DEPARTMENT OF HEALTH

Amendment and Compilation of Chapters 11-37 and 11-850
(Interim Rules)
Hawaii Administrative Rules

November 22, 2024

SUMMARY

1. Chapter 11-37 (Interim Rules) is amended and compiled.

2. Chapter 11-850 (Interim Rules) is amended and compiled.

LIEUTENANT GOVERNOR OF HAWAII
THIS IS TO CERTIFY THAT THE FOREGOING IS A
TRUE AND CORRECT COPY OF THE ORIGINAL
WHICH IS ON FILE AND OF RECORD IN THIS OFFICE
DEC -9 2024
HONOLULU, HAWAII

HAWAII ADMINISTRATIVE RULES

TITLE 11

DEPARTMENT OF HEALTH

CHAPTER 37

HEMP PROCESSING AND MANUFACTURED HEMP PRODUCTS

Subchapter 1 General Provisions

§11-37-1 Purpose and applicability
§11-37-2 Definitions
§11-37-3 Prohibitions
§11-37-4 Manufactured hemp products
§11-37-5 Edible manufactured hemp products
§11-37-6 Manufactured hemp products for sale outside the State
§11-37-7 Bulk manufactured hemp products for use as ingredients
§§11-37-8 Crude extract
§§11-37-9 to 11-37-19 (Reserved)

Subchapter 2 Testing

§11-37-20 Laboratory requirements
§11-37-21 Reserve samples
§11-37-22 Required testing for content
§11-37-23 Required testing for contamination and contaminant limits
§11-37-24 Accessibility of test results
§11-37-25 Recordkeeping for testing
§§11-37-26 to 11-37-29 (Reserved)

Subchapter 3 Packaging and Labeling

§11-37-30 Manufactured hemp product labeling
§11-37-31 Ingredient statement

§11-37-32 Responsibility statement
§11-37-33 Packaging
§11-37-34 Crude extract labeling
§§11-37-35 to 11-37-39 (Reserved)

Subchapter 4 Hemp Processor Permits

§11-37-40 Permit required
§11-37-41 Eligibility
§11-37-42 Application
§11-37-43 Renewal
§11-37-44 Fees
§11-37-45 Denial of application for permit or renewal of permit
§11-37-46 Permit issuance, term, and conditions
§11-37-47 Changes in information
§11-37-48 Permit revocation
§11-37-49 Surrender of permit

Subchapter 5 Hemp Processors - General

§11-37-50 Hemp biomass sourcing requirements
§11-37-51 General hemp processing facility requirements
§11-37-52 Solvents and processing practices
§11-37-53 Storage of hemp biomass, crude extract, manufactured hemp products, and wastes
§11-37-54 Waste disposal
§11-37-55 Recordkeeping
§11-37-56 Standard operating procedures
§§11-37-57 to 11-37-59 (Reserved)

Subchapter 6 Processing Practices and Processing Facility Standards

§11-37-60 Personnel
§11-37-61 Facility and grounds
§11-37-62 Sanitary operations

§11-37-63 Sanitary facilities and controls
§11-37-64 Equipment and utensils
§11-37-65 Processes and control
§11-37-66 Warehousing and distribution
§§11-37-67 to 11-37-69 (Reserved)

Subchapter 7 Quality Control

§11-37-70 Batch production and distribution records
§11-37-71 Quality control review and disposition decisions
§11-37-72 Returned crude extract and manufactured hemp products
§11-37-73 Product complaints
§11-37-74 Recalls
§11-37-75 Recordkeeping for quality control
§§11-37-76 to 11-37-79 (Reserved)

Subchapter 8 Enforcement

§11-37-80 Embargo and detention

SUBCHAPTER 1

GENERAL PROVISIONS

§11-37-1 Purpose and applicability. (a) The purpose of this chapter is to set forth the requirements for the processing of hemp biomass, production of manufactured hemp products, and the sale of crude extract and manufactured hemp products to provide for the protection of the health and safety of the general public. This chapter applies to the processing of hemp biomass into crude extract or a manufactured hemp product, processing crude extract

into a manufactured hemp product, using a manufactured hemp product as an ingredient in the production of another manufactured hemp product, and the sale and distribution of crude extract and manufactured hemp products. This chapter does not apply to other products that may be produced from hemp, except as otherwise provided in section 328G-3, HRS, or section 11-37-3. The prohibitions on other products that may be produced from hemp in section 11-37-3 and section 328G-3, HRS, apply to all persons.

(b) Subchapters 1 to 3 apply to all persons who sell, hold for sale, offer, or distribute crude extract or manufactured hemp products within the State, including persons who import or offer for import crude extract or manufactured hemp products into the State.

(c) All subchapters apply to hemp processors within the State.

(d) If any provision of this chapter or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this chapter which can be given effect without the invalid provision or application, and to this end the provisions of this chapter are severable. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §§328G-4, 328G-5) (Imp: HRS §§328G-2, 328G-3, 328G-4, 328G-5, 328G-6, 328G-8)

§11-37-2 Definitions. As used in this chapter:

"Actual yield" means the quantity that is actually produced at any appropriate step of processing, manufacture, or packaging of a particular crude extract or manufactured hemp product.

"Adequate" means that which is needed to accomplish the intended purpose in keeping with good public health practice.

"Adulterated" means a crude extract, manufactured hemp product, or component:

(1) Contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use indicated in the labeling or advertisement thereof, or under such conditions of use as are customary or usual;

(2) Consists in whole or in part of any filthy, putrid, or decomposed substance;

(3) Has been processed, manufactured, packaged, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

(4) Is in a container composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(5) Contains any of the contaminants listed in section 11-37-23 at levels higher than the specified limit.

"Allergen cross-contact" means the unintentional incorporation of an allergen into a crude extract or manufactured hemp product.

"Applicant" means the person applying for a permit to operate as a hemp processor under chapter 328G, HRS.

"Artificially derived cannabinoid" means a chemical substance that is created by a chemical reaction that changes the molecular structure of any chemical substance derived from the plant genus cannabis (e.g., changing cannabidiol into delta-8-tetrahydrocannabinol). "Artificially derived cannabinoid" does not include:

(1) A naturally occurring chemical substance that is separated from the plant genus cannabis by a chemical or mechanical extraction process; or

(2) Cannabinoids that are produced by decarboxylation from naturally occurring cannabinoid acid without the use of a chemical catalyst.

"Batch" means a specific quantity of crude extract or manufactured hemp product that is intended to be uniform and that is produced during a specified time period covered by a single batch production record during the same cycle of processing and manufacture.

"Batch number" means any distinctive group of letters, numbers, or symbols, or any combination of them, from which the complete history of the production, packaging, labeling, and holding of a batch of crude extract or manufactured hemp products can be determined.

"Blanching" means a pre-packaging heat treatment for an adequate time and at an adequate temperature to partially or completely inactivate naturally occurring enzymes and to effect other physical or biochemical changes.

"Cannabinoids" means any of the various naturally occurring, biologically active, chemical constituents of cannabis that bind to or interact with receptors of the endogenous cannabinoid system.

"Cannabis" means the genus of the flowering plant in the family Cannabaceae. For the purpose of this chapter, cannabis refers to any form of the plant where the delta-9 tetrahydrocannabinol concentration on a dry weight basis has not yet been determined.

"Component" means any substance intended for use in the manufacture of a crude extract or manufactured hemp product, including those that may not appear in the finished batch of the crude extract or manufactured hemp product.

"Consumer" means a person who is a member of the public, is not functioning in the capacity of an operator of a hemp processing facility, and does not process hemp biomass, produce manufactured hemp products, or offer manufactured hemp products for resale.

"Contact surface" means any surface that contacts a component, crude extract, or manufactured hemp product, and those surfaces from which drainage onto the component, crude extract, or manufactured hemp product, or onto surfaces that contact the component,

crude extract, or manufactured hemp product, occurs during the normal course of operations. Examples of contact surfaces include containers, utensils, tables, surfaces of equipment, and packaging.

"Contamination" means microbiological, chemical, radiological, or physical substances that either develop in or are added to crude extract, manufactured hemp products, or ingredients and are capable of causing manufactured hemp products to be:

(1) Unsafe for consumption or topical use, as intended; or

(2) In violation of a regulatory standard.

"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.

"Decarboxylated" means the completion of the chemical reaction that converts naturally occurring cannabinoid acid into a cannabinoid, including delta-9 tetrahydrocannabinol's acids (THCA) into delta-9-tetrahydrocannabinol. The decarboxylated value for delta-9-tetrahydrocannabinol may be calculated using a conversion formula that sums delta-9-tetrahydrocannabinol and eighty-seven and seven tenths (87.7) per cent of THCA.

"Delta-9 tetrahydrocannabinol" means one chemical in the group of cannabinoids that function as the primary psychoactive components of cannabis.

"Department" means the department of health.

"Director" means the director of the state department of health or the director's designee.

"Dry weight basis" refers to a method of determining the percentage of a chemical in a substance after removing the moisture from the substance.

"Enclosed indoor facility" means a permanent, stationary structure with a solid floor, rigid exterior walls that encircle the entire structure on all sides, and a roof that protects the entire interior area from the elements of weather. Nothing in this definition shall be construed to relieve the permitted applicant from the applicant's duty to comply with all applicable building codes and regulations.

"FDA" means the United States Food and Drug Administration.

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

"Hemp" means *Cannabis sativa* L. and any part of that plant, whether growing or not, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, with a delta-9-tetrahydrocannabinol concentration of not more than 0.3 per cent on a dry weight basis, as measured post-decarboxylation or by other similarly reliable methods.

"Hemp biomass" means the leaf and floral parts of hemp plant material.

"Hemp processing facility" means a facility where hemp processing occurs.

"Hemp processor" means a person who processes hemp biomass or prepares a crude extract or a manufactured hemp product.

"Ingredient" means any substance that is used in the production of a crude extract or manufactured hemp product and that is intended to be present in the finished batch of the crude extract or manufactured hemp product.

"In-process material" means any material that is fabricated, compounded, blended, ground, extracted, sifted, sterilized, derived by chemical reaction, or processed in any other way for use in the production of a crude extract or manufactured hemp product.

"Liquid form" means a manufactured hemp product made for oral consumption that is an oil-based tincture.

"Manufactured hemp product" means a product created by processing, as defined in this chapter, that:

(1) Is either:
  (A) Intended to be consumed orally to supplement the human or animal diet in tablet, capsule, powder, softgel, gelcap, or liquid form (e.g., hemp oil);
  (B) In a form for topical application to the skin or hair; or
  (C) Any other product specified in section 11-37-4, HRS; and
(2) Does not include any living hemp plants, viable seeds, leaf materials, or floral materials.

"Manufacturing" has the same meaning as processing.

"Microorganisms" means yeasts, molds, bacteria, viruses, and other similar microscopic organisms having public health or sanitary concern. This definition includes species that:

(1) May have public health significance;
(2) May cause a component, crude extract, or manufactured hemp product to decompose;
(3) Indicate that the component, crude extract, or manufactured hemp product is contaminated with filth; or
(4) Otherwise may cause the component, crude extract, or manufactured hemp product to be adulterated.

"Misbranded" means a crude extract or manufactured hemp product:

(1) Has labeling that is false or misleading in any particular;
(2) Fails to conform with the applicable labeling requirements in subchapter 3; or
(3) Is in a container that is so made, formed, or filled as to be misleading.

