CHAPTER 156
CONSUMABLE HEMP PRODUCTS

~~[Prior to 6/14/23, see Inspections and Appeals Department[481] Ch 32]~~

***QUALIFYING STATEMENT: This is not an official rulemaking document. This document is provided to consumable hemp industry participants to understand intended rule changes to 641 Iowa Administrative Code (IAC) chapter 156 for the implementation of HF2605, and Red Tape Review pursuant to Executive Order 10. A formal Notice of Intended Action (NOIA), including key dates, will be provided on June 12, 2024. ***

641—156.1(204) Definitions. For the purpose of these rules, the following terms ~~shall~~ have the meanings indicated in this chapter. The definitions set out in Iowa Code section 204.2 ~~shall be considered to be~~ are incorporated verbatim herein.

"Accredited laboratory" means a laboratory accredited in accordance with the International Organization for Standardization/International Electrotechnical Commission ~~Standard~~ (ISO/IEC) standard 17025:2017 ~~or a comparable or successor standard~~ for the analyses performed on consumable hemp products.

"Adulterated" means the same as in the Federal Food, Drug, and Cosmetic Act, Section 402 (August 10, 2005), except that a consumable hemp product is not deemed "adulterated" pursuant to this chapter solely because it contains a hemp product not generally recognized as safe by the ~~Federal~~ federal Food and Drug Administration.

"Approved hemp source" means a manufacturer of a consumable hemp product that is engaged in the wholesale or retail sale of the product and that is:

1. Located in this state and manufactures the consumable hemp product in compliance with Iowa Code chapter 204 and these rules; or
2. Located in a state that has a state hemp plan approved by the United States Department of Agriculture under 7 U.S.C. Chapter 38, Subchapter VII (December 20, 2018).

"*Batch*" means a specific quantity of a consumable hemp product that contains a lot number, is uniform and intended to meet specifications for identity, strength, purity, and composition, and that is manufactured, packaged, and labeled during a specified time period according to a single manufacturing, packaging, and labeling record.

"Cannabidiol" or *"CBD*" means the specific chemical compound with the Chemical Abstracts Service number 13956-29-1.

"Certificate of analysis" or *"COA*" means an official document released by an accredited laboratory following an analysis of a consumable hemp product. The certificate of analysis ~~shall~~ contains all of the concentrations of cannabinoids, pesticides, residual solvents, metals, harmful pathogens, ~~and~~ toxicants, and synthetic or semi-synthetic cannabinoids, including data on levels of total delta-9 tetrahydrocannabinol (THC) content concentration and whether a sample passed or failed any limits related to these analyses.

"Certificate of free sale" means a government certification that products such as food, drugs, medicine, or cosmetics are approved for unrestricted sale in the jurisdiction in which they originate.

"Consumable hemp establishment" means an individual or entity engaged in manufacturing, processing, packing, holding, preparing, distributing, or selling a consumable hemp product in Iowa or to purchasers located in Iowa. A consumable hemp establishment does not include an individual or entity manufacturing, processing, packing, holding, preparing, distributing, or selling a consumable hemp product containing only hemp seed or hemp seed-derived food ingredients generally recognized as safe (GRAS) under the conditions of use by the ~~United States~~ federal Food and Drug Administration.

"Consumable hemp manufacturer" means a consumable hemp establishment engaged in manufacturing, processing, packing, holding, preparing, distributing, or selling a consumable hemp

product on a wholesale basis. A consumable hemp manufacturer includes individuals and entities outside of Iowa that distribute consumable hemp products in Iowa. A consumable hemp manufacturer does not include individuals or entities exclusively engaged in the harvesting, storage, or distribution of raw hemp.

~~*"Consumable hemp product*" means a hemp product that includes a substance that is metabolized or is otherwise subject to a biotransformative process when introduced into the human body.~~

~~1. A consumable hemp product may be introduced into the human body by ingestion or absorption by any device including but not limited to an electronic device.~~

~~2. A consumable hemp product may exist in a solid or liquid state.~~

~~3. A hemp product is deemed to be a consumable hemp product if it is any of the following:~~

~~● Designed by the processor, including the manufacturer, to be introduced into the human body.~~

~~● Advertised as an item to be introduced into the human body.~~

~~● Distributed, exported, or imported for sale or distribution to be introduced into the human body.~~

