

5K-10.006 Hemp Extract

(1) Products. Milk, Milk Products, and Frozen Desserts containing Hemp or Hemp Extract are subject to the requirements of Chapter 502, F.S., and Chapter 5K-10, F.A.C., in addition to the requirements of this rule. Grade “A” milk and milk products to which Hemp Extract has been added shall be considered “Substitute Milk” or “Substitute Milk Products” as defined in Chapter 502, F.S. In addition to the requirements in Section 502.165, F.S., Substitute Milk and Substitute Milk Products containing Hemp Extract are subject to the requirements of Chapter 5K-10, F.A.C.

(2) Definitions. The definitions provided in Sections 502.012 and 581.217, F.S., and the following shall apply to this rule:

(a) “Approved Source” for the purposes of this rule means Hemp Frozen Dessert Manufacturer, Hemp Substitute Milk Manufacturer, or Hemp Substitute Milk Product Manufacturer manufacturing, processing, packing, holding, or preparing or selling Substitute Milk, Substitute Milk Products, or Frozen Desserts 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 Substitute Milk, Substitute Milk Products, and Frozen Desserts containing 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 Frozen Dessert Manufacturer” means a person who manufactures, processes, converts, partially freezes, or freezes any mix or frozen dessert containing Hemp Extract for distribution or sale.

(g) “Hemp Substitute Milk Manufacturer” means any place, premises, or establishment where Substitute Milk containing Hemp Extract is collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaging, condensed, dried, packaged, bottled, or prepared for distribution at wholesale.

(h) “Hemp Substitute Milk Product Manufacturer” means any place, premises, or establishment where Substitute Milk Products containing Hemp Extract is collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed and packaged, retort processed after packaging, condensed, dried, packaged, bottled, or prepared for distribution at wholesale.

(i) “Ingestion” means the process of taking food into the body through the mouth and into the gastrointestinal tract through eating or drinking.

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

(3) Permits and Fees. Hemp Substitute Milk, Hemp Substitute Milk Products, and Hemp Frozen Dessert Manufacturers shall obtain a permit and pay the applicable fee required in Rule 5K-10.002, F.A.C.

(4) Requirements.

(a) Substitute Milk, Substitute Milk Products, and Frozen Desserts containing Hemp Extract must be obtained from an Approved Source. The Hemp Frozen Dessert Manufacturer, Hemp Substitute Milk Manufacturer, or Hemp Substitute Milk Product Manufacturer shall provide to the department, upon request, a valid dairy or food safety license/permit and the most recent dairy or food safety inspection report from the Approved Source.

(b) Substitute Milk, Substitute Milk Products, and Frozen Desserts containing Hemp Extract must be stored and transported in accordance with Chapter 5K-10, F.A.C. Substitute Milk, Substitute Milk Products, and Frozen Desserts containing Hemp Extract must be packaged in containers minimizing the exposure to light to prevent degradation of the Cannabinoids.

(c) Substitute Milk, Substitute Milk Products, and Frozen Desserts 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 502, F.S., and Rule 5K-10.004, Substitute Milk, Substitute Milk Products, and Frozen Desserts containing Hemp Extract shall be considered adulterated pursuant to Section 502.181(2), 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. Chlormequat 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 the Substitute Milk, Substitute Milk Product, or Frozen Dessert containing Hemp Extract shall be considered adulterated.

(6) Labeling.

(a) Substitute Milk, Substitute Milk Products, and Frozen Desserts containing Hemp Extract must be labeled in accordance with Chapter 502, F.S., Section 581.217(7), F.S., and 21 CFR 101 and must declare the number of milligrams of Hemp Extract. 21 CFR 101 (Revised April 1, 2019) is hereby incorporated by reference and available online at <http://www.flrules.org/Gateway/reference.asp?No=Ref-11459>.

(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).

(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-11460>.

(b) Substitute Milk, Substitute Milk Products, or Frozen Desserts containing a Total delta-9 tetrahydrocannabinol concentration that exceeds 0.3% on a dry weight basis shall be detained pursuant to Section 502.014, F.S. Substitute Milk, Substitute Milk Products, or Frozen Desserts containing a Total delta-9 tetrahydrocannabinol concentration that exceeds 0.3% on a dry weight basis which have been detained pursuant to Section 502.014, F.S., shall not be further subdivided or renumbered such that the integrity of the lot for identification is not maintained. The establishment shall not dispose of the Substitute Milk, Substitute Milk Products, or Frozen Desserts 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 Substitute Milk, Substitute Milk Products, or Frozen Desserts 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 the manner provided for by a court of competent jurisdiction. Upon destruction of the product, the establishment shall notify the department via Notice of Disposal FDACS-14419, 10/19, incorporated in paragraph 5K-4.034(7)(c), F.A.C.

(8) Penalties. Violations of this rule will be evaluated, and penalties imposed in accordance with Rule 5K-10.005, F.A.C.

Rulemaking Authority 502.014, 502.053, 570.07(23) FS. Law Implemented 502.012, 502.014, 502.032, 502.042, 502.053, 502.091, 502.121, 502.165, 502.231, 581.217(7) FS. History—New 1-1-20.