"Pathogen" means a microorganism of public health significance.

"Permit" means the certificate issued by the department attesting that the applicant is permitted to operate as a hemp processor.

"Person" means an individual, firm, corporation, partnership, association, or any form of business or legal entity.

"Pest" means any objectionable insect or other animal including birds, rodents, flies, mites, and larvae.

"Processing" means:

(1) Making a transformative change to hemp biomass following harvest by converting it into a crude extract or manufactured hemp product; or

(2) Compounding, blending, extracting, infusing, or otherwise producing a manufactured hemp product by:

(A) Completing the manufacturing process of transforming crude extract into a manufactured hemp product; or

(B) Using a manufactured hemp product as an ingredient in the production of another manufactured hemp product.

Processing includes packaging, repackaging, labeling, and relabeling.

"Product complaint" means any communication that contains any written, electronic, or oral allegation expressing concern with the quality of a manufactured hemp product for any reason. Examples of product complaints are: Foul odor, off taste, illness or injury, disintegration time, color variation, tablet size or size variation, under-filled container, foreign material in a manufactured hemp product container, improper packaging, mislabeling, or manufactured hemp products that are superpotent, subpotent, or contain the wrong ingredient, or contain a drug or other contaminant (e.g., bacteria, pesticide, mycotoxin, glass, lead).

"Qualified individual" means a person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe crude extract or manufactured hemp

products as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the hemp processor.

"Quality" means that the crude extract or manufactured hemp product consistently meets established specifications for content, consistency, and limits on contaminants, and has been manufactured, processed, packaged, labeled, and held under conditions to prevent adulteration.

"Quality control operation" means a planned and systematic procedure for taking all actions necessary to prevent crude extract or manufactured hemp products from being adulterated.

"Quality control personnel" means any person, persons, or group, within or outside the hemp processor's organization, designated to be responsible for its quality control operations.

"Representative sample" means a sample that consists of an adequate number of units that are drawn based on rational criteria, such as random sampling, and that are intended to ensure that the sample accurately portrays the material being sampled.

"Reprocessing" means using, in the processing or manufacture of a crude extract or manufactured hemp product, clean, uncontaminated components, crude extract, or manufactured hemp products that have been previously removed from manufacturing and that have been made suitable for use in the manufacture of a crude extract or manufactured hemp product.

"Reserve sample" means a representative sample of product that is held for a designated period of time.

"Rework" means clean, unadulterated crude extract, manufactured hemp products, or ingredients that have been removed from processing or manufacture for reasons other than insanitary conditions or that have been successfully reconditioned by reprocessing and are suitable for use as or in crude extract or manufactured hemp products.

"Safe moisture level" is a level of moisture low enough to prevent the growth of undesirable microorganisms in the crude extract or manufactured hemp product under the intended conditions of

processing, packing, and holding. The safe moisture level for a crude extract or manufactured hemp product is related to its water activity (a_w). An a_w will be considered safe if adequate data are available that demonstrate that the crude extract, manufactured hemp product, or component at or below the given a_w will not support the growth of undesirable microorganisms.

"Sanitize" means to adequately treat cleaned equipment, containers, utensils, or any other cleaned contact surface by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other microorganisms, but without adversely affecting the product or its safety for the consumer.

"Standard operating procedure" or "SOP" means written instructions on how to perform tasks and descriptions of the approved or required procedures for accomplishing specific quality assurance objectives.

"Synthetic cannabinoid" means a cannabinoid that is:

(1) Produced artificially, whether from chemicals or from recombinant biological agents including but not limited to yeast and algae; and

(2) Not derived from the genus cannabis, including biosynthetic cannabinoids.

"Tetrahydrocannabinol" means the group of cannabinoids that function as the primary psychoactive components of cannabis.

"Theoretical yield" means the quantity that would be produced at any appropriate step of processing, manufacture, or packaging of a particular crude extract or manufactured hemp product, based upon the quantity of components or packaging to be used, in the absence of any loss or error in actual production.

"Time/temperature control for safety product" means a manufactured hemp product that:

(1) Requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation; and

(2) If regulated as a food, would meet the definition of a "time/temperature control for safety food" in the U.S. Food and Drug Administration 2017 Food Code (9th edition).

"Total tetrahydrocannabinol" or "total THC" means the sum of the percentage by weight of:

(1) Delta-9-tetrahydrocannabinolic acid (D9-THCA) multiplied by 0.877;

(2) Delta-9-tetrahydrocannabinol (D9-THC); and

(3) Delta-8-tetrahydrocannabinol (D8-THC).

"USDA" means the United States Department of Agriculture.

"Water activity" or "a_w" is a measure of the free moisture in a component, crude extract, or manufactured hemp product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature. [Eff 8/9/21; am and comp 2/24/22; am and comp 4/29/22; am and comp DEC - 6 2024] (Auth: HRS §§328G-4, 328G-5) (Imp: HRS §§328G-1, 328G-2, 328G-3, 328G-4, 328G-5)

§11-37-3 Prohibitions. (a) No person shall sell, hold for sale, offer, or distribute any crude extract or manufactured hemp product that is adulterated or misbranded.

(b) No person shall sell, hold for sale, offer, or distribute any crude extract or manufactured hemp product that does not meet the applicable testing requirements in subchapter 2.

(c) No person shall sell, hold for sale, offer, or distribute any food, as defined in section 328-1, into which a cannabinoid, artificially derived cannabinoid, synthetic cannabinoid, hemp, hemp biomass, or manufactured hemp product has been added as an ingredient or component, except as allowed by section 11-37-5. This subsection shall not apply to hemp that is generally recognized as safe (GRAS) by FDA for use in foods, as intended, in a public GRAS notification.

(d) No person shall sell, hold for sale, offer, or distribute any crude extract or manufactured hemp product with a total tetrahydrocannabinol concentration of more than 0.3 per cent.

(e) No person shall sell, hold for sale, offer, or distribute any hemp-derived cannabinoid, artificially derived cannabinoid, synthetic cannabinoid, or any other product containing hemp used to aerosolize for respiratory routes of delivery, such as an inhaler, vape pen, or other device designed for such purpose.

(f) No person shall sell, hold for sale, offer, or distribute any hemp leaf, hemp floral material, including but not limited to hemp cigars or hemp cigarettes, or viable hemp seeds, except for sale of hemp leaf, hemp floral material, or viable seeds to:

(1) A hemp producer holding a license to produce hemp, issued by the Secretary of the United States Department of Agriculture pursuant to title 7 United States Code section 1639q; or

(2) A permitted hemp processor.

(g) No person shall sell, hold for sale, offer, or distribute any manufactured hemp product containing any living hemp plants, viable seeds, leaf materials, or floral materials.

(h) Except for manufactured hemp products intended for external topical application to the skin or hair, no person shall sell, hold for sale, offer, or distribute any products containing a cannabinoid, artificially derived cannabinoid, synthetic cannabinoid, hemp, hemp biomass, or manufactured hemp product as an ingredient that are intended to be introduced via non-oral routes of entry to the body, including but not limited to, use in eyes, ears, and nasal cavities.

(i) No person shall sell, hold, offer, or distribute for sale crude extract directly to any consumer. Crude extract shall be sold only to a hemp processor with a valid permit issued by the department, or to a person with equivalent authority from a regulatory agency in another jurisdiction.

(j) No person shall sell, hold, offer, or distribute samples from an open package of manufactured hemp products. Sample manufactured hemp products may be distributed in accordance with all applicable requirements of subchapters 1 to 3, including testing, packaging, and labeling requirements.

(k) Product packaging, labeling, and advertising shall not make health or benefit claims that are unsubstantiated, false, or misleading in any particular. This subsection shall not apply to federal Food and Drug Administration, or successor agency, approved drugs containing cannabinoids as active pharmaceutical ingredients. [Eff 8/9/21; am and comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §§328G-4) (Imp: HRS §§328G-1, 328G-3, 328G-4)

§11-37-4 Manufactured hemp products. (a) A hemp processor may manufacture and a person may sell within the State manufactured hemp products limited to the product types listed in subsection (c) and subject to all requirements and prohibitions in this chapter.

(b) A hemp processor may manufacture product test batches as necessary to produce the documentation required in this subchapter and subchapter 2 prior to meeting all applicable requirements, however, no person shall sell, hold for sale, offer, or distribute a manufactured hemp product until all applicable requirements are met for that product.

(c) Allowed manufactured hemp products are limited to the following types:

(1) Edible manufactured hemp product types specified in section 11-37-5; and

(2) A form for topical application to the skin or hair.

(d) Manufactured hemp products shall not contain any of the following ingredients:

(1) Any color additives not listed in subpart A or C of 21 C.F.R. part 73, published by the

U.S. Government Publishing Office, as amended as of April 1, 2020;

(2) Bithionol;

(3) Vinyl chloride;

(4) Halogenated salicylanilides listed in 21 C.F.R. section 700.15, published by the U.S. Government Publishing Office, as amended as of April 1 , 2020;

(5) Chloroform;

(6) Methylene chloride;

(7) Prohibited cattle material, as defined in 21 C.F.R. section 700.27, published by the U.S. Government Publishing Office, as amended as of April 1 , 2020;

(8) Mercury compounds;

(9) Hexachlorophene;

(10) Ephedrine alkaloids;

(11) Synthetic cannabinoids;

(12) Artificially derived cannabinoids;

(13) Tobacco, nicotine, caffeine, alcohol, kava, or any other substance not derived from cannabis that:

(A) Is psychoactive; or

(B) Would increase the potency, toxicity, or addictive potential of the product or create a potentially unsafe combination with cannabinoids; and

(14) Any ingredient the department determines would render the product injurious or hazardous to health.

(e) Manufactured hemp products shall not be designed to resemble commercially available candy or other products marketed to children or have an appearance, flavor, or smell designed to appeal to children. Manufactured hemp products shall not be in the shape of or contain a depiction of a human, animal, or fruit, or a shape or depiction that bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon renderings. The words "candy" and "candies" shall not be used on packaging, labeling, advertising, product lists, or

product menus. [Eff and comp DEC -6 2024] (Auth: HRS §§328G-4, 328G-5) (Imp: HRS §§328G-3, 328G-4, 328G-5)

§11-37-5 Edible manufactured hemp products. (a) Edible manufactured hemp products are limited to the following types:

(1) Tablets;
(2) Capsules;
(3) Powders; provided that beginning on March 1, 2025, each serving of powder shall be sealed in a separate packet;
(4) Softgels;
(5) Gelcaps;
(6) Oil-based tinctures; provided that beginning on March 1, 2025, tinctures shall:
    (A) Have a maximum volume of two fluid ounces per container;
    (B) Have a maximum of seventy-five milligrams total tetrahydrocannabinol per container;
    (C) Have a maximum concentration of two and one-half (2.5) milligrams of total tetrahydrocannabinol per serving;
    (D) Not contain non-hemp derived flavors, sugars, or sweeteners;
    (E) Be packaged with a dropper or spray top; and
    (F) Be labeled for intended use measured in drops, dropperfuls, or sprays.
(7) Gummies; provided that one serving shall be one gummy and gummies shall contain no more than one milligram total tetrahydrocannabinol per serving and no more than five milligrams total tetrahydrocannabinol per container; and
(8) Beverages; provided that beverages shall:
    (A) Have a minimum volume of six fluid ounces and a maximum of twelve fluid ounces per container; and

(B) Contain no more than one half milligram (0.5 mg) total tetrahydrocannabinol per container.

