

DEPARTMENT OF HEALTH

Amendment and Compilation of Chapter 11-37 (Interim
Rules)

Hawaii Administrative Rules

April 1, 2022

SUMMARY

Chapter 11-37 (Interim Rules), Hawaii
Administrative Rules, entitled "Hemp Processing and
Hemp Products", is amended and compiled.

HAWAII ADMINISTRATIVE RULES

TITLE 11

DEPARTMENT OF HEALTH

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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 and the sale of hemp products to provide for the protection of the health and safety of the general public.

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

(c) All subchapters apply to persons processing hemp 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 **APR 29 2022**] (Auth: HRS §§328G-4, 328G-5) (Imp: HRS §§328G-2, 328G-3, 328G-4, 328G-5)

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

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

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

"Adulterated" means a 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 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 hemp product.

"Applicant" means the person applying to register as a hemp processor under this chapter.

"Batch" means a specific quantity of a 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 manufacture.

"Batch number" means any distinctive group of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacturing, packaging, labeling, and/or holding of a batch of 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.

"Certificate of registration" means the certificate issued by the department attesting that the applicant is registered to process hemp.

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

"Contact surface" means any surface that contacts a component or hemp product, and those surfaces from which drainage onto the component or hemp product, or onto surfaces that contact the component or 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 hemp products or ingredients and are capable of causing hemp products to be:

- (1) Unsafe for consumption or topical use, as intended; or
- (2) In violation of a regulatory standard.

"Decarboxylated" means the completion of the chemical reaction that converts delta-9 tetrahydrocannabinol's acids (THCA) into delta-9-tetrahydrocannabinol. The decarboxylated value 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" or "THC" means the primary psychoactive component of cannabis.

"Department" means the department of health.

"Director" means the director of health.

"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 registered applicant from the applicant's duty to comply with all applicable building codes and regulations.

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

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

"Hemp processor" means a person processing hemp to manufacture a hemp product.

"Hemp product" means a product that:

- (1) Contains naturally occurring cannabinoids, compounds, concentrates, extracts, isolates, resins or derivatives from processed hemp;

- (2) Does not include any living hemp plants, viable seeds, leaf materials, or floral materials;
- (3) Has a delta-9-tetrahydrocannabinol concentration of not more than 0.3 per cent, as measured post-decarboxylation, or other similarly reliable methods;
- (4) Is intended to be consumed orally to supplement the human or animal diet; and
- (5) Is in the form of a tablet, capsule, powder, softgel, gelcap, or liquid form (e.g. hemp oil) to be used by the consumer to infuse edible items at home for personal use or for topical application to the skin or hair.

For purposes of this chapter, a hemp product shall be considered as intended for oral ingestion in liquid form only if it is formulated in a fluid carrier and it is intended for ingestion in daily quantities measured in drops or similar small units of measure per labeled directions for use.

"Ingredient" means any substance that is used in the manufacture of a hemp product and that is intended to be present in the finished batch of the 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 manufacture of a hemp product.

"Manufacture" means to compound, blend, extract, infuse, or otherwise make or prepare a hemp product, but does not include planting, growing, harvesting, drying, curing, grading, or trimming a hemp plant or part of a hemp plant.

"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 or hemp product to decompose;

- (3) Indicate that the component or hemp product is contaminated with filth; or
- (4) Otherwise may cause the component or hemp product to be adulterated.

"Misbranded" means a hemp product:

- (1) Has labeling that is false or misleading in any particular;
- (2) Fails to conform with the 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.

"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 making a transformative change to the hemp plant following harvest by converting an agricultural commodity into a hemp product.

"Product complaint" means any communication that contains any written, electronic, or oral allegation expressing concern with the quality of a 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 hemp product container, improper packaging, mislabeling, or 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 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 hemp product consistently meets established specifications for content, consistency, and limits on contaminants, and has been manufactured, 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 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 manufacture of a hemp product, clean, uncontaminated components or hemp products that have been previously removed from manufacturing and that have been made suitable for use in the manufacture of a hemp product.

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

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

"Safe moisture level" is a level of moisture low enough to prevent the growth of undesirable microorganisms in the hemp product under the intended conditions of manufacturing, processing, packing, and holding. The safe moisture level for a 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 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.

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

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

"USDA" means the United States Department of Agriculture.

