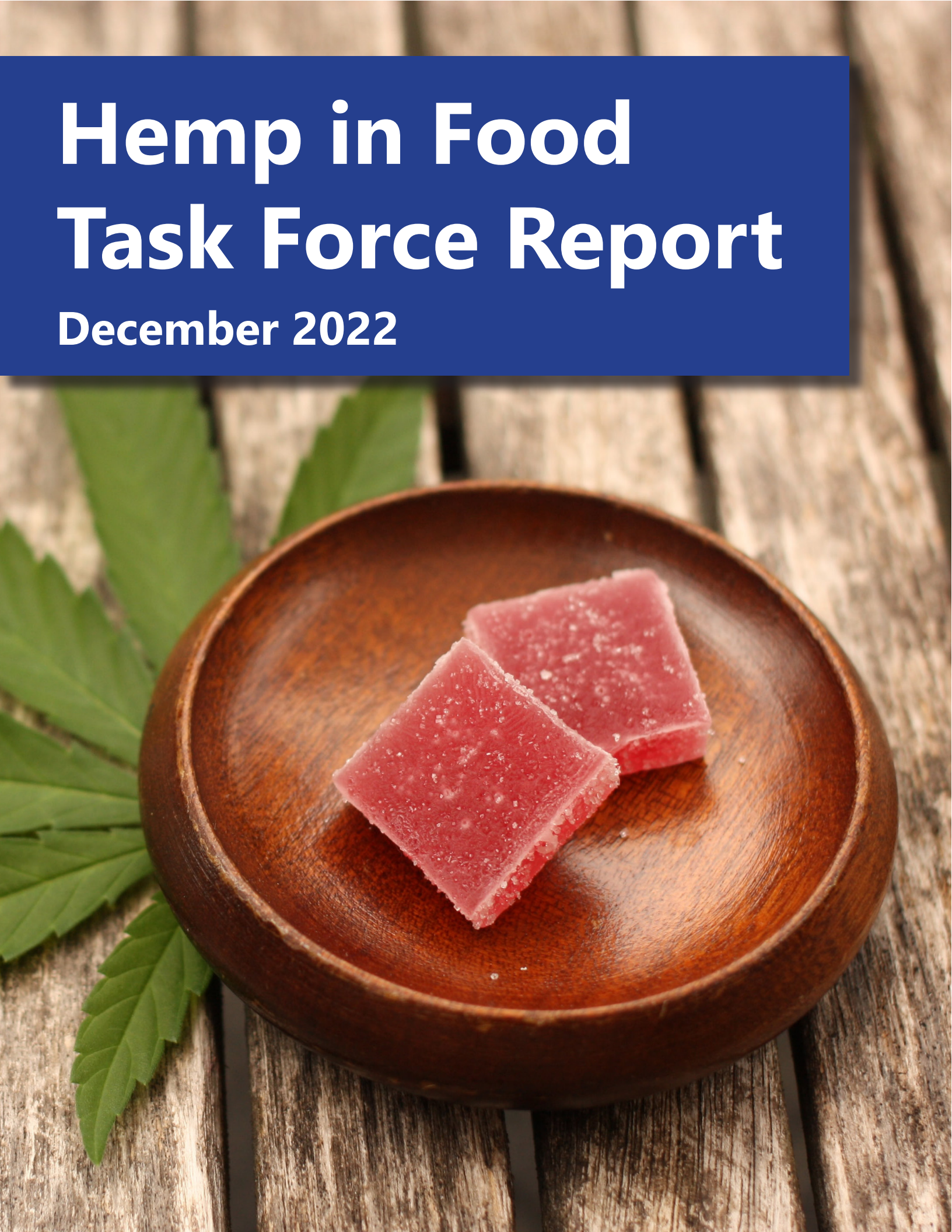
Hemp in Food Task Force Report

December 2022



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Prepared by:
Hemp in Food Task Force members

Report Authors:
Members of the Hemp in Food Task Force

Executive Summary

During the 2022 legislative session, the Washington State Legislature included a proviso in the budget for creation of a Hemp in Food Task Force at the Washington State Department of Agriculture (WSDA).

The proviso language recognizes that state agencies, hemp industry stakeholders, and the broader community share an interest in providing a safe space for inclusion of hemp extracts in foods and beverages. The inclusion of hemp as a legal commodity in the 2018 Farm Bill created a new market opportunity for Washingtonians interested in growing and processing hemp. The creation of Chapter 15.140 RCW in 2019 has led to a federally approved hemp production plan, and voluntary registration and food safety permits for hemp processors.

The new statute created for this program in 2019 specified that no parts of the hemp plant could be considered a food or food ingredient until identified as such by federal law. Normally, states would wait until the Food and Drug Administration (FDA) registers ingredients as Generally Recognized as Safe (GRAS). There has been little movement at the federal level to this point, so WSDA and this task force were directed by the Legislature to evaluate a state-based program that meets dual purposes: create a market-based pathway for Washington hemp producers and processors and ensure the marketplace protects consumer safety using the best available science.
The Task Force was tasked with evaluating the safety and science information around hemp extracts, assessing regulatory structures allowing these ingredients in food and dietary supplements in other states and countries, and recommending a path forward for Washington State that limits human ingestion/exposure risk but allows for marketing and commerce.

The Task Force sought to learn more about the current science in this space. More specifically, they sought to review and discuss the following topics:

- Roles and requirements of regulatory agencies relating to food and dietary supplement labeling, manufacturing, and sales.
- Current science around cannabinoids and human ingestion/exposure.
- Research, reports, and data from states and countries that allow hemp extracts as food or dietary supplement ingredients.
- Definitions and assumptions about a Washington State-based hemp in food program.

The Task Force was directed to develop recommendations, if appropriate, for allowing hemp extracts as state-regulated food ingredients. In addition, recommendations for delegated agency authorities to regulate and oversee food manufacturing and sales related to hemp in food were sought.