(b) Beginning on March 1, 2025, except for tinctures, gummies, and beverages:

(1) Edible manufactured hemp products shall contain no more than one milligram total tetrahydrocannabinol per serving; provided that one serving shall be one tablet, capsule, softgel, gelcap, or packet of powder; and

(2) No edible manufactured hemp product that is sold in a package of multiple servings shall contain more than five milligrams of total tetrahydrocannabinol per package.

(c) Edible manufactured hemp products shall have a total tetrahydrocannabinol concentration of no more than 0.3 per cent.

(d) An edible manufactured hemp product shall:

(1) Not be manufactured with components that are not intended to be safe for use in manufacture of a product for human consumption;

(2) Not be a time/temperature control for safety product; and

(3) Be homogenous to ensure uniform distribution of cannabinoids.

(e) An edible manufactured hemp product sold in a package of multiple servings shall meet the requirements for child-resistant special packaging for the number of openings and closings customary for the package size and contents, specified in Title 16 C.F.R. part 1700, as published by the U.S. Government Publishing Office as of January 1, 2021. [Eff and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §§328G-3, 328G-4)

§11-37-6 Manufactured hemp products for sale outside the State. (a) A hemp processor may manufacture and hold manufactured hemp products

exceeding the total tetrahydrocannabinol content limits per serving or per package or container specified in section 11-37-5(a) and (b), with a total tetrahydrocannabinol concentration of no more than 0.3 per cent, for sale outside the State. Manufactured hemp products for sale outside the State shall comply with all other applicable requirements in this chapter, except as otherwise specified in this section, and all applicable requirements of the state or jurisdiction in which they are to be sold.

(b) Testing. Manufactured hemp products for sale outside the state shall:

(1) Meet the testing requirements in section 11-37-22 and 11-37-23; or

(2) If they are to be sold in a state or jurisdiction that has its own manufactured hemp product testing requirements, meet that state or jurisdiction's testing requirements prior to shipment for sale.

(c) Labeling. Manufactured hemp products for sale outside the state shall:

(1) Meet the labeling requirements in section 11-37-30; or

(2) If they are to be sold in a state or jurisdiction that has its own manufactured hemp product labeling requirements, meet that state or jurisdiction's labeling requirements prior to shipment for sale.

(d) Storage. Manufactured hemp products for sale outside the State shall be stored in a separate, clearly demarcated, and labeled quarantine area away from other manufactured hemp products intended for sale within the State.

(e) Recordkeeping. A hemp processor manufacturing or holding a manufactured hemp product for sale outside the State shall keep the following records in accordance with section 11-37-55:

(1) The name, address, and phone number of the distributor, retailer, or individual that purchased the product;

(2) The quantity of product and date shipped.

[Eff and comp DEC -6 2024] (Auth: HRS

§§328G-4, 328G-5) (Imp: HRS §§328G-3, 328G-4, 328G-5)

§11-37-7 Bulk manufactured hemp products for use as ingredients. (a) A hemp processor with a valid permit issued by the department may sell manufactured hemp products exceeding the total tetrahydrocannabinol content limits per serving or per package or container specified in section 11-37-5(a) and (b), with a total tetrahydrocannabinol concentration of no more than 0.3 per cent, only to a hemp processor with a valid permit issued by the department, or to a person with equivalent authority from a regulatory agency in another jurisdiction in accordance with section 11-37-6. Bulk manufactured hemp products shall comply with all other applicable requirements in this chapter, except as otherwise specified in this section.

(b) A hemp processor with a valid permit issued by the department may purchase manufactured hemp products exceeding the total tetrahydrocannabinol content limits per serving or per package or container specified in section 11-37-5(a) and (b), with a total tetrahydrocannabinol concentration of no more than 0.3 per cent. Bulk manufactured hemp products shall comply with all other applicable requirements in this chapter, except as otherwise specified in this section.

(c) No person shall sell, hold, offer, or distribute for sale manufactured hemp products exceeding the total tetrahydrocannabinol content limits per serving or per package or container specified in section 11-37-5(a) and (b) directly to any consumer, except as allowed in section 11-37-6.

[Eff and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §§328G-3, 328G-4)

§11-37-8 Crude extract. (a) Following initial extraction, crude extract may be further processed by filtration, pressing, partial or complete removal of solvent, adding ingredients for purposes such as dilution or stabilization, and other physical processes that are not intended to alter the botanical constituent composition of the extract.

(b) No person shall sell, hold, offer, or distribute for sale any crude extract that contains any ingredient prohibited in section 11-37-4(d). Crude extract shall not be manufactured with components that are not intended to be safe for use in manufacture of a product for human consumption.

(c) A hemp processor with a valid permit issued by the department shall purchase crude extract produced only from hemp biomass grown by a hemp producer holding a valid license issued by the USDA pursuant to title 7 United States Codes section 1639q or by a state or tribal agency administering a plan approved by the USDA pursuant to title 7 United States Code section 1639p.

(d) A hemp processor with a valid permit issued by the department shall comply with section 11-37-3(i) and applicable requirements of subchapters 2 and 3 for sales of crude extract.

(e) Recordkeeping.

(1) A hemp processor producing crude extract or purchasing crude extract from another source shall maintain laboratory testing records associated with each batch of crude extract produced or purchased that demonstrate compliance with subchapter 2.

(2) A hemp processor purchasing crude extract from another source shall maintain records demonstrating compliance with subsection (b).

(3) Records required by this subsection shall be maintained in accordance with section 11-37-55. [Eff and comp DEC - 6 2024] (Auth: HRS §328G-4) (Imp: HRS §§328G-3, 328G-4)

§§11-37-9 to 11-37-19 (Reserved).

SUBCHAPTER 2

TESTING

§11-37-20 Laboratory requirements.

(a) Tests required by this subchapter shall be conducted by a laboratory facility that is accredited to the ISO/IEC 17025:2017 standard, "General requirements for the competence of testing and calibration laboratories," by an accreditation organization recognized by the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement.

(b) The laboratory shall:

(1) Identify and use an appropriate, scientifically valid method for each established specification for which testing is required to determine whether the specification is met; and

(2) Establish and follow written standard operating procedures for the test methods conducted to determine whether specifications are met.

(c) Laboratory reports of test results shall include a certification by laboratory staff, completed at the time of performance, that established laboratory methodology was followed and that the samples tested met the laboratory's quality assurance standards. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; comp DEC -6 2024] (Auth: HRS §§328G-4, 328G-5) (Imp: HRS §§328G-4, 328G-5)

§11-37-21 Reserve samples. (a) A hemp processor shall collect and hold representative reserve samples of each batch of packaged and labeled crude extract or manufactured hemp product that it distributes.

(b) The reserve samples shall:

(1) Be held under conditions consistent with product labels or, if no storage conditions are recommended on the label, under ordinary storage conditions;

(2) Be held using the same container-closure system in which the packaged and labeled crude extract or manufactured hemp product is distributed;

(3) Be identified with the batch number;

(4) Be retained for one year past the shelf life date (if shelf life dating is used), or for two years from the date of distribution of the last crude extract or manufactured hemp product associated with the reserve sample, for use in appropriate investigations; and

(5) Consist of at least twice the quantity necessary for all tests required by sections 11-37-22 and 11-37-23. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §§328G-4, 328G-5) (Imp: HRS §§328G-4, 328G-5)

§11-37-22 Required testing for content. (a) A representative sample of every batch of packaged manufactured hemp product shall be tested for content by a laboratory meeting the requirements of section 11-37-20, including the use of appropriate methods to quantify (in percentage content by weight) the presence of:

(1) Total tetrahydrocannabinol;

(2) Delta-9-tetrahydrocannabinolic acid;

(3) Delta-9-tetrahydrocannabinol;

(4) Delta-8-tetrahydrocannabinol;

(5) Cannabidiol (CBD); and

(6) Any other cannabinoid specifically listed, described, or advertised in the label or packaging of the manufactured hemp product.

(b) A representative sample of every batch of packaged crude extract shall be tested by a laboratory meeting the requirements of section 11-37-20 using appropriate methods to quantify (in percentage content by weight) total tetrahydrocannabinol. [Eff 8/9/21; am and comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §§328G-4, 328G-5) (Imp: HRS §§328G-4, 328G-5)

§11-37-23 Required testing for contamination and contaminant limits. (a) A representative sample of every batch of packaged manufactured hemp product shall be tested for contamination by a laboratory meeting the requirements of section 11-37-20, including the use of appropriate methods to quantify the presence of all contaminants listed in subsection (b).

(b) A sample and the associated batch of manufactured hemp product is considered adulterated if laboratory results for the testing required in subsection (a) exceed the specified concentration limit for any of the following contaminants:

(1) Heavy metals listed in Table 1;

Table 1

Heavy metal	Limit (parts per million)
Arsenic	10.0 ppm
Cadmium	4.0 ppm
Lead	6.0 ppm
Mercury	2.0 ppm

(2) Pesticides listed in Table 2, each with a limit of 1.0 parts per million (ppm);

Table 2

Pesticide	Chemical Abstracts Service Registry Number (CAS No.)
Abamectin	71751-41-2
Acephate	30560-19-1
Acequinocyl	57960-19-7
Acetamiprid	135410-20-7
Aldicarb	116-06-3
Azoxystrobin	131860-33-8
Bifenazate	149877-41-8
Bifenthrin	82657-04-3
Boscalid	188425-85-6
Carbaryl	63-25-2
Carbofuran	1563-66-2
Chlorantraniliprole	500008-45-7
Chlorfenapyr	122453-73-0
Chlorpyrifos	2921-88-2
Clofentezine	74115-24-5
Cyfluthrin	68359-37-5
Cypermethrin	52315-07-8
DDVP (Dichlorvos)	62-73-7
Diazinon	333-41-5
Dimethoate	60-51-5
Ethoprophos	13194-48-4
Etofenprox	80844-07-1
Etoxazole	153233-91-1
Fenpyroximate	134098-61-6
Fipronil	120068-37-3
Flonicamid	158062-67-0
Fludioxonil	131341-86-1
Hexythiazox	78587-05-0
Imazalil	35554-44-0
Imidacloprid	138261-41-3
Kresoxim-methyl	143390-89-0
Malathion	121-75-5
Metalaxyl	57837-19-1
Methiocarb	2032-65-7
Methomyl	16752-77-5

Methyl parathion	298-00-0
MGK-264	113-48-4
Myclobutanil	88671-89-0
Naled	300-76-5
Oxamyl	23135-22-0
Paclobutrazol	76738-62-0
Permethrins (total of cis- and trans-permethrin isomers)[1]	52645-53-1
Phosmet	732-11-6
Piperonyl butoxide	51-03-6
Prallethrin	23031-36-9
Propiconazole	60207-90-1
Propoxur	114-26-1
Pyrethrins (total of pyrethrin 1, cinerin 1, and jasmolin 1)[2]	8003-34-7
Pyridaben	96489-71-3
Spinosad	168316-95-8
Spiromesifen	283594-90-1
Spirotetramat	203313-25-1
Tebuconazole	80443-41-0
Thiacloprid	111988-49-9
Thiamethoxam	153719-23-4
Trifloxystrobin	141517-21-7

Notes to Table 2:
1. Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8, respectively).
2. Pyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1, and jasmolin 1 (CAS numbers 121-21-1, 25402-06-6, and 4466-14-2, respectively).

