

Final Proposed Filing - Coversheet

Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the “Rule on Rulemaking” adopted by the Office of the Secretary of State, this filing will be considered complete upon filing and acceptance of these forms with the Office of the Secretary of State, and the Legislative Committee on Administrative Rules.

All forms shall be submitted at 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.

**PLEASE REMOVE ANY COVERSHEET OR FORM NOT
REQUIRED WITH THE CURRENT FILING BEFORE DELIVERY!**

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801 (b) (11) for a definition), I approve the contents of this filing entitled:

Manufactured Food Rule

/s/ Todd W. Daloz , on 12/20/23
(signature) (date)

Printed Name and Title:

Todd W. Daloz
Deputy Secretary
Agency of Human Services

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)
- ☐ ICAR Minutes
- ☐ Copy of Comments
- ☐ Responsiveness Summary

1. TITLE OF RULE FILING:

Manufactured Food Rule

2. PROPOSED NUMBER ASSIGNED BY THE SECRETARY OF STATE

23P035

3. ADOPTING AGENCY:

Vermont Department of Health

4. PRIMARY CONTACT PERSON:

(A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE).

Name: Natalie Weill

Agency: Department of Health

Mailing Address: 108 Cherry St, Burlington, VT 05401

Telephone: 802-863-7280 Fax: 802-951-1275

E-Mail: ahs.vdhrules@vermont.gov

Web URL *(WHERE THE RULE WILL BE POSTED)*:

<http://www.healthvermont.gov/about-us/laws-regulations/public-comment>

5. 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: Brendan Atwood

Agency: Department of Health

Mailing Address: 108 Cherry St, Burlington, VT 05401

Telephone: 802-863-7282 Fax: 802-951-1275

E-Mail: ahs.vdhrules@vermont.gov

6. 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:

7. 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).

18 V.S.A. § 4303; 18 V.S.A. § 4353; and 3 V.S.A. § 801 (b) (11).

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. "

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.
9. THE FILING HAS NOT CHANGED SINCE THE FILING OF THE PROPOSED RULE.
10. THE AGENCY HAS NOT INCLUDED WITH THIS FILING A LETTER EXPLAINING IN DETAIL WHAT CHANGES WERE MADE, CITING CHAPTER AND SECTION WHERE APPLICABLE.
11. SUBSTANTIAL ARGUMENTS AND CONSIDERATIONS WERE NOT RAISED FOR OR AGAINST THE ORIGINAL PROPOSAL.
12. THE AGENCY HAS NOT INCLUDED COPIES OF ALL WRITTEN SUBMISSIONS AND SYNOPSES OF ORAL COMMENTS RECEIVED.
13. THE AGENCY HAS NOT INCLUDED A LETTER EXPLAINING IN DETAIL THE REASONS FOR THE AGENCY'S DECISION TO REJECT OR ADOPT THEM.
14. 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) Updates the rule for consistency with Title 21 Chapter I of the C.F.R.

(2) Reformats, reorganizes, and clarifies the federal regulations cited in the Incorporation by Reference section.

(3) Defines the scope of the Department of Health issued food manufacturing license. Specifically, the rule clarifies the prohibition of manufacturing of food containing THC under the Department of Health license.

(4) Updates the information required on food labels manufactured by license exempt food manufacturers and license exempt bakeries.

(5) Modifies the rule for clarity.

15. EXPLANATION OF WHY THE RULE IS NECESSARY:

This rulemaking is necessary for consistency with Title 21 Chapter I of the C.F.R.

16. EXPLANATION OF HOW THE RULE IS NOT ARBITRARY:

The rulemaking updates the rule for compliance with the recent updates to Title 21 Chapter I of the C.F.R.

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

Licensed exempt food manufacturers, licensed exempt bakeries, consumers, and the health care system.

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

Federal regulation requires the presence of label information on all food products. The proposed rulemaking requires an additional line of text stating, "Made in a home kitchen not inspected by the Vermont Department of Health." The proposed rulemaking has a de minimis economic cost to license exempt food manufacturers and license exempt bakeries for the additional line of text required on food labels.