Many stakeholders, including but not limited to hemp producers and processors, high-THC cannabis producers/processors, private and public scientists, university professors and medical experts, and state and local government agencies contributed valuable assistance and input. To meet the timeline established by the proviso, the task force met ten times in five months. All meetings were held virtually to ensure as much participation as possible by task force members at each meeting. In addition to this rigorous meeting schedule of the entire task force, two sub committees met weekly or biweekly in September and October to discuss biosafety and regulation, definitions, and bill drafting.

Executive Summary

The Task Force reached 14 noteworthy recommendations regarding considerations for hemp in food in Washington State:

Definition Recommendations

1. The Task Force recommends clearly defining hemp-based extracts as food and dietary supplement ingredients and structuring future regulatory programs around those defined products.
2. Hemp in food and dietary supplements will specifically refer to those extracts or parts of the plant not currently regulated for consumption elsewhere (i.e., hemp hearts by FDA, hemp greens/lettuces as produce).

Administrative Recommendations

1. Newly allowed hemp ingredients in food should be restricted to prepackaged foods and beverages and dietary supplements.
2. WSDA should create a regulatory program for hemp food and dietary supplement ingredient processing and manufacturing when legislative action directs them to do so.
3. Dietary supplements containing hemp-based ingredients should be allowed under legislation.
4. All hemp products for consumption sold in Washington State must follow federal food and dietary supplement labeling standards.
5. Any packaging must be cautious of appealing to children.
6. Packaged foods and dietary supplements in this regulatory structure that contain THC must have no more than 0.3% THC in hemp ingredients, set milligrams of Class A (THC-like effects) and Class B (non-THC-like effects). The Task Force recommends that further scientific review is needed to establish whether there is a safe ratio of CBD: THC for non-impairing human consumption.
7. Chemically transformed cannabinoids are not allowed.

Legislative Recommendations

1. The Task Force recommends that further work be done to create a legislative package brought forth by stakeholders to create an equitable hemp in food and dietary supplement regulatory program.
2. The legislation should include **a pilot program with serving size requirements** that can be implemented quickly to create market space for the hemp industry. The program in statute should be replaced by a program administered in WAC by WSDA no later than January 1, 2025.
3. Legislation should include labeling requirements, pilot program serving size allowances for foods, beverages, and dietary supplements, and rely on existing manufacturing procedures and food manufacturing sanitary standards.
4. Product maximum levels of Class A cannabinoids (THC-like effects) should be dictated by the primary Class B (non-THC-like effects) cannabinoids.
5. Legislation should exclude allowances for chemically transformed cannabinoids. These recommendations represent what could be agreed to within the time limits of meetings. The Task Force ran out of time to discuss several topics not addressed and would have required additional meetings, which was not possible within the deadlines outlined with the proviso. The timing of the task force meetings during traditional farming season added to the time restraints for the task force to meet and work together as much as they felt necessary.

This report was drafted by staff at WSDA and reviewed by members of the Hemp in Food Task Force.

Introduction

During the 2019 legislative session, the Washington State Legislature passed Engrossed Second Substitute Senate Bill (ESSB) 5276, authorizing hemp production in conformance with the 2018 Farm Bill. The Bill established that hemp can be included as a food ingredient only if allowable under federal law. Hemp producers, processors, legislators, state agencies, local health jurisdictions, and the broader community share an interest in creating a regulated structure for hemp extracts in food and dietary supplements. In 2022, the Washington State Legislature included a budget proviso that created a Hemp in Food Task Force. This task force was established at WSDA and intended to evaluate and recommend ways to create a state regulatory structure for hemp extracts that creates market space for hemp producers and processors and provides safety and transparency for end-product consumers.

The proviso in the 2022 budget created the task force to develop recommendations for creating a state-level regulatory structure for hemp in food. The Task Force was facilitated by Steven Byers of the Athena Group. Task force members were appointed by the Director of WSDA under the leadership of Kelly McLain of WSDA. The full task force membership is listed in Appendix A.

The Task Force was directed to:

- Review the roles and regulatory requirements of management and regulatory agencies relating to food and dietary supplement labeling, manufacturing, and sales.
- Review current science around cannabinoids and human ingestion/exposure.
- Review research, reports, and data from states and countries that allow hemp extracts as food or dietary supplement ingredients.
- Review definitions and assumptions about a Washington State-based hemp in food program
- Develop recommendations, if appropriate, for allowing hemp extracts as food ingredients regulated at the state level and authorities to be granted to state agencies to regulate and oversee food manufacturing and sales related to hemp in food.

Task Force Meetings

As part of their review, the Task Force held ten virtual 2–3-hour meetings starting in July 2022 to learn from state agencies, universities, organizations, and individuals involved in hemp production, processing; human health and exposure concerns from cannabinoids; and local and national food manufacturing and sales. Below are brief summaries of their meetings:

July 2022

The first convened meeting of the work group occurred on Wednesday, July 20th. After introductions, the group received a presentation from the Department of Agriculture that covered the proviso, deliverables, and due dates. Each member of the workgroup discussed the things they hoped would be accomplished between August and December 2022.

August 2022: 8/3, 8/17, & 8/31

These meetings focused on background presentations and discussions on the known science around cannabinoids and human health, state regulatory programs for food manufacturing, and an overview of regulatory programs that cover hemp derived extracts in different states and countries. August also saw the creation of three different working groups: biosafety, definitions, and legislation. See Appendix B for further details contained in captured Cannabis Observer's meeting notes.

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September 2022: 9/21 & 9/29

There was a multi-week break for the large task force while the working groups tackled questions identified during the August meetings and WSDA staff prepared a full accounting of the state and international regulatory programs. The working groups were tasked with concerns around hemp terms used in this new regulatory structure, concentration, and regulatory program questions.

