNODC corroborates this in their definition of drug-type versus hemp-type cannabis, where a ratio of the main cannabinoids ([THC] + [CBN] / [Cannabidiol], CBD] is used to distinguish between the two types [4, 9].

3. PSYCHOACTIVITY PROFILE OF CANNABINOL (CBN)

CBN is one of 80 phytocannabinoids found in *Cannabis sativa*. As a partial agonist of cannabinoid receptors, CBN only weakly stimulates CB1 receptors (found in brain, immune and peripheral tissues) and CB2 receptors (found mainly on immune system cells) [0, 11]. **CBN is not a chiral compound and thus lacks the ability to form stereoisomers indicating that there are no alternative, physiologically-active forms** [0, 5, 12].

The physiological and psychological effects of CBN in humans have been described in a small study that administered THC (25 mg) and CBN (50 mg) alone or in combination in five healthy male volunteers [13]. In contrast to the observations for THC, **CBN did not increase heart rate and did not cause participants to underestimate the passage of time. Nor did CBN alone affect changes in participant perception, emotion, cognition or sociability**. In combination, CBN seemed to augment the effects of THC on some psychological and physiological processes, but the magnitude of such effects was minimal and much less than reported for whole plant [13]. It is worth noting that industrial hemp contains 0.3% or less THC and trace to undetectable levels of CBN, signifying that neither CBN nor THC would be present in industrial hemp in amounts sufficient to mediate a psychotropic effect [0, 6].

Although popularly cited as 'weakly psychoactive' and classified as a schedule II substance in Canada, there is no evidence for CBN being psychoactive on its own and limited evidence for it being psychoactive in the absence of biologically-active levels of THC in *Cannabis sativa* [13]. International bodies affirm this as **CBN is not scheduled by the Convention on Psychotropic Substances** [14] and it is listed as non-psychoactive in a Certificate of Analysis performed by BioTrends, Switzerland [15].

4. THERAPEUTIC POTENTIAL OF CANNABINOL (CBN)

The common pharmacological characteristics attributed to CBN are as a sedative, antibiotic, anti-convulsant, and anti-inflammatory [5]. Preclinical studies have discovered additional roles for CBN in analgesia (pain relief), treatment of psoriasis, bone formation, fracture healing, multidrug resistance, inhibition of antibiotic resistant *Staphylococcus aureus* [0], and immune regulation [16, 17]. The mechanisms of action through which CBN moderates these therapeutic effects are largely unknown and further preclinical and clinical studies will be required to establish which cannabinoid receptor dependent and/or independent pathways are involved.

A novel application for CBN involves its use as a topical transdermal delivery agent for combination drug therapy. Preclinical studies using artificial membranes containing portions of the dermis show that CBN is highly soluble in oils and non/polar substances and thus may be able to cross the lipid barrier of the stratum epidermis, the outer layer of the skin, more readily than other cannabinoids [18]. Animal models are currently being used to explore the possibilities of transdermal combination therapy, and for patients with diseases such as AIDS and cancer, this delivery route would be easier to manage than swallowing pills and would require fewer doses than an oral drug delivery [18].

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Appendix B

Evidence for the Safety and Clinical Efficacy of Cannabidiol

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Summary

Cannabis sativa contains a wide variety of phytochemical constituents, many of which have not yet been fully characterized. The two most abundant (and well characterized) phytochemicals found in marijuana are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). Whereas THC is now firmly established as representing the primary psychoactive component in marijuana, considerable evidence demonstrates that CBD possesses no psychoactive properties and indeed, may counteract the psychoactive effects of THC. Thus, whereas THC has been repeatedly demonstrated, in both clinical and pre-clinical research studies to possess psychoactive effects in the mammalian brain, emerging evidence demonstrates that CBD can block the effects of THC both in terms of central nervous system side effects, and at the pharmacological level. Furthermore, a large and growing body of clinical and pre-clinical research conclusively demonstrates that CBD possesses powerful therapeutic properties across a wide domain of clinical symptoms and disorders.

