

Consumable Hemp

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Iowa Department of
INSPECTIONS & APPEALS

HF2581

- ▶ Defined Consumable Hemp Product
- ▶ Created requirements for the sale and manufacture of Consumable Hemp Products in Iowa
- ▶ Required DIA to develop rules governing packaging and labeling
- ▶ Required DIA to develop rules governing facility registration and revocation of registration

Drafting Administrative Rules

- ▶ Multi-agency approach (IDALS, IDPH, ABD, DIA, DPS, SHL)
- ▶ Engaged the AG's Office
- ▶ Engaged National Organizations (Association of Food and Drug Officials)
- ▶ Engaged other states

Consumable Hemp (IAC 481-32)

“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

“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 Retailer

“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.

Consumable Hemp Manufacturer

“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.

What is processing?

“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

Raw Hemp

“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.

Consumable Hemp Registration

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.

Online Registration

Fee: \$475

Annual registration required

Combined Manufacturing and Retail Operations

- ▶ *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.

Packaging and Labeling

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.

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.

Testing (Certificate of Analysis)

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;
- (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.

Product Documentation

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
4. Certificate of Analysis

“**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.

Other Laws and Regulations

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.

Other Laws and Regulations (continued)

- Iowa Code chapter 123 (Alcoholic Beverages)
- Iowa Code chapter 189A (Meat and Poultry)
- Iowa Code chapter 190 to 192 (Dairy)
- 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.

Prohibitions

A consumable hemp establishment shall not manufacture, process, pack, hold, prepare, distribute, or sell consumable hemp products:

- 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;
- On the premises of a temporary location, including but not limited to a food stand, roadside stand, temporary booth, or any other temporary structure;
- Door to door;
- Through vending machines; or
- At private parties.

Farmers Markets

- ▶ **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.

Prohibitions (continued)

A consumable hemp establishment shall not manufacture, process, pack, hold, prepare, distribute, or sell consumable hemp products:

- 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
- 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

Next Steps

- Iowa Administrative Code 481-32 is published and open to public comment until November 24th
- DIA will review public comments and make revisions as necessary
- Anticipated effective date is March 3, 2021
- We expect the online registration system to be available on the effective date

QUESTIONS