October 2022: 10/5, 10/19 & 10/26

All three meetings in October focused on detailed reports from the working groups on biosafety, legislative activities, and definitions. Those reports were used to create the recommendations in this report. Specific attention was focused on concentrations and definitions relevant to the concentrations and possible legislative action. WSDA announced the draft report would be available in early November for group review and approval.

November 16, 2022

The Task Force met, reviewed, and approved the final report to the Legislature of recommendations for regulating hemp in food.

Report Content

The Task Force was tasked with evaluating the safety and science information around hemp extracts, evaluating regulatory structures allowing these ingredients in food and dietary supplements in other states and countries, and recommending a path forward for Washington State that limits human ingestion/exposure risk but allows for marketing and commerce. There are many federal guidelines already in place around food and dietary supplement production to be considered. The guidelines around food and dietary supplements which were deemed relevant and are referenced within this report can be found within the Code of Federal Regulations and can be found in Appendix C. There has been a lack of federal guidelines around CBD, which is why this task force was convened. From the 2021 FDA responses to two New Dietary Ingredient Notifications (NDIN),[1,2] it is clear that Drug/IND Preclusion is the primary and controlling reason for objection to hemp extracts and CBD in dietary supplements.

In Washington state, the basic definitions of "food" and "dietary supplement" *mirror* those in the FDCA **minus** the exclusion language above. This means that for purposes of Washington state statute and code, Drug/IND Preclusion is not a gating issue for products sold within Washington state. [3,4] The task force believes hemp can safely be used as a food ingredient or in dietary supplements and should enable this market (Appendix D provides additional content on Drug/IND Preclusion).

Definition Recommendations

1. The Task Force recommends clearly defining hemp-based extracts as food ingredients and structuring future regulatory programs around those defined products.
2. Hemp in food will specifically refer to those extracts or parts of the plant not currently regulated for consumption elsewhere (i.e., hemp hearts by FDA, hemp greens/lettuces as produce).

   See *figure on page 8* for illustration of what is and is not included in the scope of these recommendations.

   Hemp extract (noun): means a substance, compound, or mixture of compounds intended for human consumption that is extracted from hemp. Extracts can be diluted, concentrated, or more purified compared to the original form. Does not include:

   (i) chemically transformed compounds, except for those that result from the application of heat, light, or pressure.
   (ii) any food (including hemp seeds), food ingredient, or food additive that is generally recognized as safe (GRAS) pursuant to federal law.
   (iii) any extract derived from hemp that is not intended for human consumption.

   Hemp Extraction (noun): The physical process whereby naturally occurring components are removed from the hemp plant.

   Extract (verb): To remove via physical or chemical processes naturally occurring components from the plant resulting in the formation of an extract.

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[1] FDA Response to Charlotte Web re: NDIN for Charlotte's Web Full Spectrum Hemp Extract. July 21, 2021.
https://www.regulations.gov/document/FDA-2021-S-0023-0053 Accessed 11/18/22

[2] FDA Response to Irwin Naturals re: NDIN for Full Spectrum Hemp Extract. July 21, 2021.
https://www.regulations.gov/document/FDA-2021-S-0023-0050 Accessed 11/18/22

[3] RCW 69.07.010(8).
https://app.leg.wa.gov/rcw/default.aspx?cite=69.07.010. Accessed 11/18/22.

[4] RCW 82.08.0293(2)(b).
https://apps.leg.wa.gov/rcw/default.aspx?Cite=82.08.0293. Accessed 11/18/22.

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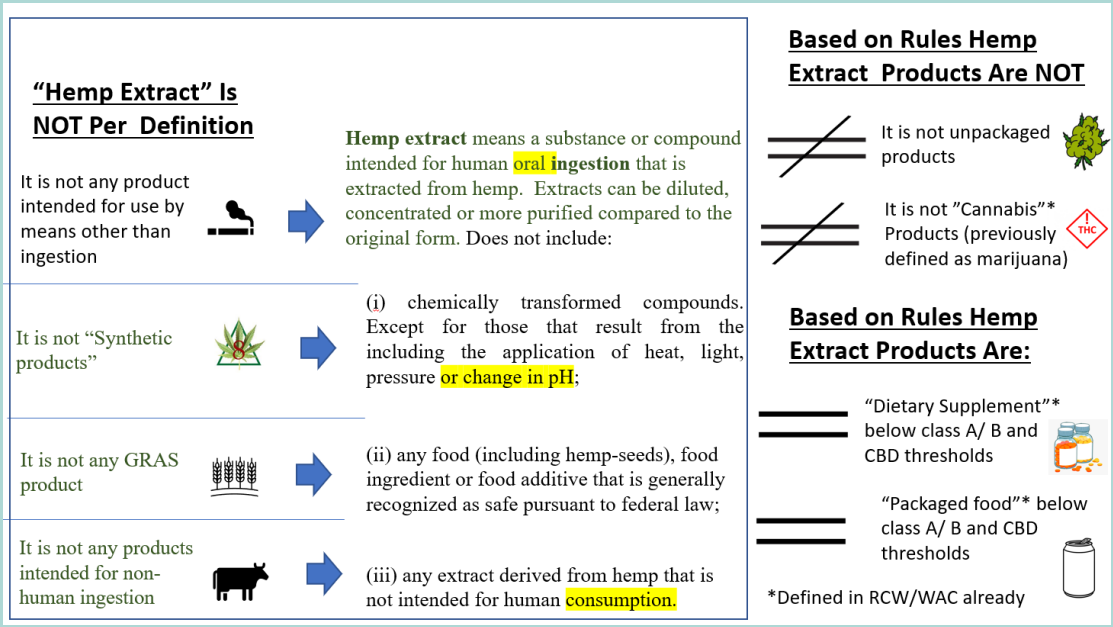

3. Defining "Class A" / "Class B"

"Class A Cannabinoid" means a substance that meets the following structural and functional criteria:

