

Summary of Amendments Ch. 11-37 (Interim Rules) Hawaii Administrative Rules – “Hemp Processing and Manufactured Hemp Products”

Effective December 6, 2024

Prepared by Department of Health – Office of Medical Cannabis Control and Regulation

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Disclaimer

This document is for informational purposes only and does not replace Chapter 11-37 (Interim Rules) as approved on November 26, 2024 (effective December 6, 2024). Readers should refer to the official version of the interim rules for complete and accurate information and consult their own legal counsel for specific legal advice.

Access to Chapter 11-37 (interim rules), HAR, be found at:

DOH - Office of Planning, Policy and Program Development <https://health.hawaii.gov/opppd/administrative-rules/>

Or DOH - Office of Medical Cannabis Control and Regulation <https://health.hawaii.gov/medicalcannabis/statutes-and-rules/>

Questions? Email DOH.hemp@doh.hawaii.gov

Summary of Key Changes to Interim Rules

- (1) Add definition and requirements for the manufacture, packaging, testing, labeling and sale of “Crude extract”.
- (2) Amend definition of “Total THC” - added Delta 8 THC to total THC equation.
- (3) Add definition of “liquid form” to clarify it means oil-based tincture.
- (4) Allow the manufacture, packaging, testing, labeling and sale of two new forms of edible manufactured hemp products (MHP): Gummies and Beverages.
- (5) Establish total THC limits for allowable edible MHP’s that can be sold in Hawaii:

Edible MHP	Max total THC p/serving	Max total THC p/container	Volume limit p/container	Total THC must remain $\leq 0.3\%$
Gummies, tablets, capsules, powders, softgels, gelcaps	1 mg (serving size must be a single gummy, tablet, etc. or a single packet of powder)	5 mg	N/A	Yes
Oil-based tincture	2.5 mg	75 mg	Max 2 fl. oz.	Yes
Beverage	N/A	0.5 mg	6 fl. oz. - 12 fl. oz.	Yes

- (6) Oil-based tinctures, tablets, capsules, powders, softgels and gelcaps that are in full compliance with previous 11- 37 interim rules can continue to be sold to consumers through Feb. 28, 2025. Effective March 1, 2025, all MHP’s sold to consumers in-state must comply with current 11-37 interim rules.

Summary of Key Changes to Interim Rules (cont.)

- (7) Clarify that “processing” includes packaging, repackaging, labeling and relabeling activities.
- (8) Child resistant packaging required for all edible MHP’s sold in multi-serving containers.
- (9) Restrictions on MHP’s being attractive to children. MHP cannot resemble commercially available candy or other products marketed to children or have appearance, flavor or smell designed to appeal to children. Cannot be in shape of human, animal, fruit, cartoon characters or caricatures. “Candy” and “candies” cannot be used on packaging, labeling, advertising.
- (10) New MHP labeling requirement - “Not for sale to persons under the age of 21” or similar phrasing.
- (11) DOH permitted hemp processor may manufacture and hold an edible MHP exceeding the total THC mg limits specified, but not exceeding 0.3% total THC, for sale outside the state or country provided it complies with rules in jurisdiction it is sold in.
- (12) Add embargo and detention section to clarify DOH enforcement powers and procedures.
- (13) Establish criteria for the sale of crude extract and bulk MHP between permitted hemp processors.

Overview of Crude Extract and Manufactured Hemp Products

- DOH hemp processor permit required to process, manufacture, package, repackage, label or relabel. Must follow 11-37 interim rules (facility design, GMP's, testing, labeling, training, recordkeeping, recall procedures, etc.).
- Comply with package labeling and lab testing requirements for cannabinoid content and contaminants
- Non-hemp ingredients must be safe for human consumption (*applies to crude extract and edible MHP*).
- Cannot contain artificially or synthetically derived cannabinoids.
- Cannot contain tobacco, nicotine, caffeine, alcohol, kava, or any other non-cannabis substance that is psychoactive or would increase potency or create potential unsafe combination with cannabinoids.
- Multi-serving package must be in continuous child resistant container (*applies to edible MHP*).
- Cannot resemble commercially available candy or other products marketed to children or have appearance, flavor or smell designed to appeal to children. Cannot be in shape of human, animal, fruit, cartoon characters or caricatures. “Candy” and “candies” cannot be used on packaging, labeling, advertising (*applies to edible and topical MHPs*)
- In-state sale to consumer: Edible MHP must comply with p/serving and p/container total THC mg limits.
- Out-of-state sale to consumer: Edible MHP that exceeds total THC mg limits for in-state sale, can be sold to consumers in another state or country.

