ARC

INSPECTIONS AND APPEALS DEPARTMENT[481]

Adopted and Filed

The Inspections and Appeals Department hereby adopts Chapter 32, "Consumable Hemp Products," Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is adopted under the authority provided in 2020 Iowa Acts, House File 2581.

State or Federal Law Implemented

This rule making implements, in whole or in part, 2020 Iowa Acts, House File 2581.

Purpose and Summary

The adoption of Chapter 32 implements 2020 Iowa Acts, House File 2581. The legislation defines "consumable hemp product" and provides for the manufacture, sale, and consumption of consumable hemp products. The legislation requires the Department to establish by rule packaging and labeling requirements for consumable hemp products. It also requires the Department to establish registration requirements for manufacturers and sellers of consumable hemp products, including standards for the revocation of registration.

Public Comment and Changes to Rule Making

Notice of Intended Action for this rule making was published in the Iowa Administrative Bulletin on November 4, 2020, as ARC 5265C.

The Department received public comments from seven individuals or entities, and spoke

with a number of individuals and entities regarding the proposed rules to answer questions. The Department received two public comments requesting the Department reconsider the prohibition against the sale of consumable hemp products at farmers markets; one public comment requesting elimination of the requirement for a certificate of free sale[1];one public comment relaying concerns regarding batch testing requirements; two public comments requesting the Department reconsider the prohibition against sales in private residences; one public comment requesting the Department reconsider the prohibition against sales through vending machines or at private parties; one public comment requesting the Department strike the requirement for a telephone number or email address for the manufacturer; and one public comment requesting the Department eliminate the consumable hemp retailer registration[2].

The Department made the following revisions to the rules from the Notice:

- Rule 32.1, Definitions: The definition of "accredited laboratory" was revised to clarify that the accreditation shall be for the analyses performed on consumable hemp products; the definition of "'Cannabidiol' or 'CBD'" was revised to reference its specific chemical compound number; the definition of "'Certificate of analysis' or 'COA'" was revised to clarify that it shall state whether a sample passed or failed any limits related to these analysis; a definition for "Delta-9 tetrahydrocannabinol (THC)" was added and references its specific chemical compound number; a definition of "Tetrahydrocannabinolic acid (THCA)" was adopted and references its specific chemical compound number; a definition of "Total delta-9 tetrahydrocannabinol (total THC)" was adopted.
- Rule 32.2, Registration and posting: This rule was revised to provide that a registered consumable hemp manufacturer that exclusively sells consumable

[1] Note that a certificate of free sale is not required.
[2] Note that consumable hemp retailer registration is required by 2020 Iowa Acts, House File 2581.

hemp products they have manufactured to consumers on a retail basis is not required to register as a consumable hemp retailer.

- Rule 32.3 Testing requirements and documentation:
    - 32.3(1)“b”“2”: The certificate of analysis requirements were revised to clarify that the presence and concentration of cannabinoids includes delta-9 tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol, and any other cannabinoids for which the product is being marketed;
    - 32.3(2): Toxicant limits were revised for consistency with testing required by other jurisdictions, particularly Oregon, and Iowa Medical Cannabidiol. Specific limits were modified as follows:
        - Abamectin, deleted;
        - Acephate, deleted;
        - Acequinocyl, deleted;
        - Acetamiprid, revised from 3,000 parts per billion to .2 parts per million;
        - Aldicarb, revised from 100 parts per billion to .4 parts per million;
        - Azoxystrobin, revised from 3,000 parts per billion to .2 parts per million;
        - Bifenazate, revised from 3,000 parts per billion to .2 parts per million;
        - Bifenthrin, deleted;
        - Boscalid, revised from 3,000 parts per billion to .4 parts per million;
        - Captan, deleted;