(i) The substance exhibits the structural backbone of tetrahydrocannabinols and tetrahydrocannabinol-like (THC-like) molecules that include the interconnected three-ring system of a) a six-carbon aromatic ring, b) a pyran ring; and a cyclohexene/ cyclohexane ring. Known compounds that fit the description provided in this subsection (3)(d)(i) include:

(A) Tetrahydrocannabinols – a single double-bond in the C ring:
(1) Delta-10-THC and isomers;
(2) Delta-9-THC and isomers;
(3) Delta-8-THC and isomers;
(4) Delta-7-THC and isomers;
(5) Delta-6a-THC and isomers; and
(6) Delta-10a-THC and isomers;

(B) Hexahydrocannabinol – no double bonds in the C ring

(C) Carboxylates (C-2 and C-4) of tetrahydrocannabinols or hexahydrocannabinol:
(I) Delta-9-THC acid (Delta-9-THCA);
(II) Similar carboxylates of Delta-9-THCA for tetrahydrocannabinols in (d)(i)(A)(1) through (6) of this subsection; and
(III) Carboxylate esters in (d)(i)(A)(1) through (6) of this subsection.

(D) Alkyl analogues (C-3) of tetrahydrocannabinols or hexahydrocannabinol:
(I) Delta-9-THCP (Delta-9-tetrahydrocannabiphorol) and n-alkyl analogues;
(II) Similar alkylated analogues of Delta-9-THC for tetrahydrocannabinols in (d)(i)(A)(1) through (6) of this subsection; and

(E) Hydroxylated analogues of tetrahydrocannabinols or hexahydrocannabinol:
(I) 11-hydroxy-delta-9-THC and 8- and 10-hydroxy analogues; and
(II) Similar hydroxylated analogues of Delta-9-THC for tetrahydrocannabinols in (d)(i)(A)(1) through (6) of this subsection.

(ii) Possesses statistically significant CB1 agonist activity as demonstrable by binding affinity (Ki) and potency (EC50) to CB1 receptors at less than 200 nM; and

(iii) Results in positive effects for all four components of the tetrad test in rodents or reliably causes functional impairment in humans as assessed by a method possessing scientific consensus.

"Class B Cannabinoid" means all cannabinoids that do not meet the form and function of Class A cannabinoids.

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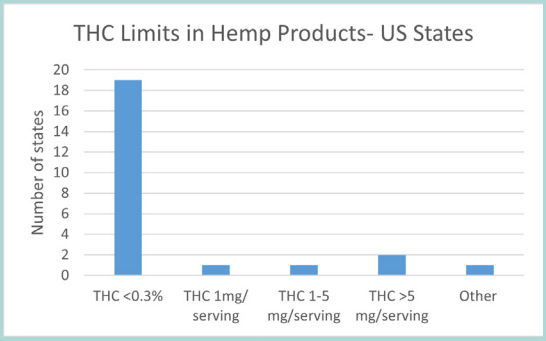
Safety and Allowances Considerations

The Task Force examined effects due to long-term exposure.

THC: The Task Force reviewed an extensive amount of data from state and federal jurisdictions (including other countries) as well as peer-reviewed publications to gather as much relevant data as possible. The full list of regulations reviewed can be found in Appendix G. The safety of both CBD and THC were reviewed closely and are summarized separately below. To reduce the potential for abuse or harm from accidental overexposure, the Task Force felt the need to establish maximum product thresholds by considering both the safety of these types of products (avoiding acute impairment) and prevention of potential detrimental effects from long-term usage. Of the 25 states that allow hemp in food, 19 states regulate products based on the definition of hemp being 0.3% THC or less.

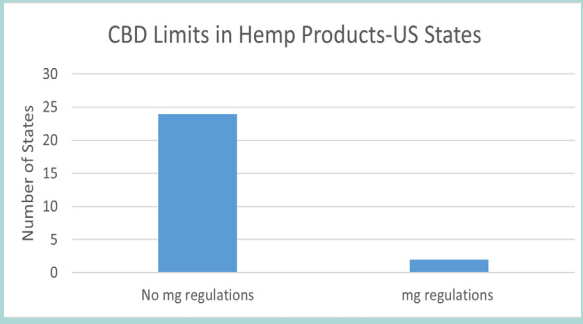


The Task Force recommends that Washington adds a limit on total milligrams (mg) of THC per package to prevent larger packages from containing large quantities of THC. We believe by setting a mg concentration limit that safety concerns can be mitigated.

When evaluating safe levels, the Task Force found limited data. The most extensive study to date from the European Union noted "A NOAEL (No Observed Adverse Effect Level) for THC is derived through this combination of results, demonstrating a threshold for impairment of psychomotor function only after intake of an oral THC bolus beyond 2.5 mg for the average healthy adult."[5]

The Task Force recommends maximum allowance for Class A (THC-like effect) compounds be set in rules when the pilot program allowances are replaced by a program administered in WAC by WSDA no later than January 1, 2025. Given the short amount of time, the Task Force was unable to come to a consensus on safety levels due to one task force member requiring more time to review. A task force vote was not called. In light of this, we recommend a more extensive literature review be done as soon as possible and levels be reviewed periodically.

CBD: The Task Force did not have concerns around CBD causing impairment but did want to review any possible significant detrimental long-term effects. The Task Force reviewed regulations from 25 other states and 9 countries which regulate CBD in food or supplements. At a state level, most states do not have mg/serving limits for CBD in food or dietary supplements. Washington would be one of the first states to enforce a mg per serving limit.