19. A HEARING WAS HELD.

20. 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.

Date: 11/9/2023

Time: 10:30 AM

Street Address: 108 Cherry St. Burlington, VT Rm 3B

Zip Code: 05401

URL for Virtual: https://teams.microsoft.com/l/meetup-join/19%3ameeting_NDFkZjFhOTAtOWI1Mi00YTEzLWE2MDQtZmJmMTU0NmQ4NWQx%40thread.v2/0?context=%7b%22Tid%22%3a%2220b4933b-baad-433c-9c02-70edcc7559c6%22%2c%22Oid%22%3a%22e6440c4f-7582-4db1-800b-a2038a1e1e68%22%7d

Date:

Time: AM

Street Address:

Zip Code:

URL for Virtual:

Date:

Time: AM

Street Address:

Zip Code:

URL for Virtual:

Date:

Time: AM

Street Address:

Zip Code:

URL for Virtual:

21. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING):

11/16/2023

KEYWORDS (PLEASE PROVIDE AT LEAST 3 KEYWORDS OR PHRASES TO AID IN THE SEARCHABILITY OF THE RULE NOTICE ONLINE).

Food Safety

Home Bakery

Home Bakeries

Kitchen

Food Producer

Good Manufacturing Practices

Food Processing

Food Manufacturing

Food Labels

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.

1. TITLE OF RULE FILING:

Manufactured Food Rule

2. ADOPTING AGENCY:

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 if 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*):

The Good Manufacturing Practices for Food Rule; March 14, 2015 Secretary of State Rule Log #15-006; July 2015 [correction to numbering in Section 4.0]

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.

1. TITLE OF RULE FILING:

Manufactured Food Rule

2. ADOPTING AGENCY:

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:

License exempt food manufacturers and license exempt bakeries: There is a de minimis economic cost to license exempt food manufacturers and license exempt bakeries for the additional line of text required on food labels. While federal regulation requires the presence of label information on all food products, the proposed rulemaking requires an additional line of text

that states: "Made in a home kitchen not inspected by the Vermont Department of Health". No other impacts are anticipated.

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):

There is a de minimis economic cost to license exempt food manufacturers and license exempt bakeries for the additional line of text required on food labels. Federal regulation requires the presence of label information on all food products, regardless of the size of the business.

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 to license exempt food manufacturers and license exempt bakeries is de minimis.

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:

Because the economic impact will be de minimis, alternatives have not been considered.

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 Health 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

1. TITLE OF RULE FILING:

Manufactured Food Rule

2. ADOPTING AGENCY:

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.):*
No anticipated impact.

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.*

Because there is no anticipated environmental impact, there is no 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:

1. TITLE OF RULE FILING:

Manufactured Food Rule

2. ADOPTING AGENCY:

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:

A public hearing will be held.

The rule will be posted on the Department of Health website.

<https://www.healthvermont.gov/laws-regulations/laws/public-comment>

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

The Department worked with Vermont licensed food manufacturers, license exempt food processors, Vermont retailers, and the VT Specialty Foods Association (VSFA).

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.

1. TITLE OF RULE FILING:

Manufactured Food Rule

2. ADOPTING AGENCY:

Vermont Department of Health

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

The Good Manufacturing Practices for Food 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), the FDA FSMA Final Rule on Sanitary Transportation of Human and Animal Food 21 C.F.R. § 1 (2016), the FDA FSMA Final Rule for Mitigation Strategies to Protect Food Against Intentional Adulteration rule 21 C.F.R. § 121 (2016), the Federal Food, Drug and Cosmetic Act 21 U.S.C. § 321 (m), the Prohibited Act 21 U.S.C. § 331 (e), (f), and (k), with exceptions set forth in relevant subsections.