~~4. "Consumable hemp product" includes, but is not limited to, any of the following:~~

~~● A noncombustible form of hemp that may be digested, such as food; internally absorbed, such as chew or snuff; or absorbed through the skin, such as a topical application.~~

~~● Hemp processed or otherwise manufactured, marketed, sold, or distributed as human food, a human food additive, a human dietary supplement, or a human drug.~~

~~5. "Consumable hemp product" does not include a hemp product if the intended use of the hemp product is introduction into the human body by any method of inhalation, as prohibited under Iowa Code section 204.14A.~~

"Consumable hemp retailer" means a consumable hemp establishment selling consumable hemp product to consumers on a retail basis. A consumable hemp retailer includes an establishment selling consumable hemp products online.

"*Container*" means the object which holds one or more servings of a consumable hemp product.

"Delta-9 tetrahydrocannabinol" or *"THC*" means the specific chemical compound with the Chemical Abstracts Service number 1972-08-3.

~~*"Department*" means the Iowa department of health and human services.~~

"Expiration date" means the month and year as determined by the manufacturer, packer, or distributor on the basis of tests showing that the product, until that date, under the conditions of handling, storage, preparation, and use per label directions, will, when consumed, contain not less than the quantity of each ingredient as set forth on its label.

"Food" means the same as defined in Iowa Code section 137F.1. Food includes human dietary supplements and alcoholic beverages.

"Harvesting" applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in Section 201(gg) of the Federal Food, Drug, and Cosmetic Act (as amended through P.L. 118-15, enacted September 30, 2023). ~~Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.~~

"Jurisdiction of origin" means the federal, state, or local regulatory jurisdiction that has the authority to conduct inspections of the facility in which a consumable hemp product was most recently subject to a manufacturing/processing activity.

"Lot number" means a specific quantity of raw hemp or processed hemp product that is uniform and intended to meet specifications for identity, strength, purity, and composition that ~~shall~~ contains the

manufacturer's, processor's, or distributor's number and a sequence to allow for inventory, traceability, and identification of the plant batches used in the production of consumable hemp products.

"Manufacturing/processing" means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. ~~Examples of manufacturing/processing activities include: baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, eviscerating, extracting juice, formulating, freezing, grinding, homogenizing, irradiating, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing.~~ For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

"Misbranded" means a food that violates 21 U.S.C. Section 343 (March 23, 2010).

"QR code" means a quick response machine-readable code that can be read by a camera, consisting of an array of black and white squares used for storing information or directing or leading a user to product information regarding manufacturer data and accredited laboratory certificates of analysis.

"Raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

"Raw hemp" means an unprocessed hemp plant, or any part of the hemp plant, in its raw or natural state. Raw hemp is a raw agricultural commodity.

"*Serving*" means the size or portion customarily consumed per eating occasion, expressed in a common household measure as established in table 2 of 21 CFR 101.12 (as amended through May 27, 2016). If a solid consumable hemp product is packaged in a manner that includes more than a single serving, each serving must be clearly identified and severable from the other servings in the container. If a liquid consumable hemp product is packaged in a manner that includes more than a single serving, the number of servings must be conspicuously labeled. Liquid consumable hemp products shall be packaged in a container that holds a minimum of 12 fluid ounces.

"*Synthetic consumable hemp products*" means products containing synthetic or semi-synthetic cannabinoids. Synthetic and semi-synthetic cannabinoids refer to a class of cannabinoids created through a chemical process, and are structurally similar to naturally occurring cannabinoids, or cannabinoids that may occur in very small amounts naturally. Examples of synthetic consumable hemp products include, but may not be limited to: Delta-8 ~~THC~~tetrahydrocannabinol, Delta-10 ~~THC~~tetrahydrocannabinol, Hexahydrocannabinol (HHC), Tetrahydrocannabiphorol (THC-P), Tetrahydrocannabinol-O-acetate (THC-O)

"Tetrahydrocannabinolic acid" or *"THCA*" means the specific chemical compound with the Chemical Abstracts Service number 23978-85-0.

"Total delta-9 tetrahydrocannabinol" or *"total THC*" means 87.7 percent of the amount of tetrahydrocannabinolic acid plus the amount of delta-9 tetrahydrocannabinol.

