EMERGENCY RULE # _____

Emergency Filing - Coversheet

Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the "Rule on Rulemaking" (CVR 04-000-001) adopted by the Office of the Secretary of State, this emergency filing will be considered complete upon filing and acceptance of these forms with the Office of the Secretary of State, the Legislative Committee on Administrative Rules and a copy with the Chair of the Interagency Committee on Administrative Rules.

All forms shall be submitted to the Office of the Secretary of State, no later than 3:30 pm on the last scheduled day of the work week.

The data provided in text areas of these forms will be used to generate a notice of rulemaking in the portal of "Proposed Rule Postings" online, and the newspapers of record if the rule is marked for publication. Publication of notices will be charged back to the promulgating agency.

This emergency rule may remain in effect for a total of 180 days from the date it first takes effect.

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801(b)(11) for a definition), I believe there exists an imminent peril to public health, safety or welfare, requiring the adoption of this emergency rule.

The nature of the peril is as follows (*PLEASE USE ADDITIONAL SHEETS IF SPACE IS INSUFFICIENT*). Act 42 (2025) Sec. 6 requires the Department of Health to adopt an emergency rule for the purpose of implementing and administering the Act prior to regular rulemaking.

I approve the contents of this filing entitled:

Manufactured Food Emergency Rule

/s/ Kristin L. McClure _____ , on 12/22/25

(signature) (date)

Printed Name and Title:

RECEIVED BY: _____

- ☐ Coversheet
- ☐ Adopting Page
- ☐ Economic Impact Analysis
- ☐ Environmental Impact Analysis
- ☐ Strategy for Maximizing Public Input
- ☐ Scientific Information Statement (if applicable)
- ☐ Incorporated by Reference Statement (if applicable)
- ☐ Clean text of the rule (Amended text without annotation)
- ☐ Annotated text (Clearly marking changes from previous rule)

Kristin McClure, Deputy Secretary, Agency of Human Services

1. TITLE OF RULE FILING:
   Manufactured Food Emergency Rule
2. ADOPTING AGENCY:
   Agency of Human Services - Vermont Department of Health
3. PRIMARY CONTACT PERSON:
   (A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE).

   Name: Jessica Schifano, Policy Director

   Agency: Agency of Human Services - Vermont Department of Health

   Mailing Address: 280 State Street, Building C

   Waterbury, VT 05671

   Telephone: 802-798-6756 Fax:

   E-Mail: jessica.schifano@vermont.gov

   Web URL*(WHERE THE RULE WILL BE POSTED)*:
   https://www.healthvermont.gov/laws-regulations/laws/rules-public-comment
4. SECONDARY CONTACT PERSON:
   (A SPECIFIC PERSON FROM WHOM COPIES OF FILINGS MAY BE REQUESTED OR WHO MAY ANSWER QUESTIONS ABOUT FORMS SUBMITTED FOR FILING IF DIFFERENT FROM THE PRIMARY CONTACT PERSON).

   Name: Sarah Gregorek, Executive Assistant

   Agency: Agency of Human Services - Vermont Department of Health

   Mailing Address: 280 State Street, Building C

   Waterbury, VT 05671

   Telephone: 802-863-7280 Fax:

   E-Mail: sarah.gregorek@vermont.gov
5. RECORDS EXEMPTION INCLUDED WITHIN RULE:
   (DOES THE RULE CONTAIN ANY PROVISION DESIGNATING INFORMATION AS CONFIDENTIAL; LIMITING ITS PUBLIC RELEASE; OR OTHERWISE EXEMPTING IT FROM INSPECTION AND COPYING?) No

   IF YES, CITE THE STATUTORY AUTHORITY FOR THE EXEMPTION:

   PLEASE SUMMARIZE THE REASON FOR THE EXEMPTION:

6. LEGAL AUTHORITY / ENABLING LEGISLATION:
(THE SPECIFIC STATUTORY OR LEGAL CITATION FROM SESSION LAW INDICATING WHO THE ADOPTING ENTITY IS AND THUS WHO THE SIGNATORY SHOULD BE. THIS SHOULD BE A SPECIFIC CITATION NOT A CHAPTER CITATION).
Act 42 (2025) Sec. 6 requires the Department of Health to adopt an emergency rule for the purpose of implementing and administering the Act prior to regular rulemaking.