- Carbaryl, revised from 500 parts per billion to .5 parts per million;
- Carbofuran, revised from 100 parts per billion to .2 parts per million;
- Chlorantraniliprole, revised from 3,000 parts per billion to .2 parts per million;
- Chlordane, deleted;
- Chlorfenapyr, deleted;
- Chlormequat chloride, deleted;
- Chlorpyrifos, revised from 100 parts per billion to .6 parts per million;
- Clofentezine, deleted;
- Coumaphos, deleted;
- Cyfluthrin, deleted;
- Cypermethrin, revised from 1,000 parts per billion to 18 parts per million;
- Daminozide, deleted;
- DDVP (Dichlorvos), revised from 100 parts per billion to .1 parts per million;
- Diazinon, revised from 200 parts per billion to 2.6 parts per million;
- Dimethoate, deleted;
- Dimethomorph, deleted;
- Ethoprop(hos), 100 parts per billion revised to Ethoprophos, .4 parts per billion;

- Etofenprox, revised from 100 parts per billion to .4 parts per million;
- Etoxazole, deleted;
- Fenhexamid, deleted;
- Fenoxycarb, deleted;
- Fenpyroximate, deleted;
- Fipronil, revised from 100 parts per billion to 1 part per million;
- Flonicamid, revised from 2,000 parts per billion to 1 part per million;
- Fludioxonil, deleted;
- Hexythiazox, deleted;
- Imazalil, deleted;
- Imidacloprid, revised from 3,000 parts per billion to .4 parts per million;
- Kresoxim-methyl, deleted;
- Malathion, deleted;
- Metalaxyl, revised from 3,000 parts per billion to .2 parts per million;
- Methiocarb, revised from 100 parts per billion to .4 parts per million;
- Methomyl, revised from 100 parts per billion to .4 parts per million;
- Methyl parathion, revised from 100 parts per billion to 8.5 parts per million;
- Mevinphos, deleted;

- Myclobutanil, revised from 3,000 parts per billion to .3 parts per million;
- Naled, deleted;
- Oxamyl, revised from 500 parts per billion to 1 parts per million;
- Paclobutrazol, deleted;
- Pentachloronitrobenzene, deleted;
- Permethrin, revised from 1,000 parts per billion to 1.1 parts per million;
- Phosmet, deleted;
- Piperonyl butoxide, deleted;
- Prallethrin, deleted;
- Propiconazole, deleted;
- Propoxur, deleted;
- Pyrethrins, deleted;
- Pyridathben, 3,000 parts per billion revised to Pyridaben, .2 parts per million;
- Spinetoram, deleted;
- Spinosad A and D, deleted;
- Spiromesifen, deleted;
- Spirotetramat, deleted;
- Spiroxamine, revised 100 parts per billion to 2 parts per million;
- Tebuconazole, revised 1,000 parts per billion to .2 parts per million;
- Thiacloprid, revised 100 parts per billion to .2 parts per million;
- Thiamethoxam, revised 1,000 parts per billion to .2 parts per

million;

- Trifloxystrobin, deleted;
- 1,2-Dichloroethene, deleted;
- 1,1-Dichloroethene, deleted;
- Added 1,2-Dimethoxethane, 100 parts per billion;
- Added 1,4-Dioxane, 380 parts per billion;
- Added 1-Butanol, 5000 parts per billion;
- Added 1-Pentanol, 5000 parts per billion;
- Added 1-Propanol, 5000 parts per billion;
- Added 2-Butanol, 5000 parts per billion;
- Added 2-Butanone, 5000 parts per billion;
- Added 2-Ethoxyethanol, 5000 parts per billion;
- Added 2-methylbutane, 5000 parts per billion;
- Added 2-Propanol (IPA), 5000 parts per billion;
- Acetonitrile, revised 410 parts per million to parts per billion;
- Benzene, 2 parts per million to parts per billion;
- Butane, revised 2,000 parts per million to 5000 parts per billion;
- Chloroform, deleted;
- Added Cumene, 70 parts per billion;
- Added Cyclohexane, 3880 parts per billion;
- Added Dichloromethane, 600 parts per billion;
- Added 2,2-dimethylbutane, 290 parts per billion;
- Added 2,3-dimethylbutane, 290 parts per billion;
- Added 1,2-dimethylbenzene, 2170 parts per billion;
- Added 1,3-dimethylbenzene, 2170 parts per billion;