"Water activity" or " a_w " is a measure of the free moisture in a component or 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 APR 29 2022] (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 hemp product that is adulterated or misbranded.

(b) No person shall sell, hold for sale, offer, or distribute any hemp product that does not meet the 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, synthetic cannabinoid, hemp extract, hemp derivatives, or other hemp product has been added as an ingredient or component. 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 cannabinoid products used to aerosolize for respiratory routes of delivery, such as an inhaler, nebulizer, or other device designed for such purpose.

(e) No person shall sell, hold for sale, offer, or distribute any hemp leaf or hemp floral material that is intended to be smoked or inhaled, including but not limited to hemp cigars or hemp cigarettes.

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

(g) Except for 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 hemp or hemp derivatives 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.

(h) No person shall sell, hold for sale, offer, or distribute any hemp product containing 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) Cannabinoids created through isomerization, including delta-8-tetrahydrocannabinol and delta-10-tetrahydrocannabinol; and
- (13) Any ingredient the department determines would render the product injurious or hazardous to health.

(i) No person shall sell, hold for sale, offer, or distribute any aerosol hemp product containing zirconium.

(j) Except for hemp products intended for external topical application to the skin or hair, no person shall sell, hold for sale, offer, or distribute any hemp product manufactured with components that are not intended to be safe for use in manufacture of a product for human consumption. [Eff 8/9/21; am and comp 2/24/22; comp APR 29 2022] (Auth: HRS §§328G-4) (Imp: HRS §§328G-1, 328G-3, 328G-4)

§§11-37-4 to 11-37-19 (Reserved).

SUBCHAPTER 2

HEMP PRODUCT 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

APR 29 2022] (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 hemp products 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;

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- (2) Be held using the same container-closure system in which the packaged and labeled 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 hemp products 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 **APR 29 2022**] (Auth: HRS §§328G-4, 328G-5) (Imp: HRS §§328G-4, 328G-5)

§11-37-22 Required testing for content and consistency. A representative sample of every batch of packaged and labeled hemp product shall be tested for content and consistency 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-tetrahydrocannabinol;
- (3) Cannabidiol (CBD); and
- (4) Any other cannabinoid specifically listed, described, or advertised in the label or packaging of the hemp product, including but not limited to cannabigerol (CBG) and cannabinal (CBN). [Eff 8/9/21; am and comp 2/24/22; comp **APR 29 2022**] (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 and labeled 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 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:
- (A) The limit for ethanol does not apply to tinctures; and
 - (B) The limit for ethanol does not apply to 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)
Benzene	71-43-2	1.0 ppm
Butane	106-97-8	5,000 ppm
Ethanol	64-17-5	5,000 ppm
Heptane	142-82-5	5,000 ppm
Hexane	110-54-3	290 ppm
Pentane	109-66-0	5,000 ppm
Toluene	108-88-3	890 ppm



Total xylenes (ortho-, meta-, para-)	1330-20-7	2,170 ppm
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- (4) The following microbial contaminants, which must not be detected in one gram of hemp product:
- (A) *Escherichia coli*;
 - (B) *Salmonella spp.*;
 - (C) *Aspergillus fumigatus*;
 - (D) *Aspergillus flavus*; and
 - (E) *Aspergillus niger*; 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

[Eff 8/9/21; am, and comp 2/24/22; am and comp APR 29 2022] (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 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 APR 29 2022] (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 APR 29 2022] (Auth: HRS §§328G-4, 328G-5) (Imp: HRS §§328G-4, 328G-5)

§§11-37-26 to 11-37-29 (Reserved).

SUBCHAPTER 3

HEMP PRODUCT PACKAGING AND LABELING



§11-37-30 Labeling. (a) Except as provided in subsection (d), every 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:

- (1) Product name;
- (2) Product net weight;
- (3) The total quantity (in milligrams) of the following cannabinoids contained in the packaged hemp product:
 - (A) Total tetrahydrocannabinol;
 - (B) Delta-9-tetrahydrocannabinol;
 - (C) Cannabidiol (CBD); and
 - (D) Any other cannabinoid specifically listed, described, or advertised in the label or packaging of the hemp product, including but not limited to cannabigerol (CBG) and cannabinal (CBN);
- (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) Directions for use;
- (8) 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;
- (9) The statement "Keep out of the reach of children." or words of similar meaning;
- (10) The statement "This product has been tested pursuant to chapter 11-37 subchapter 2, Hawaii Administrative Rules."; and
- (11) A QR code or website that displays test results as required by section 11-37-24.