Hemp Crude Extract - New

“Crude extract” means an extract from hemp biomass that:

- (1) Has not been processed to concentrate or remove botanical constituents after the initial extraction is made;
- (2) Has not undergone the complete manufacturing process into a manufactured hemp product; and
- (3) Is not yet fit for use or consumption by consumers.



Establish unique requirements for testing, labeling and sale of crude extract:

Lab Test for Cannabinoid Content and Contaminants	Label Information (partial list)	Sale Allowed	Sale Prohibited
<ul style="list-style-type: none"> • Total THC (sum of THCA, D9 THC and D8 THC) <p style="text-align: center;">AND</p> <ul style="list-style-type: none"> • Mycotoxins 	<ul style="list-style-type: none"> • Total THC mg p/container. • Provides access to lab results • Ingredient list • Required statements informing not fit for consumer consumption and sale allowed only to permitted hemp processors. 	<ul style="list-style-type: none"> • Only between DOH permitted hemp processors. <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • To/from a permitted hemp processor in another state or country (if allowed). 	<ul style="list-style-type: none"> • To consumer • If total THC > 0.3% • Exceeds mycotoxin limit

- Specific section detailing allowance to filter, press, add ingredients that only dilute and stabilize.
- Cannot contain artificially or synthetically derived cannabinoids.
- Cannot contain tobacco, nicotine, caffeine, alcohol, kava, or any other non-cannabis substance that is psychoactive or would increase potency or create potential unsafe combination with cannabinoids.

GUMMIES - New Edible MHP

“Gummy” or “gummies” means a chewable soft confection made primarily from sugar with gelatin or another gelling agent such as starch or pectin.

- Cannot contain artificially or synthetically derived cannabinoids.
- Cannot contain tobacco, nicotine, caffeine, alcohol, kava, or any other non-cannabis substance that is psychoactive or would increase potency or create potential unsafe combination with cannabinoids.
- Restrictions established to reduce attractiveness to children.



Requirements for manufacture, testing, packaging and labeling of gummies:

Serving size limit	Max Total THC p/serving	Max Total THC p/container	Total THC must remain $\leq 0.3\%$	Non-hemp Ingredients	Compliant with Required Lab Testing	Child resistant packaging	Label Information (partial list)
1 gummy	1 mg	5 mg	Yes	Safe for human use	<ul style="list-style-type: none"> • Cannabinoid content • Contaminants 	Required for container with multi-servings	<ul style="list-style-type: none"> • Total THC mg p/serving, plus amount p/serving of other cannabinoids (i.e., CBD) • Provides access to lab results • Ingredient list • Directions for use • Required statements and warnings, including “Not for sale to persons under the age of 21.”

BEVERAGE - New Edible MHP

Newly allowed as edible manufactured hemp product.

- Cannot contain artificially or synthetically derived cannabinoids.
- Cannot contain tobacco, nicotine, caffeine, alcohol, kava, or any other non-cannabis substance that is psychoactive or would increase potency or create potential unsafe combination with cannabinoids.
- Restrictions established to reduce attractiveness to children.



Requirements for manufacture, testing, packaging and labeling of a beverage:

Max Total THC p/container	Total THC must remain ≤0.3%	Volume limit p/container	Non-hemp Ingredients	Compliant with Required Lab Testing	Child resistant packaging	Label Information (partial list)
0.5 mg	Yes	No less than 6 fl. oz and no more than 12 fl. oz.	Safe for human use	<ul style="list-style-type: none"> • Cannabinoid content • Contaminants 	Required for container with multi-servings	<ul style="list-style-type: none"> • Total THC mg p/serving, plus amount p/serving of other cannabinoids (i.e., CBD) • Provides access to lab results • Ingredient list • Directions for use • Required statements and warnings, including “Not for sale to persons under the age of 21.”

OIL-BASED TINCTURE - New limits on total THC, Ingredients, Volume

New definition of “Liquid form” means oil-based tincture to be orally consumed.

- Cannot contain artificially or synthetically derived cannabinoids.
- Cannot contain tobacco, nicotine, caffeine, alcohol, kava, or any other non-cannabis substance that is psychoactive or would increase potency or create potential unsafe combination with cannabinoids.
- Restrictions established to reduce attractiveness to children.
- Must be packaged with dropper or spray top.



