

PRELIMINARY TEXT

THE PRELIMINARY TEXT OF THE PROPOSED RULE IS:

64-4.205 Standards for Production of Edibles

(1) An MMTC that produces edibles must comply with all requirements for food establishments in Chapter 500, F.S., and any rules adopted pursuant to that chapter.

(2) All edibles must be produced by the MMTC in the MMTC's department-approved processing facility and packaged and labeled in accordance with s. 381.986, F.S., and the department's MMTC Packaging and Labeling rule.

(3) Before producing and dispensing edibles, an MMTC must:

(a) Comply with the variance procedure in Rule 64-4.023, F.A.C., and obtain department approval of the edible;

1. Through the variance request procedure, an MMTC must obtain approval of each edible product the MMTC intends to produce and dispense. The variance request must demonstrate that the proposed edible, including its packaging and labeling, are compliant with s. 381.986, F.S., and department rules. Each variance request will be considered on a case-by-case basis.

2. As part of the variance approval process, the MMTC must submit a picture or detailed depiction of the proposed edible bearing the universal symbol, and the measurements of the edible and universal symbol, if applicable.

(b) Provide the department with a copy of a current valid permit to operate as a food establishment pursuant to Chapter 500, F.S., from the Department of Agriculture and Consumer Services; and

(c) Provide the department with documentation from a nationally accredited certifying body that the MMTC's processing facility, including the area where edibles will be produced, has passed a Food Safety Good Manufacturing Practices inspection.

(4) Edibles shall be one of the following shapes (including the three-dimensional form of each shape):

(a) Square;

(b) Circle;

(c) Rectangle;

(d) Triangle;

(e) Parallelogram;

(f) Oval; or

(g) Diamond.

- 29 (5) Edibles shall be in one of the following forms:
- 30 (a) Lozenges. For purposes of this rule, a “lozenge” is a hard edible that is held in the mouth and slowly dissolved.
- 31 (b) Gelatins. For purposes of this rule, a “gelatin” is a semi-translucent edible made with water-soluble protein
32 derived from collagen, or a plant-based alternative.
- 33 (c) Baked goods. For purposes of this rule, a “baked good” is an edible comprised of dough or batter baked in an
34 oven by the MMTC.
- 35 (d) Chocolates. For purposes of this rule, a “chocolate” is a solid edible made of milk chocolate, dark chocolate,
36 or a chocolate substitute such as carob. Chocolates may not contain any caramel, nougat, nuts, fruit, honey,
37 marshmallows, or any other such ingredient, toppings, or fillings. However, chocolates may contain as an ingredient
38 natural flavor or artificial flavor, as those terms are defined in 21 CFR 101.22 (4-1-20 Edition), which is incorporated
39 by reference and available at <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>. Natural flavors or
40 artificial flavors must not change the color of the chocolate and must be fully homogenized therein.
- 41 (e) Drink Powders. For purposes of this rule, “drink powder” is an edible comprised of powder which is combined
42 with a fluid for consumption as a beverage by a qualified patient. Drink powders are exempt from the requirements of
43 subsection (4).
- 44 (6) In the case of multi-serving edibles, each single serving portion must be physically distinct or clearly marked
45 or delineated in a way that enables a reasonable person to determine the portion of the entire edible that constitutes a
46 single serving. If the single serving portion is not physically distinct, it must be easily separable in order to allow the
47 qualified patient to physically separate, with minimal effort, the single serving portion.
- 48 (7) An MMTC shall not produce or dispense any edibles that:
- 49 (a) Contain any color additives, whether natural or artificial;
- 50 (b) Contain or bear a reasonable resemblance to commercially available candy. For the purposes of this rule, a
51 product bears a reasonable resemblance to commercially available candy if the product is similar in appearance to an
52 existing candy product that is familiar to the public as a widely distributed, branded food product, such that the edible
53 could be mistaken for the branded product, especially by children;
- 54 (c) Bear any markings, symbols, images, graphics, or words, other than the universal symbol, as described herein;
- 55 (d) Are decorated with icing, sprinkles, or other toppings of any kind; or

56 (e) Are a primary or bright color. Edibles shall be produced in a manner to minimize color intensity and other
57 color and visual characteristics attractive to children.

58 (8) Edibles shall not contain the following prohibited ingredients:

59 (a) Meat, poultry, or fish. For purposes of this rule, gelatin is not considered meat, poultry, or fish;

60 (b) Anything other than marijuana oil and ingredients that meet the definitions of “food” or “food additive” in s.
61 500.03, F.S.;

62 (c) Commercially manufactured food products that were not produced by the MMTC, unless the products are
63 used as an ingredient in a manner that renders them unrecognizable as the original commercial food product and the
64 MMTC does not state or advertise the edible contains the commercially manufactured food products;

65 (d) Any additive that increases potency or toxicity, or any psychoactive substance (e.g. nicotine, alcohol, and
66 caffeine).

67 (9) Edibles shall be marked with the universal symbol, unless impractical.