- Added 1,4-dimethylbenzene, 2170 parts per billion;
- Added Dimethyl sulfoxide, 5000 parts per billion;
- Ethanol, revised 5,000 parts per million to parts per billion;
- Ethyl Acetate, revised 5,000 parts per million to parts per billion;
- Ethyl Ether, 5,000 parts per million to parts per billion;
- Ethylene Oxide, revised 5 parts per million to 50 parts per billion;
- Heptane, revised 5,000 parts per million to parts per billion;
- Revised Hexane, 290 parts per million to n-Hexane, 290 parts per billion;
- Revised Isopropyl alcohol, 500 parts per million to Isopropyl acetate, 5000 parts per billion;
- Methanol, revised 3,000 parts per million to parts per billion;
- Methylene Chloride, deleted;
- Added Methylpropane, 5000 parts per billion;
- Added 2-Methylpentane, 290 parts per billion;
- Added 3-Methylpentane, 290 parts per billion;
- Added N,N-dimethylacetamide, 1090 parts per billion;
- Pentane, revised 5,000 parts per million to parts per billion;
- Propane, revised 2,100 parts per million to parts per billion;
- Added Pyridine, 200 parts per billion;
- Added Sulfolane, 160 parts per billion;
- Added Tetrahydrofuran, 720 parts per billion;
- Toluene, revised 890 parts per million to parts per billion;
- Trichloroethylene (1,1,2-Trichloroethene), deleted;

- Xylenes, Total (ortho-, meta-, para-), revised 2170 parts per million to parts per billion;
- Cadmium, revised 0.5 micrograms/gram to 0.3 parts per million;
- Lead, revised 0.5 micrograms/gram to 1.0 parts per million;
- Arsenic, revised 1.5 micrograms/gram to parts per million;
- Mercury, revised 3.0 micrograms/gram to .5 parts per million;
- "Pathogen limits" revised for clarification to "microbiological impurities limits;"
- "Other pathogenic E. coli" was removed from the shiga toxin-producing *Escherichia coli* (STEC) limit, and the limit was revised to include "no detection" in addition to "none present;"
- Listeria monocytogenes limit was deleted;
- A limit for "total aerobic microbial count" was added;
- Salmonella limit was revised to include "no detection" in addition to "none present;"
- A "total combined yeast mold count" was added.

- Rule 32.5, Applicability of other laws and regulations: Subrules 32.5(2), (3), and (4) were revised to make clear that a consumable hemp retailer may introduce any consumable hemp product into alcoholic beverage products, meat or poultry, or dairy products sold to consumers on a retail basis in intrastate commerce.
- Rule 32.6, Prohibitions: Subrule 32.6(1)(b) was revised to remove "farmers market food stand" from the list of prohibited temporary locations; subrule 32.6(2) was revised to set forth conditions under which consumable hemp products may be sold at farmers market food stands; and subrules 32.6(2)–(4)

were renumbered to 32.6(3)–(5).

- Rule 32.8, Denial, suspension, or revocation of registration: Subrule 32.8(3)"d" was revised to add "until discharged."

Adoption of Rule Making

This rule making was adopted by the Department on January 6, 2021.

Fiscal Impact

After analysis and review of this rule making, the Department anticipates the following fiscal impact to the State of Iowa:

	Year 1 Costs	Year 2 Costs
Electronic Registration System Implementation Cost	$45,000	—
Annual System Support and Maintenance Costs	—	$15,000
0.5 Clerk FTE Position	$30,000	$30,000
1.0 Environmental Specialist Senior Position	$72,000	$72,000
Miscellaneous Costs	$15,000	$5,000
Total Bureau Costs	$162,000	$122,000

Jobs Impact

After analysis and review of this rule making, there may be a positive impact on jobs. This rule making, in conjunction with the authorizing legislation (2020 Iowa Acts, House File 2581), legalizes the manufacture and sale of consumable hemp in the state of Iowa. Growers, manufacturers, and retail stores now have the ability to grow, manufacture, and sell consumable hemp products in Iowa. After initial conversations with industry, the Department anticipates approximately 125 grocery stores, 118 convenience stores, 50 smoke/vape/tobacco stores, 60 hemp/CBD stores, and 50 restaurants may register to sell

consumable products and approximately 20 manufacturers may register to manufacture consumable hemp products. House File 2581 authorizes the Department to charge for the cost of processing the registration. The cost for processing the registration will only impact entities wanting to sell or manufacture consumable hemp products in Iowa.