(3) Solvents listed in Table 3, provided that the limits for ethanol and isopropyl alcohol do not apply to manufactured hemp products intended for topical application to the skin or hair;

Table 3

Solvent	Chemical Abstracts Service Registry Number (CAS No.)	Limit (parts per million)
1,1-Dichloroethene	75-35-4	8.0 ppm
1,1,1-Trichloroethane	71-55-6	1,500 ppm
1,2-Dichloroethane	107-06-2	1.0 ppm
Acetone	67-64-1	5000 ppm
Acetonitrile	75-05-8	410 ppm
Benzene	71-43-2	1.0 ppm
Butane	106-97-8	5,000 ppm
Carbon tetrachloride	56-23-5	4.0 ppm
Chloroform	67-66-3	1.0 ppm
Ethanol	64-17-5	5,000 ppm
Ethyl acetate	141-78-6	5000 ppm
Ethyl ether	60-29-7	5000 ppm
Heptane	142-82-5	5,000 ppm
Hexane	110-54-3	290 ppm
Isopropyl alcohol	67-63-0	5000 ppm
Methanol	67-56-1	3000 ppm
Methylene chloride	75-09-2	1.0 ppm
Pentane	109-66-0	5,000 ppm
Propane	74-98-6	5000 ppm
Toluene	108-88-3	890 ppm
Total xylenes (ortho-, meta-, para-)	1330-20-7	2,170 ppm
Trichloroethylene	79-01-6	1.0 ppm

(4) The following microbial contaminants, which must not be detected in one gram of manufactured hemp product:

(A) *Escherichia coli;*

(B) *Salmonella spp.;*

(C) *Aspergillus fumigatus;*
(D) *Aspergillus flavus;*
(E) *Aspergillus niger;* and
(F) *Aspergillus terreus;* and

(5) Mycotoxins listed in Table 4.

Table 4

Mycotoxin	Limit (parts per billion)
Aflatoxins (total of B1, B2, G1, G2)	20 ppb
Ochratoxin A	20 ppb

(c) A representative sample of every batch of packaged crude extract shall be tested for contamination by a laboratory meeting the requirements of section 11-37-20, including the use of appropriate methods to quantify the presence of all contaminants listed in subsection (d).

(d) A sample and the associated batch of crude extract is considered adulterated if laboratory results for the testing required in subsection (c) exceed the specified concentration limit for any of the following contaminants: mycotoxins listed in Table 4 in subsection (b)(5). [Eff 8/9/21; am and comp 2/24/22; am and comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §§328G-4, 328G-5) (Imp: HRS §§328G-4, 328G-5)

§11-37-24 Accessibility of test results. The laboratory results for all tests required by sections 11-37-22 and 11-37-23 shall be made available to the purchaser of any crude extract or manufactured hemp product by:

(1) Placing a scannable QR code on the label or packaging that directs the electronic scanning device (typically a smart phone or tablet) to a website displaying test results for the specific batch; or

(2) Identifying a website on the label or packaging where the batch number can be entered to view test results for the specific batch. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §§328G-4, 328G-5) (Imp: HRS §§328G-4, 328G-5)

§11-37-25 Recordkeeping for testing. (a) A hemp processor shall make and keep records required under this subchapter in accordance with section 11-37-55.

(b) A hemp processor shall make and keep the following records:

(1) Sampling plan(s) for obtaining representative samples;

(2) The testing laboratory's ISO/IEC 17025:2017 accreditation;

(3) Laboratory reports for all samples tested, including reserve samples, including:

(A) A certification by laboratory staff, completed at the time of performance, that established laboratory methodology was followed and that the samples tested met the laboratory's quality assurance standards; and

(B) The results of the testing;

(4) Written procedures for holding and distributing operations; and

(5) Records of product distribution. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; comp DEC -6 2024] (Auth: HRS §§328G-4, 328G-5) (Imp: HRS §§328G-4, 328G-5)

§§11-37-26 to 11-37-29 (Reserved).

SUBCHAPTER 3

PACKAGING AND LABELING

§11-37-30 Manufactured hemp product labeling. (a) Except as provided in subsection (d), every manufactured hemp product shall be labeled with the following information displayed prominently and conspicuously, but in no case may the letters or numbers be less than one-sixteenth inch in height based on the letter "O" or, if both upper and lower case letters are used, the lower case "o":

(1) Product name;
(2) Product net weight;
(3) An ingredient statement that meets the requirements of section 11-37-31;
(4) A responsibility statement that meets the requirements of section 11-37-32;
(5) Batch number;
(6) Directions for use; provided that beginning on March 1, 2025, a tincture shall be labeled for use in drops, dropperfuls, or sprays;
(7) The statement "Use this product under the guidance of a physician if you have a medical condition or are pregnant or lactating." or words of similar meaning;
(8) The statement "Keep out of the reach of children." or words of similar meaning;
(9) The statement "Not for sale to persons under the age of 21." or words of similar meaning; and
(10) A QR code or website that displays test results as required by section 11-37-24.

(b) Except as provided in subsection (d), every edible manufactured hemp product shall be labeled with the following information displayed prominently and conspicuously, but in no case may the letters or numbers be less than one-sixteenth inch in height

based on the letter "O" or, if both upper and lower case letters are used, the lower case "o":

(1) The statement "This product is not intended to diagnose, treat, cure, or prevent any disease." or words of similar meaning;

(2) The net quantity (in terms of weight, measure, or numerical count) of each serving; provided that beginning on March 1, 2025, the serving size for a tincture shall be in drops, dropperfuls, or sprays;

(3) The number of servings in the package;

(4) The content (in milligrams) per serving of the following cannabinoids:
   (A) Total tetrahydrocannabinol; and
   (B) Any other cannabinoid specifically listed, described, or advertised in the label or packaging of the manufactured hemp product;

(5) The content (in milligrams) per serving of the following cannabinoids, unless the testing required by section 11-37-22 returns a result of non-detect:
   (A) Delta-9-tetrahydrocannabinolic acid;
   (B) Delta-9-tetrahydrocannabinol;
   (C) Delta-8-tetrahydrocannabinol; and
   (D) Cannabidiol (CBD); and

(6) All major food allergens the product contains or has protein derived from shall be listed on the label and shall be preceded by the word "Contains". This statement shall include all of the following that are present in the product:
   (A) Milk;
   (B) Egg;
   (C) Fish;
   (D) Crustacean shellfish;
   (E) Tree nuts;
   (F) Wheat;
   (G) Peanuts;
   (H) Soybeans; and
   (I) Sesame.

Highly refined oils derived from any of the nine major food allergens and any ingredient derived from such highly refined oils are exempt from this requirement.

(c) Every manufactured hemp product intended for topical application to the skin or hair shall be labeled with the following information displayed prominently and conspicuously, but in no case may the letters or numbers be less than one-sixteenth inch in height based on the letter "O" or, if both upper and lower case letters are used, the lower case "o":

(1) The statement "For external use only." or words of similar meaning;

(2) The total quantity (in milligrams) of the following cannabinoids contained in the packaged manufactured hemp product:

(A) Total tetrahydrocannabinol;

(B) Any other cannabinoid specifically listed, described, or advertised in the label or packaging of the manufactured hemp product; and

(3) The total quantity (in milligrams) of the following cannabinoids contained in the packaged manufactured hemp product, unless the testing required by section 11-37-22 returns a result of non-detect:

(A) Delta-9-tetrahydrocannabinolic acid;

(B) Delta-9-tetrahydrocannabinol;

(C) Delta-8-tetrahydrocannabinol; and

(D) Cannabidiol (CBD).

(d) Allowed exceptions. If the immediate container of a manufactured hemp product is too small to accommodate a label containing all the applicable information required by subsection (a), (b), and (c), the information in paragraph (a)(7) and (b)(1) may be included on a package insert that accompanies the immediate container or included on labeling attached to outer packaging.

(e) All words, statements, and other information required by this section shall be prominently placed with such conspicuousness (as compared with other words, statements, designs, or devices, in the

labeling) and in such terms as to render them likely to be read and understood by the ordinary individual under customary conditions of purchase and use. A word, statement, or other required information may lack that prominence and conspicuousness required by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by this subchapter to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(f) The words "candy" and "candies" shall not be used on packaging, labeling, advertising, product lists, or product menus. [Eff 8/9/21; am and comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §§328G-3, 328G-4)

§11-37-31 Ingredient statement. (a) All ingredients shall be listed on the label in order of prominence by weight and shall be preceded by the word "Ingredients".

(b) The common or usual name of ingredients shall be consistent with the names standardized in:

(1) For ingredients that are botanicals (including fungi and algae): *Herbs of Commerce,* third edition, published by the American Herbal Products Association. The listing of these names on the label shall be followed by statements of:

(A) The part of the plant (e.g., root, leaves) from which the ingredient is derived (e.g., "Hemp flower" or "Hemp (flower)"), except that this designation is not required for algae; and

(B) The Latin binomial name of the plant, in parentheses, except that this name is not required when it is available in *Herbs of Commerce*, third edition, for the common or usual name listed on the label, and, when required, the Latin binomial name may be listed before the part of the plant. Any name in Latin form shall be in accordance with internationally accepted rules on nomenclature, such as those found in the *International Code of Botanical Nomenclature* (Shenzhen Code), 2018 edition, published by the International Association for Plant Taxonomy, and shall include the designation of the

author or authors who published the Latin name, when a positive identification cannot be made in its absence.

(2) For cosmetic ingredients in topical manufactured hemp products: 21 C.F.R. section 701.3(c), published by the U.S. Government Publishing Office, as amended as of April 1, 2020. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §§328G-3, 328G-4)

§11-37-32 Responsibility statement. (a) The responsibility statement on the label shall include:

(1) The name and address of the manufacturer, packer, or distributor; and

(2) A statement such as "manufactured by" or "distributed by" that identifies which party is included on the label.

(b) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name, which may be preceded or followed by the name of the particular division of the corporation. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.

(c) The statement of the address shall include the street address or P.O. box, city, state, and zip code.

(d) If a person manufactures, packs, or distributes a crude extract or manufactured hemp product at a place other than their principal place of business, the label may state the principal place of business in lieu of the actual place where such product was manufactured or packed or is to be distributed. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §§328G-3, 328G-4)

§11-37-33 Packaging. The immediate container that is in contact with the crude extract or manufactured hemp product shall be made of material that:

(1) Protects the crude extract or manufactured hemp product from contamination and does not impart any toxic or harmful substance to the crude extract or manufactured hemp product; and

(2) Is not reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the crude extract or manufactured hemp product. [Eff and comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §328G-4)

§11-37-34 Crude extract labeling. All crude extract shall be labeled with the following information displayed prominently and conspicuously, but in no case may the letters or numbers be less than one-sixteenth inch in height based on the letter "O" or, if both upper and lower case letters are used, the lower case "o":

(1) Product name;

(2) Product net weight;

(3) The total quantity (in milligrams) of total tetrahydrocannabinol contained in the packaged crude extract;

(4) An ingredient statement that meets the requirements of section 11-37-31;

(5) A responsibility statement that meets the requirements of section 11-37-32;

(6) Batch number;

(7) The statement "This product is not fit for use or consumption by consumers.";

(8) The statement "This product shall be sold only to a hemp processor with a valid permit from the Hawaii Department of Health or equivalent authority in another jurisdiction."; and

(9) A QR code or website that displays test results as required by section 11-37-24.