Requirements for manufacture, testing, packaging and labeling of oil-based tinctures:

Max Total THC p/serving	Max Total THC p/container	Total THC must remain ≤0.3%	Volume limit p/container	Non-hemp Ingredients	Compliant with Lab Testing	Child resistant packaging	Label Information (partial list)
2.5 mg	75 mg	Yes	Max 2 fl. oz.	<ul style="list-style-type: none"> • Safe for human use • Cannot be used to sweeten or to add flavor 	<ul style="list-style-type: none"> • Cannabinoid content • Contaminants 	Required for container with multi-servings	<ul style="list-style-type: none"> • Total THC mg p/serving, plus amount p/serving of other cannabinoids (i.e., CBD) • Provides access to lab results • Ingredient list • Directions for use • Required statements and warnings, including “Not for sale to persons under the age of 21.”

TABLETS, CAPSULES, POWDERS, SOFTGELS, AND GELCAPS

Allowed as manufactured hemp product to be orally consumed.

- Cannot contain artificially or synthetically derived cannabinoids.
- Cannot contain tobacco, nicotine, caffeine, alcohol, kava, or any other non-cannabis substance that is psychoactive or would increase potency or create potential unsafe combination with cannabinoids.
- Restrictions established to reduce attractiveness to children.



Requirements for manufacture, testing, packaging and labeling of tablets, capsules, powders, softgels, and gelcaps:

Serving size limit	Max Total THC p/serving	Max Total THC p/container	Total THC must remain $\leq 0.3\%$	Non-hemp Ingredients	Compliant with Required Lab Testing	Child resistant packaging	Label Information (partial list)
<ul style="list-style-type: none"> • 1 tablet • 1 capsule • 1 pk powder • 1 softgel • 1 gelcap 	1 mg	5 mg	Yes	Safe for human use	<ul style="list-style-type: none"> • Cannabinoid content • Contaminants 	Required for container with multi-servings	<ul style="list-style-type: none"> • Total THC mg p/serving, plus amount p/serving of other cannabinoids (i.e., CBD) • Provides access to lab results • Ingredient list • Directions for use • Required statements and warnings, including “Not for sale to persons under the age of 21.”

TOPICAL MANUFACTURED HEMP PRODUCTS

Allowed as manufactured hemp product to be applied topically

- Cannot contain artificially or synthetically derived cannabinoids.
- Cannot contain tobacco, nicotine, caffeine, alcohol, kava, or any other non-cannabis substance that is psychoactive or would increase potency or create potential unsafe combination with cannabinoids.
- Restrictions established to reduce attractiveness to children.



Requirements for manufacture, testing, packaging and labeling of a topical:

Max Total THC p/container	Total THC must remain ≤0.3%	Volume limit p/container	Non-hemp Ingredients	Compliant with Required Lab Testing	Child resistant packaging	Label Information (partial list)
N/A	Yes	N/A	Safe for human use	<ul style="list-style-type: none"> • Cannabinoid content • Contaminants 	N/A	<ul style="list-style-type: none"> • Total THC mg p/container, plus amounts of other cannabinoids (i.e., CBD) in container. • Provides access to lab results • Ingredient list • Directions for use • Required statements and warnings, including “For external use only” and “Not for sale to persons under the age of 21.”

Manufactured Hemp Products for Sale Outside the State

DOH Permitted Hemp Processor requirements for the manufacture, holding and sale of MHPs that are not allowed for sale in Hawaii because it exceeds the total THC mg limits established in 11-37-6:

Total THC must remain ≤0.3%	Required Lab Testing Prior to Sale	Required Label Information Prior to Sale	Sale Allowed	Sale Prohibited	Limitations
Yes	<ul style="list-style-type: none"> • Must meet lab testing requirements in interim rules to determine cannabinoid content and compliance with contaminant limits. <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • Meet the testing requirements of state or country MHP to be sold in prior to shipment. 	<ul style="list-style-type: none"> • Must meet labeling requirements found in interim rules. <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • Meet the labeling requirements of the state or country to be sold in prior to shipment. 	To consumers, retailers and distributors in another state or country (if allowed)	To consumers, retailers and distributors in Hawaii.	<p>MHP must comply with all other requirements in interim rules. This means only:</p> <ul style="list-style-type: none"> • Oil-based tinctures, • Gummies, • Beverages, • Tablets, • Capsules, • Powders, • Softgels, • Gelcaps, • Topicals <p>can be made and must adhere to all rules regarding packaging, volume, use of ingredients, etc.</p>

- DOH permitted hemp processor must store MHP intended for out of state sale in clearly marked quarantine area that is separate from other MHP's intended for sale to consumers in Hawaii.
- Records maintained on quantity of product shipped and name, address, phone number of distributor, retailer or individual.