Waivers

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to 481—Chapter 6.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee's meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

Effective Date

This rule making will become effective on March 3, 2021.

The following rule-making action is adopted:

Adopt the following **new** 481—Chapter 32:

CHAPTER 32

CONSUMABLE HEMP PRODUCTS

481—32.1(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 incorporated verbatim herein.

"Accredited laboratory" means a laboratory accredited in accordance with the International Organization for Standardization/International Electrotechnical Commission Standard (ISO/IEC) 17025 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, 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 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.

"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 contain the concentrations of cannabinoids, pesticides, residual solvents, metals, harmful pathogens, and toxicants, 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 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.

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

"Department" means the Iowa department of inspections and appeals.

"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. 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 contain 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.

"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.

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

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

481—32.2(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.

32.2(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 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.

32.2(2) *Consumable hemp retailers.* Consumable hemp retailers shall register with the department at least 30 days prior to selling any consumable hemp product in Iowa or to purchasers located in Iowa. The consumable hemp retailer 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 retailer intends to sell, along with documentation of the jurisdiction of origin for each consumable hemp product.

32.2(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 for each activity. A registered consumable hemp manufacturer that exclusively sells consumable hemp products they have manufactured to consumers on a retail basis is not required to register as a consumable hemp retailer.

32.2(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 each physical location.

32.2(5) *Expiration and renewal.* A consumable hemp registration, unless sooner suspended or revoked, shall expire one year after the registration is approved by the department. A consumable hemp registration shall be renewed annually through the department's online registration system, accompanied by the required fee, at least 30 days prior to expiration. Consumable hemp registrations that are expired more than 60 days will be revoked without notice.

32.2(6) *Transferability.* A consumable hemp registration is not transferable to a new owner or new physical location.

32.2(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.

32.2(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 481—32.7(204) and 481—32.8(204) (violations and enforcement; denial, suspension, or revocation of registration).

481—32.3(204) Testing requirements and documentation.

32.3(1) *Approved hemp source; certificate of analysis.* A consumable hemp product shall not 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. Container size in terms of net quantity of contents; and

3. Lot number.

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;

(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 pesticides, residual solvents, metals, harmful pathogens, and toxicants and does not exceed limits established in this rule.

32.3(2) *Toxicant limits.* If a testing sample is found to contain levels of any pesticide,

residual solvent, metal, harmful pathogen, or toxicant that exceeds limits enumerated in this rule or by Iowa law, the product shall be considered adulterated and shall not 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 parts per million.

(16) Flonicamid, 1 parts 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 parts 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-Dimethoxethane, 100 parts per billion.

(2) 1,4-Dioxane, 380 parts per billion.

(3) 1-Butanol, 5000 parts per billion

(4) 1-Pentanol, 5000 parts per billion

(5) 1-Propanol, 5000 parts per billion

(6) 2-Butanol, 5000 parts per billion

(7) 2-Butanone, 5000 parts per billion

(8) 2-Ethoxyethanol, 5000 parts per billion

(9) 2-methylbutane, 5000 parts per billion

(10) 2-Propanol (IPA), 5000 parts per billion

(11) Acetone, 5000 parts per billion.

(12) Acetonitrile, 410 parts per billion.

(13) Benzene, 2 parts per billion.

(14) Butane, 5000 parts per billion.

(15) Cumene, 70 parts per billion.

(16) Cyclohexane, 3880 parts per billion.

(17) Dichloromethane, 600 parts per billion.

(18) 2,2-dimethylbutane, 290 parts per billion.

(19) 2,3-dimethylbutane, 290 parts per billion.

(20) 1,2-dimethylbenzene, 2170 parts per billion.

(21) 1,3-dimethylbenzene, 2170 parts per billion.

(22) 1,4-dimethylbenzene, 2170 parts per billion.

(23) Dimethyl sulfoxide, 5000 parts per billion.

(24) Ethanol, 5000 parts per billion.

(25) Ethyl Acetate, 5000 parts per billion.

(26) Ethylbenzene, 2170 parts per billion.

(27) Ethyl Ether, 5000 parts per billion.

