Chapter 5 – Food Safety

Rules Subchapter 1

Manufactured Food Rule

1.0 Authority

This rule is adopted pursuant to 18 V.S.A. §§ 4303 and 4353.

2.0 Purpose

This rule provides the requirements for the safe and sanitary manufacturing, packing, holding, and distributing of human food offered for sale in Vermont.

3.0 Scope

This rule applies to food manufacturing establishments, as defined in 18 V.S.A. § 4301(a)(7). This rule does not pertain to food service establishments, as defined by 18 V.S.A. § 4301(a)(8), or to establishments that process food solely under the regulatory oversight of the Vermont Agency of Agriculture, Food, & Markets, or the Vermont Cannabis Control Board.

4.0 Definitions

4.1 Words and phrases used in this rule and not defined herein shall have the meaning given to them in 18 V.S.A. Chapter 85 and Title 21 Chapter I of the Code of Federal Regulations (C.F.R.). In the event of inconsistency between meanings given in 18 V.S.A. Chapter 85 and the Title 21 Chapter I of the C.F.R., Title 21 Chapter I of the C.F.R. shall apply, except where meanings given in 18 V.S.A. Chapter 85 serve to narrow, limit, or restrict the applicability of a word or phrase. In such cases, the narrower meaning shall apply.

4.1.1 “Acid foods or acidified food” means foods that have an equilibrium pH of 4.6 or below.

4.1.2 “Bakery product” means products made wholly or partially with flour such as loaf breads, rolls, biscuits, cakes (including celebration cakes such as for weddings or birthdays), pastries, cookies, or fruit pies.

4.1.3 “C.F.R.” means Code of Federal Regulations. Citations in this Code to the CFR refer sequentially to the Title, Part, and Section numbers, such as 40

CFR 180.194 refers to Title 40, Part 180, Section 194.

4.1.4 "Cottage food operation" means a food manufacturing establishment where a cottage food product is produced.

4.1.5 "Cottage food operator" means any person who produces or packages cottage food products solely in the home kitchen of the person's private residential dwelling or a kitchen on the person's personal property.

4.1.6 "Cottage food product" means food sold by a cottage food operator that does not require refrigeration or time or temperature control for safety, such as:

4.1.6.1 nonpotentially hazardous baked goods;

4.1.6.2 candy;

4.1.6.3 jams and jellies;

4.1.6.4 dry herbs;

4.1.6.5 trail mix;

4.1.6.6 granola;

4.1.6.7 cereal;

4.1.6.8 mixed nuts;

4.1.6.9 flavored vinegar;

4.1.6.10 popcorn;

4.1.6.11 coffee beans;

4.1.6.12 dry tea;

4.1.6.13 home-canned pickles, vegetables, or fruits having an equilibrium pH value of 4.6 or lower or a water activity value of 0.85 or less that are made using recipes:

4.1.6.13.1 approved by the National Center for Home Food Preservation; or

4.1.6.13.2 reviewed by a food processing authority for safety; and

4.1.6.14 any other goods defined by the Commissioner in policy or pursuant to law.

4.1.7 "Department" means the Vermont Department of Health.

4.1.8 "FDA" means the U.S. Food and Drug Administration.

4.1.9 "Food" means any article of food, drink, confectionery, or condiment for human consumption, whether simple, mixed, or compound, and all substances and ingredients used in preparation thereof.

4.1.10 "Food manufacturing establishment" or "food processor" means all buildings, rooms, basements, cellars, lofts, or other premises or part thereof used, occupied, or maintained for the purpose of manufacturing, preparing, packing, canning, bottling, keeping, storing, handling, serving, or distributing food for sale. A food manufacturing establishment shall include food processors, bakeries, distributers, and warehouses. A food manufacturing establishment shall not include a place where only maple syrup or maple products, as defined in 6 V.S.A. § 481, are prepared for human consumption.

4.1.11 "Isolated" means enclosed such that cross-contamination via air-to-surface or surface-to-surface is not possible.

4.1.12 "License" means the document issued by the Department of Health that authorizes a person to operate a food manufacturing establishment.

4.1.13 "License exemption" and "license exempt" means a food manufacturing establishment that is exempt from the licensing fee.

4.1.14 "Low-acid food" means any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (aw) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods.

4.1.15 "Nonpotentially hazardous baked good" means a bakery product that can be stored at room temperature without the risk of growth of

microorganisms that could cause foodborne illness.