~~[**ARC 5404C**, IAB 1/27/21, effective 3/3/21; Editorial change: IAC Supplement 6/14/23]~~

641—156.2(204) Registration and posting. A consumable hemp establishment shall not engage in manufacturing, processing, packing, holding, preparing, distributing, or selling a consumable hemp product in Iowa or to purchasers located in Iowa until it has submitted a consumable hemp registration that is approved by the department.

156.2(1) *Consumable hemp manufactures/distributors.* ~~Consumable hemp manufacturers shall register with the department.~~ At least 30 days prior to manufacturing, processing, packing, holding, preparing, distributing, or selling any consumable hemp product in Iowa or to purchasers located in Iowa~~. The~~, a consumable hemp manufacturer shall:

a. Complete the online registration form prescribed by the department;

b. Remit the registration fee set by the department in accordance with Iowa Code section 204.7; and

c. Submit a complete list of all consumable hemp products the consumable hemp manufacturer intends to manufacture, process, pack, hold, prepare, distribute, or sell, along with documentation of the jurisdiction of origin for each consumable hemp product.

156.2(2) *Consumable hemp retailers.* ~~Consumable hemp retailers shall register with the department a.~~ At least 30 days prior to selling any consumable hemp product in Iowa or to purchasers located in Iowa~~. The~~, a consumable hemp retailer shall register with the department by doing the following:

a. Complete the online registration form prescribed by the department;

b. Remit the registration fee set by the department in accordance with Iowa Code section 204.7; and

c. Submit a complete list of all consumable hemp products the consumable hemp retailer intends to sell, along with documentation of the jurisdiction of origin for each consumable hemp product.

156.2(3) *Combined consumable hemp manufacturers and retailers.* A consumable hemp establishment engaged in activities of a consumable hemp manufacturer and a consumable hemp retailer shall ~~submit a separate registration~~ register separately for each activity. A registered consumable hemp manufacturer that exclusively sells consumable hemp products it has manufactured to consumers on a retail basis is not ~~required~~ mandated to register as a consumable hemp retailer.

156.2(4) *Physical location.* A consumable hemp establishment's registration is valid for one physical location. A consumable hemp establishment that manufactures, processes, packs, holds, prepares, distributes, or sells a consumable hemp product at more than one physical location shall ~~submit a separate registration for~~ separately register each physical location.

156.2(5) *Expiration and renewal.* A consumable hemp registration, unless sooner suspended or revoked, ~~shall~~ expires one year after the registration is approved by the department. A consumable hemp registration ~~shall~~ may be renewed annually through the department's online registration system, accompanied by the ~~required~~ registration fee, at least 30 days prior to expiration. Consumable hemp registrations that are expired more than 60 days will be revoked without notice.

156.2(6) *Transferability.* A consumable hemp registration is not transferable to a new owner or new physical location.

156.2(7) *Posting of registrations.* A valid registration shall be posted on the premises of the consumable hemp establishment in a location that is visible to the public. An image of the valid registration must also be posted on any website or online point of sale in a location that is visible to the public prior to payment.

156.2(8) *Returned payments.* The department will attempt to redeem a payment submitted for a consumable hemp registration that is not honored by the bank on which it is drafted. The department will notify the applicant of the need to provide sufficient payment. An additional fee of $25 shall be assessed for each dishonored payment. If the department does not receive payment, the establishment will be operating without a valid registration and is subject to penalties set forth in rules 641—156.7(204) ~~and 641—156.8(204) (violations and enforcement; denial, suspension, or revocation of registration).~~

~~[**ARC 5404C**, IAB 1/27/21, effective 3/3/21; Editorial change: IAC Supplement 6/14/23]~~

641—156.3(204) Testing requirements and documentation.

156.3(1) *Approved hemp source; certificate of analysis.* A consumable hemp product ~~shall~~ cannot be distributed or sold unless:

a. The consumable hemp product is from an approved hemp source and is accompanied by documentation that identifies the jurisdiction of origin. Documentation that identifies the jurisdiction of origin includes:

(1) Certificate of free sale issued by the jurisdiction of origin;

(2) Product label statements, provided the product label identifies the jurisdiction of origin; or

(3) Other documentation that identifies the jurisdiction of origin and also identifies the following:

1. Brand name;

2. Product ~~Name~~ name;

~~2~~3. Serving and ~~Container~~ container size in terms of net quantity of contents; and

~~3~~4. Lot number for the batch.