[5] A broader view on deriving a reference dose for THC traces in foods, Beitzke and Pate, Feb 2022. https://www.tandfonline.com/doi/full/10.1080/10408444.2021.2008867

Report Content

Appendix F contains a summary of other state's regulations for CBD. The Task Force identified several comprehensive scientific reviews of the **safety of CBD** in food or dietary supplements by other countries. Of note,

- Australia which allows 150 mg/serving of CBD has undergone two extensive scientific review cycles specifically noting a goal of identifying a level of CBD "that would not require the oversight by a medical practitioner."[6]
- Canada's scientific committee unanimously agreed CBD is safe and tolerable for short-term use (a maximum of 30 days) at doses from 20 milligrams per day (mg/day) to a maximum dose of 200 mg/day through oral administration[7].
- Additionally, a complete review of the scientific literature around the safety of CBD was done by the Lambert Center at the University of Sydney recently and noted "400 mg/day did not appear to be associated with an increased frequency of adverse effects."[8]

The Task Force is not providing an exact number within this report. We recommend a more extensive literature review as soon as possible and levels be reviewed periodically. Reference explaining this approach and data supporting it can be found in Appendix G.

20:1 Requirement: The Task Force further recommends products contain a minimum of a 20:1 ratio of Class B (non-THC-like effects) to Class A (THC-like effects).

The Task Force also found additional data that high levels of compounds with non-THC-like effect may enable the NOAEL allowances of THC to be raised in the future (this is specific to CBD at this point). Specifically, a Health Canada panel noted[9],

> "In general, there appear to be two types of mechanisms which could govern possible interactions between CBD and Δ9-THC: those of a pharmacokinetic origin, and those of a pharmacodynamic origin. Despite the limited and complex nature of the available information, it generally appears that pre-administration of CBD may potentiate some of the effects of THC (through a pharmacokinetic mechanism). Potentiation of THC effects by CBD may be caused by inhibition of THC metabolism in the liver, resulting in higher plasma levels of THC. Simultaneous co-administration of CBD and THC may result in the attenuation of some of the effects of THC (through a pharmacodynamic mechanism). Furthermore, the ratio between the two phytocannabinoids also appears to play a role in determining whether the overall effect will be of a potentiating or antagonistic nature. CBD-mediated attenuation of THC-induced effects may be observed when the ratio of CBD to THC is at least 8: 1, whereas CBD appears to potentiate some of the effects associated with THC when the CBD to THC ratio is around 2: 1. Some emerging pre-clinical evidence suggests combined anti-emetic sub-threshold doses of THC and CBD or cannabidiolic acid (CBDA) may be effective in animal models of acute nausea and/or anticipatory nausea."

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[6] Over-the-counter access to low dose cannabidiol, Dec 2020. https://www.tga.gov.au/news/media-releases/over-counter-access-low-dose-cannabidiol

[7] Review of cannabidiol: Report of the Science Advisory Committee on Health Products Containing Cannabis, July 2022. https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/health-products-containing-cannabis/review-cannabidiol-health-products-containing-cannabis.html

[8] The safety and efficacy of low oral doses of cannabidiol: An evaluation of the evidence. Oct. 2022. https://ascpt.onlinelibrary.wiley.com/doi/10.1111/cts.13425

[9] Information for Health Care Professionals: Cannabis (marihuana, marijuana) and the cannabinoids, prepared by Health Canada, Spring 2018. https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/information-medical-practitioners/information-health-care-professionals-cannabis-cannabinoids.html#a1.1.1)

Report Content

After considering these various references and studies, the Task Force has compiled the following recommendations reflecting the administrative or legislative aspects that would need updating if our recommendations were to be followed. This report was drafted by staff at WSDA and reviewed and evaluated by members of the Task Force.

Workgroup Findings and Recommendations

The Task Force identified specific categories of recommendations, including definitions, legislative, and administrative or overarching recommendations. Additionally, there are recommendations for further study to determine maximum limits of cannabinoids in products, Appendices with supporting information and definitions.

Administrative Recommendations

1. Food products containing hemp-based ingredients will only be allowed in prepackaged foods and beverages and dietary supplements.
2. WSDA should create a regulatory program for hemp food and dietary supplement ingredient processing and manufacturing when legislative action directs them to do so.
3. Dietary supplements containing hemp-based ingredients should be allowed under legislation.
4. All hemp products for consumption sold in Washington State must follow federal food and dietary supplement labeling standards.
5. Any packaging must be cautious of appealing to children.
6. Packaged foods and dietary supplements in this regulatory structure that contain THC must have no more than 0.3% THC in hemp ingredients, set milligrams of Class A (THC-like effects) and Class B (non-THC-like effects). The Task Force recommends that further scientific review is needed to establish whether there is a safe ratio of CBD: THC for non-impairing human consumption.
7. Chemically transformed cannabinoids are not allowed.

Legislative Recommendations

1. The Task Force recommends that further work be done to create a legislative package brought forth by stakeholders to create an equitable hemp in food and dietary supplement regulatory program.
2. The legislation should include a **pilot program with serving size requirements** that can be implemented quickly to create market space for the hemp industry. The program in statute should be replaced by a program administered in WAC by WSDA no later than January 1, 2025.

   Cannabinoid Allowances and Limits Recommendations: Due to the this being a rapidly evolving area of research, the Task Force would recommend allowances be evaluated periodically to incorporate best available science and stakeholder input.

3. Legislation should include labeling requirements, pilot program concentration allowances for foods, beverages, and dietary supplements, and rely on existing manufacturing procedures and food manufacturing sanitary standards.

   a. **Testing Recommendations:** Testing standards will be evaluated periodically to incorporate best available science and stakeholder input.

   Hemp in packaged food is allowed if the product meets safety standards for contaminants, established for food and beverages by applicable federal and state laws and regulations, including 21 CFR 117, WA state food laws and any other additional WA state hemp regulations implemented. Hemp in dietary supplements is allowed if the product complies with 21 CFR 111 and any other WA state hemp regulations implemented. This may include pesticides, heavy metals, or other contaminants of concern as appropriate.