1. The Pharmacology of Cannabidiol

CBD represents one of ~85 identified constituents of *Cannabis sativa* and represents ~40% of the plant's phytochemical derivatives, depending upon the strain (1). CBD has extremely low pharmacological affinity for central or peripheral cannabinoid receptors (2) (CB1 and CB2, respectively). In fact, considerable evidence demonstrates that CBD can strongly antagonise the pharmacological actions of THC and other cannabinoid receptor ligands at central cannabinoid receptors (3,4). At the cellular level, CBD can act to regulate intercellular levels of calcium (5). Furthermore, CBD has been demonstrated to act as a partial agonist at the serotonergic 5-HT1-A receptor subtype (6,7,8). In summary, CBD's known pharmacological profile is not only highly distinct from that of THC, but it appears to primarily produce its physiological actions via the serotonergic system and to directly antagonise the psychoactive effects of marijuana, via its ability to block the actions of THC at central and peripheral cannabinoid receptors.

2. Cannabidiol has no known psychoactive properties

Despite the fact that CBD is not scheduled by the *Convention on Psychotropic Substances*, it remains classified as a schedule II substance in Canada. Nevertheless, there is currently no scientific evidence to demonstrate that CBD possesses any psychoactive properties. In addition, in contrast to the known psychoactive effects of THC (9,10), there is currently no evidence to suggest that CBD possesses reinforcing or addictive liability. On the contrary, current scientific evidence (both pre-clinical and clinical) suggests that strains of marijuana possessing relatively lower levels of CBD vs. higher levels of THC (e.g. cannabis strains such as "sinsemilla") possess far greater abuse liability and risks for psychoactive side effects (11-13). Such evidence is consistent with the established scientific evidence demonstrating that CBD and THC produce opposite effects within brain regions associated with addiction and other psychiatric disorders such as schizophrenia (14,15). Furthermore, these findings are consistent with the established role of CBD as a pharmacological blocker of the central, psychoactive properties of THC (2,3).

3. Cannabidiol's Therapeutic Properties and Potential

There is now compelling clinical and pre-clinical evidence demonstrating that CBD possesses powerful potential for therapeutic applications in the treatment of numerous disorders. For example, pre-clinical studies have found that CBD blocks many of the neuropsychiatric side-effects associated with THC

(14,15). Furthermore, compelling clinical evidence has found that CBD acts as a highly effective anti-psychotic medication for the treatment of serious psychiatric conditions such as schizophrenia (16-18), with greater tolerability and fewer side-effects, relative to traditional schizophrenia medications. In terms of other neurological disorders, a recent series of studies have found that CBD serves as a highly effective treatment in children and young adults for treatment-resistant epilepsy, showing high tolerability and minimal side-effects (19,20). In addition, compelling clinical and pre-clinical evidence is pointing to a potential therapeutic role for CBD in the treatment of chronic, neurodegenerative brain disorders including Alzheimer's, Parkinson's and Multiple Sclerosis (21). Notably, virtually all of the extant clinical evidence demonstrates a high tolerability and excellent safety profile for the clinical use of CBD, with efficacy rates comparable or superior to traditional pharmacological treatments.

4. Conclusions

A wealth of clinical and pre-clinical scientific evidence now points to the therapeutic potential and efficacy of CBD in the treatment of numerous medical conditions. CBD possesses no psychoactive properties, is non-habit forming, and well tolerated in patient populations. Importantly, CBD has been demonstrated to pharmacologically and functionally counteract the negative effects of THC, the actual psychoactive component of marijuana, and to interact with pharmacological and molecular pathways that are distinct from those of THC. Currently, there is no justification for the classification of CBD as a narcotic compound. Indeed, the current controlled status of CBD as a schedule II compound in Canada continues to impede progress in the scientific and medical research communities. Currently, access to CBD as a clinical or experimental compound is difficult to acquire for Canadian Scientists performing either pre-clinical or clinical medical research. Given the above described scientific evidence pertaining to CBD, de-scheduling of CBD and CBD-containing products would invariably open exciting new opportunities for the development of novel, natural and safe pharmacotherapeutic compounds. Given the urgent need for more effective treatments for mental health and neurological disorders, research into the clinical potential of CBD is of timely importance.