[Eff and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §§328G-3, 328G-4)

§§11-37-35 to 11-37-39 (Reserved).

SUBCHAPTER 4

HEMP PROCESSOR PERMITS

§11-37-40 Permit required. (a) No person shall process hemp biomass or produce a manufactured hemp product without a valid permit issued by the department pursuant to this subchapter.

(b) A hemp processor shall not begin hemp processing activities until the department issues a permit pursuant to this subchapter.

(c) A hemp processor shall display a copy of the current, valid hemp processor permit in the hemp processing facility at all times. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §§328G-2, 328G-4)

§11-37-41 Eligibility. To apply for a permit, an applicant shall:

(1) Have a Hawaii tax identification number;

(2) Be registered to do business in the State of Hawaii, unless the business is a sole proprietorship; and
(3) Not have a disqualifying conviction for a state or federal felony related to a controlled substance during the ten years prior to the date the application is submitted. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §§328G-2, 328G-4)

§11-37-42 Application. (a) To apply for a permit, an applicant shall submit the following information to the department on a form and in a manner prescribed by the department:
(1) The applicant's name, mailing address, and phone number in Hawaii;
(2) Proof of no disqualifying felony convictions, which shall be established by an individual applicant or, if the applicant is a firm, corporation, partnership, association, or any form of business or legal entity, an individual acting on behalf of the entity by providing either:
(A) A copy of the applicant's license to produce hemp, issued by the USDA pursuant to title 7 United States Code section 1639q; or
(B) Consent to a background check that includes but is not limited to fingerprinting and criminal history checks pursuant to section 846-2.7, HRS, and documentation of the authority of the individual to act on behalf of the applying entity;
(3) The physical address and tax map key (TMK) number of the land on which the hemp processor is to operate;
(4) A description of the enclosed indoor facility where the hemp processor will

operate, demonstrating how the hemp processing facility meets the applicable facility requirements of subchapters 5 and 6;

(5) Attestation that the hemp processing facility complies with section 11-37-51(a), if applicable; and

(6) Documentation and attestation that:

(A) The hemp processor's indoor facility and planned hemp processing operation complies with all zoning ordinances, building codes, and fire codes; or

(B) The planned processing will not include heat, volatile compounds, or gases under pressure and will take place in an enclosed indoor facility that is:

(i) Exempt from building permit and building code requirements pursuant to section 46-88, HRS; or

(ii) In a food hub or agricultural park.

(b) Every application shall be signed by a person with authority to represent the applicant and shall constitute an acknowledgment and agreement that the applicant will comply with this chapter.

(c) In addition to the application form, each applicant shall submit a non-refundable application fee in accordance with section 11-37-44. If the fee does not accompany the application, the application shall be deemed incomplete.

(d) The department may require the submission of additional information after the application has been submitted and may suspend the processing of the application until such time as the applicant has supplied all required information or otherwise corrected the deficiency. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §§328G-2, 328G-4) (Imp: HRS §§328G-2, 328G-4)

§11-37-43 Renewal. (a) To ensure timely renewal, a hemp processor shall submit a complete renewal application, consisting of all parts listed in section 11-37-42(a), (b), and (c) to the department at least sixty days prior to the expiration date of the current permit.

(b) The department may require the submission of additional information after the renewal application has been submitted and may suspend the processing of the application until such time as the applicant has supplied all required information or otherwise corrected the deficiency. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §§328G-2, 328G-4)

§11-37-44 Fees. (a) The fee for a new or renewal permit shall be $500.

(b) Payment of fees shall be made in a form and manner prescribed by the department. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §§27G-2, 328G-2, 328G-4) (Imp: HRS §§328G-2, 328G-4)

§11-37-45 Denial of application for permit or renewal of permit. (a) The department may deny an application for a new or renewed permit for any of the following reasons:

(1) Failure to provide the information required in section 11-37-42 for a new permit application or section 11-37-43 for renewal;
(2) Failure to pay application fees;
(3) Providing misleading, incorrect, false, or fraudulent information;
(4) Violation of any applicable requirement of this chapter or chapter 328G, HRS.

(b) If the department denies an initial or renewal application, the department shall notify the

applicant in writing of the reason for the department's denial.

(c) An applicant whose application is denied may appeal the decision by submitting a written request for a hearing to the department not later than twenty days from the date of receipt of the department's denial.

(d) Upon receipt of a timely request for a hearing, the department will provide a hearing in accordance with chapter 91, HRS. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §§328G-2, 328G-4)

§11-37-46 Permit issuance, term, and conditions. (a) Upon the department's determination that an applicant has met the requirements of section 11-37-42 or 11-37-43, confirmation that the applicant or its representative does not have a disqualifying conviction for a state or federal felony related to a controlled substance during the ten years prior to the date the application is submitted, and payment of the application fee, and contingent upon compliance with this chapter and chapter 328G, HRS, the department may issue a permit to the applicant.

(b) A permit shall have a term of one year.

(c) A permit shall not be assigned or otherwise transferred to another person. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §§328G-2, 328G-4)

§11-37-47 Changes in information. (a) After obtaining a permit, a hemp processor shall notify the department, on a form and in a manner prescribed by the department, within thirty days after any change to the information previously submitted to the department pursuant to section 11-37-42 or section 11-37-43.

(b) Notwithstanding subsection (a), if a hemp processor intends to relocate its hemp processing

facility or add a new hemp processing facility, the hemp processor shall submit a new permit application to the department pursuant to section 11-37-42. The hemp processor shall not engage in hemp processing at the new facility until the department issues a new permit. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §§328G-2, 328G-4)

§11-37-48 Permit revocation. (a) The department may revoke any person's hemp processor permit for violation of any applicable provision of this chapter or chapter 328G, HRS.

(b) If the department revokes a person's hemp processor permit, the department shall notify the person in writing of the reason for the revocation.

(c) A person whose permit is revoked may appeal the decision by submitting a written request for a hearing to the department not later than twenty days from the date of the department's notice of revocation.

(d) Upon receipt of a timely request for a hearing, the department will provide a hearing in accordance with chapter 91, HRS.

(e) Upon revocation of a hemp processor permit pursuant to subsection (a), the hemp processor shall immediately:

(1) Cease hemp processing operations;
(2) Surrender the permit to the department;
(3) Dispose of all hemp biomass, crude extract, manufactured hemp products that exceed the total tetrahydrocannabinol content limits per serving or per package or container specified in section 11-37-5(a) and (b), and all other hemp-derived products that do not meet the manufactured hemp product requirements in subchapters 1 to 3; and
(4) Submit to the department evidence of compliance with paragraph (3).

(f) Following a permit revocation, the department may allow a hemp processor to apply for a new permit after the hemp processor has corrected the violations. [Eff and comp DEC -6 2024] (Auth: HRS §328G-6) (Imp: HRS §328G-6)

§11-37-49 Surrender of permit. (a) A hemp processor may voluntarily surrender a permit to the department at any time. Upon surrender of a hemp processor permit, the hemp processor shall immediately:

(1) Cease hemp processing operations;

(2) Surrender the permit to the department;

(3) Dispose of all hemp biomass, crude extract, manufactured hemp products that exceed the total tetrahydrocannabinol content limits per serving or per package or container specified in section 11-37-5(a) and (b), and all other hemp-derived products that do not meet the manufactured hemp product requirements in subchapters 1 to 3; and

(4) Submit to the department evidence of compliance with paragraph (3).

(b) No portion of the permit fee shall be returned to the permittee if the permit is voluntarily surrendered prior to its expiration. [Eff and comp DEC -6 2024] (Auth: HRS §328G-6) (Imp: HRS §328G-6)

SUBCHAPTER 5

HEMP PROCESSORS - GENERAL

§11-37-50 Hemp biomass sourcing requirements. (a) Hemp processors shall obtain hemp biomass only from a hemp producer holding a valid license issued by

the USDA pursuant to title 7 United States Codes section 1639q or by a state or tribal agency administering a plan approved by the USDA pursuant to title 7 United States Code section 1639p.

(b) For all hemp biomass not grown by the hemp processor, the hemp processor shall maintain records demonstrating compliance with subsection (a) in accordance with section 11-37-55. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §§328G-3, 328G-4)

§11-37-51 General hemp processing facility requirements. (a) Hemp biomass shall not be processed into crude extract or a manufactured hemp product within five hundred feet of a pre-existing playground, school, state park, state recreation area, residential neighborhood, hospital, or daycare facility.

(b) A hemp processing facility shall not be located within a house, dwelling unit, residential apartment, or other residential structure.

(c) A hemp processing facility shall:

(1) Be an enclosed indoor facility;

(2) Comply with all applicable zoning, building, and fire codes; and

(3) Be secured to prevent unauthorized entry and cross-contamination or unintended exposure to physical, chemical, and biological sources of contamination, including any hazardous by-products of hemp processing, including but not limited to delta-9 tetrahydrocannabinol.

(d) Only authorized personnel shall be allowed access into processing, production, storage, and product control areas.

(e) All personnel and visitors shall be properly supervised while in a hemp processing facility.

(f) Hemp processors shall allow any member of the department, or any agent or third party authorized by the department, to enter at reasonable times upon

any private property in order to inspect, sample, and test any hemp biomass, crude extract, or manufactured hemp product, equipment, and facilities incident to the processing or storage of hemp biomass, crude extract, or manufactured hemp products and to review all pertinent records. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §§328G-2, 328G-3, 328G-4)

§11-37-52 Solvents and processing practices. (a) Solvents used in processing shall be of the highest purity, with the minimum standard being solvent intended to be safe for use in manufacturing a product for human consumption.

(b) The following solvents shall not be used in processing:

(1) Benzene;

(2) Carbon tetrachloride;

(3) 1,2-Dichloroethane;

(4) 1,1-Dichloroethene; and

(5) 1,1,1-Trichloroethane.

(c) Hemp biomass, crude extract, and manufactured hemp products shall not be processed using butane in an open system where fumes are not contained nor by use of any other method of processing the department determines poses a risk to health and safety. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §§328G-3, 328G-4)

§11-37-53 Storage of hemp biomass, crude extract, manufactured hemp products, and wastes. Hemp biomass, crude extract, manufactured hemp products, and any toxic or otherwise hazardous by-products of hemp processing, including but not limited to delta-9 tetrahydrocannabinol, shall be stored within a hemp processing facility that meets the requirements of this subchapter and subchapter 6. [Eff 8/9/21; comp

2/24/22; comp 4/29/22; am and comp DEC -6 2024]
(Auth: HRS §328G-4) (Imp: HRS §§328G-3, 328G-4)

§11-37-54 Waste disposal. Any crude extract, manufactured hemp product, or processing by-product that meets the definition of marijuana in section 712-1240, HRS, shall be disposed of in accordance with chapter 23-200. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §328G-4)

§11-37-55 Recordkeeping. (a) Records required by this chapter shall:

(1) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic records;
(2) Contain the actual values and observations obtained during monitoring and verification activities;
(3) Be accurate, indelible, and legible;
(4) Be created concurrently with performance of the activity documented;
(5) Be as detailed as necessary to provide history of work performed; and
(6) Include:
    (A) Information adequate to identify the facility (e.g., the name and, when necessary, the location of the facility);
    (B) The date and, when appropriate, the time of the activity documented;
    (C) The signature or initials of the person performing the activity; and
    (D) Where appropriate, the identity of the product and the batch number.