   Final packaged products should be tested for cannabinoid levels based on a continuous batch lot.

b. **Processing Recommendations:** The appropriate state regulatory body will outline processor requirements and restrictions, including any relevant testing methods consistent with processing methods.

c. **Product Labeling Recommendations:**

- All hemp consumables must conform to applicable federal and state labeling laws including, without limitation, 21 CFR 101, 21 CFR 111, and 21 CFR 117.
- Label information on food and dietary supplement products must include:
  (a) The common name of the food or, absent a common name, an adequately descriptive identity statement.
  (b) If made from two or more ingredients, a list of ingredients in descending order of predominance by weight, including a declaration of artificial color or flavor and chemical preservatives, if contained in the food.
  (c) An accurate declaration of the quantity of contents.
  (d) Net weight or volume in U.S. customary and metric units.
  (e) Serving size and number of servings per container.
  (f) The name and place of business of the manufacturer, packer, or distributor.

d. **Product Label Warning Recommendations:**

- "Keep out of reach of children."
- "This product should not be consumed if you are pregnant or nursing."

4. Product maximum levels of Class A cannabinoids (THC-like effects) should be dictated by the primary Class B (non-THC-like effects) cannabinoids.
5. Legislation should exclude allowances for chemically transformed cannabinoids.

Conclusion

The Hemp in Food Task Force completed a significant amount of work in a very short period of time to meet the deadlines identified in the 2022 budget. There is still more work to be done to build out the possible scope for a hemp in food regulatory program in Washington State. Given current resources, WSDA intends to keep the Hemp in Food Task Force active and available to continue their work until June 30, 2023.

Hemp-based extracts as ingredients in food and beverage and dietary supplement products would increase market space for Washington hemp growers and processors while providing consumer protections in the marketplace that do not currently exist. Creating a program that limits youth access and includes robust labeling, serving size limits, required product testing, and more will make Washington State a safer place to buy and produce hemp ingredients in food and dietary supplement products.

This work would not have been possible without significant input from the Task Force members. Their contributions have been and continue to be invaluable. Task Force members are listed in Appendix A.

Appendix A

Hemp in Food Task Force Members

Dave Wyckoff, Wyckoff Farms
Amber Wise, PhD, Medicine Creek Analytics
David Gang, PhD, Washington State University
Jessica Tonani, Verda Bio
Bonny Jo Peterson, Industrial Hemp Association of WA
Dylan Summers, Lazarus Naturals
Dr. Nephi Stella, University of Washington
Dr. Jay Noller, Global Hemp Innovation Center
Jim Makoso, I-502 participant and Social Equity in Cannabis Task Force co-chair
John Hunt, Hemp extraction – 405 Labs LLC
Ryan Hevly, WSDA
Jedidiah Haney, Natural Family Farms, LLC
Eric Elgar, NeXraction
Brad Douglas, PhD, Scientist
Dan Carter, CEO Canadian Hemp Farmers Alliance
Joy Beckerman, Hemp Ace International
Lukas Barfield, Quality West Cannabis
Jessica Allenton, WSDA
Kelly McLain, WSDA
Rob Oliver, Washington State Department of Health
Joe Laxson, Washington State Department of Health
Luisa Castro, WSDA

Appendix B

Cannabis Observer meeting Summaries

The Hemp in Food Task Force invited representatives from the Cannabis Observer, an organization that creates information about cannabis policymaking in Washington State, to attend meetings. The following links provide additional information about task force and workgroup meetings.

Cannabis Observer Resources

- Archived task force meeting materials
- Information from the "Concentration and Safety" workgroup
- Information from the "Definitions" workgroup

Appendix C

Relevant code of federal regulations (CFRs)

CFR TITLE	CFR PART # & LINK
Current Good Manufacturing Practice, Hazard Analysis, And Risk-Based Preventive Controls for Human Food	21 CFR 117
Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements	21 CFR 111
Food Labeling	21 CFR 101
Nutrition Labeling of Dietary Supplements	21 CFR 101.36

Appendix D

DRUG/IND PRECLUSION AND HEMP

The Federal Food, Drug, and Cosmetic Act (FDCA) provides that a product cannot be marketed as a dietary supplement if it includes an "article" that has been: (1) approved as a new drug; or (2) authorized for investigation as a new drug (a) for which substantial clinical investigations have been instituted on the article and their existence made public, and (b) was not marketed as a food or dietary supplement prior to being authorized for investigation as a new drug.

Similarly, but not identically, the FDCA also prohibits the introduction or delivery for introduction into interstate commerce of any food to which has been added (1) an approved drug (2) an approved biologic OR (3) a drug or a biological product for which "substantial clinical investigations" have been instituted and for which the existence of such investigations has been made public.

In Washington state, the basic definitions of "food" and "dietary supplement" *mirror* those in the FDCA **minus** the exclusion language above. This means that for purposes of Washington state statute and code, Drug/IND Preclusion is not a gating issue for products sold within Washington state. One can only presume that the Washington State Legislature intentionally truncated the definition of food and dietary supplements.

Why Does Drug/IND Preclusion Exist?

There is a succinct regulatory adage that sums up the effects of Drug/IND Preclusion: "First a food, always a food. First a drug, never a food." More elaborately, this means that if an "article" is first studied to become a drug before it has been marketed as a food or dietary supplement, then it can only ever be a drug and never a food. However, if an "article" is marketed as a food and/or dietary supplement product first, then it could still become a drug without impeding its legal status in food and dietary supplement products.

The rationale for Drug/IND Preclusion stems from the Dietary Supplement Health and Education Act of 1994 (DSHEA), which amended the FDCA. The Congressional rationale for Drug/IND Preclusion was to: 1) maintain sufficient incentives for drug companies to undertake the clinical development necessary to produce prescription drugs and 2) avoid bad actors bypassing the drug development pathway by selling drugs under the guise of dietary supplements without conducting the clinical efficacy evaluations that are a hallmark of the prescription drug approval process.

The intent of Congress with the passage of DSHEA was to create a "race-to-market" dynamic that would presumably benefit the consumer. If consumers were first presented with the opportunity to access an "article" as a food or dietary supplement, then they should always be permitted that access. However, if a drug company undertook the resource intensive work to demonstrate that an "article" was useful to diagnose, cure, mitigate or treat a disease then that investment should also be protected. The idea was that both access to a substance AND clinical data for a substance are both important and should be balanced.