7. EXPLANATION OF HOW THE RULE IS WITHIN THE AUTHORITY OF THE AGENCY:
18 V.S.A. §4303(a) states, "The Commissioner shall adopt rules pursuant to 3 V.S.A. chapter 25 to establish minimum standards for the safe and sanitary operation of food or lodging establishments or children's camps or any combination thereof and for their administration and enforcement. The rules shall require that an establishment be constructed, maintained, and operated with strict regard for the health of the employees and the public…"

18 V.S.A. §4353 states, "(a)The Commissioner may establish by rule any requirement the Department needs to determine the applicable categories or exemptions for licenses. "

Act 42 (2025) states that "Pending the adoption of permanent rules pursuant to 3 V.S.A. chapter 25 to implement the provisions of this act, the Commissioner of Health shall adopt emergency rules pursuant to 3 V.S.A. § 844, which shall be deemed to meet the emergency rulemaking standard in 3 V.S.A. § 844(a)."

3 V.S.A. §801(b)(11) states "Adopting authority" means,for agencies that are attached to the Agencies of Administration, of Commerce and Community Development,of Natural Resources, of Human Services, and of Transportation, or any of their components, the secretaries of those agencies; for agencies attached to other departments or any of their components, the

commissioners of those departments.

8. CONCISE SUMMARY (**150 WORDS OR LESS**):

The purpose of the rule is to provide the requirements for the safe and sanitary manufacturing, packing, holding, and distributing of human food offered for sale in Vermont. This rulemaking does the following:

1) Defines cottage food operation, cottage food operator, and cottage food product; non-potentially hazardous baked good, and time or temperature control for safety;

2) Substitutes the more narrow bakery product exemption for a broader exemption categorized as the cottage food exemption and raises the exemption threshold of gross annual sales to $30,000;

3) Amends the existing exemption filing requirement frequency from prior to operation to an annual filing;

4) Creates a required annual training for license-exempt food manufacturers; and

5) Creates a process for cottage food operators to submit requests to the Department for determination whether the product they are making is a cottage food.

9. EXPLANATION OF WHY THE RULE IS NECESSARY:

This rulemaking is necessary for compliance with Act 42 (2025) that requires the Department to adopt emergency rules pursuant to 3 V.S.A. § 844, which shall be deemed to meet the emergency rulemaking standard in 3 V.S.A. § 844(a).

10. EXPLANATION OF HOW THE RULE IS NOT ARBITRARY AS DEFINED IN 3 V.S.A. § 801(b)(13(A):

The changes in the rule are not arbitrary because they are tailored to comply with the specific requirements of Act 42 (2025) that was established to create and implement the cottage food exemption.

11. LIST OF PEOPLE, ENTERPRISES AND GOVERNMENT ENTITIES AFFECTED BY THIS RULE:

Cottage food operators manufacturing up to $30,000 gross annual sales of cottage foods, license-exempt manufacturers producing up to $10,000 gross annual sales of non-bakery products, and potential indirect impacts on Agency of Commerce and Community Development(ACCD).

12. BRIEF SUMMARY OF ECONOMIC IMPACT (150 WORDS OR LESS):

The raised exemption theshold frees licensed-exempt producers manufacturing up to $30,000 gross annual sales of cottage foods and/or $10,000 gross annual sales of non-bakery products from the obligation to obtain a license, pay associated licensure fees, and obtain a commerical facility thereby creating an economic savings. However, an annual training and filing requirement may have a small economic cost to the extent time and resources are diverted to these requirements. There are no anticipated direct impacts on ACCD. Lessening the economic burden on small food manufacturers may have indirect impacts on ACCD to the extent that there is an increase in new small business selling licensed-exempt food products and their participation in ACCD's programming.