The rulemaking removes 21 C.F.R. Chapter I Part 106: Infant Formula Quality Control Procedures, Part 129: Processing and Bottling of Bottled Drinking Water, Part 118: Production, Storage and Transportation of Shell

Eggs, Part 105: Foods for Special Dietary Use, and Part 107: Infant Formula.

4. FORMAL CITATION OF MATERIALS INCORPORATED BY REFERENCE:

The incorporations by reference include extensive citations and exceptions of Title 21 Chapter I of the C.F.R. Accordingly, these citations have not been listed here but can be viewed at <https://www.ecfr.gov/current/title-21/chapter-I>. The Department will provide electronic copies of Title 21 Chapter I of the C.F.R. upon request.

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

Title 21 of the C.F.R. can be viewed at <https://www.ecfr.gov/current/title-21/chapter-I>. The Department will provide electronic copies of Title 21 Chapter I of the C.F.R. upon request.

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*):

The incorporations by reference include extensive citations and exceptions of Title 21 Chapter I of the C.F.R. Accordingly, these citations have not been listed here but can be viewed at <https://www.ecfr.gov/current/title-21/chapter-I>. The Department will provide electronic copies of Title 21 Chapter I of the C.F.R. upon request.

Run Spell Check

Chapter 5 – Food Safety

Rules Subchapter 1

~~Good Manufacturing Practices for Food Rule~~ Manufactured Food Rule

1.0 Authority

This rule is adopted pursuant to ~~Chapter 85~~ 18 V.S.A. §§ 4303 and 4353.

2.0 Purpose

This rule provides the requirements for the safe and sanitary manufacturing, packing, ~~or~~ holding, and distributing of human food ~~products 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). ~~that process food for human consumption, and provide processed food for sale and distribution to other business entities such as other food establishments.~~
Requirements do not pertain to food service establishments as defined by 18 V.S.A. § 4301(a)(8), or food 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

~~3.14.1~~ 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 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, the Code of Federal Regulations Title 21 Chapter I 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.

~~Whenever used in these Regulations, the following terms shall be construed as follows:~~

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 “CFR” 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 “Department” means the Vermont Department of Health.

~~3.1.4~~4.1.5 “FDA” means the U.S. Food and Drug Administration.

4.1.6 “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 “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, distributors, 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 “Isolated” means enclosed such that cross-contamination via air-to-surface or surface-to-surface is not possible.

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

4.1.10 “License exemption” and “license exempt” means a food manufacturing establishment that is exempt from the licensing fee. An establishment is exempt from licensure only after the Department has acknowledged, in writing, the receipt of the Self-Certification of Licensing Exemption form.

4.1.11 “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.

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

4.1.13 “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.

4.1.14 “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.

4.1.15 “Significant renovation” means a physical change to a facility or portion of a facility, including the following:

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

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

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

4.1.16 “THC” means tetrahydrocannabinol.

4.1.17 “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 “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.

“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. Bakery products do not include time/temperature control for safety food.

~~3.2 “Adequate” means that which is needed to accomplish the intended purpose in keeping with good public health practices.~~

~~3.3 “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. Bakery products do not include time/temperature control for safety food.~~

~~3.4 “Batter” means a semi fluid substance, usually composed of flour and other ingredients, into which principal components of food are dipped or with which they are coated, or which may be used directly to form bakery foods.~~

~~3.5 “Blanching, except for tree nuts and peanuts” means a prepackaging heat treatment of foodstuffs for a sufficient time and at a sufficient temperature to partially or completely inactivate the naturally occurring enzymes and to effect other physical or biochemical changes in the food.~~

~~“Commissioner” means the Commissioner for the Vermont Department of Health or a subordinate to whom the commissioner has assigned his or her their functions.~~

~~3.6 “Critical control point” means a point in a food process where there is a high probability that improper control may cause, allow, or contribute to a hazard or to filth in the final food or decomposition of the final food.~~