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[10] 21 USC § 321(ff)(3)(B). https://www.law.cornell.edu/uscode/text/21/321. Accessed 11/18/22.

[11] 21 USC § 331(ll). https://www.law.cornell.edu/uscode/text/21/331. Accessed 11/18/22.

[12] RCW 69.07.010(8). https://app.leg.wa.gov/rcw/default.aspx?cite=69.07.010. Accessed 11/18/22.

[13] RCW 82.08.0293(2)(b). https://apps.leg.wa.gov/rcw/default.aspx?Cite=82.08.0293. Accessed 11/18/22.

[14] US Congress. Public Law No. 103-417, 108 Stat. 4325. 25 October 1994. [Dietary Supplement Health and Education Act of 1994]. https://www.govinfo.gov/content/pkg/STATUTE-108/pdf/STATUTE-108-Pg4325.pdf. Accessed 11/18/22.

Appendix D

Criticism of Drug/IND Preclusion in Practice

The U.S. Food and Drug Administration (FDA) has been criticized in the decades since the passage of DSHEA for mismanaging the balanced intent of Congress and interpreting the Drug/IND Preclusion provisions in an overly broad manner to favor the pharmaceutical industry at the expense of the American public. Although hemp extracts and cannabidiol (CBD) are a recent example that has elevated criticism over FDA's position on Drug/IND Preclusion, it is not the only example. The history, specifics and other examples of FDA's Drug/IND policies have been addressed by others and will not be repeated here.[15]

The below includes a list of the objections to Drug/IND Preclusion – not as a concept – but merely as it is currently implemented by FDA:

1. **No time limit** on Drug Preclusion exists.
2. **Any dose** studied/approved as a drug, no matter how large, precludes the legal use in food/supplements, no matter how small.
3. **Any indication** that a drug may be approved for even if it impacts a tiny segment of the population (e.g. pediatric drugs), precludes use in food/supplements for all.
4. A drug studied for any route of administration other than ingestion (e.g. inhalation, injection, transdermal) precludes legal use in food/supplements which require ingestion.
5. Investigational New Drug (IND) Applications have been used as a key timepoint to demarcate "substantial clinical investigations" **yet even the existence of an IND is confidential** until the IND sponsor chooses to disclose creating a retroactive cudgel.
6. When "substantial clinical investigations" do not lead to a commercially available drug product for non-safety-related factors, current FDA policy holds that Drug Preclusion remains in effect preventing any legal access to that article by patient or consumer.

The Rationale for Breaking with FDA on Drug/IND Preclusion Policy for Hemp and CBD

In Washington state, consumers clearly desire access to manufactured and ingestible products made with hemp extract and/or CBD. This is similar to the situation in most states and is evidenced by the substantial grey market for these goods. The market remains "grey" and largely unregulated specifically because FDA has not acted expeditiously to resolve the matter.

For Washingtonians, that wish to consume CBD for general wellness or non-therapeutic applications, it seems inane that they have two choices: 1) obtain a prescription for a drug product (see Epidiolex®)[16] that is only indicated for various, clinical seizure disorders at a daily dosage substantially greater than wellness applications and 2) risk consuming products that have been produced without oversight in terms of what goes into them (e.g., how much THC is present) or how they were manufactured. This is certainly not the consumer-benefiting concept that Congress sanctioned with the passage of DSHEA.

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[15] Olsen M, Garza D. Drug preclusion and public health: The case for a narrow interpretation of 'article.' Regulatory Focus. 17 November 2022. https://www.raps.org/news-and-articles/news-articles/2022/11/drug-preclusion-and-public-health-the-case-for-a-n. Accessed 11/18/22

[16] Epidiolex Highlights of Prescribing Information. GW Pharmaceuticals https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210365lbl.pdf Accessed 11/18/22

Appendix D

From the 2021 FDA responses to two New Dietary Ingredient Notifications (NDIN),[17,18] it is clear that Drug/IND Preclusion is the primary and controlling reason for objection to hemp extracts and CBD in dietary supplements. Secondarily, FDA has expressed continued concerns or uncertainty regarding the safety of hemp extracts and CBD for ingestion. The issue of safety, particularly in the context of daily exposure limits and the extant grey market availability of food and supplement products containing hemp extracts and CBD, has been addressed by the Washington State Hemp in Food (HIF) Task Force and forms the foundation of its recommendations for maximum serving and package limits for CBD in food and dietary supplement products.

Also, the HIF Task Force is acutely aware that its own recommendations and position on practical limits on Drug/IND Preclusion for purposes of hemp extracts and CBD inclusion into foods and dietary supplements is not new. In fact, various bills have been introduced by Congress to address this very same concern. The Task Force can only conclude that the HIF Task Force's own position on limiting Drug/IND Preclusion for hemp/CBD is hardly revolutionary.[19,20]

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[17] FDA Response to Charlotte Web re: NDIN for Charlotte's Web Full Spectrum Hemp Extract. July 21, 2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210365lbl.pdf Accessed 11/18/22

[18] FDA Response to Irwin Naturals re: NDIN for Full Spectrum Hemp Extract. July 21, 2021. https://www.regulations.gov/document/FDA-2021-S-0023-0050 Accessed 11/18/22

[19] The Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2020 (H.R. 841). 116th Congress.

[20] Hemp Access and Consumer Safety Act of 2021 (S. 1698). 117th Congress.

Appendix E

Regulatory Framework Comparison Research

The attached spreadsheet illustrates the comprehensive research conducted to inform development of the included hemp in food recommendations.

Link to appendix document

Appendix F

Review of CBD safety and allowances from other jurisdictions

Due to the this being a rapidly evolving area of research, the Task Force would recommend allowances be evaluated periodically to incorporate best available science and stakeholder input.