13. A HEARING IS NOT SCHEDULED.

14. HEARING INFORMATION
(THE FIRST HEARING SHALL BE NO SOONER THAN 30 DAYS FOLLOWING THE POSTING OF NOTICES ONLINE).

IF THIS FORM IS INSUFFICIENT TO LIST THE INFORMATION FOR EACH HEARING PLEASE ATTACH A SEPARATE SHEET TO COMPLETE THE HEARING INFORMATION NEEDED FOR THE NOTICE OF RULEMAKING.

Date:

Time: AM

Street Address:

Zip Code:

URL for Virtual:

Date:

Time: AM

Street Address:

Zip Code:

URL for Virtual:

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15. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING): N/A
16. EMERGENCY RULE EFFECTIVE: 12/29/2025
17. EMERGENCY RULE WILL REMAIN IN EFFECT UNTIL *(A DATE NO LATER THAN 180 DAYS FOLLOWING ADOPTION OF THIS EMERGENCY RULE)*: 06/27/2026
18. NOTICE OF THIS EMERGENCY RULE SHOULD NOT BE PUBLISHED IN THE WEEKLY NOTICES OF RULEMAKING IN THE NEWSPAPERS OF RECORD.
19. KEYWORDS (PLEASE PROVIDE AT LEAST 3 KEYWORDS OR PHRASES TO AID IN THE SEARCHABILITY OF THE RULE NOTICE ONLINE).

    Cottage food

    Cottage food operator

    License exempt

    Food manufacturing establishment

Adopting Page

Instructions:

This form must accompany each filing made during the rulemaking process:

Note: To satisfy the requirement for an annotated text, an agency must submit the entire rule in annotated form with proposed and final proposed filings. Filing an annotated paragraph or page of a larger rule is not sufficient. Annotation must clearly show the changes to the rule.

When possible the agency shall file the annotated text, using the appropriate page or pages from the Code of Vermont Rules as a basis for the annotated version. New rules need not be accompanied by an annotated text.

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1. TITLE OF RULE FILING:
   Manufactured Food Emergency Rule
2. ADOPTING AGENCY:
   Agency of Human Services - Vermont Department of Health
3. TYPE OF FILING (*PLEASE CHOOSE THE TYPE OF FILING FROM THE DROPDOWN MENU BASED ON THE DEFINITIONS PROVIDED BELOW*):

   - **AMENDMENT -** Any change to an already existing rule, even if it is a complete rewrite of the rule, it is considered an amendment as long as the rule is replaced with other text.
   - **NEW RULE -** A rule that did not previously exist even under a different name.
   - **REPEAL** - The removal of a rule in its entirety, without replacing it with other text.

   This filing is **AN AMENDMENT OF AN EXISTING RULE .**

4. LAST ADOPTED (*PLEASE PROVIDE THE SOS LOG#, TITLE AND EFFECTIVE DATE OF THE LAST ADOPTION FOR THE EXISTING RULE)*:
   24-005; Manufactured Food Rule; 8/1/2024.

Economic Impact Analysis

Instructions:

In completing the economic impact analysis, an agency analyzes and evaluates the anticipated costs and benefits to be expected from adoption of the rule; estimates the costs and benefits for each category of people enterprises and government entities affected by the rule; compares alternatives to adopting the rule; and explains their analysis concluding that rulemaking is the most appropriate method of achieving the regulatory purpose. If no impacts are anticipated, please specify "No impact anticipated" in the field.

Rules affecting or regulating schools or school districts must include cost implications to local school districts and taxpayers in the impact statement, a clear statement of associated costs, and consideration of alternatives to the rule to reduce or ameliorate costs to local school districts while still achieving the objectives of the rule (see 3 V.S.A. § 832b for details).

Rules affecting small businesses (excluding impacts incidental to the purchase and payment of goods and services by the State or an agency thereof), must include ways that a business can reduce the cost or burden of compliance or an explanation of why the agency determines that such evaluation isn't appropriate, and an evaluation of creative, innovative or flexible methods of compliance that would not significantly impair the effectiveness of the rule or increase the risk to the health, safety, or welfare of the public or those affected by the rule.

