

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 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*” 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. 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*” 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]