**R66. Agriculture and Food, Medical Cannabis and Industrial Hemp.**

**R66-31. Industrial Hemp Cannabinoid Product Testing.**

**R66-31-1. Authority and Purpose.**

Pursuant to Subsection 4-41-204(2), this rule establishes the standards for industrial hemp cannabinoid product potency testing and sets limits for foreign matter, microbial life, pesticides, residual solvents, heavy metals, and mycotoxins.

**R66-31-2. Definitions.**

(1) "Adulterant" means any poisonous or deleterious substance in a quantity that may be injurious to health, including:

(a) pesticides;

(b) heavy metals;

(c) solvents;

(d) microbial life;

(e) mycotoxins; or

(f) foreign matter.

(2) "Analyte" means a substance or chemical component that is undergoing analysis.

(3) "Batch or lot" means a quantity of:

(a) cannabinoid concentrate produced on a particular date and time, following clean up until the next clean up during which the same lots of industrial hemp are used; or

(b) cannabinoid product produced on a particular date and time, following clean up until the next clean up during which industrial hemp concentrate is used.

(4) "Cannabinoid" means any:

(a) naturally occurring derivative of cannabigerolic acid (CAS 25555-57-1); or

(b) any chemical compound that is both structurally and chemically similar to a derivative of cannabigerolic acid.

(5) "Cannabinoid concentrate" means:

(a) the product of any chemical or physical process applied to naturally occurring biomass that concentrates or isolates the cannabinoids contained in the biomass; and

(b) any amount of a natural, derivative, or synthetic cannabinoid in the synthetic cannabinoid's purified state.

(6) "Cannabinoid product" means the same as the term is defined in Subsection 4-41-102(1).

(7) "Cannabinoid product THC level" means a combined concentration of total THC and any THC analog of less than 0.3% on a dry weight basis if laboratory testing confirms a result within a measurement of uncertainty that includes the combined concentration of 0.3%.

(8) "CBD" means cannabidiol (CAS 13956-29-1).

(9) "CBDA" means cannabidiolic acid, (CAS 1244-58-2).

(10) "Certificate of analysis" (COA) means a document produced by a testing laboratory listing the results for which that testing was performed.

(11) "Department" means the Utah Department of Agriculture and Food.

(12) "Final product" means a reasonably homogenous cannabinoid product in its final packaged form created using the same standard operating procedures and the same formulation.

(13) "Foreign matter" means:

(a) any matter that is present in a cannabis lot that is not a part of the cannabis plant; or

(b) any matter that is present in a cannabis or cannabinoid product that is not listed as an ingredient.

(14) "Industrial hemp" means a cannabis plant that contains less than 0.3% total THC by dry weight.

(15) "Industrial hemp manufacturer" means an entity that holds, stores, packages, or labels an industrial hemp cannabinoid product.

(16) "Pest" means:

(a) any insect, rodent, nematode, fungus, weed; or

(b) any other form of terrestrial or aquatic plant or animal life, virus, bacteria, or other microorganisms that are injurious to health or to the environment or that the department declares to be a pest.

(17) "Pesticide" means any:

(a) substance or mixture of substances, including a living organism, that is intended to prevent, destroy, control, repel, attract, or mitigate any insect, rodent, nematode, snail, slug, fungus, weed, or other forms of plant or animal life that are normally considered to be a pest or that the commissioner declares to be a pest;

(b) any substance or mixture of substances intended to be used as a plant regulator, defoliant, or desiccant; and

(c) any spray adjuvant, such as a wetting agent, spreading agent, deposit builder, adhesive, or emulsifying agent with deflocculating properties of its own used with a pesticide to aid in the application or effect of a pesticide.

(18) "THC" means total composite tetrahydrocannabinol, including delta-9-tetrahydrocannabinol, tetrahydrocannabinolic acid, and any THC analogs as defined in Subsection 58-37-4(2)(a)(ii)(AA).