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1. TITLE OF RULE FILING:

   Manufactured Food Emergency Rule

2. ADOPTING AGENCY:

   Agency of Human Services - Vermont Department of Health

3. CATEGORY OF AFFECTED PARTIES:

   LIST CATEGORIES OF PEOPLE, ENTERPRISES, AND GOVERNMENTAL ENTITIES POTENTIALLY AFFECTED BY THE ADOPTION OF THIS RULE AND THE ESTIMATED COSTS AND BENEFITS ANTICIPATED:

   ACCD: No anticipated direct impact associated with this rulemaking. Lessening the economic burden on small food manufacturers may have indirect impacts on ACCD to the extent that there is an increase in new small business selling licensed-exempt food products and their participation in ACCD's programming.

License-exempt producers manufacturing up to $30,000 gross annual sales of cottage foods and/or $10,000 gross annual sales of non-bakery products: The raised exemption theshold frees these individuals from the obligation to obtain a license, pay associated licensure fees, and obtain a commerical facility thereby creating an economic savings. A home bakery license costs $100/yr and a small manufacturing license costs $175/yr. The approximate cost of renting a commercial manufacturing facility is $25-35/hour depending on equipment needed. A one day/month kitchen rental would be estimated at approximately $3,500/year. Because these are very small enterprises making on average $5,000/year, the Department does not estimate the cost of purchasing a manufacturing facility because these are very small businesses making on average $5K/year. Based on these approximations, the estimated savings of is approproximated $3,675/year. However, an annual training and filing requirement may have a small economic cost to the extent time and resources are diverted to these requirements.

Department of Health: There is an anticipated minimal impact to revenues for the Department's Food and Lodging Fee Fund. The Department does not collect information about the gross receipts of food manufacturing establishments or establishments that may fall under the newly-created definition of cottage food operators, making it challenging to assign exact impacts to the fee exemptions. Additionally, there is a de minimus impact on the Department to create a training program and determination process of license-exempt food products.

4. IMPACT ON SCHOOLS:

INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON PUBLIC EDUCATION, PUBLIC SCHOOLS, LOCAL SCHOOL DISTRICTS AND/OR TAXPAYERS CLEARLY STATING ANY ASSOCIATED COSTS:

There is no anticipated impact on schools.

5. ALTERNATIVES: *CONSIDERATION OF ALTERNATIVES TO THE RULE TO REDUCE OR AMELIORATE COSTS TO LOCAL SCHOOL DISTRICTS WHILE STILL ACHIEVING THE OBJECTIVE OF THE RULE.*

   This rulemaking does not have an anticipated effect on schools, therefore alternatives have not been considered.

6. IMPACT ON SMALL BUSINESSES:
   INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON SMALL BUSINESSES (EXCLUDING IMPACTS INCIDENTAL TO THE PURCHASE AND PAYMENT OF GOODS AND SERVICES BY THE STATE OR AN AGENCY THEREOF):

   License-exempt producers manufacturing up to $30,000 gross annual sales of cottage foods and/or $10,000 gross annual sales of non-bakery products: The raised exemption theshold frees these individuals from the obligation to obtain a license and pay associated licensure fees, thereby creating an economic savings. However, an annual training and filing requirement may have a small economic cost to the extent time and resources are diverted to these requirements.

7. SMALL BUSINESS COMPLIANCE: *EXPLAIN WAYS A BUSINESS CAN REDUCE THE COST/BURDEN OF COMPLIANCE OR AN EXPLANATION OF WHY THE AGENCY DETERMINES THAT SUCH EVALUATION ISN'T APPROPRIATE.*

   The cost/burden on small businesses to comply with the license-exempt requirements are minimal and are explicitly required by Act 42 (2025). The annual training and filing requirements are necessary for the protections to public health.

8. COMPARISON:
   COMPARE THE IMPACT OF THE RULE WITH THE ECONOMIC IMPACT OF OTHER ALTERNATIVES TO THE RULE, INCLUDING NO RULE ON THE SUBJECT OR A RULE HAVING SEPARATE REQUIREMENTS FOR SMALL BUSINESS:
   The annual filing and training requirements are explicitly required by Act 42 (2025). There are no alternatives to these mandatory statutory requirements.

9. SUFFICIENCY: *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*

The estimate is based on information available to the Department.