b. The consumable hemp product has a certificate of analysis prepared by an independent accredited laboratory that verifies and states:

(1) The consumable hemp product is from a batch that has been tested by the independent accredited laboratory consistent with generally accepted industry standards for herbal and botanical substances;

(2) The presence and concentration of cannabinoids, including delta-9 tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol, and any other cannabinoids for which the product is being marketed;

(3) The consumable hemp product is from a batch that contained a total delta-9 tetrahydrocannabinol concentration that did not exceed 0.3 percent on a dry weight basis as calculated pursuant to an official postdecarboxylation analysis, as provided in Iowa Code section 204.8; and

(4) The consumable hemp product is from a batch that has been tested for, and does not contain more than trace amounts of, pesticides, residual solvents, metals, harmful pathogens, and toxicants ~~and does not exceed limits established in this rule~~.

(5) ~~The certificate of analysis shall indicate that the~~The batch does not contain synthetic or semisynthetic cannabinoids as described in these rules.

The certificate of analysis shall not be considered valid and usable for the batch of consumable hemp if its issuance date is greater than one year old.

156.3(2) *Toxicant limits.* If a testing sample is found to contain ~~levels~~ greater than trace amounts of any pesticide, residual solvent, metal, harmful pathogen, or toxicants ~~that exceeds limits enumerated in this rule or by Iowa law~~, the product ~~shall be~~ is considered adulterated and ~~shall~~ cannot enter commerce. ~~The following lists of contaminants do not constitute authorization to use or apply any of the following during hemp cultivation or processing.~~

~~*a.* Pesticide limits.~~

~~(1) Acetamiprid, .2 parts per million.~~
~~(2) Aldicarb, .4 parts per million.~~
~~(3) Azoxystrobin, .2 parts per million.~~
~~(4) Bifenazate, .2 parts per million.~~
~~(5) Boscalid, .4 parts per million.~~
~~(6) Carbaryl, .5 parts per million.~~
~~(7) Carbofuran, .2 parts per million.~~
~~(8) Chlorantraniliprole, .2 parts per million.~~
~~(9) Chlorpyrifos, .6 parts per million.~~
~~(10) Cypermethrin, 18 parts per million.~~
~~(11) Diazinon, 2.6 parts per million.~~
~~(12) Dichlorvos, .1 parts per million.~~
~~(13) Ethoprophos, .4 parts per million.~~
~~(14) Etofenprox, .4 parts per million.~~
~~(15) Fipronil, 1 part per million.~~
~~(16) Flonicamid, 1 part per million.~~
~~(17) Imidacloprid, .4 parts per million.~~
~~(18) Metalaxyl, .2 parts per million.~~
~~(19) Methiocarb, .4 parts per million.~~
~~(20) Methomyl, .4 parts per million.~~
~~(21) Methyl parathion, 8.5 parts per million.~~
~~(22) Myclobutanil, .3 parts per million.~~
~~(23) Oxamyl, 1 part per million.~~
~~(24) Permethrin, 1.1 parts per million.~~