~~“Department” means the Vermont Department of Health.~~

~~“FDA” means the U.S. Food and Drug Administration.~~

~~3.7~~

~~“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, or intended to be used by human beings for food, drink, confection, or condiment, whether simple, mixed, or compound and all substances and ingredients used in the preparation thereof.~~

~~“Food contact surfaces” are those surfaces that contact human food and those surfaces from which drainage onto surfaces that contact the food ordinarily occurs during the normal course of operations. Food contact surfaces include utensils and food contact surfaces of equipment.~~

~~“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, distributors, 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.~~

~~“Home Bakery” means a domestic home kitchen where non time/temperature control for safety baked goods are produced and wrapped using only standard home kitchen equipment and only for sale directly to the consumer or in retail stores.~~

~~“License” means the document issued by the Department of Health that authorizes a person to operate a food services establishment. from licensure~~

~~“Lot” means the food produced during a period of time indicated by a specific code.~~

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

~~“Microorganisms” means yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance. The term “undesirable microorganisms” includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated within the meaning of these Regulations.~~

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

~~“Plant” means the building or facility or parts thereof, used for or in connection with the manufacturing, packaging, labeling, or holding of human food.~~

~~“Pest” means any objectionable animals or insects including, but not limited to, birds, rodents, flies, and larvae.~~

~~“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.~~

~~“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.~~

~~“Quality control operation” means a planned and systematic procedure for taking all actions necessary to prevent food from being adulterated within the meaning of these Regulations.~~

~~“Rework” means clean, unadulterated food that has been removed from processing for reasons other than unsanitary conditions or that has been successfully reconditioned by reprocessing and that is suitable for use as food.~~

~~“Safe and suitable” means that the ingredient performs an appropriate function in the food in which it is used and is used at a level no higher than necessary to achieve its intended purpose in that food.~~

~~“Safe moisture level” is a level of moisture low enough to prevent the growth of undesirable microorganisms in the finished product under the intended conditions of manufacturing, storage, and distribution. The maximum safe moisture level for a food is based on its water activity (a_w). An a_w will be considered safe for a food if adequate data are available that demonstrate that the food at or below the given a_w will not support the growth of undesirable microorganisms.~~

~~“Sanitize” means to adequately treat food contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.~~

~~“Significant renovation” means a physical change to a facility or portion of a facility, including the following:~~

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

~~Demolition of the interior or exterior of a building or portion of the building; and~~

~~Replacement, demolition, or installation of interior walls and partitions, whether fixed or movable or;~~

~~“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.~~

~~“Water activity (a_w)” 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

~~3.7.1~~ A person shall not maintain or operate a food processing or food manufacturing establishment ~~facility or food warehouse~~ unless they receive a license for that establishment issued by the Department pursuant to ~~the provisions of~~ 18 V.S.A. §4351.

5.1.1

~~3.7.2~~

5.1.2 Each individual establishment shall require a separate license, regardless of ownership. A food manufacturing establishment license expires annually, unless ~~sooner~~ 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 license before operating the business.

5.2 License Application

5.2.1 A ~~person~~individual seeking licensure for an establishment shall submit the following to the Department for review at least~~no less than~~ 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

~~—, a~~ A ~~payment check or money order~~ for the applicable fees determined in 18 V.S.A. §4353 ~~.; and~~and

5.2.1.2

~~—c~~ Copies of all other required documentation and permits must be submitted to the Department for review no less than 30 days before the expected start of operation.

5.2.2 Additional documentation shall be submitted, when applicable and upon request~~ed~~ by the Department, including but not limited to:

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

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

5.2.2.2

~~Local permit or zoning approval for proposed operation; and~~

5.2.2.3 Local permit or zoning approval for proposed operation; and

~~3.7.2.1~~ 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.

5.2.2.4

~~—~~ 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.