(19) "THCA" means delta-9-tetrahydrocannabinolic acid (CAS 23978-85-0).

(20) "Total CBD" means the sum of the determined amounts of CBD and CBDA, according to the formula: Total CBD = CBD + (CBDA x 0.877).

(21) "Total THC" means the sum of the determined amounts of THC and THCA, according to the formula: Total THC = THC + (THCA x 0.877).

(22) "Unit" means each individual portion of an individually packaged product.

**R66-31-3. Required Cannabinoid Product Tests.**

(1) An industrial hemp manufacturer may not register or sell a cannabinoid product unless a third party testing laboratory has tested a representative sample of the cannabinoid product to determine:

(a) the amount of any THC analogs present in the sample; and

(b) the presence of adulterants in the sample.

(2) A certificate of analysis shall be included with each batch of cannabinoid product in accordance with Section R68-26-4.

**R66-31-4. Foreign Matter Standards.**

A sample and related batch of cannabinoid product fails quality assurance testing if:

(1) the sample contains foreign matter visible to the unaided human eye;

(2) the sample is found to contain microscopic foreign matter considered to be harmful or estimated to comprise greater than 3% of the mass of the representative sample as determined by the testing laboratory; or

(3) foreign matter is found that is suspected to have been intentionally added to the sample to increase its visual appeal or market value.

**R66-31-5. Potency Testing and Standards.**

(1) A batch of cannabinoid product shall have the following determined and listed on the COA:

(a) quantity of any cannabinoid it is known to contain, including any THC analog; and

(b) the cannabinoid profile by percentage of mass.

(2) Cannabinoid products may not exceed the cannabinoid product THC level.

**R66-31-6. Microbial Standards.**

A sample and related batch of cannabinoid product fails quality assurance testing for microbiological contaminants if the results exceed the limits as set forth in Table 1.

|  |  |
| --- | --- |
| TABLE 1  Microbial Analytes and Action Levels | |
| Material | Microbial Limit Requirement (cfu) |
| Cannabinoid Concentrate | Total Aerobic Microbial Count ≤100,000  Absence of E. Coli and Salmonella spp.  Absence of Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger, and Aspergillus terreus |
| Orally Consumable Products | Total Aerobic Microbial Count ≤10,000  Total Combined Yeast and Mold Count ≤1,000  Absence of E. Coli and Salmonella spp.  Absence of Staph |
| Transdermal Products | Total Aerobic Microbial Count ≤250  Total Yeast and Mold ≤250  Absence of Pseudomonas  Absence of Staph |

**R66-31-7. Pesticide Standards.**

(1) A sample and related batch of cannabinoid product fails quality assurance testing for pesticides if the results exceed the limits as set forth in Table 2.