68 (a) It shall be considered impractical to mark a single serving portion of an edible with the universal symbol when
69 the edible is so small that a mark, stamp, or imprint of 1/16 inch by 1/16 inch would not fit on the edible or when the
70 edible is made of a substance that cannot be marked, stamped or imprinted (e.g. drink powder).

71 (b) The universal symbol shall be:

72 1. Marked on at least one side of each single serving portion of an edible such that the universal symbol is
73 distinguishable and easily recognizable;

74 2. Centered either horizontally or vertically on each single serving portion of an edible;

75 a. If centered horizontally on an edible, the height and width of the universal symbol shall be of a size that is at
76 least 25% of the single serving’s width, but not less than 1/16 inch by 1/16 inch;

77 b. If centered vertically on an edible, the height and width of the universal symbol shall be of a size that is at least
78 25% of the single serving’s height, but not less than 1/16 inch by 1/16 inch; and

79 3. Used only by MMTCs licensed by the department.

80 (10) Tetrahydrocannabinol (THC) content in edibles shall meet the following requirements:

81 (a) A multi-serving edible may not contain more than 200 milligrams of THC. A single serving edible, or a single
82 serving portion of a multi-serving edible, may not exceed 10 milligrams of THC.

83 (b) Edibles may have a potency variance of up to 15 percent from the 200 milligram and 10 milligram THC
84 thresholds in paragraph (10)(a).

85 (11) In addition to the food sanitation requirements in Chapter 500, F.S., and rules adopted pursuant to that
86 chapter, an MMTC shall ensure that:

87 (a) All edibles are shelf stable. For purposes of this rule, “shelf stable” means that the edible can be safely stored
88 at room temperature in a sealed container and does not require refrigeration after opening;

89 (b) Edibles are not to be dispensed after the labeled expiration date. Expired edibles shall be disposed of in
90 accordance with the MMTC Marijuana Waste Management and Disposal rule;

91 (c) Edibles on display in a dispensing facility are contained in a secure, locked case, cabinet, or container;

92 (d) Edibles and edible ingredients are stored, displayed, transported and handled in a sanitary manner and under
93 such conditions and temperatures to protect against contaminants unsafe for human consumption as defined by the
94 CMTL Definitions rule; and

95 (e) Edibles and edible ingredients are protected from dust, insects, rodents, or other vermin, toxic materials,
96 unclean equipment and utensils, germs, flooding by sewage, and overhead leakage.

97 (12) Except as provided herein, an MMTC may not sell, offer, or dispense any other food or beverages to its
98 customers, other than complimentary water.

99 (13) An MMTC must immediately institute recall procedures upon discovery or receipt of written notice that a
100 recall of edibles is required in accordance with s. 381.986(8)(e)11.d., F.S. Recall procedures shall include direct
101 communication of the recall to all affected qualified patients and caregivers and a press release. The press release must
102 be published in a publication of general circulation in the geographical area in which the recalled edibles were
103 dispensed and on the MMTCs website. The direct communication and press release must include, at a minimum:

104 (a) The product name and batch number of the recalled edibles;

105 (b) The specific reason for the recall;

106 (c) The location of the dispensing facilities that dispensed the recalled edibles;

107 (d) The date range that the recalled edibles were dispensed;

108 (e) An instruction not to consume the recalled edibles;

109 (f) An explanation of how affected qualified patients or caregivers can return the recalled edibles; and

110 (g) The contact information of the MMTC for communications regarding the recall.

111 (14) An MMTC must provide written notice to the department of any disciplinary action proposed by the
112 Department of Agriculture and Consumer Services in connection with the MMTC's permit to operate as a food
113 establishment. Such notification by the MMTC must be provided to the department within one business day of
114 receiving an administrative complaint, a stop-sale order, a stop-use order, a release order, a destruction order, a notice
115 of non-compliance, a permit suspension or revocation, or an immediate final order for any alleged violations of
116 Chapter 500, F.S., or any rules adopted pursuant to that chapter.

117 (15) If an MMTC has obtained prior approval of a usable product that now meets the definition of edible, the
118 MMTC must comply with the variance request procedure in Rule 64-4.023, F.A.C., and obtain department approval
119 of the edible, which shall include packaging and labeling that complies with the MMTC Packaging and Labeling rule.
120 An MMTC shall have six months from the effective date of this rule to obtain such approval and to discontinue
121 dispensation of usable products and packaging that have not received department approval as an edible through the
122 variance request procedure.

123 (16) Prior to December 31, 2026, the department shall review this rule and amend, modify or repeal the rule if it
124 is determined to create barriers to entry for private business competition, is duplicative, outdated, obsolete, overly
125 burdensome, or imposes excessive costs. In the event the department fails to complete this rule review, the department
126 shall begin the rule repeal process in accordance with chapter 120, F.S.

127 Rulemaking Authority 381.986(8)(e)8., 381.986(8)(k) FS. Law Implemented 386.986(1)(d), 381.986(8)(e),
128 381.986(8)(f), 381.986(8)(g) FS. History—New.