(b) Except as provided in subsection (d), every hemp product intended to be consumed 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:

- (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;
- (3) The content (in milligrams) per serving of the following cannabinoids:
 - (A) Total tetrahydrocannabinol;
 - (B) Cannabidiol (CBD); and
 - (C) Any other cannabinoid specifically listed, described, or advertised in the label or packaging of the hemp product, including but not limited to cannabigerol (CBG) and cannabinal (CBN); and
- (4) A statement of the major food allergens the product contains or has protein derived from, to include:
 - (A) Milk;
 - (B) Egg;
 - (C) Fish;
 - (D) Crustacean shellfish;
 - (E) Tree nuts;
 - (F) Wheat;
 - (G) Peanuts; and
 - (H) Soybeans.

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

(c) Every 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: the statement "For external use only." or words of similar meaning.

(d) Allowed exceptions.

- (1) If the container of any hemp product is too small to accommodate a label containing all of the information required by subsection

(a) and (b), the information in paragraph (b)(1) may be included on labeling attached to or inserted into the package using a type size no smaller than one-sixteenth inch in height.

- (2) In lieu of being included on the product label, the information in paragraphs (a)(10) and (a)(11) may be included on labeling attached to or inserted into the package using a type size no smaller than one-sixteenth inch in height.

(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. [Eff 8/9/21; am and comp 2/24/22; comp APR 29 2022] (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*, second 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*, second 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 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 APR 29 2022] (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 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 APR 29 2022] (Auth: HRS §328G-4) (Imp: HRS §§328G-3, 328G-4)

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

- (1) Protects the product from contamination and does not impart any toxic or harmful substance to the hemp product; and
- (2) Is not reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the hemp product. [Eff and comp 2/24/22; comp APR 29 2022] (Auth: HRS §328G-4) (Imp: HRS §328G-4)

§§11-37-34 to 11-37-39 (Reserved).

SUBCHAPTER 4

HEMP PROCESSOR REGISTRY

§11-37-40 Registration required. No person shall engage in the processing of hemp without a valid certificate of registration issued by the department pursuant to this subchapter. [Eff 8/9/21; comp

APR 29 2022

§11-37-41

2/24/22; comp APR 29 2022] (Auth: HRS §328G-4)
(Imp: HRS §§328G-2, 328G-4)

§11-37-41 Eligibility. (a) To apply for a certificate of registration, 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) Have a license to produce hemp issued by the USDA pursuant to title 7 United States Code section 1639q. [Eff 8/9/21; comp 2/24/22; comp APR 29 2022] (Auth: HRS §328G-4)
(Imp: HRS §§328G-2, 328G-4)

§11-37-42 Application. (a) To apply for a certificate of registration, 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) A copy of the applicant's license to produce hemp, issued by the USDA pursuant to title 7 United States Code section 1639q;
- (3) The physical address and tax map key (TMK) number of the land on which each hemp processing facility is to be located;
- (4) A description of the enclosed indoor facility where hemp processing will occur 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); and
- (6) Documentation and attestation that the hemp processing facility and planned operation

complies with all zoning ordinances, building codes, and fire codes.

(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 **APR 29 2022**] (Auth: HRS §§328G-2, 328G-4) (Imp: HRS §§328G-2, 328G-4)

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

(b) A complete renewal application for a certificate of registration shall include:

- (1) A renewal form updating the registered hemp processor's registry information or certifying that all information remains unchanged, in accordance with section 11-37-47;
- (2) A copy of the registered hemp processor's current USDA license to produce hemp; and
- (3) A non-refundable renewal fee in accordance with section 11-37-44. If the fee does not accompany the application, the application shall be deemed incomplete. [Eff 8/9/21;

§11-37-44

comp 2/24/22; comp HRS §328G-4) (Imp: HRS §§328G-2, 328G-4)] (Auth: APR 29 2022

§11-37-44 Fees. (a) The fee for a new or renewal certificate of registration 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 HRS §§27G-2, 328G-2, 328G-4) (Imp: HRS §§328G-2, 328G-4)] (Auth: APR 29 2022

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

- (1) Failure to provide the information required in section 11-37-42 for new registration or section 11-37-43 for renewal;
- (2) Failure to pay registration 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 or the registered hemp processor in writing of the reason for the department's denial.