|  |  |  |
| --- | --- | --- |
| TABLE 2  Pesticide Analytes and Action Levels | | |
| Analyte | Chemical Abstract Service | Action Level |
|  | (CAS) Registry number | ppm |
| Abamectin | 71751-41-2 | 0.5 |
| Acephate | 30560-19-1 | 0.4 |
| Acequinocyl | 57960-19-7 | 2 |
| Acetamiprid | 135410-20-7 | 0.2 |
| Aldicarb | 116-06-3 | 0.4 |
| Azoxystrobin | 131860-33-8 | 0.2 |
| Bifenazate | 149877-41-8 | 0.2 |
| Bifenthrin | 82657-04-3 | 0.2 |
| Boscalid | 188425-85-6 | 0.4 |
| Carbaryl | 63-25-2 | 0.2 |
| Carbofuran | 1563-66-2 | 0.2 |
| Chlorantraniliprole | 500008-45-7 | 0.2 |
| Chlorfenapyr | 122453-73-0 | 1 |
| Chlorpyrifos | 2921-88-2 | 0.2 |
| Clofentezine | 74115-24-5 | 0.2 |
| Cypermethrin | 52315-07-8 | 1 |
| Daminozide | 1596-84-5 | 1 |
| DDVP (Dichlorvos) | 62-73-7 | 0.1 |
| Diazinon | 333-41-5 | 0.2 |
| Dimethoate | 60-51-5 | 0.2 |
| Ethoprophos | 13194-48-4 | 0.2 |
| Etofenprox | 80844-07-1 | 0.4 |
| Etoxazole | 153233-91-1 | 0.2 |
| Fenoxycarb | 72490-01-8 | 0.2 |
| Fenpyroximate | 134098-61-6 | 0.4 |
| Fipronil | 120068-37-3 | 0.4 |
| Flonicamid | 158062-67-0 | 1 |
| Fludioxonil | 131341-86-1 | 0.4 |
| hexythiazox | 78587-05-0 | 1 |
| imazalil | 35554-44-0 | 0.2 |
| Imidacloprid | 138261-41-3 | 0.4 |
| Kresoxim-methyl | 143390-89-0 | 0.4 |
| Malathion | 143390-89-0 | 0.2 |
| Metalaxyl | 57837-19-1 | 0.2 |
| Methiocarb | 2032-65-7 | 0.2 |
| Methomyl | 16752-77-5 | 0.4 |
| Methyl parathion | 298-00-0 | 0.2 |
| MGK-264 | 113-48-4 | 0.2 |
| Myclobutanil | 88671-89-0 | 0.2 |
| Naled | 300-76-5 | 0.5 |
| Oxamyl | 23135-22-0 | 1 |
| Paclobutrazol | 76738-62-0 | 0.4 |
| Permethrins | 52645-53-1 | 0.2 |
| Phosmet | 732-11-6 | 0.2 |
| Piperonyl\_butoxide | 51-03-6 | 2 |
| Prallethrin | 23031-36-9 | 0.2 |
| Propiconazole | 60207-90-1 | 0.4 |
| Propoxur | 114-26-1 | 0.2 |
| Pyrethrins | 8003-34-7 | 1 |
| Pyridaben | 96489-71-3 | 0.2 |
| Spinosad | 168316-95-8 | 0.2 |
| Spiromesifen | 283594-90-1 | 0.2 |
| Spirotetramat | 203313-25-1 | 0.2 |
| Spiroxamine | 118134-30-8 | 0.4 |
| Tebuconazole | 80443-41-0 | 0.4 |
| Thiacloprid | 111988-49-9 | 0.2 |
| Thiamethoxam | 153719-23-4 | 0.2 |
| Trifloxystrobin | 141517-21-7 | 0.2 |

(2) Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (CAS numbers 54774-45-7 and 51877-74-8).

(3) Pyrethrins should be measured as the cumulative residues of pyrethrin I (CAS 121-21-1), pyrethrin II (CAS 121-29-9), cinerin 1 (CAS 25402-06-6), and jasmolin 1 (CAS 4466-14-2).

(4) Abamectin is a composite of the amounts of avermectin B1a and avermectin B1b.

**R66-31-8. Residual Solvent Standards.**

(1) A sample and related batch of cannabinoid product fails quality assurance testing for residual solvents if the results exceed the limits provided in Table 3 unless the solvent is:

(a) a component of the product formulation;

(b) listed as an ingredient; and

(c) generally considered to be safe for the intended form of use.