Environmental Impact Analysis

Instructions:

In completing the environmental impact analysis, an agency analyzes and evaluates the anticipated environmental impacts (positive or negative) to be expected from adoption of the rule; compares alternatives to adopting the rule; explains the sufficiency of the environmental impact analysis. If no impacts are anticipated, please specify "No impact anticipated" in the field.

Examples of Environmental Impacts include but are not limited to:

- Impacts on the emission of greenhouse gases
- Impacts on the discharge of pollutants to water
- Impacts on the arability of land
- Impacts on the climate
- Impacts on the flow of water
- Impacts on recreation
- Or other environmental impacts

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1. TITLE OF RULE FILING:

   Manufactured Food Emergency Rule

2. ADOPTING AGENCY:

   Agency of Human Services - Vermont Department of Health

3. GREENHOUSE GAS: *EXPLAIN HOW THE RULE IMPACTS THE EMISSION OF GREENHOUSE GASES (E.G. TRANSPORTATION OF PEOPLE OR GOODS; BUILDING INFRASTRUCTURE; LAND USE AND DEVELOPMENT, WASTE GENERATION, ETC.):*
   No anticipated impact.

4. WATER: *EXPLAIN HOW THE RULE IMPACTS WATER (E.G. DISCHARGE / ELIMINATION OF POLLUTION INTO VERMONT WATERS, THE FLOW OF WATER IN THE STATE, WATER QUALITY ETC.):*
   There may be potential wastewater impacts associated with increased cottage food production. Because cottage food is defined as food produced in a home kitchen, the anticipated economic impact would affect homeowners. Depending on the nature and volume of the food products being manufactured, there could be adverse effects to the existing potable water supply and wastewater system serving the home. Cottage food production may significantly increase the amount of potable water

required for food preparation, that may exceed the capacity of the home's exisiting onsite potable water supply and adversely impact the quantity of the potable water available for use and consumption by household residents. There is no anticipated impact from cottage food producers on public water systems due to typical safety factors utilized in the design of public water systems. Similarly, adding significant bakery wastewater can increase the total volume discharged which the wastewater (septic) system may not be designed to handle, and may also increase the organic strength of the wastewater discharged to the drain field, leading to the possibility of accelerated septic system failure. Cottage food producers with failing septic systems would be a hazard to human health and may impact drinking water wells or surface water bodies. There is no anticipated wastewater impact for cottage food producers on sewer systems due to sewer systems design to handle large volume of wastewater generated by larger populations.

5. LAND: *EXPLAIN HOW THE RULE IMPACTS LAND (E.G. IMPACTS ON FORESTRY, AGRICULTURE ETC.):*
   No anticipated impact.
6. RECREATION: *EXPLAIN HOW THE RULE IMPACTS RECREATION IN THE STATE:*
   No anticipated impact.
7. CLIMATE: *EXPLAIN HOW THE RULE IMPACTS THE CLIMATE IN THE STATE:*
   No anticipated impact.
8. OTHER: *EXPLAIN HOW THE RULE IMPACT OTHER ASPECTS OF VERMONT'S ENVIRONMENT:*
   No anticipated impact.
9. SUFFICIENCY: *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*
   The estimate is based on information from neighboring states with cottage food laws and regulations including the Rhode Island Department of Health and Connecticut Department of Consumer Protection. Additionally, the Department used information from the Association of Food and Drug Officials to conduct our analysis.

Public Input Maximization Plan

Instructions:

Agencies are encouraged to hold hearings as part of their strategy to maximize the involvement of the public in the development of rules. Please complete the form below by describing the agency's strategy for maximizing public input (what it did do, or will do to maximize the involvement of the public).

This form must accompany each filing made during the rulemaking process:

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1. TITLE OF RULE FILING:

   Manufactured Food Emergency Rule

2. ADOPTING AGENCY:

   Agency of Human Services - Vermont Department of Health

3. PLEASE DESCRIBE THE AGENCY'S STRATEGY TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE, LISTING THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO COMPLY WITH THAT STRATEGY:
   The Department is in the final stages of completing formal rulemaking, where there was public notice, a public comment period, and a public hearing.