(b) All records required by this chapter shall be retained at the facility for at least 2 years after the date they were prepared. Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location.

(c) Records pertaining to manufactured hemp products or crude extract shall be retained for 1 year past the shelf life date, if shelf life dating is used, or 2 years beyond the date of distribution of the last batch of manufactured hemp products or crude extract associated with those records.

(d) Records that relate to the general adequacy of the equipment or processes being used by a facility, including the results of scientific studies and evaluations, shall be retained at the facility for at least 2 years after their use is discontinued.

(e) If reduction techniques, such as microfilming, are used, the hemp processor shall make suitable reader and photocopying equipment readily available to the department. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §328G-4)

§11-37-56 Standard operating procedures. (a) A hemp processor shall establish written processing and control standard operating procedures (SOPs; for example, formulations, processing procedures, in-process control methods, packaging procedures, procedures for operating equipment).

(b) Standard operating procedures shall include provisions to ensure that:

(1) The selection, weighing, and measuring of ingredients and the determination of finished yield are reviewed by a second individual;

(2) Major equipment, transfer lines, containers and tanks used for processing, holding, or

filling are identified to indicate contents, batch identification, stage of processing, and control status;

(3) There are appropriate measures to prevent contamination with microorganisms, chemicals, filth, or other extraneous material;

(4) There are in-process controls to ensure product uniformity, integrity (for example, in-process batch weights), accurate fill of mixing containers, and adequacy of mixing;

(5) The theoretical yield for a production batch is compared with the actual yield;

(6) The storage and handling of packaging materials that are intended to come into direct contact with the product prevent mix-ups and microbiological or chemical contamination; and

(7) Finished product packages bear permanent, meaningful, unique batch numbers.

(c) Documentation of standard operating procedures shall be sufficient to prevent errors of interpretation and loss of information.

(d) Documentation of standard operating procedures shall be established and maintained subject to the requirements of section 11-37-55. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §328G-4)

§§11-37-57 to 11-37-59 (Reserved).

SUBCHAPTER 6

PROCESSING PRACTICES AND PROCESSING FACILITY STANDARDS

§11-37-60 Personnel. (a) The management of a hemp processing facility shall ensure that all individuals who manufacture, process, pack, or hold crude extract or manufactured hemp products are qualified to perform their assigned duties.

(b) Each individual engaged in manufacturing, processing, packing, or holding crude extract or manufactured hemp products (including temporary and seasonal personnel) or in the supervision thereof shall:

(1) Be a qualified individual, as that term is defined in section 11-37-2; and

(2) Receive training in the principles of hygiene and safety, including the importance of employee health and personal hygiene, as appropriate to the crude extract or manufactured hemp product, the facility, and the individual's assigned duties.

(c) The management of the hemp processing facility shall take reasonable measures and precautions to ensure the following:

(1) Disease control. Any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of crude extract, manufactured hemp products, components, contact surfaces, or packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected, unless conditions such as open lesions, boils, and infected wounds are adequately covered (e.g., by an impermeable cover). Personnel shall be instructed to report such health conditions to their supervisors.

(2) Cleanliness. All persons working in direct contact with crude extract, manufactured

hemp products, components, contact surfaces, and packaging materials shall conform to hygienic practices while on duty to the extent necessary to protect against allergen cross-contact and against contamination of crude extract or manufactured hemp products. The methods for maintaining cleanliness include:

(A) Wearing outer garments suitable to the operation in a manner that protects against allergen cross-contact and against the contamination of crude extract, manufactured hemp products, components, contact surfaces, or packaging materials;

(B) Maintaining adequate personal cleanliness;

(C) Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand-washing facility before starting work, after each absence from the workstation, and at any other time when the hands may have become soiled or contaminated;

(D) Removing all unsecured jewelry and other objects that might fall into crude extract, manufactured hemp products, components, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which crude extract, manufactured hemp products, or components are manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the crude extract, manufactured hemp

products, components, contact surfaces, or packaging materials;

(E) Maintaining gloves, if they are used in handling crude extract, manufactured hemp products, or components, in an intact, clean, and sanitary condition;

(F) Wearing, where appropriate, in an effective manner, hair nets, headbands, caps, beard covers, or other effective hair restraints;

(G) Storing clothing or other personal belongings in areas other than where crude extract, manufactured hemp products, or components are exposed or where equipment or utensils are washed;

(H) Confining the following to areas other than where crude extract, manufactured hemp products, or components may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco; and

(I) Taking any other necessary precautions to protect against allergen cross-contact and against contamination of crude extract, manufactured hemp products, components, contact surfaces, or packaging materials with microorganisms or foreign substances (including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin).

(d) Responsibility for ensuring compliance by individuals with the requirements of this chapter shall be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe crude extract or manufactured hemp products.

(e) Records that document training required by subsection (b)(2) shall be established and maintained subject to the requirements of section 11-37-55. [Eff

8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §328G-4)

§11-37-61 Facility and grounds. (a) Grounds. The grounds about a hemp processing facility under the control of the hemp processor shall be kept in a condition that will protect against the contamination of crude extract or manufactured hemp products. The methods for adequate maintenance of grounds shall include:

(1) Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the facility that may constitute an attractant, breeding place, or harborage for pests;

(2) Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where crude extract, manufactured hemp products, or components are exposed;

(3) Adequately draining areas that may contribute contamination to crude extract, manufactured hemp products, or components by seepage, foot-borne filth, or providing a breeding place for pests;

(4) Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where crude extract, manufactured hemp products, or components are exposed; and

(5) If the facility grounds are bordered by grounds not under the hemp processor's control and not maintained in the manner described in paragraphs (1) to (4), care shall be exercised in the facility by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of contamination.

(b) Facility construction and design. The facility shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for manufacturing, processing, packing, and holding crude extract or manufactured hemp products. The facility shall:

(1) Provide adequate space for such placement of equipment and storage of materials as is necessary for maintenance, sanitary operations, and the production of safe crude extract or manufactured hemp products;

(2) Permit the taking of adequate precautions to reduce the potential for mix-ups and allergen cross-contact and for contamination of crude extract, manufactured hemp products, components, contact surfaces, or packaging materials with microorganisms, chemicals, filth, and other extraneous material. The potential for allergen cross-contact and for contamination may be reduced by adequate safety controls and operating practices and effective design, including the separation of operations in which allergen cross-contact and contamination are likely to occur, by one or more of the following means: location, time, partition, air flow systems, dust control systems, enclosed systems, or other effective means;

(3) Be constructed in such a manner that:

(A) Floors, walls, and ceilings may be adequately cleaned, kept clean, and kept in good repair;

(B) Drip or condensate from fixtures, ducts, and pipes does not contaminate crude extract, manufactured hemp products, components, contact surfaces, or packaging materials; and

(C) Aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of adequate width to permit employees to perform their duties and to protect against

contaminating crude extract, manufactured hemp products, components, contact surfaces, or packaging materials with clothing or personal contact;

(4) Provide adequate lighting in hand-washing areas, dressing and locker rooms, and toilet rooms and in all areas where crude extract, manufactured hemp products, or components are examined, manufactured, processed, packed, or held and where equipment or utensils are cleaned;

(5) Provide shatter-resistant light bulbs, fixtures, skylights, or other glass suspended over exposed crude extract, manufactured hemp products, or components in any step of preparation, or otherwise protect against contamination in case of glass breakage;

(6) Provide adequate ventilation or control equipment to minimize dust, odors, and vapors (including steam and noxious fumes) in areas where they may cause allergen cross-contact or contaminate crude extract, manufactured hemp products, or components;

(7) Locate and operate fans and other air-blowing equipment in a manner that minimizes the potential for allergen cross-contact and for contaminating crude extract, manufactured hemp products, components, contact surfaces, and packaging materials; and

(8) Provide, where necessary, adequate screening or other protection against pests. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §328G-4)

§11-37-62 Sanitary operations. (a) General maintenance. Buildings, fixtures, and other

physical facilities shall be maintained in a clean and sanitary condition and shall be kept in repair adequate to prevent crude extract or manufactured hemp products from becoming adulterated. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against allergen cross-contact and against contamination of crude extract, manufactured hemp products, components, contact surfaces, or packaging materials.

(b) Substances used in cleaning and sanitizing; storage of toxic materials.

(1) Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means, including purchase of these substances under a letter of guarantee or certification or examination of these substances for contamination. Only the following toxic materials may be used or stored in a facility where hemp biomass is processed or crude extract, manufactured hemp products, or components are exposed:

(A) Those required to maintain clean and sanitary conditions;

(B) Those necessary for use in laboratory testing procedures;

(C) Those necessary for facility and equipment maintenance and operation; and

(D) Those necessary for use in the facility's operations.

(2) Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of crude extract, manufactured hemp products, components, contact surfaces, or packaging materials.

(c) Pest control. Pests shall not be allowed in any area of a facility. Guard, guide, or pest-

detecting dogs may be allowed in some areas of a facility if the presence of the dogs is unlikely to result in contamination of crude extract, manufactured hemp products, components, contact surfaces, or packaging materials. Effective measures shall be taken to exclude pests from the manufacturing, processing, packing, and holding areas and to protect against the contamination of crude extract, manufactured hemp products, or components on the premises by pests. The use of pesticides to control pests in the facility is permitted only under precautions and restrictions that will protect against the contamination of crude extract, manufactured hemp products, components, contact surfaces, and packaging materials.

(d) Sanitation of contact surfaces. All contact surfaces, including utensils and contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against allergen cross-contact and against contamination of crude extract, manufactured hemp products, or components.

(1) Contact surfaces used for manufacturing, processing, packing, or holding low-moisture crude extract, manufactured hemp products, or components shall be in a clean, dry, sanitary condition before use. When the surfaces are wet-cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.

(2) In wet processing, when cleaning is necessary to protect against allergen cross-contact or the introduction of microorganisms into crude extract, manufactured hemp products, or components, all contact surfaces shall be cleaned and sanitized before use and after any interruption during which the contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and contact surfaces of the equipment shall be cleaned and sanitized as necessary.

(3) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) shall be stored, handled, and disposed of in a manner that protects against allergen cross-contact and against contamination of crude extract, manufactured hemp products, components, contact surfaces, or packaging materials.

(e) Sanitation of non-contact surfaces. Non-contact surfaces of equipment used in the operation of a facility shall be cleaned in a manner and as frequently as necessary to protect against allergen cross-contact and against contamination of crude extract, manufactured hemp products, components, contact surfaces, and packaging materials.