(28) Ethelyne glycol, 620 parts per billion.

(29) Ethylene Oxide, 50 parts per billion.

(30) Heptane, 5000 parts per billion.

(31) n-Hexane, 290 parts per billion.

(32) Isopropyl acetate, 5000 parts per billion.

(33) Methanol, 3000 parts per billion.

(34) Methylpropane, 5000 parts per billion.

(35) 2-Methylpentane, 290 parts per billion.

(36) 3-Methylpentane, 290 parts per billion.

(37) N,N-dimethylacetamide, 1090 parts per billion.

(38) Pentane, 5000 parts per billion.

(39) Propane, 5000 parts per billion.

(40) Pyridine, 200 parts per billion.

(41) Sulfolane, 160 parts per billion.

(42) Tetrahydrofuran, 720 parts per billion.

(43) Toluene, 890 parts per billion.

(44) Xylenes, Total (ortho-, meta-, para-), 2170 parts per billion.

c. Metals limits.

(1) Cadmium, 0.3 parts per million.

(2) Lead, 1.0 parts 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, 1 $x10^3$ CFU/g (max acceptable count: 2000)

(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.

32.3(3) *Examination of records.* All documentation required by this rule shall be maintained by the consumable hemp establishment and provided to the department or other regulatory authority immediately upon request.

32.3(4) *Independent accredited laboratory.* A consumable hemp establishment shall not 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.

481—32.4(204) Packaging and labeling requirements.

32.4(1) *Contents.* Each consumable hemp product intended for individual retail sale shall be labeled such that a reasonable consumer would plainly identify the product as a consumable hemp product and shall contain the following information:

a. Lot number;

b. Expiration date;

c. Product name;

d. Name, telephone number, and email address of the product manufacturer;

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

f. 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.

32.4(2) *Form.* The labeling requirements of paragraphs 32.4(1)*"d"* and *"f"* 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 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.

481—32.5(204) Applicability of other laws and regulations.

32.5(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.

32.5(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 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.

32.5(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 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.

32.5(4) An individual or entity subject to Iowa Code chapters 190 to 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 192, unless the consumable hemp product is generally recognized as safe by the 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.

32.5(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.

481—32.6(204) Prohibitions.

32.6(1) A consumable hemp establishment shall not 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.

32.6(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.

32.6(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.

32.6(4) A consumable hemp retailer shall not 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 by rule 481—32.4(204) (packaging and labeling requirements) to the consumer through the menu, a menu board, placard, table tent, or other effective means.

32.6(5) A consumable hemp product that does not conform to this chapter shall be considered adulterated or misbranded and shall not enter commerce.

481—32.7(204) Violations and enforcement.

32.7(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 481—32.2(204) (registration and posting) is subject to immediate embargo.

32.7(2) A consumable hemp product that is adulterated or misbranded when introduced into commerce is subject to immediate embargo.

32.7(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.

32.7(4) The embargo of a consumable hemp product shall be 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, 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 481—32.8(204) (denial, suspension, or revocation of registration).

32.7(5) A consumable hemp manufacturer shall 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.

481—32.8(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:

32.8(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 481—32.2(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.

32.8(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.

32.8(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 considered a conviction for purposes of this rule.

32.8(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.

32.8(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.

32.8(6) Successive violations. A third violation of any provision of this chapter in a five-year period shall result in the denial, suspension, or revocation of the registration. The department shall disapprove any registration of a consumable hemp establishment for a five-year period following the date of the last violation.

32.8(7) Materially false information supplied. An individual or entity who materially falsifies any information contained in a consumable hemp registration shall be ineligible for registration.

481—32.9(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 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.

481—32.10(204) Public examination of records.

32.10(1) *Public information.* Generally, information collected by the food and consumer safety bureau 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.

32.10(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.

32.10(3) *Other agencies' records.* For records of other state or federal agencies, the department shall refer the requester of such information to the appropriate agency.

481—32.11(204) Appeals. All decisions of the food and consumer safety bureau may be contested by an adversely affected party. A request for a hearing must be made in writing to the Department of Inspections and Appeals, 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 481—Chapter 9, "Contested Cases."

These rules are intended to implement 2020 Iowa Acts, House File 2581.