**5E-3.021 Other Hemp Extract Animal Ingestant**

(1) Definitions.

(a) “Distribute” means to offer for sale, sell, barter, or exchange or to supply, furnish, or otherwise provide for use by any consumer or customer in the state.

(b) “Hemp” is defined in Section 581.217(3)(d), F.S.

(c) “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.

(d) “Label” means a display of written, printed, or graphic matter upon or affixed to the container in which a product is distributed, or on the invoice accompanying the product.

(e) “Other Hemp Extract Animal Ingestant” means a hemp extract product intended for animal ingestion that is not a drug, commercial feed, feedstuff or treat.

(f) “Total delta-9-tetrahydrocannabinol concentration” means [delta-9-tetrahydrocannabinol] + (0.877 x [tetrahydrocannabinolic acid)

(2) Registration; reporting.

(a) Each distributor of “Other Hemp Extract Animal Ingestant” must annually obtain a registration before her or his brands are distributed in this state. All registrations expire on June 30 of each year.

(b) The Application for Registration (Form DACS-XXXXX, Rev. XX/XX) shall be submitted annually by each distributor of “Other Hemp Extract Animal Ingestant”. If a distributor has been in business less than 1 year, the anticipated receipts shall be estimated by the distributor for the first year and based on the actual gross receipts from the sale of “Other Hemp Extract Animal Ingestant” thereafter.

(c) Registration shall be conditioned on the distributor’s compliance with all provisions of chapter 581.217(7), F.S. and this rule.

(d) Each distributor shall maintain a bookkeeping system and records necessary to indicate accurately the gross receipts of “Other Hemp Extract Animal Ingestant” distributed in this state.

(e) Each distributor shall allow the department to verify the accuracy of reported gross receipts and to otherwise examine pertinent records at reasonable times.

(f) The department shall provide a copy of the registration to the registrant to signify that administrative requirements have been met.

(g) Failure of any distributor to comply with registration shall be considered prima facie evidence of an attempt to violate this rule, and the department shall have full authority to assess penalties where violations are found for “Other Hemp Extract Animal Ingestant” distributed in the state prior to registration.

(3) Labels; requirements.

(a) The information listed in subsection (b), shall appear in its entirety on the label, or on the container, and further provided that precautions and directions for use may appear on the reverse side of the label. The information shall not be subordinated or obscured by other statements and designs.

(b) Any “Other Hemp Extract Animal Ingestant” distributed in this state, shall be accompanied by a legible label bearing the following information:

1. An accurate statement of the net weight or volume.

2. The name and principal address of the registrant.

3. The brand name and product name, if any, under which the “Other Hemp Extract Animal Ingestible” is distributed.

4. The date of manufacture or expiration date of the “Other Hemp Extract Animal Ingestible” sold at retail.

5. The common or usual name of each ingredient used in the manufacture of the “Other Hemp Extract Animal Ingestible”.

6. “Not for human consumption.”

7. The number of milligrams of Hemp extract.

8. If specific cannabinoids are claimed, the number of milligrams of each cannabinoid per serving must be declared on the label.

9. The serving size.

10. “Other Hemp Extract Animal Ingestant” must be labeled as required in Section 581.217(7), F.S.

(c) When an “other hemp extract animal ingestible” is distributed in this state in bags or other containers, a label shall be placed on or affixed to each container; when an “other hemp extract animal ingestible” is distributed in bulk, a label shall accompany delivery and be furnished to the customer at time of delivery.

(d) A package or a bulk lot of “Other Hemp Extract Animal Ingestant” shall not be accompanied by conflicting labeling on tags, containers, delivery ticket or invoice.

(e) The label and labeling for “Other Hemp Extract Animal Ingestant” consisting of or containing Hemp extract shall not contain claims indicating the product is intended for diagnosis, cure, mitigation, treatment, or prevention of disease rendering it a drug as defined by Section 580.031(9), F.S.

(f) Fat, fiber, protein or other nutritional substances, when guaranteed must be determinable by laboratory methods approved by the department in chapter 580.

(4) Ingredient Statement.

(a) Each ingredient shall be specifically named

(b) No reference to quality or grade of an ingredient shall appear in the ingredient statement of “Other Hemp Extract Animal Ingestant”.