|  |  |  |
| --- | --- | --- |
| TABLE 3  List of Solvents and Action Levels | | |
| Solvent | Chemical Abstract Service | Action level |
|  | (CAS)Registry number | Ppm |
| 1,2 Dimethoxyethane | 110-71-4 | 100 |
| 1,4 Dioxane | 123-9 | 380 |
| 1-Butanol | 71-36-3 | 5,000 |
| 1-Pentanol | 71-41-0 | 5,000 |
| 1-Propanol | 71-23-8 | 5,000 |
| 2-Butanol | 78-92-2 | 5,000 |
| 2-Butanone | 78-93-3 | 5,000 |
| 2-Ethoxyethanol | 110-80-5 | 160 |
| 2-methylbutane | 78-78-4 | 5,000 |
| 2-Propanol (IPA) | 67-63-0 | 5,000 |
| Acetone | 67-64-1 | 5,000 |
| Acetonitrile | 75-05-8 | 410 |
| Benzene | 71-43-2 | 2 |
| Butane | 106-97-8 | 5,000 |
| Cumene | 98-82-8 | 70 |
| Cyclohexane | 110-82-7 | 3,880 |
| Dichloromethane | 75-09-2 | 600 |
| 2,2-dimethylbutane | 75-83-2 | 290 |
| 2,3-dimethylbutane | 79-29-8 | 290 |
| 1,2-dimethylbenzene | 95-47-6 | See Xylenes |
| 1,3-dimethylbenzene | 108-38-3 | See Xylenes |
| 1,4-dimethylbenzene | 106-42-3 | See Xylenes |
| Dimethyl sulfoxide | 67-68-5 | 5,000 |
| Ethanol | 64-17-5 | 5,000 |
| Ethyl acetate | 141-78-6 | 5,000 |
| Ethylbenzene | 100-41-4 | See Xylenes |
| Ethyl ether | 60-29-7 | 5,000 |
| Ethylene glycol | 107-21-1 | 620 |
| Ethylene Oxide | 75-21-8 | 50 |
| Heptane | 142-82-5 | 5,000 |
| n-Hexane | 110-54-3 | 290 |
| Isopropyl acetate | 290 | 5,000 |
| Methanol | 67-56-1 | 3,000 |
| Methylpropane | 75-28-5 | 5,000 |
| 2-Methylpentane | 107-83-5 | 290 |
| 3-Methylpentane | 96-14-0 | 290 |
| N,N-dimethylacetamide | 127-19-5 | 1,090 |
| N,N-dimethylformamide | 68-12-2 | 880 |
| Pentane | 109-66-0 | 5,000 |
| Propane | 74-98-6 | 5,000 |
| Pyridine | 110-86-1 | 100 |
| Sulfolane | 126-33-0 | 160 |
| Tetrahydrofuran | 109-99-9 | 720 |
| Toluene | 108-88-3 | 890 |
| Xylenes | 1330-20-7 | 2,170 |

(2) Xylenes is a combination of the following:

(a) 1,2-dimethylbenzene;

(b) 1,3-dimethylbenzene;

(c) 1,4-dimethylbenzene; and

(d) ethyl benzene.

**R66-31-9. Heavy Metal Standards.**

A sample and related batch of cannabinoid product fails quality assurance testing for heavy metals if the results exceed the limits provided in Table 4.

|  |  |
| --- | --- |
| TABLE 4  Heavy Metals | |
| Metals | Natural Health Products Acceptable |
|  | limits in parts per million |
| Arsenic | <2 |
| Cadmium | <.82 |
| Lead | <1.2 |
| Mercury | <.4 |

**R66-31-10. Mycotoxin Standards.**

A sample and related batch of cannabinoid product fails quality assurance testing for mycotoxin if the results exceed the limits provided in Table 5.

|  |  |
| --- | --- |
| TABLE 5  Mycotoxin | |
| Test | Specification |
| The Total of |  |
| Aflatoxin B1, |  |
| Aflatoxin B2, |  |
| Aflatoxin G1, and |  |
| Aflatoxin G2 | <20 ppb of substance |
| Ochratoxin A. | <20 ppb of substance |

**R66-31-11. Prohibited Additives.**

Vitamin E Acetate may not be permitted to be present in any inhalable cannabinoid product.

**KEY: industrial hemp, cannabinoid, testing**

**Date of Last Change: May 13, 2024**

**Authorizing, and Implemented or Interpreted Law: 4-41-204(2)**