(f) Storage and handling of cleaned portable equipment and utensils. Cleaned and sanitized portable equipment with contact surfaces and utensils shall be stored in a location and manner that protects contact surfaces from allergen cross-contact and from contamination. [Eff 8/9/21; am and comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §328G-4)

§11-37-63 Sanitary facilities and controls. Each hemp processing facility shall be equipped with adequate sanitary facilities and accommodations including:

(1) Water supply. The water supply shall be adequate for the operations intended and shall be derived from an adequate source. Any water that contacts crude extract, manufactured hemp products, components, contact surfaces, or packaging materials shall be safe and of adequate sanitary quality. Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of crude extract or manufactured hemp products, for the

cleaning of equipment, utensils, and packaging materials, or for employee sanitary facilities;

(2) Plumbing. Plumbing shall be of adequate size and design and adequately installed and maintained to:
   (A) Carry adequate quantities of water to required locations throughout the facility;
   (B) Properly convey sewage and liquid disposable waste from the facility;
   (C) Avoid constituting a source of contamination to crude extract, manufactured hemp products, components, water supplies, equipment, or utensils or creating an unsanitary condition;
   (D) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and
   (E) Provide that there is not backflow from, or cross-connection between, piping systems that discharge wastewater or sewage and piping systems that carry water for crude extract or manufactured hemp product processing or manufacturing;

(3) Sewage disposal. Sewage shall be disposed of into an adequate sewerage system or disposed of through other adequate means;

(4) Toilet facilities. Each hemp processing facility shall provide employees with adequate, readily accessible toilet facilities. Toilet facilities shall be kept clean and shall not be a potential source of contamination of crude extract, manufactured hemp products, components, contact surfaces, or packaging materials;

(5) Hand-washing facilities. Each hemp processing facility shall provide hand-washing facilities designed to ensure that

an employee's hands are not a source of contamination of crude extract, manufactured hemp products, components, contact surfaces, or packaging materials, by providing facilities that are adequate, convenient, and furnish running water at a suitable temperature; and

(6) Rubbish disposal. Rubbish shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of crude extract, manufactured hemp products, components, contact surfaces, packaging materials, water supplies, and ground surfaces. [Eff 8/9/21; am and comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §328G-4)

§11-37-64 Equipment and utensils. (a) All hemp processing facility equipment and utensils used in manufacturing, processing, packing, or holding crude extract or manufactured hemp products shall be so designed and of such material and workmanship as to be adequately cleanable and shall be adequately maintained to protect against allergen cross-contact and against contamination.

(b) Equipment and utensils shall be designed, constructed, and used appropriately to avoid the adulteration of crude extract, manufactured hemp products, or components with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(c) Equipment shall be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

(d) Contact surfaces shall be corrosion-resistant.

(e) Contact surfaces shall be made of non-toxic materials and designed to withstand the environment of their intended use and the action of crude extract, manufactured hemp products, and components, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.

(f) Contact surfaces shall be maintained to protect crude extract, manufactured hemp products, and components from allergen cross-contact and from being contaminated by any source.

(g) Seams on contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms and allergen cross-contact.

(h) Equipment that is in areas where crude extract or manufactured hemp products are manufactured, processed, packed, or held and that does not come into contact with crude extract, manufactured hemp products, or components shall be so constructed that it can be kept in a clean and sanitary condition.

(i) Holding, conveying, processing, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate clean and sanitary condition.

(j) Each freezer and cold storage compartment used to store and hold crude extract, manufactured hemp products, or components capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature-measuring device, or temperature-recording device so installed as to show the temperature accurately within the compartment.

(k) Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in crude extract, manufactured hemp products, or components shall be accurate and precise and

adequately maintained, and adequate in number for their designated uses.

(l) Compressed air or other gases mechanically introduced into crude extract, manufactured hemp products, or components or used to clean contact surfaces or equipment shall be treated in such a way that crude extract, manufactured hemp products, or components are not adulterated.

(m) Equipment and utensils used in measuring, mixing, or weighing shall be:

(1) Of suitable size and accuracy for measuring, mixing, and weighing operations;

(2) Calibrated regularly or checked according to an SOP with results documented, where appropriate; and

(3) Removed from use if they are defective, do not meet recommended tolerances, or cannot be repaired and calibrated immediately.

[Eff 8/9/21; am and comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §328G-4)

§11-37-65 Processes and controls. (a) General.

(1) All operations in the manufacturing, processing, packing, and holding of crude extract, manufactured hemp products, and components (including receiving, inspecting, transporting, and segregating) shall be conducted in accordance with adequate sanitation principles.

(2) Appropriate quality control operations shall be employed to ensure that manufactured hemp products are suitable for consumption by humans or animals or for topical application to the skin or hair, as applicable, and that packaging materials are safe and suitable.

(3) Overall sanitation of the facility shall be under the supervision of one or more competent individuals assigned responsibility for this function.

(4) Adequate precautions shall be taken to ensure that production procedures do not contribute to allergen cross-contact or to contamination from any source.

(5) Chemical, microbial, or extraneous-material testing procedures shall be used where necessary to identify sanitation failures or possible allergen cross-contact and contamination.

(6) All components and in-process materials that have become contaminated to the extent that they are adulterated shall be rejected, or if appropriate, treated or processed to eliminate the contamination.

(b) Ingredients.

(1) Ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into crude extract or manufactured hemp products and shall be stored under conditions that will protect against allergen cross-contact and against contamination and minimize deterioration. Ingredients shall be washed or cleaned as necessary to remove soil or other contamination. Water used for washing, rinsing, or conveying crude extract, manufactured hemp products, or components shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying crude extract, manufactured hemp products, or components if it does not cause allergen cross-contact or increase the level of contamination of the crude extract, manufactured hemp product, or component.

(2) Ingredients shall either not contain levels of microorganisms that may render the crude extract or manufactured hemp product injurious to the health of humans, or they shall be treated during manufacturing operations so that they no longer contain

levels that would cause the product to be adulterated.

(3) Ingredients susceptible to contamination with aflatoxins or other natural toxins shall not be adulterated before these ingredients are incorporated into a finished crude extract or manufactured hemp product.

(4) Ingredients and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall be examined and, based on examination results, shall not be adulterated before these ingredients are incorporated into a finished crude extract or manufactured hemp product.

(5) Ingredients and rework shall be held in bulk or in containers designed and constructed so as to protect against mix-ups, allergen cross-contact, and contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the ingredients, crude extract, or manufactured hemp product from becoming adulterated. Material scheduled for rework shall be identified as such.

(6) Frozen ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the ingredients from becoming adulterated.

(7) Liquid or dry ingredients received and stored in bulk form shall be held in a manner that protects against allergen cross-contact and against contamination.

(8) Ingredients that are allergens, and rework that contains allergens, shall be identified and held in a manner that prevents allergen cross-contact.

(9) Water used as an ingredient shall be:
   (A) Of a defined quality;
   (B) Unaffected by materials used in the water treatment equipment;

(C) Tested or monitored regularly to verify that it meets applicable chemical, physical, and microbiological specifications for quality; and

(D) Supplied by a system set up to avoid stagnation and risks of contamination that is routinely cleaned and sanitized according to an appropriate SOP that ensures no biofilm build-up.

(c) Manufacturing operations.

(1) Equipment, utensils, and containers shall be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.

(2) All manufacturing, processing, packing, and holding shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination, and deterioration.

(3) Crude extract, manufactured hemp products, and components that can support the rapid growth of undesirable microorganisms shall be held at temperatures that will prevent the crude extract, manufactured hemp product, or component from becoming adulterated during manufacturing, processing, packing, and holding.

(4) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms shall be adequate under the conditions of processing, manufacture, handling, and distribution to prevent crude extract, manufactured hemp products, or components from being adulterated.

(5) Work-in-process and rework shall be handled in a manner that protects against allergen

cross-contact, contamination, and growth of undesirable microorganisms.

(6) Effective measures shall be taken to protect finished crude extract or manufactured hemp products from allergen cross-contact and from contamination by ingredients, other components, or refuse. When ingredients, other components, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in allergen cross-contact or contamination of crude extract or manufactured hemp products. Crude extract, manufactured hemp products, or components transported by conveyor shall be protected against allergen cross-contact and against contamination as necessary.

(7) Equipment, containers, and utensils used to convey, hold, or store crude extract, manufactured hemp products, components, work-in-process, or rework shall be constructed, handled, and maintained during manufacturing, processing, packing, and holding in a manner that protects against allergen cross-contact and against contamination.

(8) Adequate measures shall be taken to protect against the inclusion of metal or other extraneous material in crude extract or manufactured hemp products.

(9) Crude extract, manufactured hemp products, and components that are adulterated:

(A) Shall be disposed of in a manner that protects against the contamination of other crude extract, manufactured hemp products, and components; or

(B) If an adulterated crude extract, manufactured hemp product, or component is capable of being reconditioned, it shall be:

(i) Reconditioned (if appropriate) using a method that has been proven to be effective; or

(ii) Reconditioned (if appropriate) and reexamined and subsequently found not to be adulterated before being incorporated into crude extract or a manufactured hemp product.

(10) All operations in the manufacturing, processing, packing, and holding of crude extract, manufactured hemp products, and components shall be performed so as to protect crude extract, manufactured hemp products, and components against allergen cross-contact, contamination, and the growth of undesirable microorganisms. Crude extract, manufactured hemp products, and components shall be protected from contaminants that may drip, drain, or be drawn into them.

(11) Heat blanching, when required in the preparation of crude extract, manufactured hemp products, or components capable of supporting microbial growth, shall be effected by heating the crude extract, manufactured hemp product, or component to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling it or passing it to subsequent processing or manufacturing without delay. Growth and contamination by thermophilic microorganisms in blanchers shall be minimized by the use of adequate operating temperatures and by periodic cleaning and sanitizing as necessary.

(12) Crude extract, manufactured hemp products, and components that rely principally on the control of a_w for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level.

(13) Crude extract, manufactured hemp products, and components that rely principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below.

(14) When ice is used in contact with crude extract, manufactured hemp products, or components, it shall be made from water that is safe and of adequate sanitary quality in accordance with section 11-37-63(1) and manufactured in accordance with current good manufacturing practice. [Eff 8/9/21; am and comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §328G-4)

§11-37-66 Warehousing and distribution. Storage and transportation of crude extract, manufactured hemp products, and components shall be under conditions that will protect against allergen cross-contact and against biological, chemical (including radiological), and physical contamination of crude extract, manufactured hemp products, or components, as well as against deterioration of the crude extract, manufactured hemp product, or component and the container. [Eff 8/9/21; am and comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §328G-4)

§§11-37-67 to 11-37-69 (Reserved).

SUBCHAPTER 7

QUALITY CONTROL

§11-37-70 Batch production and distribution records. (a) Production records shall document, for each batch of crude extract or manufactured hemp product:

(1) Review of ingredient records to determine if ingredients are adequately controlled;
(2) Ingredients (name, code, batch number, quantity, etc.) added to the batch;
(3) Production steps (for example, processing, handling, transferring, holding, and filling);
(4) In-process sampling, controlling, and adjusting steps;
(5) Compliance with or deviations from SOPs;
(6) Detailed description of any deviations from standard procedures, justifications for the deviations, and corrective measures taken;
(7) Any quality control review and disposition decision and follow-up required by section 11-37-71; and
(8) Batch number.

(b) Distribution records shall identify, for each batch of crude extract or manufactured hemp product:

(1) The product;
(2) The batch number;
(3) The consignee; and
(4) The date of distribution.