(25) Pyridaben, .2 parts per million.
(26) Spiroxamine, 2 parts per million.
(27) Tebuconazole, .4 parts per million.
(28) Thiacloprid, .2 parts per million.
(29) Thiamethoxam, .2 parts per million.
b. Residual solvent limits.
(1) 1,2-Dimethoxyethane, 100 parts per million.
(2) 1,4-Dioxane, 380 parts per million.
(3) 1-Butanol, 5,000 parts per million.
(4) 1-Pentanol, 5,000 parts per million.
(5) 1-Propanol, 5,000 parts per million.
(6) 2-Butanol, 5,000 parts per million.
(7) 2-Butanone, 5,000 parts per million.
(8) 2-Ethoxyethanol, 5,000 parts per million.
(9) 2-methylbutane, 5,000 parts per million.
(10) 2-Propanol (IPA), 5,000 parts per million.
(11) Acetone, 5,000 parts per million.
(12) Acetonitrile, 410 parts per million.
(13) Benzene, 2 parts per million.
(14) Butane, 5,000 parts per million.
(15) Cumene, 70 parts per million.
(16) Cyclohexane, 3,880 parts per million.
(17) Dichloromethane, 600 parts per million.
(18) 2,2-dimethylbutane, 290 parts per million.
(19) 2,3-dimethylbutane, 290 parts per million.
(20) 1,2-dimethylbenzene, 2,170 parts per million.
(21) 1,3-dimethylbenzene, 2,170 parts per million.
(22) 1,4-dimethylbenzene, 2,170 parts per million.
(23) Dimethyl sulfoxide, 5,000 parts per million.
(24) Ethanol, 5,000 parts per million.
(25) Ethyl acetate, 5,000 parts per million.
(26) Ethylbenzene, 2,170 parts per million.
(27) Ethyl ether, 5,000 parts per million.
(28) Ethylene glycol, 620 parts per million.
(29) Ethylene oxide, 50 parts per million.
(30) Heptane, 5,000 parts per million.
(31) n-Hexane, 290 parts per million.
(32) Isopropyl acetate, 5,000 parts per million.
(33) Methanol, 3,000 parts per million.
(34) Methylpropane, 5,000 parts per million.
(35) 2-Methylpentane, 290 parts per million.
(36) 3-Methylpentane, 290 parts per million.
(37) N,N-dimethylacetamide, 1,090 parts per million.
(38) Pentane, 5,000 parts per million.
(39) Propane, 5,000 parts per million.
(40) Pyridine, 200 parts per million.
(41) Sulfolane, 160 parts per million.
(42) Tetrahydrofuran, 720 parts per million.
(43) Toluene, 890 parts per million.
(44) Xylenes, Total (ortho-, meta-, para-), 2,170 parts per million.
c. Metals limits.

~~(1) Cadmium, 0.3 parts per million.~~
~~(2) Lead, 1.0 part per million.~~
~~(3) Arsenic, 1.5 parts per million.~~
~~(4) Mercury, 0.5 parts per million.~~
~~*d.* Microbiological impurities limits.~~
~~(1) Shiga toxin-producing *Escherichia coli* (STEC), none present or no detection.~~
~~(2) Total aerobic microbial count, 1x10$_3$ CFU/g (max acceptable count: 2,000).~~
~~(3) Salmonella, none present or no detection.~~
~~(4) Total combined yeast mold count, 1x10$_2$ CFU/g (max acceptable count: 200).~~
~~*e.* Mycotoxin limits.~~
~~(1) Total aflatoxin (B1, B2, G1, G2), 20 parts per billion.~~
~~(2) Ochratoxin, 20 parts per billion.~~

156.3(3) *Examination of records.* All documentation ~~required~~ mandated by this rule shall be maintained by the consumable hemp establishment and provided to the department or other regulatory authority immediately upon request.

156.3(4) *Independent accredited laboratory.*

a. A consumable hemp establishment ~~shall~~ cannot utilize an accredited laboratory in which it has an ownership interest, unless the consumable hemp establishment holds less than a 10 percent ownership interest in the accredited laboratory if the accredited laboratory is a publicly traded company.

~~*a*~~*b.* ~~HHS~~ The department may determine that any testing laboratory that does not operate formal management systems under the International Organization for Standardization is not an accredited laboratory and may require that a representative sample of a batch of the product be retested by a testing laboratory that meets this requirement.

~~[**ARC 5404C**, IAB 1/27/21, effective 3/3/21; **ARC 5671C**, IAB 6/2/21, effective 7/7/21; Editorial change: IAC Supplement 6/14/23]~~

641—156.4(204) Packaging and labeling ~~requirements~~.

156.4(1) *Contents.* Each consumable hemp product intended for individual retail sale ~~shall be~~ is labeled such that a reasonable consumer would plainly identify the product as a consumable hemp product and ~~shall~~ contains the following information:

a. Lot number for the batch;
b. Expiration date;
c. Brand ~~Name~~name;
~~*c*~~*d.* Product name;
e. List of ingredients;
~~*d*~~*f.* Name, telephone number, and email address of the product manufacturer;

(1). If the registered manufacturer uses a contracted third party or white label manufacturer, the name of that entity must also be included on the container or label and is not proprietary or confidential under Iowa Code section Chapter 22.7.

~~*e*~~*g.* If specific cannabinoids are contained within or marketed for the product, the number of milligrams of each cannabinoid per serving and serving size;

~~*f*~~*h.* A certificate of analysis that the batch contained a total delta-9 tetrahydrocannabinol concentration that did not exceed 0.3 percent on a dry weight basis as calculated pursuant to an official test as provided in Iowa Code section 204.8.

i. ~~*k.*~~ A declaration of the net quantity of contents, indicating the numbers of servings and total THC per serving and per container in compliance with Iowa Code section 204.2.