4. BEYOND GENERAL ADVERTISEMENTS, PLEASE LIST THE PEOPLE AND ORGANIZATIONS THAT HAVE BEEN OR WILL BE INVOLVED IN THE DEVELOPMENT OF THE PROPOSED RULE:

   Vermont licensed food manufacturers, licensed home bakers, and license exempt food processors who previously filed exemption forms in the past.

Incorporation by Reference

THIS FORM IS ONLY REQUIRED WHEN INCORPORATING MATERIALS BY REFERENCE. PLEASE REMOVE PRIOR TO DELIVERY IF IT DOES NOT APPLY TO THIS RULE FILING:

Instructions:

In completing the incorporation by reference statement, an agency describes any materials that are incorporated into the rule by reference and how to obtain copies.

This form is only required when a rule incorporates materials by referencing another source without reproducing the text within the rule itself (e.g. federal or national standards, or regulations).

Incorporated materials will be maintained and available for inspection by the Agency.

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1. TITLE OF RULE FILING:

   Manufactured Food Emergency Rule

2. ADOPTING AGENCY:

   Agency of Human Services - Vermont Department of Health

3. DESCRIPTION (*DESCRIBE THE MATERIALS INCORPORATED BY REFERENCE*):

   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.

4. FORMAL CITATION OF MATERIALS INCORPORATED BY REFERENCE:
   FDA 2022 Food Code, January 18. 2023 version

5. OBTAINING COPIES: *EXPLAIN WHERE THE PUBLIC MAY OBTAIN THE MATERIAL(S) IN WRITTEN OR ELECTRONIC FORM, AND AT WHAT COST*):

   The FDA 2022 Food Code, January 18 2023 version can be found for free online at a publically available government website.

6. MODIFICATIONS (*PLEASE EXPLAIN ANY MODIFICATION TO THE INCORPORATED MATERIALS E.G., WHETHER ONLY PART OF THE MATERIAL IS ADOPTED AND IF SO, WHICH PART(S)ARE MODIFIED*):

There are no modifications to the incorporated materials.

Run Spell Check

280 State Drive - Center Building
Waterbury, VT 05671-1000

OFFICE OF THE SECRETARY
TEL: (802) 241-0440
FAX: (802) 241-0450

JENNEY SAMUELSON
SECRETARY

KRISTIN MCCLURE
DEPUTY SECRETARY

STATE OF VERMONT
AGENCY OF HUMAN SERVICES

MEMORANDUM

TO: Sarah Copeland Hanzas, Secretary of State

FROM: Jenney Samuelson, Secretary, Agency of Human Services

DATE: November 21, 2024

SUBJECT: Signatory Authority for Purposes of Authorizing Administrative Rules

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I hereby designate Kristin McClure, Deputy Secretary, Agency of Human Services as signatory to fulfill the duties of the Secretary of the Agency of Human Services as the adopting authority for administrative rules as required by Vermont's Administrative Procedures Act, 3. V.S.A § 801 et seq.

CC: KristinMcClure@vermont.gov

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 ~~Code of Federal Regulations~~ Title 21 Chapter I of the C.F.R., ~~the Code of Federal Regulations~~ 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~~l~~ other goods defined by the Commissioner in policy or pursuant to law.

~~4.1.4~~4.1.7 "Department" means the Vermont Department of Health.

~~4.1.5~~4.1.8 "FDA" means the U.S. Food and Drug Administration.

~~4.1.6~~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.

~~4.1.7~~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.

~~4.1.8~~4.1.11 "Isolated" means enclosed such that cross-contamination via air-to-surface or surface-to-surface is not possible.

~~4.1.9~~4.1.12 "License" means the document issued by the Department of Health that authorizes a person to operate a food manufacturing establishment.

~~4.1.10~~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.

~~4.1.11~~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.

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

4.1.134.1.17 "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.

4.1.144.1.18 "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.

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

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

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

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

4.1.20 "THC" means tetrahydrocannabinol.

4.1.164.1.21 "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.

4.1.174.1.22 "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.