(c) Batch production and distribution records shall be adequate to conduct an effective recall.

(d) Batch production and distribution records shall be established and maintained subject to the requirements of section 11-37-55. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §§328G-4, 328G-5) (Imp: HRS §§328G-4, 328G-5)

§11-37-71 Quality control review and disposition decisions. (a) A hemp processor shall establish and follow written standard operating procedures and assign specific staff persons as quality control personnel to fulfill the requirements of this section.

(b) Quality control personnel shall conduct a review and make a disposition decision if:

(1) A contaminant limit established in section 11-37-23 is exceeded;

(2) Production of a batch deviates from established standard operating procedures, including when any step is not completed;

(3) There is any unanticipated occurrence during the processing or manufacturing operations that adulterates or may lead to adulteration of a component, crude extract, manufactured hemp product, or packaging, or could lead to the use of an incorrect label;

(4) Calibration of an instrument or control suggests a problem that may have resulted in a failure to ensure the quality of a batch of crude extract or manufactured hemp product; or

(5) A manufactured hemp product is returned.

(c) The quality control review shall include examination of the following, as applicable:

(1) Batch production records;

(2) Certificates of analysis or other testing records for ingredients;

(3) Testing records for finished product;

(4) Label and packaging integrity;

(5) Expiration date or use by date; and

(6) Any other examinations necessary to determine whether quality standards are met.

(d) When there is a deviation or unanticipated occurrence during the production and in-process control system that results in or could lead to adulteration of a component, crude extract, or manufactured hemp product, or packaging, or could lead to the use of an incorrect label, quality control personnel shall reject the component, crude extract, manufactured hemp product, packaging, or label unless

quality control personnel approve a treatment, an in-process adjustment, or reprocessing to correct the applicable deviation or occurrence.

(e) When a contaminant limit established in section 11-37-23(b) or (d) is exceeded during testing required by section 11-37-23(a) or (c), quality control personnel shall reject the crude extract or manufactured hemp product.

(f) The person who conducts the review and makes the disposition decision shall, at the time of performance, document that review and disposition decision in accordance with section 11-37-75. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC - 6 2024] (Auth: HRS §§328G-4, 328G-5) (Imp: HRS §§328G-4, 328G-5)

§11-37-72 Returned crude extract and manufactured hemp products. (a) Standard operating procedures. A hemp processor shall establish and follow written standard operating procedures to fulfill the requirements of this section.

(b) Quarantine and investigation of manufacturing processes. Returned crude extract or manufactured hemp products shall be identified and quarantined until quality control personnel conduct a review and make a disposition decision as required by section 11-37-71.

(c) Destruction or other suitable disposal. A hemp processor shall destroy, or otherwise suitably dispose of, any returned crude extract or manufactured hemp product unless the outcome of the review and disposition decision conducted under section 11-37-71 is that quality control personnel:

(1) Approve the salvage of the returned crude extract or manufactured hemp product for redistribution; or

(2) Approve the returned crude extract or manufactured hemp product for reprocessing.

(d) Salvaging and reprocessing.

(1) A hemp processor may salvage a returned crude extract or manufactured hemp product only if quality control personnel conduct a review in accordance with section 11-37-71 and make a disposition decision to allow the salvage;

(2) A hemp processor shall ensure that any returned crude extract or manufactured hemp products that are reprocessed meet all contaminant limits established in section 11-37-23; and

(3) Quality control personnel shall approve or reject the release for distribution of any returned crude extract or manufactured hemp product that is reprocessed.

(e) Investigation of other batches. If the reason for a crude extract or manufactured hemp product being returned implicates other batches, the hemp processor shall conduct an investigation of each of those other batches to determine compliance with subchapter 6 and the contamination limits in section 11-37-23. [Eff 8/9/21; am and comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §§328G-4, 328G-5) (Imp: HRS §§328G-4, 328G-5)

§11-37-73 Product complaints. (a) A hemp processor shall establish and follow written procedures to fulfill the requirements of this section.

(b) Review and investigation of product complaints. A qualified person shall:

(1) Review all product complaints to determine whether the product complaint involves a possible failure of a crude extract or manufactured hemp product to meet any of the contaminant limits in section 11-37-23 or any other requirements of this chapter, including those requirements that, if not met, may result in a risk of illness or injury; and

(2) Investigate any product complaint that involves a possible failure of a crude extract or manufactured hemp product to meet any of the contaminant limits in section 11-37-23 or any other requirements of this chapter, including those requirements that, if not met, may result in a risk of illness or injury.

(c) Quality control personnel shall review and approve decisions about whether to investigate a product complaint and review and approve the findings and follow-up action of any investigation performed.

(d) The review and investigation of the product complaint by a qualified person, and the review by quality control personnel about whether to investigate a product complaint, and the findings and follow-up action of any investigation performed, shall extend to all relevant batches and records. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §328G-4) (Imp: HRS §328G-4)

§11-37-74 Recalls. (a) A hemp processor shall establish a written recall plan for each crude extract or manufactured hemp product.

(b) The written recall plan shall include procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:

(1) Directly notify the direct consignees of the product being recalled, including how to return or dispose of the affected product;

(2) Notify the public about any hazard presented by the product when appropriate to protect public health;

(3) Conduct effectiveness checks to verify that the recall is carried out; and

(4) Appropriately dispose of recalled product (e.g., through reprocessing, diverting to a

use that does not present a safety concern, or destroying the product).

(c) A hemp processor shall notify the department in writing within twenty-four hours of initiating a recall. [Eff 8/9/21; comp 2/24/22; comp 4/29/22; am and comp DEC - 6 2024] (Auth: HRS §328G-4) (Imp: HRS §328G-4)

§11-37-75 Recordkeeping for quality control. (a) A hemp processor shall establish and maintain the following records documenting compliance with this subchapter:

(1) Written procedures for quality control operations, including:
  (A) Conducting a review and making a disposition decision;
  (B) Approving or rejecting any reprocessing;
  (C) Identifying and investigating additional potentially implicated batches;
  (D) Handling of returned manufactured hemp products, including procedures for quarantine, destruction or other suitable disposal, and salvaging and reprocessing; and
  (E) Reviewing and investigating product complaints;

(2) Written documentation, at the time of performance, that quality control personnel performed the review, approval, or rejection requirements by recording the following:
  (A) Date that the review, approval, or rejection was performed; and
  (B) Signature of the person performing the review, approval, or rejection;

(3) Documentation of any quality control review and disposition decision and follow-up shall be included in the appropriate batch production record and shall include:

(A) Identification of the specific deviation or unanticipated occurrence;
(B) Description of the investigation into the cause of the deviation or unanticipated occurrence;
(C) Evaluation of whether or not the deviation or unanticipated occurrence has resulted in or could lead to a failure to ensure the quality of the crude extract or manufactured hemp product or adulterating or misbranding of the crude extract or manufactured hemp product;
(D) Identification of the action(s) taken to correct, and prevent a recurrence of, the deviation or unanticipated occurrence;
(E) Explanation of what was done with the crude extract, manufactured hemp product, packaging, or label;
(F) A scientifically valid reason for any reprocessing of a crude extract or manufactured hemp product that is rejected; and
(G) The signature of the individual(s) designated to perform the quality control operation, who conducted the review and made the disposition decision, and of each qualified individual who provides information relevant to the review and disposition decision;

(4) The results of any laboratory testing conducted as part of a quality control review or product complaint investigation;
(5) Documentation of the re-evaluation by quality control personnel of any crude extract or manufactured hemp product that is reprocessed and the determination by quality control personnel of whether the reprocessed crude extract or manufactured hemp product

meets contaminant limits established in section 11-37-23;

(6) A written record of every product complaint and the review of every product complaint:

(A) The person who performs the requirements of section 11-37-73 shall document, at the time of performance, that the requirement was performed; and

(B) The written record of the product complaint shall include the following:

(i) The name and description of the manufactured hemp product;

(ii) The batch number of the manufactured hemp product, if available;

(iii) The date the complaint was received and the name, address, or telephone number of the complainant, if available;

(iv) The nature of the complaint including, if known, how the product was used;

(v) The reply to the complainant, if any; and

(vi) Findings of the investigation and follow-up action taken when an investigation is performed; and

(7) A written recall plan as required by section 11-37-74.

(b) The records required by subsection (a) are subject to the requirements of section 11-37-55. [Eff 8/9/21; am and comp 2/24/22; comp 4/29/22; am and comp DEC -6 2024] (Auth: HRS §§328G-4, 328G-5) (Imp: HRS §§328G-4, 328G-5)

§§11-37-76 to 11-37-79 (Reserved).

SUBCHAPTER 8

ENFORCEMENT

§11-37-80 Embargo and detention. (a) Based upon the department's findings or other evidence, the director or their designee may embargo or detain any product containing hemp or derived from hemp that is adulterated, misbranded, or otherwise determined to be a potential health hazard.

(b) Any product containing hemp or derived from hemp that is held for sale, offered for sale, sold, or distributed in violation of this chapter or chapter 328G, HRS, shall be automatically determined to be a potential health hazard.

(c) A product embargoed or detained pursuant to this subsection shall not be sold, moved, or used unless the embargo or detainment has been rescinded.

(d) The department shall attach a tag or other appropriate marking to the product being embargoed or detained. The tag or other marking shall be removed only by the department.

(e) The tag or other marking indicating that a product has been embargoed or detained shall:

(1) Provide the department's findings and conclusions with respect to the product determined to be a potential health hazard; and

(2) Notify the person whose product has been embargoed or detained of their right to request a hearing.

(f) If the owner of a product which has been embargoed or detained submits a written request to the department for a hearing to contest the embargo or detainment within twenty days from the date the tag or other marking was affixed to the product, the director or their designee shall provide a hearing as soon as practicable. At such hearing the director or their designee shall:

(1) Determine whether the embargoed or detained product is held for sale, offered for sale,

sold, or distributed in violation of this chapter or chapter 328G, HRS, or is otherwise a potential health hazard;

(2) Determine whether the product must be destroyed and under what circumstances; and

(3) Issue a final order for the continued embargo or detainment and ultimate disposition of the embargoed or detained product, or rescind the action.

(g) If no written request is submitted to the department within twenty days from the date the tag or other marking of embargo or detainment was affixed to the product, the department's findings and conclusions shall become final and the owner or seller of the product shall dispose of the embargoed or detained product in the manner prescribed by the department.

(h) Every product sold, moved, or used, and every tag or other appropriate marking removed, in violation of this section shall be a separate violation and subject to further enforcement pursuant to section 328G-6, HRS. [Eff and comp DEC -6 2024] (Auth: HRS §§321-1, 328G-4) (Imp: HRS §§328G-4, 328G-6)

DEPARTMENT OF HEALTH

Chapters 11-37 and 11-850 (Interim Rules), Hawaii Administrative Rules, on the Summary Page dated November 22, 2024 were amended and compiled on November 22, 2024.

The foregoing rulemaking actions shall take effect ten days after filing with the Office of the Lieutenant Governor.

Kenneth S. Fink, MD, MGA, MPH
Director of Health

Josh Green, M.D.
Governor of Hawaii

Dated: 11/26/2024

APPROVED AS TO FORM:

Andrew D. Goff
Deputy Attorney General

NOV 26 2024
Filed