

### **5K-4.034 Hemp Extract**

(1) Products. Hemp or Hemp Extract intended to be ingested is a Food as defined in Section 500.03, F.S., and are subject to the requirements of Chapter 500, F.S., and Rules 5K-4.002; 5K-4.004; 5K-4.020; 5K-4.021, and 5K-4.035, F.A.C., in addition to the requirements of this rule.

(2) Definitions. The definitions provided in Sections 500.03 and 581.217, F.S., and the following shall apply to this rule:

(a) "Approved Source" for the purposes of this rule means a food establishment manufacturing, processing, packing, holding, or preparing food or selling food at wholesale or retail that meets local, state, or federal food safety standards from the jurisdiction of origin.

(b) "Batch Number" or "Lot Number" means the Hemp Extract produced during a period of time under similar conditions and identified by a specific code that allows traceability.

(c) "Expiration Date" means the month and year as determined by the manufacturer, packer, or distributor on the basis of tests or other information 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.

(d) "Hemp" is defined in Section 581.217(3)(d), F.S.

(e) "Hemp Extract" is defined in Section 581.217(3)(e), F.S. Hemp Extract does not include any material, compound, mixture or preparation that contains any quantity of Synthetic Cannabinoids as defined in Section 893.03(1)(c)190., F.S.

(f) "Hemp Food Establishment" means an establishment as defined in Section 500.03(1)(p), F.S., manufacturing, processing, packing, holding, preparing, or selling Food consisting of or containing Hemp Extract at wholesale or retail.

(g) "Ingestion" means the process of taking Food into the body through the mouth and into the gastrointestinal tract through eating or drinking.

(h) "Total delta-9 tetrahydrocannabinol concentration" means  $[\text{delta-9 tetrahydrocannabinol}] + (0.877 \times [\text{tetrahydrocannabinolic acid}])$ .

(3) Food Permit Fees. Hemp Food Establishments shall obtain a food permit as required in Rule 5K-4.020, F.A.C., and shall pay an annual fee of \$650.

(4) Requirements.

(a) Food consisting of or containing Hemp or Hemp Extract must be obtained from an Approved Source. The Hemp Food Establishment shall provide to the department, upon request, a valid food license/permit and the most recent food safety inspection report from the Approved Source.

(b) Food consisting of or containing Hemp Extract may not be manufactured, processed, packed, held, prepared, or sold under the Cottage Food Operations Law in Section 500.80, F.S.

(c) If a Food is considered a Potentially Hazardous Food (PHF) or a Food requiring Time and Temperature Control for Safety (TCS Food) as defined in Rule 5K-4.0010, F.A.C., it must be stored in accordance with Rule 5K-4.002, F.A.C. All Food products consisting of or containing Hemp Extract must be packaged in containers minimizing the exposure to light to prevent degradation of the Cannabinoids.

(d) Food consisting of or containing Hemp Extract shall not contain a Total delta-9 tetrahydrocannabinol concentration of more than 0.3% on a dry weight basis.

(5) Contaminants. In addition to the requirements listed in Chapter 500, F.S., and Rule 5K-4.002, F.A.C., Food consisting of or containing Hemp Extract shall be considered adulterated pursuant to Section 500.10(1)(a), F.S., if contaminants are detected at levels greater than those listed in this rule.

(a) Pesticide Limits. The following list of contaminants does not constitute authorization to use or apply any of the following during Hemp cultivation or processing.

1. Abamectin, 300 parts per billion.
2. Acephate, 3,000 parts per billion.
3. Acequinocyl, 2,000 parts per billion.
4. Acetamiprid, 3,000 parts per billion.
5. Aldicarb, 100 parts per billion.
6. Azoxystrobin, 3,000 parts per billion.
7. Bifenazate, 3,000 parts per billion.
8. Bifenthrin, 500 parts per billion.

9. Boscalid, 3,000 parts per billion.
10. Captan, 3,000 parts per billion.
11. Carbaryl, 500 parts per billion.
12. Carbofuran, 100 parts per billion.
13. Chlorantraniliprole, 3,000 parts per billion.
14. Chlordane, 100 parts per billion.
15. Chlorfenapyr, 100 parts per billion.
16. Chloromequat chloride, 3,000 parts per billion
17. Chlorpyrifos, 100 parts per billion.
18. Clofentezine, 500 parts per billion.
19. Coumaphos, 100 parts per billion.
20. Cyfluthrin, 1,000 parts per billion.
21. Cypermethrin, 1,000 parts per billion.
22. Daminozide, 100 parts per billion.
23. DDVP (Dichlorvos), 100 parts per billion.
24. Diazinon, 200 parts per billion.
25. Dimethoate, 100 parts per billion.
26. Dimethomorph, 3,000 parts per billion.
27. Ethoprop(hos), 100 parts per billion.
28. Etofenprox, 100 parts per billion.
29. Etoxazole, 1,500 parts per billion.
30. Fenhexamid, 3,000 parts per billion.
31. Fenoxycarb, 100 parts per billion.
32. Fenpyroximate, 2,000 parts per billion.
33. Fipronil, 100 parts per billion.
34. Flonicamid, 2,000 parts per billion.
35. Fludioxonil, 3,000 parts per billion.
36. Hexythiazox, 2,000 parts per billion.
37. Imazalil, 100 parts per billion.
38. Imidacloprid, 3,000 parts per billion.
39. Kresoxim-methyl, 1,000 parts per billion.
40. Malathion, 2,000 parts per billion.
41. Metalaxyl, 3,000 parts per billion.
42. Methiocarb, 100 parts per billion.
43. Methomyl, 100 parts per billion.
44. Methyl parathion, 100 parts per billion.
45. Mevinphos, 100 parts per billion.
46. Myclobutanil, 3,000 parts per billion.
47. Naled, 500 parts per billion.
48. Oxamyl, 500 parts per billion.
49. Paclobutrazol, 100 parts per billion.
50. Pentachloronitrobenzene, 200 parts per billion.
51. Permethrin, 1,000 parts per billion.
52. Phosmet, 200 parts per billion.
53. Piperonyl butoxide, 3,000 parts per billion.
54. Prallethrin, 400 parts per billion.
55. Propiconazole, 1,000 parts per billion.
56. Propoxur, 100 parts per billion.
57. Pyrethrins, 1,000 parts per billion.