(c) Copyrighted brand, trade, or proprietary names shall not be used in the ingredient statement.

(5) Inspection; Sampling; Analysis; Reporting Rejected“Other Hemp Extract Animal Ingestant”**.**

(a) Inspection. All “Other Hemp Extract Animal Ingestant” distributed for use in Florida are subject to inspection by the Department of Agriculture and Consumer Services or its authorized agent at any public or business premises, manufacturing or mixing establishment, and in any vehicle of transport during regular business hours in order to have access to such “Other Hemp Extract Animal Ingestant” and records relating to their manufacture, transportation and sale.

(b) Analysis of “Other Hemp Extract Animal Ingestant”.

1. Hemp extract as defined in Section 581.217(3)(e), F.S. used in “Other Hemp Extract Animal Ingestant” must be tested and have a certificate of analysis prepared by an independent testing laboratory as required in Section 581.217(7), F.S.

2. “Other Hemp Extract Animal Ingestant” shall not contain more than 0.3% total delta-9-tetrahydrocannabinol concentration.

3. “Other Hemp Extract Animal Ingestant” having a total delta-9-tetrahydrocannabinol concentration that exceeds 0.3%, shall be detained pursuant to Section 581.031(30), F.S. Those products having a total delta-9-tetrahydrocannabinol concentration that exceeds 0.3% which have been detained pursuant to Section 581.031(30), F.S., shall not be further subdivided or renumbered such that the integrity of the lot for identification is not maintained. The manufacturer or distributor shall not dispose of the “Other Hemp Extract Animal Ingestant” in any manner until written permission is given by the Department or a court of competent jurisdiction.

4. Upon receipt of written permission by the Department or a court of competent jurisdiction, the “Other Hemp Extract Animal Ingestant” shall be disposed of in accordance with the Hemp Waste Disposal Manual FDACS-08115, 12/19, 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 manufacturer or distributor shall notify the Department via Notice of Disposal FDACS-13411, 10/19, incorporated herein by reference and available online at <https://www.flrules.org/Gateway/reference.asp?No=Ref-11419>.

(6) Tolerances for Cannabinoids, Guarantees, Minerals, Aflatoxin and Pesticide Residues.

(a) The following tolerances or analytical variations will be permitted in determining whether or not “Other Hemp Extract Animal Ingestant” are deficient or excessive in any cannabinoids, guarantees, aflatoxin, or pesticide residue:

Tolerances

|  |  |
| --- | --- |
| 1. Cannabinoids  2. Guarantees: | 15% |
| a. Moisture | 4% |
| b. Protein 0-20% | 1% |
| c. Protein over 20% | 2% |
| d. Fat | 0.5% |
| e. Fiber 0-20% | 1% |
| f. Fiber over 20% | 2% |
| g. Ash | 3% |
| h. Equiv. Protein from NPN (Excess) | 5% or > than max guarantee |
| i. Total Sugar as Invert | 2% |
| j. Brix | 2% |
| 3. Minerals: |  |
| a. Calcium (Ca) | \* |
| b. Phosphorus (P) | \* |
| c. Salt (NaCl) | \*\* |
| d. Iron (Fe) | \*\*\* |
| e. Magnesium (Mg) | \*\*\* |
| f. Zinc (Zn) | 50% of Guarantee |
| g. Copper (Cu) | 50% of Guarantee |
| h. Cobalt (Co) | 50% of Guarantee |
| i. Manganese (Mn) | 50% of Guarantee |
| j. Potassium (K) | \*\*\* |

\* 10% of Guarantee but not less than 0.4%

\*\* 10% of Guarantee but not less than 0.5%

\*\*\* 20% of Guarantee but not less than 0.05%

(b) Aflatoxin:

1. The maximum permissible level of aflatoxin in “Other Hemp Extract Animal Ingestant” shall be 20 ppb for immature or lactating animals. Those tolerances listed under U.S. FDA Compliance Policy Guide No. 7126.33 (8/28/94) shall be applied.

2. U.S. FDA Compliance Policy Guide No. 7126.33 (8/28/94) is hereby incorporated by reference. Copies may be obtained from the Florida Department of Agriculture and Consumer Services, Bureau of Licensing and Enforcement, 3125 Conner Boulevard, Tallahassee, Florida 32399-1650, (850)617-7997.