(c) An applicant or a registered hemp processor 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 HRS §328G-4) (Imp: HRS §§328G-2, 328G-4)] (Auth: APR 29 2022

§11-37-46 Certificate of registration. (a)

Upon the department's determination that an applicant has met the requirements of section 11-37-42 or 11-37-43, the department shall issue a certificate of registration to the applicant.

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

(c) A certificate of registration shall not be assigned or otherwise transferred to another person. [Eff 8/9/21; comp 2/24/22; comp APR 29 2022] (Auth: HRS §328G-4) (Imp: HRS §§328G-2, 328G-4)

§11-37-47 Changes in information. (a)

After obtaining a certificate of registration, 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 registered hemp processor intends to add a new hemp processing facility, the hemp processor shall obtain prior approval from the department by submitting the information required in section 11-37-42(a)(3) to (6) to the department at least thirty calendar days prior to the intended start date of the new hemp processing facility. The hemp processor shall not engage in the processing of hemp at the new facility until the department issues a new certificate of registration. [Eff 8/9/21; comp 2/24/22; comp APR 29 2022] (Auth: HRS §328G-4) (Imp: HRS §§328G-2, 328G-4)

§§11-37-48 to 11-37-49 (Reserved).

HEMP PROCESSORS - GENERAL

§11-37-50 Hemp sourcing requirements. (a) Hemp processors shall obtain hemp 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 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 **APR 29 2022**] (Auth: HRS §328G-4) (Imp: HRS §§328G-3, 328G-4)

§11-37-51 General hemp processing facility requirements. (a) Hemp processing facilities shall not be located within 500 feet of a pre-existing playground, school, state park, state recreation area, residential neighborhood, hospital, or daycare facility.

(b) 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 of or unintended exposure to any hazardous by-products of hemp processing, including but not limited to delta-9 tetrahydrocannabinol.

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

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

(e) 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 the hemp processing area, hemp products, equipment, and facilities incident to the processing or storage of hemp, and to review all pertinent records. [Eff 8/9/21; comp 2/24/22; comp] (Auth: HRS §328G-4) (Imp: HRS §§328G-2, 328G-3, 328G-4)

APR 29 2022

§11-37-52 Solvents and processing practices.

(a) Solvents used in processing hemp 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 hemp processing:

- (1) Benzene;
- (2) Carbon tetrachloride;
- (3) 1,2-Dichloroethane;
- (4) 1,1-Dichloroethene; and
- (5) 1,1,1-Trichloroethane.

(c) Hemp 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] (Auth: HRS §328G-4) (Imp: HRS §§328G-3, 328G-4)

APR 29 2022

§11-37-53 Storage of hemp, hemp products, and wastes.

Hemp, 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

3470

§11-37-54

2/24/22; comp **APR 29 2022**] (Auth: HRS §328G-4)
(Imp: HRS §§328G-3, 328G-4)

§11-37-54 Waste disposal. Any 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 **APR 29 2022**] (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 hemp products 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 hemp products 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 APR 29 2022] (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 **APR 29 2022**] (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

hemp products are qualified to perform their assigned duties.

(b) Each individual engaged in manufacturing, processing, packing, or holding 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 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 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 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 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 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 hemp products, components, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which 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 hemp products, components, contact surfaces, or packaging materials;
- (E) Maintaining gloves, if they are used in handling 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 hemp products or components are exposed or where equipment or utensils are washed;
- (H) Confining the following to areas other than where 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 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 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 APR 29 2022] (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 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 hemp products or components are exposed;
- (3) Adequately draining areas that may contribute contamination to 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 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 hemp product production purposes (i.e., manufacturing, processing, packing, and holding). 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 hemp products;
- (2) Permit the taking of adequate precautions to reduce the potential for mix-ups and allergen cross-contact and for contamination of 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 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 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 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 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 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 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 **APR 29 2022**
(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 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 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 is processed or 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 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 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 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 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 hemp products or components.
- (1) Contact surfaces used for manufacturing, processing, packing, or holding low-moisture 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 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 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 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

APR 29 2022] (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 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 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 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 hemp product 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 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 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 hemp products, components, contact surfaces, packaging materials, water supplies, and ground surfaces. [Eff 8/9/21; am and comp 2/24/22; comp APR 29 2022]
(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 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 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 hemp products and components, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.