58. Pyridaben, 3,000 parts per billion.
59. Spinetoram, 3,000 parts per billion.
60. Spinosad A & D, 3,000 parts per billion.
61. Spiromesifen, 3,000 parts per billion.
62. Spirotetramat, 3,000 parts per billion.
63. Spiroxamine, 100 parts per billion.
64. Tebuconazole, 1,000 parts per billion.
65. Thiacloprid, 100 parts per billion.
66. Thiamethoxam, 1,000 parts per billion.
67. Trifloxystrobin, 3,000 parts per billion.

(b) Residual Solvent Limits.

1. 1,2-Dichloroethene, 5 parts per million
2. 1,1-Dichloroethene, 8 parts per million
3. Acetone, 5,000 parts per million
4. Acetonitrile, 410 parts per million
5. Benzene, 2 parts per million
6. Butane, 2,000 parts per million
7. Chloroform, 60 parts per million
8. Ethanol, 5,000 parts per million
9. Ethyl Acetate, 5,000 parts per million
10. Ethyl Ether, 5,000 parts per million
11. Ethylene Oxide, 5 parts per million
12. Heptane, 5,000 parts per million
13. Hexane, 290 parts per million
14. Isopropyl Alcohol, 500 parts per million
15. Methanol, 3,000 parts per million
16. Methylene Chloride, 600 parts per million
17. Pentane, 5,000 parts per million
18. Propane, 2,100 parts per million
19. Toluene, 890 parts per million
20. Trichloroethylene (1,1,2-Trichloroethene), 80 parts per million
21. Xylenes, Total (ortho-, meta-, para-), 2170 parts per million

(c) Metals Limits.

1. Cadmium, 0.5 micrograms/gram.
2. Lead, 0.5 micrograms/gram.
3. Arsenic, 1.5 micrograms/gram.
4. Mercury, 3.0 micrograms/gram.

(d) Biological Limits.

1. Shiga toxin-producing *Escherichia coli* (STEC *E. coli*) and other pathogenic *E. coli*, none present.
2. *Listeria monocytogenes*, none present.
3. *Salmonella*, none present.

(e) Mycotoxin Limits.

1. Total Aflatoxin (B1, B2, G1, G2), 20 parts per billion.
2. Ochratoxin, 20 parts per billion.

(f) Cannabinoid Limits. Total delta-9 tetrahydrocannabinol concentration shall not exceed 0.3% on a dry weight basis.

(g) If a testing sample is found to contain levels of any pathogen, toxicant, residual solvent, metal, or pesticide not enumerated in this rule or by Florida law, then the Food shall be considered adulterated.

(6) Labeling.

(a) Food consisting of or containing Hemp Extract must be labeled as required by Chapter 500, F.S., Section 581.217(7), F.S.,

and 21 CFR 101, as incorporated by reference in Section 5K-4.002(4), F.A.C., and must declare the number of milligrams of Hemp Extract.

(b) If specific cannabinoids are marketed, the number of milligrams of each cannabinoid per serving must be declared on the label. The serving size shall be displayed on the nutrition facts label of the product.

(c) The label and advertisement shall not contain claims indicating the product is intended for diagnosis, cure, mitigation, treatment, or prevention of disease, rendering it a drug as defined in 21 U.S.C. 321(g)(1). Pursuant to Section 500.03(1)(n)4., F.S., such articles are not considered Food and shall be considered misbranded as Food.

(7) Disposal.

(a) Laboratory samples found to contain more than a Total delta-9 tetrahydrocannabinol concentration of 0.3% on a dry weight basis shall be disposed of in accordance with 21 CFR 1317. 21 CFR 1317 (Revised April 1, 2019) is hereby incorporated by reference and available online at <http://www.flrules.org/Gateway/reference.asp?No=Ref-11452>.

(b) Food containing a Total delta-9 tetrahydrocannabinol concentration that exceeds 0.3% on a dry weight basis shall be detained pursuant to Section 500.172, F.S. Food containing a Total delta-9 tetrahydrocannabinol concentration that exceeds 0.3% on a dry weight basis which has been detained pursuant to Section 500.172, F.S. shall not be further subdivided or renumbered such that the integrity of the lot is not maintained. The establishment shall not dispose of the Food in any manner until written permission is given by the department or a court of competent jurisdiction.

(c) Upon receipt of written permission by the department or a court of competent jurisdiction, the Food shall be disposed of in accordance with the Hemp Waste Disposal Manual FDACS-08115, 10/19, incorporated in paragraph 5B-57.014(6)(b), F.A.C., or in a manner approved by a court of competent jurisdiction. Upon destruction of the product, the Hemp Food Establishment shall notify the department via Notice of Disposal FDACS-14419, 10/19, incorporated herein by reference and available online at <http://www.flrules.org/Gateway/reference.asp?No=Ref-11458>.

(8) Penalties. Violations of this rule will be evaluated and penalties imposed in accordance with Rule 5K-4.035, F.A.C.

*Rulemaking Authority 500.09, 500.12, 570.07(23) FS. Law Implemented 500.03, 500.04, 500.09, 500.10, 500.11, 500.12, 500.121, 500.13, 500.172, 581.217 FS. History—New 1-1-20.*