~~*i*~~*j.* A warning label with the following information. This warning label may be divided into multiple sections on a label, provided all information is present on the container:

~~(1)~~ "This product has not been analyzed or approved by the United States Food and Drug Administration. There is limited information on the side effects of using this product, and there may be associated health risks and medication interactions. This product may cause the consumer to fail a drug

test for THC. Products containing THC may cause impairment and a consumer's ability to operate a vehicle. This product is not recommended for use by pregnant or breastfeeding women. KEEP THIS PRODUCT OUT OF REACH OF CHILDREN."

~~j.~~ The labeling must not contain any claim that the product may be used or is effective for the prevention, treatment, or cure of a disease or that it may be used to alter the structure or function of human or animal bodies, unless the claim has been approved by the ~~FDA~~federal Food and Drug Administration.

156.4(2) *Form.* The labeling ~~requirements of~~ mandated in paragraphs 156.4(1)*"~~d~~ f"* and *"~~f~~ h"* may be in the form of:

a. A uniform resource locator (URL) for the manufacturer's Internet website that provides or links to the information ~~required~~ mandated by this section; or

b. A QR code or other bar code that may be scanned and that leads to the information required on the label.

~~**156.4(3)** *Limitations on Serving and Container Size*. The following limitations regarding serving and container size shall be applied to packaging and labeling for specified product forms:~~

~~a. A closed container beverage shall be defined as one serving per container, regardless of its ability to be re-sealed or the fluid ounces it contains.~~

~~b. A sugar or gelatin based edible gummy product shall be defined as one serving per gummy~~

~~[**ARC 5404C**, IAB 1/27/21, effective 3/3/21; Editorial change: IAC Supplement 6/14/23]~~

641—156.5(204) Applicability of other laws and regulations.

156.5(1) A consumable hemp establishment shall comply with all relevant Iowa laws and regulations applicable to the manufacturing, processing, storage, distribution, and sale of food, including but not limited to Iowa Code chapter 137F ~~(food establishments and food processing plants)~~, Iowa Code chapter 137D ~~(home bakeries)~~, and regulations promulgated under those chapters.

156.5(2) An individual or entity subject to Iowa Code chapter 123 shall not introduce any consumable hemp product into the alcoholic beverage product for which the individual or entity is subject to Iowa Code chapter 123, unless the consumable hemp product is generally recognized as safe by the ~~Federal~~ federal Food and Drug Administration and is thus not deemed adulterated ~~pursuant to the Federal Food, Drug, and Cosmetic Act, Section 402~~. A consumable hemp retailer may introduce any consumable hemp product into alcoholic beverage products sold to consumers on a retail basis in intrastate commerce.

156.5(3) An individual or entity subject to Iowa Code chapter 189A shall not introduce any consumable hemp product into the meat or poultry product for which the individual or entity is subject to Iowa Code chapter 189A~~,~~ unless the consumable hemp product is generally recognized as safe by the ~~Federal~~ federal Food and Drug Administration and is thus not deemed adulterated ~~pursuant to the Federal Food, Drug, and Cosmetic Act, Section 402~~. A consumable hemp retailer may introduce any consumable hemp product into meat or poultry sold to consumers on a retail basis in intrastate commerce.

156.5(4) An individual or entity subject to Iowa Code chapters 190 ~~to~~ through 192 shall not introduce any consumable hemp product into the dairy product for which the individual or entity is subject to Iowa Code chapters 190 ~~to~~through 192, unless the consumable hemp product is generally recognized as safe by the ~~Federal~~ federal Food and Drug Administration and is thus not deemed adulterated ~~pursuant to the Federal Food, Drug, and Cosmetic Act, Section 402~~. A consumable hemp retailer may introduce any consumable hemp products into dairy products sold to consumers on a retail basis in intrastate commerce.

156.5(5) Consumable hemp products in interstate commerce are subject to federal law. Compliance with Iowa Code chapter 204 and this chapter does not represent compliance with federal law.

~~[**ARC 5404C**, IAB 1/27/21, effective 3/3/21; Editorial change: IAC Supplement 6/14/23]~~

641—156.6(204) Prohibitions.