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Position of the Canadian Hemp Trade Alliance on Criminal Record Checks

The Canadian Hemp Trade Alliance (CHTA) would like to address the practice of securing annual Criminal Record Checks (CRC) from all applicants for hemp licenses of any nature. It is the view of the members of the CHTA that this procedure is needlessly time consuming and largely ineffective in achieving the goals it sets out to achieve.

Current Procedure

Due to industrial hemp's classification as a Schedule 2 Controlled Substance under the Controlled Substances Act the Industrial Hemp Regulations (IHR) stipulates that anyone involved in the production, handling, import and export of industrial hemp must, as part of the application process, undergo a Criminal Record Check. This requirement is also restated in the Guidance Document for the IHR as part of the application process for an Industrial Hemp Licence.
The IHR refers to the need or reasoning for the check in Section 8.1m, 8.1n as well as Section 9.2g and Section 13.2b. All applicants, including directors and officers of corporations, co-operatives and partnerships must also undergo CRCs. The review requires a clear record for the past 10 years and a criminal record from either Canada or another country could result in a refusal.
This document must be submitted to Health Canada along with other information as required depending on the type of licence requested. The wait time for the CRC can range from one hour to as many as 60 days. The wait time for a hemp licence is greater than 30 days and can, in many cases, be as long as several months.

Issues

Participants in the hemp industry, in particular those who are simply re-applying for a licence, find the annual requirement for a CRC to be excessive and unnecessary.

A survey of our members actively involved in the day to day operations of production and processing yielded a common set of comments related to the Criminal Record Check process. They are included below:

> *"The turnaround time to get the checks can sometimes delay the application for hemp licenses. In the rural areas the turnaround time is usually not too bad (less than a week), but the time required to get them done, not to mention the need to tie up administration with the RCMP, is a bother."*

> *"There have been occasions where the delay in the criminal record check has delayed the application for the Health Canada license. I have a situation right now with a grower being delayed in his hemp license application due to a delay in the background check, and this is preventing him from moving his crop for cleaning and eventual sale."*

> *"Local RCMP detachments find it strange for a farmer to require a background check simply to grow a crop – to them it seems pointless."*

> *"There are loopholes in the background check process that make this part of the legislation ineffective. The purpose of the check is to stop the "bad guys" from obtaining a license."*

> *"If you do have a record it is very easy to get around the issue by having someone else get a record check and put a field in that person's name. "*

> *"I have been an authorized hemp sampler for over 10 years. We appreciated the time when the IHR office ran the checks on our behalf. This streamlined the process to apply ("renew"). Although my local RCMP provides the CRC on the same day it is still time consuming. 1) They only accept money orders 2) The drive in from*

country office 3) Posting the document to HC 4) Time for turnaround from IHR office. Please streamline or remove this requirement at least for renewals"

These quotes point to the realities of industrial hemp as an agricultural crop and the impediments the CRC is causing. In fact, it is likely that the majority of growers are in an illegal position with respect to possession of a controlled substance as of January 1 of each year. This legally limits the grower from moving for cleaning or selling their hemp. This is a unique characteristic in agriculture and not at all reflective of the realities of the industry.

Observations

The Industrial Hemp Regulations makes reference to the need for a criminal record check and the requirement that anyone applying for a license must not have a *"criminal record in respect of any offence that if committed in Canada would constitute a designated drug offence."* It does not however stipulate the frequency in which those checks need to be repeated. The requirement to renew the industrial hemp licence annually is not in question. But the need to renew the CRC each year is the point of this communiqué.

Applicants can 'get around' the check by having another family member apply for the application.
RCMP themselves question the need for this check as it lacks purpose and uses their resources in a pointless manner.
In retrospect has this process resulted in the failure of any licence applications or in the discovery of criminal activity of any kind?