(c) Pesticide Residues:

1. Those tolerances listed in 21 C.F.R. pt. 573 (4/1/01) – Food Additives Permitted in Feed and Drinking Water of Animals and 40 C.F.R. pt. 180 (7/1/01) – Tolerances and Exemptions from Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities shall be applied.

2. The following materials are hereby incorporated by reference. Copies may be obtained from the Superintendent of Documents, U.S. Government Printing Office, 732 North Capitol Street, N. W., Mail Stop #SDE, Washington, D.C. 20401.

a. 21 C.F.R. pt. 573 (4/1/01), Food Additives Permitted in Feed and Drinking Water of Animals.

b. 40 C.F.R. pt. 180 (7/1/01), Tolerances and Exemptions from Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities.

(7) Violations

(a) Adulteration. No person shall distribute an adulterated “Other Hemp Extract Animal Ingestible”. An “Other Hemp Extract Animal Ingestible” shall be deemed to be adulterated if:

1. If it bears or contains any poisonous, deleterious, or nonnutritive substance that may render it injurious to animal or human health. However, if the substance is not an additive, the “Other Hemp Extract Animal Ingestible” shall not be considered adulterated if the quantity of the substance does not ordinarily render it injurious to animal or human health;

2. It consists, in whole or in part, of any filthy, putrid, or decomposed substance or is otherwise unfit for a “Other Hemp Extract Animal Ingestible”;

3, It is prepared, packaged, or held under unsanitary conditions in which it may have become contaminated with filth or rendered injurious to health.

3. Any valuable constituent has been in whole or in part omitted or removed, or any less valuable substance has been substituted.

4. Its composition or quality falls below or differs from that which it is purported or is represented to possess by its labeling.

(b) Misbranding**.** No person shall distribute misbranded “Other Hemp Extract Animal Ingestant”. A “Other Hemp Extract Animal Ingestible” shall be deemed to be misbranded if:

1. Its labeling is false or misleading.

2. It is distributed under the name of another “Other Hemp Extract Animal Ingestible”.

3. It is not labeled as required by this rule.

4. Any word, statement, or other information required by Chapter 581.217(7), F.S., and this rule to appear on the label or labeling is not prominently and conspicuously placed thereon in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

5. It is not appropriate for its intended or purported use.

(c) Certain acts prohibited. The following acts, or the causing thereof knowingly, within the state are prohibited:

1. The adulteration or misbranding of any “Other Hemp Extract Animal Ingestant”.

2. The dissemination of any false advertisement with reference to the distribution of any “Other Hemp Extract Animal Ingestant”.

3. The refusal to permit entry, inspection, or collection of samples of “Other Hemp Extract Animal Ingestant” by authorized department personnel.

4. The removal or disposal of a lot of “Other Hemp Extract Animal Ingestant” that has had a stop-sale, stop-use, removal, or hold order issued, prior to release by the department or the court.

5. The use of any label that does not comply with the provisions of Chapter 581, F.S. and this rule.

6. The forging, counterfeiting, simulating, or false representing of any label.

7. Placing or permitting to be placed any false advertisement or misleading statement on a label.

8. The failure or refusal to register, file reports, or perform any other affirmative act required by this rule.

(8) Penalties

(a) The department may impose one or more of the following penalties against any person who violates any provision of this rule:

1. Imposition of an administrative fine in the Class II category pursuant to s. 570.971 for each occurrence.

2. Revocation or suspension of the registration.

3. Probation for up to 1 year, with conditions.

(b) In cases where the department has determined a pattern of noncompliance with the provisions of this chapter, penalties may be imposed in accordance with subsection (8)(a). Such penalties are in addition to any penalty or penalties that might be imposed under any other portion of this rule.

(c) Detained commercial feed and feedstuff.

