

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

“Accredited laboratory” means a laboratory accredited in accordance with the International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) Standard 17025:2017 (July 17, 2024) by an International Laboratory Accreditation Cooperation (ILAC)-recognized accreditation body for the analyses performed on consumable hemp products.

“Adulterated” means the same as in 21 U.S.C. Section 342(a)(4) (as amended to July 17, 2024), 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 (GRAS) 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 (as amended to July 17, 2024).

“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 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 contains all of the concentrations of cannabinoids, pesticides, residual solvents, metals, harmful pathogens, toxicants, and synthetic or semisynthetic cannabinoids, including data on levels of total delta-9 tetrahydrocannabinol 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 GRAS under the conditions of use by the 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 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 that 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.

“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 to July 17, 2024).

“*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 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. 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 (as amended to July 17, 2024).

“*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 to July 17, 2024). 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 semisynthetic cannabinoids. Synthetic and semisynthetic cannabinoids refer to a class of cannabinoids that are 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 tetrahydrocannabinol, delta-10 tetrahydrocannabinol, hexahydrocannabinol (HHC), tetrahydrocannabiphorol (THC-P), and 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.

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