4.1.16 "Plan review" means the submission of blueprints, drawings, or plans for proposed new construction, renovation, or remodeling of a food processing facility.

4.1.17 "Process Authority Review" means a product review conducted by a person(s) or organization(s) having expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions.

4.1.18 "Processed food" means any food other than a raw agricultural commodity and includes any raw agricultural commodity that has been subject to processing, such as canning, cooking, freezing, dehydration, grinding, churning, separating, extracting, packaging, or milling, but does not mean the sorting, trimming, cleaning, or water-rinsing of food.

4.1.19 "Significant renovation" means a physical change to a facility or portion of a facility, including the following:

4.1.19.1 Replacing or upgrading any major system, such as the electrical, plumbing, heating, ventilation, or air-conditioning systems;

4.1.19.2 Demolition of the interior or exterior of a building or portion of the building; or

4.1.19.3 Replacement, demolition, or installation of interior walls and partitions, whether fixed or movable.

4.1.20 "THC" means tetrahydrocannabinol.

4.1.21 "Time or temperature control for safety" or "TCS" has the same meaning as the term "time/temperature control for safety food" as defined in the FDA 2022 Food Code, January 18, 2023 version.

4.1.22 "Variance" means a written document issued by the Department of Health that authorizes a modification or waiver of one or more requirements of this Rule if, in the opinion of the Department of Health, a health hazard or nuisance will not result from the modification or waiver.

4.1.23 "Water activity (aw)" means a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

5.0 License Requirements

5.1 General Provisions

5.1.1 A person shall not maintain or operate a food processing or food manufacturing establishment unless they receive a license for that establishment issued by the Department pursuant to 18 V.S.A. §4351.

5.1.2 Each individual establishment shall require a separate license, regardless of ownership. A food manufacturing establishment license expires annually, unless revoked earlier by the Department.

5.1.3 A license shall not be transferred.

5.1.3.1 When a licensed establishment is sold, the corporation changes, or the establishment relocates, the former licensee shall return the license for that establishment to the Department.

5.1.3.2 When a food manufacturing establishment changes proprietors, the new proprietor of that establishment must apply for and receive a new license before operating the business.

5.2 License Application

5.2.1 A person seeking licensure for an establishment shall submit the following to the Department for review at least 30 days before the expected start of operation:

5.2.1.1 A completed Application for License to Operate a Food and Lodging Establishment, found on the Department's website; and

5.2.1.2 A payment for the applicable fees pursuant to 18 V.S.A. §4353.

5.2.2 Additional documentation shall be submitted when applicable and upon request by the Department, including the following:

5.2.2.1 Wastewater system documentation and permits from the Vermont Agency of Natural Resources;

5.2.2.2 Water system documentation for water systems requiring a permit from the Vermont Agency of Natural Resources;

5.2.2.3 Local permit or zoning approval for proposed operation; and

5.2.2.4 Documentation of Process Authority Review for low-acid canned foods, acidified foods, and products where the Department has requested documentation that there are no biological concerns with the food production process.

5.2.3 Prior to any new construction or significant renovation of an existing licensed facility, a licensee shall submit to the Department a plan review documenting proposed changes and the licensee shall return the license for that establishment to the Department and re-apply for a new license.

5.3 Variances

5.3.1 A variance may be granted by the Department to modify or waive one or more requirements of this rule if the Department determines that a health hazard, safety hazard, or nuisance will not result from the variance.

5.3.2 The person requesting a variance shall submit the following to the Department:

5.3.2.1 A written statement of the proposed variance from the regulatory requirement;

5.3.2.2 Documentation of how the proposed variance addresses public health hazards at least at the same level of protection as that of the original requirement; and

5.3.2.3 Any other relevant information requested by the Department.

5.3.3 For each variance granted, the licensee shall:

5.3.3.1 Follow the plans and procedures approved by the Department;

5.3.3.2 Maintain a permanent record of the variance at the establishment; and

5.3.3.3 Maintain and provide to the Department, upon request, records that demonstrate that the variance is being followed.

5.4 THC Prohibited

5.4.1 A food processor license issued by the Department of Health does not permit manufacturing, adding, using, storing, or handling THC or products containing THC.

5.4.2 A food processor licensed by the Department of Health may only manufacture, use, store, and handle food in a location that is physically isolated from any area that contains THC or products containing THC, and in such a manner as to prevent THC cross-contamination.