Bulk Manufactured Hemp Products for Use as Ingredients

DOH Permitted Hemp Processor requirements for the sale and purchase of bulk MHPs for use as ingredients that are not allowed for sale in Hawaii because it exceeds the total THC mg limits established in 11-37-6:

Total THC must remain $\leq 0.3\%$	Required Lab Testing Prior to Sale	Required Label Information Prior to Sale	Sale and Purchase Allowed	Sale Prohibited	Limitations
Yes	<ul style="list-style-type: none"> • Must meet lab testing requirements in interim rules to determine cannabinoid content and compliance with contaminant limits. <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • Meet the testing requirements of state or country where MHP is to be sold prior to shipment. 	<ul style="list-style-type: none"> • Must meet labeling requirements found in interim rules. <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • Meet the labeling requirements of the state or country to be sold in prior to shipment. 	<ul style="list-style-type: none"> • To/from DOH permitted processor <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> • To/from permitted hemp processor in another state or country (if allowed) 	To consumers, retailers, distributors and processors not authorized by the state or country they operate in.	<p>Bulk MHP must comply with all other requirements in interim rules. This means only bulk packages of:</p> <ul style="list-style-type: none"> • Oil-based tinctures, • Gummies, • Beverages, • Tablets, • Capsules, • Powders, • Softgels, • Gelcaps, • Topicals <p>can be made and must adhere to all rules regarding use of ingredients, artificial and synthetic cannabinoids, etc.</p>

Crude Extract and MHPs for Use by Medical Cannabis Licensees

- 11-850-77 interim rules amended to allow a medical cannabis licensee to use hemp crude extract and MHPs, that are compliant with 11-37 interim rules, for use in a medical cannabis product (except medical cannabis liquid SPA cartridges).
- A medical cannabis licensee must obtain a DOH hemp processor permit to purchase crude extract and bulk MHPs as in-state sale of these products are only allowed between DOH permitted hemp processors (see 11-37-3(i) and 11-37-7 for criteria to sell crude and bulk MHPs).

PROHIBITIONS ON SALE 11-37-3

Sale, hold for sale, offer or distribute of the following is PROHIBITED:

- Crude extract or MHP that is adulterated or misbranded
- Crude extract or MHP that fails to meet applicable testing requirements
- Any food into which a cannabinoid, artificially derived cannabinoid, synthetic cannabinoid, hemp, hemp biomass, or MHP has been added as ingredient. *This does not apply to hemp that is GRAS by FDA for use in foods, nor allowable edible MHP forms that are compliant with 11-37-5 (tablets, capsules, powders, softgels, gelcaps, oil-based tinctures, gummies, beverages).
- Crude extract or MHP that has total THC concentration above 0.3%.
- Vape or other product used to aerosolize for respiratory routes of delivery containing hemp-derived cannabinoid, artificially derived cannabinoid, synthetic cannabinoid, or hemp.
- Hemp leaf, hemp floral material, including but not limited to hemp cigars or hemp cigarettes, viable seeds. *This does not apply to sale of hemp leaf, hemp floral material, or viable seeds to a USDA licensed hemp producer or a DOH permitted hemp processor.

PROHIBITIONS ON SALE 11-37-3 (continued)

Sale, hold for sale, offer or distribute of the following is PROHIBITED:

- MHP containing any viable seeds, leaf or floral materials.
- Except for external topically applied MHP, any product containing a hemp-derived cannabinoid, artificially derived cannabinoid, synthetic cannabinoid, hemp, hemp biomass, or MHP as an ingredient intended to be introduced via non-oral routes of entry to body (i.e., eyes, ears and nasal cavities, etc.).
- Crude extract directly to a consumer. *Crude extract shall only be sold to a permitted hemp processor or person with equivalent authority from regulatory agency in another jurisdiction (i.e., another state or country).
- Contents from an open package of MHP to a consumer. *Sample packs of MHP must comply with all packaging, labeling and testing requirements.
- Advertising, packaging, labeling that contains health or benefit claims that are unsubstantiated, false, or misleading in any way. *Excludes FDA approved drugs that contain cannabinoids.