1. STOP-SALE, STOP-USE, REMOVAL, OR HOLD ORDERS. When the department has cause to believe any lot of “Other Hemp Extract Animal Ingestant” is being distributed in violation of this rule, it may issue and enforce a written or printed stop-sale, stop-use, removal, or hold order, warning the possessor not to dispose of the “Other Hemp Extract Animal Ingestant” in any manner until written permission is given by the department or a court of competent jurisdiction. The department shall release the “Other Hemp Extract Animal Ingestant” so withdrawn when the provisions and rules have been complied with and all costs and expenses incurred in the withdrawal have been paid. The department may permit any lot of “Other Hemp Extract Animal Ingestant” under stop-sale, stop-use, removal, or hold order to be sold to a consumer who shall sign a statement at the time of purchase professing knowledge of the violation. If compliance is not obtained within 30 days, the department may begin proceedings for condemnation.

2. CONDEMNATION AND CONFISCATION. Any lot of “Other Hemp Extract Animal Ingestant” not in compliance with this rule shall be subject to seizure on complaint of the department to the circuit court of the circuit in which the “Other Hemp Extract Animal Ingestant” is located. In the event the court finds the commercial feed or feedstuff to be in violation of this chapter or rules promulgated hereunder and orders the condemnation of the “Other Hemp Extract Animal Ingestant”, it shall be disposed of in the manner provided by the circuit court in the order of condemnation. In no instance shall the disposition of the “Other Hemp Extract Animal Ingestant” be ordered by the court without first giving the claimant an opportunity to apply to the court for release of the commercial feed or feedstuff or to apply for permission to process or relabel the “Other Hemp Extract Animal Ingestant” to bring it into compliance with this chapter.

(d) Notice of Noncompliance. Any department investigation or inspection which reveals minor violations of this rule chapter in which the department determines that the violator was unaware of the rule or unclear as to how to comply with it will result in the issuance of a notice of noncompliance as the department’s first response to the minor violation. The following violations shall result in the issuance of a notice of noncompliance:

1. Failure to comply with subsection 5E-3.021(3)(b), F.A.C.

(e) Major violations. Major violations are all violations other than those classified as minor violations.

(f) Fines. For major violations or repeat minor violations, the Department shall impose an administrative fine not to exceed $5,000 per violation plus any other penalty allowed by the law including suspension or revocation of the registration. When imposing a fine, the Department will consider the degree and extent of harm or potential harm, that was or could have been caused by the violation, whether the violation was committed willfully, the compliance history of the violator, and the scope of the violation.

(g) Fine Guide. FINE GUIDE = (A(B+C+D+E))$50. This guide shall apply for each violation of this rule for which a fine is imposed. The maximum fine is $5,000 per violation. The terms and values used in the fine guide calculation shall be:

1. DEGREE AND EXTENT OF HARM

A = Animal, Human and Environmental Hazards

1 No animal, human or environmental effects identified,

2 Possibility, probability, or potential for harm existed, or

3 Any harm to animals, humans or the environment.

B = Level of financial harm to the consumer that is created by the violation

1 Unknown or under $1,000,

2 $1,000 or over and under $5,000, or

3 $5,000 or over.

2. WHETHER THE VIOLATION WAS COMMITTED WILLFULLY

C = Whether the violation was committed willfully.

1 No evidence or insufficient evidence of willful intent by the violator, or

3 Evidence of willful intent by the violator.

3. COMPLIANCE RECORD OF THE VIOLATOR

D = Compliance record of the violator

0 No prior actions

1 One prior action dissimilar to the current violation.

2 Two or more prior actions dissimilar to current violation.

3 Previous action for the same or similar violation or previously fined for a different violation, or

4 Previous action for the same or similar violation.

4. SCOPE OF THE VIOLATION

E = The scope of the violation and/or distribution of the violative product(s)

1 Very limited distribution, quantity or limited purchasers; violation is limited to a single lot.

2 Distribution is limited to a specific region of the state; violations are limited to one or two products; quantity of product distributed is small (<50 ton distributed); small number of animals effected.

3 Distribution is statewide and/or impacts other states; violations are seen in multiple products across multiple lots; quantity of products distributed is large (>50 tons effected), or

4 Distribution is unlimited, potentially nationwide.

*Rulemaking Authority 570.07(23), 581.217(12) Law Implemented 580.071, 580.081,* 581.031(30), *581.211(1)(a), (3), 581.217(7) History-New\_\_\_\_\_\_\_\_\_.*