156.6(1) A consumable hemp establishment ~~shall~~cannot manufacture, process, pack, hold, prepare, distribute, or sell consumable hemp products:

a. On the premises of a private residence, except a portion of a private residence that is distinctly separate from any living space, that is dedicated to the production or sale of food, and that meets all applicable state and local regulations;

b. On the premises of a temporary location, including but not limited to a food stand, roadside stand, temporary booth, or any other temporary structure;

c. Door to door;

d. Through vending machines; or

e. At private parties.

156.6(2) A consumable hemp product may be sold at a stand at a farmers market, provided:

a. The farmers market is listed on the Iowa department of agriculture and land stewardship's farmers market directory;

b. The individual selling the consumable hemp maintains a valid consumable hemp retailer registration at any location where consumable hemp is stored;

c. The consumable hemp establishment registration is posted in plain sight at the farmers market stand; and

d. All consumable hemp products sold are listed and maintained up to date with the department.

156.6(3) A consumable hemp product label and any associated marketing materials shall not contain any claims that the consumable hemp product can be used in the diagnosis, cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body.

156.6(4) A consumable hemp retailer ~~shall~~ cannot manufacture, process, package, repackage, relabel, mix, blend, or otherwise manipulate a consumable hemp product. This subrule does not apply to a food service establishment that utilizes a consumable hemp product from an approved hemp source as a food ingredient intended for immediate consumption by the consumer, provided that the food service establishment discloses all label information ~~required~~ mandated by rule 641—156.4(204) ~~(packaging and labeling requirements)~~ to the consumer through the menu, ~~a~~ menu board, placard, table tent, or other effective means.

156.6(5) A consumable hemp product that does not conform to this chapter ~~shall be~~ is considered adulterated or misbranded and ~~shall~~ cannot enter commerce.

~~[**ARC 5404C**, IAB 1/27/21, effective 3/3/21; Editorial change: IAC Supplement 6/14/23]~~

156.6(6) A consumable hemp retailer or manufacturer shall not sell or distribute consumable hemp products to person under 21 years of age, subject to verification.~~*a.*~~ Proof of age may be established by a valid driver's license, identification card issued by Iowa or another state, or other form of government issued identification, and must include the photograph and date of birth of the person.

641—156.7(204) Violations and enforcement.

156.7(1) Any consumable hemp product introduced into commerce by an individual or entity without a consumable hemp registration approved by the department in accordance with rule 641—156.2(204) ~~(registration and posting)~~ is subject to immediate embargo.

156.7(2) A consumable hemp product that is adulterated or misbranded when introduced into commerce is subject to immediate embargo.

156.7(3) A consumable hemp product that the department reasonably believes may be injurious to public health or that has entered commerce and is not in conformance with this chapter is subject to immediate embargo.

156.7(4) The embargo of a consumable hemp product ~~shall be~~ is effective until such a time as the violation is remedied or the product is disposed of in a reasonable manner as determined by the department. If the violation cannot be remedied and disposal is ~~required~~ necessary, the cost of disposal is the responsibility of the consumable hemp establishment. Disposal shall be observed by a person approved by the department. The embargo of a consumable hemp product may be appealed in accordance with rule 641—156.8(204) ~~(denial, suspension, or revocation of registration)~~.

156.7(5) A consumable hemp manufacturer ~~shall~~ will conduct a recall of a consumable hemp product lot that has been tested and found to be adulterated. The cost of a recall or disposal of the product is the responsibility of the consumable hemp manufacturer.

~~[**ARC 5404C**, IAB 1/27/21, effective 3/3/21; Editorial change: IAC Supplement 6/14/23]~~

641—156.8(204) Denial, suspension, or revocation of registration. The department may deny, suspend, or revoke a registration in any case where the department finds ~~that~~ there has been repeated failure on the part of the consumable hemp establishment to comply with the provisions of this chapter, or for any of the following reasons:

156.8(1) Failure to register. An individual or entity that introduces a consumable hemp product into commerce without a consumable hemp registration approved by the department in accordance with rule 641—156.2(204) ~~(registration and posting)~~ may be denied a consumable hemp registration for a period of up to 30 days for a first violation~~;~~, up to one year for a second violation~~;~~, and up to five years for a third or any subsequent violation.