6.0 Requirements for Operating Under a Department of Health License Exemption

6.1 In each calendar year on or before a date established by the Department, a food manufacturing establishment claiming a license exemption shall submit a licensing exemption filing to the Department containing such information requested by the Department to demonstrate compliance with this Rule and attesting to completion of the training required in accordance with 18 V.S.A. § 4303(a)(7) and Section 6.2.2 of this Rule.

6.1.1 The following food manufacturing establishments are exempt from the requirement to obtain a license: :

6.1.1.1 A non-bakery food manufacturing establishment that has gross annual sales of $10,000 or less; and

6.1.1.2 A cottage food operation, as defined in this rule, that has gross annual sales of $30,000 or less from the sale of cottage food products.

6.1.2 If a cottage food operator is making a food product that is not specified in Sections 4.1.6.1 – 4.1.6.13 or in Department policy or is unclear whether the food product being manufactured falls within the definition of a cottage food product, the cottage food operator may submit a request to the Department for a determination regarding whether the product the cottage food operator is making is a cottage food.

6.2 A food manufacturing establishment that is exempt from the Vermont Department of Health's licensing requirement is required to comply with all other applicable provisions of the law and this rule, including the labeling requirements listed in Section 6.2.1 and training requirements listed in Section 6.2.2.

6.2.1 Labeling Requirements for License Exempt Food Manufacturing Establishments

6.2.1.1 A licensed exempt food manufacturing establishment shall label products for sale with the following information:

6.2.1.1.1 The name and address of the operation;

6.2.1.1.2 The name of the food product;

6.2.1.1.3 The ingredients of the food product, in descending order of predominance by weight;

6.2.1.1.4 The net weights or net volumes of the food product;

6.2.1.1.5 Allergen information as specified by federal labeling requirements;

6.2.1.1.6 Nutritional labeling as specified by federal labeling requirements is required if any nutrient content claim, health claim, or other nutritional information is provided; and

6.2.1.1.7 The following statement printed in at least 10-point type in a color that provides a clear contrast to the background label: "Made in a home kitchen not inspected by the Vermont Department of Health."

6.2.2 Training Requirements for License Exempt Food Manufacturing Establishments

6.2.2.1 Both before beginning manufacturing and annually thereafter, a license exempt food manufacturing establishment shall complete training approved by the Department in food handling, cleanliness, sanitation, and healthfulness and attest to the completion of the training as required by Section 6.1 of this Rule.

7.0 Incorporation by Reference

7.1 This rule incorporates by reference the FDA Food Safety Modernization Act (FSMA) Final Rule on Preventive Controls for Human Food 21 C.F.R. § 117 (2015), not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with this rule.

7.2 This rule incorporates by reference the FDA FSMA Final Rule on Sanitary Transportation of Human and Animal Food 21 C.F.R. § 1 (2016), not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with this rule.

7.3 This rule incorporates by reference the FDA FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration rule 21 C.F.R. § 121 (2016), not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with this rule.

7.4 This rule incorporates by reference the definition of "time/temperature control for safety food" from the FDA 2022 Food Code, January 18. 2023 version, not including any further editions or amendments thereof.

7.5 All licensees and permit holders shall comply with all federal regulations that are applicable to the type of food processing that they conduct. Such regulations include the following:

7.5.1 Food Processing

7.5.1.1 21 C.F.R. Part 109: Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Materials;

7.5.1.2 21 C.F.R. Part 113: Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers;

7.5.1.3 21 C.F.R. 108.35: Emergency Permit Control - Thermal Processing of Low-Acid Foods Packaged in Hermetically Sealed Containers;

7.5.1.4 21 C.F.R. Part 114: Acidified Foods;

7.5.1.5 21 C.F.R. 108.25: Emergency Permit Control - Acidified Foods;

7.5.1.6 21 C.F.R. Part 117: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food;

7.5.1.7 21 C.F.R. Part 120: Hazard Analysis and Critical Control Point (HACCP) Systems;

7.5.1.8 21 C.F.R. Part 123: Fish and Fishery Products;

7.5.2 Food Labeling

7.5.2.1 21 C.F.R. Part 1: General Enforcement Regulations (§1.20-1.24): Subpart O (§1.900-1.934);

7.5.2.2 21 C.F.R. Part 100: General (ONLY § 100.155);

7.5.2.3 21 C.F.R. Part 101: Food Labeling (except § 101.69 and § 101.108);

7.5.2.4 21 C.F.R. Part 102 (except § 102.19): Common or Usual Name for Non-standardized Foods;

7.5.2.5 21 C.F.R. Part 104: Nutritional Quality Guidelines for Foods;