Conclusion

As the documentation and scientific evidence supplied as part of this submission demonstrates, the safety and non-harmful characteristics of industrial hemp are clear. While still recognized as a Controlled Substance, industrial hemp presents no threat with respect to designated drug offences. Producers, processors and exporters should not be held in the same view as drug traffickers and sellers with respect to criminal activity.

The need for periodic or random checks would be deemed acceptable however annual checks for every participant in the industry are excessive and pointless in our view.

The CHTA respectfully requests the annual requirement for annual Criminal Record Checks be relaxed in favour of a more moderate approach reflecting the unlikely and minor effect of the activity the mechanism is intended to control.

MODERNIZING THE INDUSTRIAL HEMP REGIME

Position of the Canadian Hemp Trade Alliance on Delta-9-tetrahydrocannabinol (THC) Testing

Executive Summary

The current Industrial Hemp Regulations requires:

- THC testing of all fields, with the exception of cultivars that have been shown to be particularly low in THC in a given province;
- THC sampling and testing in the production process (food derivatives);

This is very costly for producers and processors, and requires significant administrative investment by Health Canada to monitor results.

The Canadian Hemp Trade Alliance (CHTA) is proposing an infield science-based alternative that would be efficient and would generate reliable results. Candidate cultivars would be tested in orthogonal trials in at least ten environments to ensure that samples are taken at the proper stage for each cultivar.
CHTA is proposing removal of THC testing on grain/seed derivatives within food processing. Since 1998 all grain derivatives have met the 10 ppm (micrograms per gram) and therefore caused no public safety issue.

The changes requested would achieve the objective of ensuring low THC crops, but with substantially less costs.

Current Situation

The requirements and protocols for THC testing of industrial hemp production is aimed at ensuring that all hemp crops have no more than 0.3% THC in the field sample and 10 ppm (micrograms per gram) in grain/seed derivatives . This is achieved by:

1) all new hemp lines must meet THC content criteria before being registered by the Canadian Seed Growers' Association (CSGA) and being added to Health Canada's list of approved cultivars (LOAC);
2) all non-exempt commercially-grown hemp fields must be tested for THC content by an Authorized Sampler and analyzed at an Approved Laboratory;
3) all grain/seed derivatives must be tested at final stage of processing prior to release for sale.

The Issue

The current THC regulatory requirements are costly for producers, processors and the industry as a whole. Health Canada, in turn, invests significant limited administrative resources to monitor the data from each and every result.

Such extensive monitoring is not necessary since THC content of *Cannabis* plants is a highly heritable trait, and is very stable across different environments.

In addition to financial and social costs, the current testing regime has many practical constraints. THC levels fluctuate during the course of plant development, so sampling at a uniform stage is critical. Samplers generally cover large geographic areas, making it impossible to sample all fields at the correct maturity stage. As well, THC degrades if samples are not dried soon after harvest. The delay from harvest to drying can be several days, since drying facilities are seldom close to production fields.
As it relates to THC testing for grain/food derivatives the testing is unnecessary and results in significant costs and burden to processors and the regulatory system.

Proposed Amendments

CHTA is proposing amendments to the Industrial Hemp Regulations that are based on the science of cannabinoid synthesis (Appendix I) and sound protocols for field crop evaluation. Adoption of these amendments would result in a more precise and efficient method of monitoring THC levels in commercial hemp production fields, but still achieves the goal of ensuring low THC hemp production.

Candidate lines for registration should be tested in orthogonal trials at five sites in each of two years. Those which are consistently below 0.3% THC would then be eligible for registration as cultivars and inclusion in the LOAC. No further testing by producers would be required, but Health Canada could continue making 'spot checks' as deemed appropriate.
The testing sites would be situated in contrasting environments, where hemp is currently cultivated. For example, one site in each of the northern prairies, southern prairies, Ontario, Québec and Atlantic Canada would be appropriate.

Replicated (2-rep) trials would be established at each site using standard protocols. Samples would be taken from each cultivar when it reaches the appropriate maturity stage, and placed in a suitable dryer within an hour of harvesting. The replications would be analyzed individually in order to compare variation due to sampling and lab analysis with variation among cultivars and environments. This would determine the reliability of individual data points.