156.8(2) Nonconforming consumable hemp product. A registered consumable hemp establishment that introduces a consumable hemp product into commerce that is not in conformance with Iowa Code chapter 204 or this chapter is subject to the immediate revocation of its registration.

156.8(3) Qualifying criminal offense.

a. The conviction of any individual with an ownership interest in a consumable hemp establishment constituting a felony, serious misdemeanor, or aggravated misdemeanor and resulting from an activity constituting a criminal offense in the consumable hemp establishment may result in the denial, suspension, or revocation of the registration.

b. A conviction for committing a criminal offense involving a controlled substance as described in Iowa Code section 204.7 may result in the denial, suspension, or revocation of the registration.

c. A certified copy of the final order or judgment of conviction or plea of guilty shall be conclusive evidence of the conviction of the registration holder.

d. A deferred judgment, until discharged, ~~shall be~~ is considered a conviction for purposes of this rule.

156.8(4) False or misleading information. Providing false or misleading information to the department under this chapter, including by submitting a false registration, may result in the denial, suspension, or revocation of the registration.

156.8(5) Failure to comply. Failing to comply with an order issued by the department under this chapter may result in the denial, suspension, or revocation of the registration.

156.8(6) Successive violations. A third violation of any provision of this chapter in a five-year period ~~shall~~ results in the denial, suspension, or revocation of the registration. The department ~~shall~~ will disapprove any registration of a consumable hemp establishment for a five-year period following the date of the last violation.

156.8(7) Materially false information supplied. An individual or entity who materially falsifies any information contained in a consumable hemp registration ~~shall be~~ is ineligible for registration.

~~[**ARC 5404C**, IAB 1/27/21, effective 3/3/21; Editorial change: IAC Supplement 6/14/23]~~

641—156.9(204) Inspection and access to records. The department may enter a consumable hemp establishment at any reasonable hour to assess compliance with Iowa Code chapter 204 and these rules. The manager or person in charge of the consumable hemp establishment ~~shall~~ will afford free access to every part of the premises, including access to records related to consumable hemp products, and ~~shall~~ render all aid and assistance necessary to enable the regulatory authority to make a thorough and complete assessment.

~~[**ARC 5404C**, IAB 1/27/21, effective 3/3/21; Editorial change: IAC Supplement 6/14/23]~~

641—156.10(204) Public examination of records.

156.10(1) *Public information.* Generally, information collected by the department and contractors is considered public information. Records are stored in computer files and are not matched with any

other data system. Information is available for public review and will be provided when requested from the ~~office of the director~~ department.

156.10(2) *Confidential information.*

a. The following are examples of confidential records:

(1) Trade secrets and proprietary information including items such as formulations, processes, policies and procedures, and customer lists;

(2) Health information related to foodborne illness complaints and outbreaks;

(3) The name or any identifying information of a person who files a complaint with the department; and

(4) Other state or federal agencies' records.

b. A party claiming that information submitted to the department contains trade secrets or proprietary information should clearly mark those portions of the submission as confidential/trade secret.

~~**156.10(3)** *Other agencies' records.* For records of other state or federal agencies, the department shall~~ will ~~refer the requester of such information to the appropriate agency.~~

~~[**ARC 5404C**, IAB 1/27/21, effective 3/3/21; Editorial change: IAC Supplement 6/14/23]~~

641—156.11(204) Appeals. All decisions of the department may be contested by an adversely affected party in accordance with~~. A request for a hearing must be made in writing to the Department of Health and Human Services, Lucas State Office Building, Des Moines, Iowa 50319, within 30 days of the mailing or service of a decision. Appeals and hearings are controlled by~~ 441—Chapter 7.

~~[**ARC 5404C**, IAB 1/27/21, effective 3/3/21; Editorial change: IAC Supplement 6/14/23]~~

These rules are intended to implement Iowa Code section 124.506 and Iowa Code chapter 204 as amended by 2024 Iowa Acts, House File 2506. ~~2020 Iowa Acts, House File 2581.~~

~~[Filed ARC 5404C (Notice ARC 5265C, IAB 11/4/20), IAB 1/27/21, effective 3/3/21]~~

~~[Filed ARC 5671C (Notice ARC 5552C, IAB 4/7/21), IAB 6/2/21, effective 7/7/21]~~

~~[Editorial change: IAC Supplement 6/14/23]~~