7.5.3 Standards of Identity

7.5.3.1 21 C.F.R. Part 130: Food Standards: General (except 130.5-6, 130.17);

7.5.3.2 21 C.F.R. Part 136: Bakery Products;

7.5.3.3 21 C.F.R. Part 137: Cereal Flours and Related Products;

7.5.3.4 21 C.F.R. Part 139: Macaroni and Noodle Products;

7.5.3.5 21 C.F.R. Part 145: Canned Fruits;

7.5.3.6 21 C.F.R. Part 146: Canned Fruit Juices;

7.5.3.7 21 C.F.R. Part 150: Fruit Butters, Jellies, Preserves and Related Products;

7.5.3.8 21 C.F.R. Part 152: Fruit Pies;

7.5.3.9 21 C.F.R. Part 155: Canned Vegetables;

7.5.3.10 21 C.F.R. Part 156: Vegetable Juice;

7.5.3.11 21 C.F.R. Part 158: Frozen Vegetables;

7.5.3.12 21 C.F.R. Part 160: Eggs and Egg Products;

7.5.3.13 21 C.F.R. Part 161: Fish and Shellfish;

7.5.3.14 21 C.F.R. Part 163: Cacao Products;

7.5.3.15 21 C.F.R. Part 164: Tree Nut and Peanut Products;

7.5.3.16 21 C.F.R. Part 165: Beverages;

7.5.3.17 21 C.F.R. Part 166: Margarine;

7.5.3.18 21 C.F.R. Part 168: Sweeteners and Table Syrups (except 168.140);

7.5.3.19 21 C.F.R. Part 169: Food Dressings and Flavorings;

7.5.4 Food Additives

7.5.4.1 21 C.F.R. Part 170: Food Additives (except § 170.6, 170.15, 170.17);

7.5.4.2 21 C.F.R. Part 172: Food Additives Permitted for Direct Addition to Food for Human Consumption;

7.5.4.3 21 C.F.R. Part 173: Secondary Direct Food Additives Permitted in Food for Human Consumption;

7.5.4.4 21 C.F.R. Part 174: Indirect Food Additives: General;

7.5.4.5 21 C.F.R. Part 175: Indirect Food Additives: Adhesives and Components of Coatings;

7.5.4.6 21 C.F.R. Part 176: Indirect Food Additives: Paper and Paperboard Components;

7.5.4.7 21 C.F.R. Part 177: Indirect Food Additives: Polymers;

7.5.4.8

7.5.4.9 21 C.F.R. Part 178: Indirect Food Additives: Adjuvants, Production Aids and Sanitizers;

7.5.4.10 21 C.F.R. Part 180: Food Additives Permitted in Food or in Contact with Food on an Interim Basis Pending Additional Study;

7.5.4.11 21 C.F.R. Part 181: Prior-Sanctioned Food Ingredients;

7.5.4.12 21 C.F.R. Part 182: Substances Generally Recognized as Safe;

7.5.4.13 21 C.F.R. Part 184: Direct Food Substances Affirmed as Generally Recognized as Safe;

7.5.4.14 21 C.F.R. Part 186: Indirect Food Substances Affirmed as Generally Recognized as Safe;

7.5.4.15 21 C.F.R. Part 189: Substances Prohibited from Use in Human Food.

7.5.5 Color Additives

7.5.5.1 21 C.F.R. Part 70: Color Additives (only § 70.20-70.25);

7.5.5.2 21 C.F.R. Part 73: Listing of Colors Exempt from Certification (only § 73.1-73.615);

7.5.5.3 21 C.F.R. Part 74: Listing of Color Additives Subject to Certification (only § 74.101-706);

7.5.5.4 21 C.F.R. Part 81: General Restrictions for Provisional Color Additives for Use in Foods, Drugs and Cosmetics;

7.5.5.5 21 C.F.R. Part 82: Listing of Certified Provisionally Listed Colors and Specifications (only § 82.3-82.706).

7.5.6 Intentional Adulteration

7.5.6.1 21 C.F.R. 121: Mitigation Strategies to Protect Food Against Intentional Adulteration.

7.5.7 Federal Food, Drug and Cosmetic Act

7.5.7.1 Definitions: 21 U.S.C. § 321(f), (k), (m);

7.5.7.2 Prohibited Acts: 21 U.S.C. § 331(e), (f), (k);

7.5.7.3 Records of Interstate Shipments: 21 U.S.C. § 373.