Plant breeders and/or cultivar distributors would have the option of including their current cultivars in these trials.

CHTA is proposing that the requirement for grain/food THC derivative testing be removed.

The Bottom Line

It is scientifically proven that THC content in hemp is a highly heritable trait, under fairly simple genetic control (the B locus). Other traits can affect THC content, but to a much lesser extent and these traits appear to be quite heritable as well.

Proper testing in a few environments is adequate to definitively establish the THC content of any given cultivar, and there is little or any possibility that a low-THC cultivar will 'spike' in another environment. Therefore, all crops grown with that cultivar will necessarily be low in THC, and monitoring of every field is completely unnecessary.

However, good sampling protocol – adequate sample size, taken at the appropriate growth stage and dried immediately after harvest – is an essential element of reliable cultivar testing for THC. This element is not being met currently, and is undoubtedly leading to erroneous data being generated. Extensive testing (i.e. every field) does not compensate for unreliable data from individual fields.
This science-based protocol would achieve the objective of ensuring low THC crops, but with substantially less costs.

Removal of the redundant derivatives testing will reduce costs for the industry and improve customer acceptance of hemp foods.

Appendix C

The Genetic Basis of 9-THC Synthesis

The level of THC in *Cannabis* plants is controlled in large part by a single gene which regulates 9-THC synthesis, known as the 'B' locus. In the THC metabolic pathway, a precursor compound, cannabigerolic acid (CBGA) is converted to tetrahydrocannabiollic acid (THCA) if the B_T allele is present, or to cannabidiolic acid (CBDA) if the B_D allele is present[(1)]. THCA subsequently forms THC, and CBDA forms CBD, a non-psychoactive cannabinoid.

Each plant contains two alleles, which determine its 9-THC/CBD profile:

B_T / B_T - Chemotype I; high9- THC and low CBD

B_D/ B_T - Chemotype II; intermediate 9- THC and CBD

B_D/ B_D - Chemotype III; high CBD, low 9-THC

Hemp cultivars are populations of individual plants, most of which are B_D/ B_D, and therefore produce little or no 9-THC. However, most cultivars contain a few individuals carrying a B_T allele. The frequency of these alleles (and individuals carrying them) will determine, in large part, the THC level of that cultivar. Cultivars which have very few B_T alleles are very low 9-THC, and are very consistent across environments. Cultivars with a higher B_T frequency have higher THC, but appear to be less stable. This is due to variability in sampling: if a few plants with B_T / B_T or B_D/ B_T happen to be sampled at one site, but not in another, the 0-THC results from the two samples would be very different.

The level of 9-THC in a given crop is also influenced by other factors, such as density of trichomes (which produce the resin that carries cannabinoids), the proportion of leaves and flowers on the stalk (leaves have fewer trichomes, and thus lower cannabinoid content), as well as environmental conditions. Stress is often cited as a factor causing high 9-THC levels, but there does not appear to be any scientific data to substantiate that conjecture. Age of the plant, however, is an important factor, so stage of sampling is critical[2].

Genotype x environment interaction (GxE) – the relative performance of plants in different environments – is an important factor in assessing genotypes. In most crops, some traits (yield, disease reaction) show high GxE, while other traits (like protein content in wheat) have very low GxE. In this case, protein levels may differ across environments, but the ranking of individual cultivars is quite stable. There is no scientific evidence showing significant GxE for 9-THC content in hemp.

[1] D. Rotherham and S.A. Harbison 2011. Differentiation of drug and non-drug Cannabis using a single nucleotide polymorphism (SNP) assay. Forensic Science International 207: 193–197.

[2] Oier Aizpurua-Olaizola, Umut Soydaner, Ekin Öztürk, Daniele Schibano, Yilmaz Simsir, Patricia Navarro, Nestor Etxebarria, and Aresatz Usobiaga. 2016. Evolution of the Cannabinoid and Terpene Content during the Growth of Cannabis sativa Plants from Different Chemotypes. Journal of Natural Products. (in press).