The Task Force reviewed regulation from 25 other states and 9 countries which regulate CBD in food or supplements. At a state level, most states do not have mg/serving limits for limits in food or dietary supplements CBD. Washington would be one of the first states to enforce a mg per serving limit.

	No mg restrictions US	mg restrictions US
CBD Levels	(24) AK, CA*, CO, CT, FL, HI, IA, IN, KY, LA, MI, MN, NM, NJ, OH, RI, SD, TX, UT, VT, VA, WI, WV, WY	NY: Hemp Food/Beverage: 0.3% THC; No more than 25 mg of total cannabinoids (including CBD) per individually packaged product. Hemp Supplement: 0.3% THC; No more than 3,000 mg of total cannabinoids (including CBD) per product with no more than 100 mg per serving. OR: Hemp Concentrates, Extracts, or Tinctures: 100 mg total THC per container. Hemp Edibles: 20 mg per unit/2 mg per serving. (in addition to 0.3% THC limit).

The Task Force found key countries had undertaken impressive scientific reviews of the safety of CBD in food or dietary supplements. Of note,

- Australia which allows 150 mg/serving of CBD has undergone two extensive scientific review cycles specifically noting a goal of identifying a level of CBD "that would not require the oversight of by a medical practitioner."
- Canada's scientific committee **unanimously agreed CBD is safe and tolerable for short-term use (a maximum of 30 days) at doses from 20 milligrams per day (mg/day) to a maximum dose of 200 mg/day through oral administration.**
- Additionally, a complete review of the scientific literature around the safety of CBD was done by the Lambert Center at the University of Sydney recently and noted "400 mg/day did not appear to be associated with an increased frequency of adverse effects."

Appendix G

SUMMARY OF THC SAFETY AND ALLOWANCES FROM OTHER JURISDICTIONS

The Task Force reviewed regulation from 25 other states and 9 countries which regulate hemp in food or supplements. 19 of the 25 states defer to 0.3% weight restrictions for THC levels. The Task Force acknowledges this metric can enable high levels of THC levels in larger packaged products. We recommend a mg threshold be set for products in Washington.

	No mg restrictions US	mg restrictions US
THC Levels	(19) CA (.3%), CO (.3%), CT (.3%), FL (.3%), HI (.3%), IA (.3%), IN (.3%), KY (.3%), NM, NJ, OH, RI, SD, TX, VA, VT, WI, WV, WY	AK= 50 mg D-9, LA= 8 mg Total THC per serving/0.3% delta 9 THC/1.0% Total THC. MI=1 mg THC per serving/10mg THC per container/0.3% THC. MN=5 mg any THC per serving/ 50 mg any THC per package/0.3% THC. OR=*100 mg total THC per container, UT=total THC and any THC analog that does not exceed 10% of the tot
Synthetic Ban	CO (ban), HI (ban), NY ban)	

Appendix H

HEMP IN FOOD DEFINITIONS (ADAPTED FROM WORKGROUP NOTES)

HEMP EXTRACT (noun): means a substance, compound, or mixture of compounds intended for human consumption that is extracted from hemp. Extracts can be diluted, concentrated, or more purified compared to the original form. Does not include:

(i) chemically transformed compounds, except for those that result from the application of heat, light, or pressure.
(ii) any food (including hemp seeds), food ingredient, or food additive that is generally recognized as safe (GRAS) pursuant to federal law.
(iii) any extract derived from hemp that is not intended for human consumption.

HEMP EXTRACTION (noun): The physical process whereby naturally occurring components are removed from the hemp plant.

EXTRACT (verb): To remove via physical or chemical processes naturally occurring components from the plant resulting in the formation of an extract.

"CLASS A CANNABINOID" means a substance that meets the following structural and functional criteria:

(i) The substance exhibits the structural backbone of tetrahydrocannabinols and tetrahydrocannabinol-like (THC-like) molecules that include the interconnected three-ring system of a) a six-carbon aromatic ring, b) a pyran ring; and a cyclohexene/cyclohexane ring. Known compounds that fit the description provided in this subsection (3)(d)(i) include:

(A) Tetrahydrocannabinols – a single double-bond in the C ring:
(1) Delta-10-THC and isomers;
(2) Delta-9-THC and isomers;
(3) Delta-8-THC and isomers;
(4) Delta-7-THC and isomers;
(5) Delta-6a-THC and isomers; and
(6) Delta-10a-THC and isomers;

(B) Hexahydrocannabinol – no double bonds in the C ring

(C) Carboxylates (C-2 and C-4) of tetrahydrocannabinols or hexahydrocannabinol:
(I) Delta-9-THC acid (Delta-9-THCA);
(II) Similar carboxylates of Delta-9-THCA for tetrahydrocannabinols in (d)(i)(A)(1) through (6) of this subsection; and
(III) Carboxylate esters in (d)(i)(A)(1) through (6) of this subsection.

(D) Alkyl analogues (C-3) of tetrahydrocannabinols or hexahydrocannabinol:
(I) Delta-9-THCP (Delta-9-tetrahydrocannabiphorol) and n-alkyl analogues;
(II) Similar alkylated analogues of Delta-9-THC for tetrahydrocannabinols in (d)(i)(A)(1) through (6) of this subsection; and

(E) Hydroxylated analogues of tetrahydrocannabinols or hexahydrocannabinol:
(I) 11-hydroxy-delta-9-THC and 8- and 10-hydroxy analogues; and
(II) Similar hydroxylated analogues of Delta-9-THC for tetrahydrocannabinols in (d)(i)(A)(1) through (6) of this subsection.

(ii) Possesses statistically significant CB1 agonist activity as demonstrable by binding affinity (Ki) and potency (EC50) to CB1 receptors at less than 200 nM; and
(iii) Results in positive effects for all four components of the tetrad test in rodents or reliably causes functional impairment in humans as assessed by a method possessing scientific consensus.

"CLASS B CANNABINOID" means all cannabinoids that do not meet the form and function of Class A cannabinoids.