(f) Contact surfaces shall be maintained to protect 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 hemp products are manufactured, processed, packed, or held and that does not come into contact with hemp products or components shall be so constructed that it can be kept in a clean and sanitary condition.

(i) Holding, conveying, 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 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 hemp products or components shall be accurate and

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

(1) Compressed air or other gases mechanically introduced into hemp products or components or used to clean contact surfaces or equipment shall be treated in such a way that 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

APR 29 2022] (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 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 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 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 hemp products or components shall be safe and of adequate sanitary quality. Water may be reused for washing, rinsing, or conveying hemp products or components if it does not cause allergen cross-contact or increase the level of contamination of the hemp product or component.
 - (2) Ingredients shall either not contain levels of microorganisms that may render the 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 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 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 or 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 hemp product 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) Hemp products and components that can support the rapid growth of undesirable microorganisms shall be held at temperatures that will prevent the 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 manufacture, handling, and distribution to prevent 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 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 hemp products. 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 components, work-in-process, rework, or other hemp products 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 hemp products.
- (9) Hemp products and components that are adulterated:
 - (A) Shall be disposed of in a manner that protects against the contamination of other hemp products and components; or
 - (B) If an adulterated 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 other hemp products.
- (10) All operations in the manufacturing, processing, packing, and holding of hemp products and components shall be performed so as to protect hemp products and components against allergen cross-contact, contamination, and the growth of undesirable microorganisms. 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 hemp products or components capable of supporting microbial growth, shall be effected by heating the 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 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) 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) 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 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
APR 29 2022] (Auth: HRS §328G-4)
(Imp: HRS §328G-4)

§11-37-66 Warehousing and distribution. Storage and transportation of 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 hemp products or components, as well

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as against deterioration of the hemp product or component and the container. [Eff 8/9/21; am and comp 2/24/22; comp APR 29 2022] (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 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 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 **APR 29 2022**] (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 manufacturing operations that adulterates or may lead to adulteration of a component, 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 a hemp product; or
 - (5) A 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

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(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, hemp product, or packaging, or could lead to the use of an incorrect label, quality control personnel shall reject the component, 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) is exceeded during testing required by section 11-37-23(a), quality control personnel shall reject the 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 APR 29 2022] (Auth: HRS §§328G-4, 328G-5) (Imp: HRS §§328G-4, 328G-5)

§11-37-72 Returned 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 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 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 hemp product for redistribution; or

- (2) Approve the returned hemp product for reprocessing.
- (d) Salvaging and reprocessing.
 - (1) A hemp processor may salvage a returned 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 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 hemp product that is reprocessed.
- (e) Investigation of other batches. If the reason for a 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 (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 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

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(2) Investigate any product complaint that involves a possible failure of a 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 APR 29 2022] (Auth: HRS §328G-4) (Imp: HRS §328G-4)

§11-37-74 Recalls. (a) A hemp processor shall establish a written recall plan for each 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, reworking, 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 APR 29 2022] (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 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 hemp product or adulterating or misbranding of the 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 hemp product, packaging, or label;
 - (F) A scientifically valid reason for any reprocessing of a 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 hemp product that is reprocessed and the determination by quality control personnel of whether the reprocessed 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 hemp product;
 - (ii) The batch number of the 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 APR 29 2022]
(Auth: HRS §§328G-4, 328G-5) (Imp: HRS §§328G-4, 328G-5)

DEPARTMENT OF HEALTH

Chapter 11-37 (Interim Rules), Hawaii
Administrative Rules, on the Summary Page dated April
1, 2022 was amended and compiled on April 1, 2022.

The foregoing rulemaking action shall take effect
immediately upon filing with the Office of the
Lieutenant Governor.



ELIZABETH A. CHAR, M.D.
Director of Health



DAVID Y. IGE
Governor of Hawaii

Dated: 4/19/2022

APPROVED AS TO FORM:



Wade H. Hargrove III
Deputy Attorney General

Filed

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OFFICE
LIEUTENANT GOVERNOR S

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