~~4.1.18~~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 ~~Prior to operation and i~~In each calendar year on or before a ~~fixed~~ date established by the Department, a food manufacturing establishment claiming a license exemption shall submit ~~the Department's Self-Certification of Licensing Exemption form~~ a licensing exemption filing to the Department containing such information requested by the Department to demonstrate compliance with this~~e~~ Rule~~s~~ 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 R~~r~~ule. ~~The manufacturer is exempt from licensure once the Department confirms, in writing, the receipt of the Self-Certification of Licensing Exemption form~~licensing exemption filing~~.~~

6.1.1 The following food manufacturing establishments are exempt from the requirement to obtain a licens~~ing requirement described in 18 V.S.A. §§ 4353 and 4358~~e:

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 ~~An individual manufacturing and selling bakery products, as defined in this rule, from one's own home kitchen whose average gross retail sales do not exceed $125.00 per week.~~ 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 ~~that~~ regarding whether the product the cottage food operator is~~y are~~ 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

~~6.2.1.2~~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. ~~to the Department.~~

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.

~~7.4~~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:

~~7.4.1~~7.5.1 Food Processing

~~7.4.1.1~~7.5.1.1 21 C.F.R. Part 109: Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Materials;

~~7.4.1.2~~7.5.1.2 21 C.F.R. Part 113: Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers;

~~7.4.1.3~~7.5.1.3 21 C.F.R. 108.35: Emergency Permit Control - Thermal Processing of Low-Acid Foods Packaged in Hermetically Sealed Containers;

~~7.4.1.4~~7.5.1.4 21 C.F.R. Part 114: Acidified Foods;

~~7.4.1.5~~7.5.1.5 21 C.F.R. 108.25: Emergency Permit Control - Acidified Foods;

~~7.4.1.6~~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;

~~7.4.1.7~~7.5.1.7 21 C.F.R. Part 120: Hazard Analysis and Critical Control Point (HACCP) Systems;

~~7.4.1.8~~7.5.1.8 21 C.F.R. Part 123: Fish and Fishery Products;

~~7.4.2~~7.5.2 Food Labeling

~~7.4.2.1~~7.5.2.1 21 C.F.R. Part 1: General Enforcement Regulations (§1.20-1.24): Subpart O (§1.900-1.934);

~~7.4.2.2~~7.5.2.2 21 C.F.R. Part 100: General (ONLY § 100.155);

~~7.4.2.3~~7.5.2.3 21 C.F.R. Part 101: Food Labeling (except § 101.69 and § 101.108);

~~7.4.2.4~~7.5.2.4 21 C.F.R. Part 102 (except § 102.19): Common or Usual Name for Non-standardized Foods;

~~7.4.2.5~~7.5.2.5 21 C.F.R. Part 104: Nutritional Quality Guidelines for Foods;

~~7.4.3~~7.5.3 Standards of Identity

~~7.4.3.1~~7.5.3.1 21 C.F.R. Part 130: Food Standards: General (except 130.5-6, 130.17);

~~7.4.3.2~~7.5.3.2 21 C.F.R. Part 136: Bakery Products;

~~7.4.3.3~~7.5.3.3 21 C.F.R. Part 137: Cereal Flours and Related Products;

~~7.4.3.4~~7.5.3.4 21 C.F.R. Part 139: Macaroni and Noodle Products;

~~7.4.3.5~~7.5.3.5 21 C.F.R. Part 145: Canned Fruits;

~~7.4.3.6~~7.5.3.6 21 C.F.R. Part 146: Canned Fruit Juices;

~~7.4.3.7~~7.5.3.7 21 C.F.R. Part 150: Fruit Butters, Jellies, Preserves and Related Products;

~~7.4.3.8~~7.5.3.8 21 C.F.R. Part 152: Fruit Pies;

~~7.4.3.9~~7.5.3.9 21 C.F.R. Part 155: Canned Vegetables;

~~7.4.3.10~~7.5.3.10 21 C.F.R. Part 156: Vegetable Juice;

~~7.4.3.11~~7.5.3.11 21 C.F.R. Part 158: Frozen Vegetables;

~~7.4.3.12~~7.5.3.12 21 C.F.R. Part 160: Eggs and Egg Products;

~~7.4.3.13~~7.5.3.13 21 C.F.R. Part 161: Fish and Shellfish;

~~7.4.3.14~~7.5.3.14 21 C.F.R. Part 163: Cacao Products;

~~7.4.3.15~~7.5.3.15 21 C.F.R. Part 164: Tree Nut and Peanut Products;

~~7.4.3.16~~7.5.3.16 21 C.F.R. Part 165: Beverages;

~~7.4.3.17~~7.5.3.17 21 C.F.R. Part 166: Margarine;

~~7.4.3.18~~7.5.3.18 21 C.F.R. Part 168: Sweeteners and Table Syrups (except 168.140);

~~7.4.3.19~~7.5.3.19 21 C.F.R. Part 169: Food Dressings and Flavorings;

~~7.4.4~~7.5.4 Food Additives

~~7.4.4.1~~7.5.4.1 21 C.F.R. Part 170: Food Additives (except § 170.6, 170.15, 170.17);

~~7.4.4.2~~7.5.4.2 21 C.F.R. Part 172: Food Additives Permitted for Direct Addition to Food for Human Consumption;

~~7.4.4.3~~7.5.4.3 21 C.F.R. Part 173: Secondary Direct Food Additives Permitted in Food for Human Consumption;

~~7.4.4.4~~7.5.4.4 21 C.F.R. Part 174: Indirect Food Additives: General;

~~7.4.4.5~~7.5.4.5 21 C.F.R. Part 175: Indirect Food Additives: Adhesives and Components of Coatings;

~~7.4.4.6~~7.5.4.6 21 C.F.R. Part 176: Indirect Food Additives: Paper and Paperboard Components;

~~7.4.4.7~~7.5.4.7 21 C.F.R. Part 177: Indirect Food Additives: Polymers;
~~7.4.4.8~~7.5.4.8
~~7.4.4.9~~7.5.4.9 21 C.F.R. Part 178: Indirect Food Additives: Adjuvants, Production Aids and Sanitizers;

~~7.4.4.10~~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;

~~7.4.4.11~~7.5.4.11 21 C.F.R. Part 181: Prior-Sanctioned Food Ingredients;

~~7.4.4.12~~7.5.4.12 21 C.F.R. Part 182: Substances Generally Recognized as Safe;

~~7.4.4.13~~7.5.4.13 21 C.F.R. Part 184: Direct Food Substances Affirmed as Generally Recognized as Safe;

~~7.4.4.14~~7.5.4.14 21 C.F.R. Part 186: Indirect Food Substances Affirmed as Generally Recognized as Safe;

~~7.4.4.15~~7.5.4.15 21 C.F.R. Part 189: Substances Prohibited from Use in Human Food.

~~7.4.5~~7.5.5 Color Additives

~~7.4.5.1~~7.5.5.1 21 C.F.R. Part 70: Color Additives (only § 70.20-70.25);

~~7.4.5.2~~7.5.5.2 21 C.F.R. Part 73: Listing of Colors Exempt from Certification (only § 73.1-73.615);

~~7.4.5.3~~7.5.5.3 21 C.F.R. Part 74: Listing of Color Additives Subject to Certification (only § 74.101-706);

~~7.4.5.4~~7.5.5.4 21 C.F.R. Part 81: General Restrictions for Provisional Color Additives for Use in Foods, Drugs and Cosmetics;

~~7.4.5.5~~7.5.5.5 21 C.F.R. Part 82: Listing of Certified Provisionally Listed Colors and Specifications (only § 82.3-82.706).

~~7.4.6~~7.5.6 Intentional Adulteration

~~7.4.6.1~~7.5.6.1 21 C.F.R. 121: Mitigation Strategies to Protect Food Against Intentional Adulteration.

~~7.4.7~~7.5.7 Federal Food, Drug and Cosmetic Act

~~7.4.7.1~~7.5.7.1 Definitions: 21 U.S.C. § 321(f), (k), (m);

~~7.4.7.2~~7.5.7.2 Prohibited Acts: 21 U.S.C. § 331(e), (f), (k);

~~7.4.7.3~~7.5.7.3 Records of Interstate Shipments: 21 U.S.C. § 373.

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.

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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.