~~3.7.3~~

~~Establishments shall submit a plan review pPrior to any new construction or significant renovation of an existing facility, a licensee shall submit to the Department for review a plan documenting such proposed changes.~~

Transference of Licenses Prohibited

~~A license shall not be transferred from one person or corporation to another.~~

5.2.3 ~~When a licensed establishment is sold, the corporation changes, or the establishment relocates, or the establishment enlarges its operation, X shall return the license for that establishment held by the former entity or person shall be returned to the Department.~~

~~The new proprietor of that establishment or management must apply for and receive a license before operating the business.~~

5.3 Variances

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

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

~~3.7.4~~

5.3.2.1 A written statement of the proposed variance ~~of 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

~~3.7.4.1~~

5.3.2.3 Any other relevant information requested by the Department.~~if required by the Commissioner.~~

5.3.3 For each variance granted, the licensee shall ~~meet the following requirements:~~

5.3.3.1 Follow the plans and procedures approved by the ~~Commissioner~~Department;

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

~~3.7.4.2~~

5.3.3.3 Maintain and provide to the ~~Commissioner~~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, ~~and/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, ~~a~~A food manufacturing establishment ~~claiming a license~~ing exemption shall submit ~~the~~a Department's Self-Certification of Licensing Exemption form ~~to the Department, and provide notice to the receiving formal acknowledgment~~to the Department, and provide notice to the receiving formal acknowledgment. The manufacturer is exempt from licensure once the Department confirms, in writing, the receipt of the Self-Certification of Licensing Exemption form.

6.1.1 The following food manufacturing establishments are exempt from the licensing requirement described in 18 V.S.A. § § 4353 and 4358:

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.

~~3.7.4.3~~ 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.

6.2

~~3.7.5~~6.2.1 Labeling Requirements for License Exempt Food Manufacturing
~~Unlicensed~~ Establishments

~~3.7.5.1~~6.2.1.1 A ~~licensed exempt~~unlicensed kitchen food manufacturing establishment shall label products for sale with the following information:

~~3.7.5.1.1~~6.2.1.1.1 The name and address of the operation;

~~3.7.5.1.2~~6.2.1.1.2 The name of the food product;

~~3.7.5.1.3~~6.2.1.1.3 The ingredients of the food product, in descending order of predominance by weight;

~~3.7.5.1.4~~6.2.1.1.4 The net weights or net volumes of the food product;

~~3.7.5.1.5~~6.2.1.1.5 Allergen information as specified by federal labeling requirements;

~~3.7.5.1.6~~ Nutritional labeling as specified by federal labeling requirements is required if any nutrient content claim, health claim, or other nutritional information is provided; and

6.2.1.1.6

~~3.7.5.1.7~~ The following statement printed in at least 10-point type in a color that provides a clear contrast to the background label: “~~This product is exempt from licensing and routine food safety inspection in Vermont~~Made in a home kitchen~~that has not been inspected by the Vermont Department of Health.~~”

6.2.1.1.7

Current Good Manufacturing Practice

~~The plant management shall take all reasonable measures and precautions to ensure the following:~~

~~Disease Control~~

~~Any person who, by medical examination or supervisory observation, is shown to have or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination by which there is a reasonable possibility of food, food contact surfaces, or food packaging materials becoming contaminated, shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected.~~

~~Personnel shall be instructed to report such health conditions to their supervisors.~~

~~Cleanliness~~

~~All persons working in direct contact with food, food contact surfaces, and food packaging materials shall conform to accepted industry standard hygienic practices while on duty to the extent necessary to protect against contamination of food.~~

~~The methods for maintaining cleanliness include, but are not limited to:~~

~~Wearing clean garments suitable to the operation in a manner that protects against the contamination of food, food contact surfaces, or food packaging materials.~~

~~Maintaining adequate personal cleanliness.~~

~~Washing hands thoroughly (and sanitizing if necessary to protect against contamination with undesirable microorganisms) in an adequate hand washing facility before starting work, after each absence from the work station, and at any other time when the hands may have become soiled or contaminated.~~

~~Removing all unsecured jewelry and other objects that might fall into food, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which food is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects against the contamination by these objects of the food, food contact surfaces, or food packaging materials.~~

~~Using utensils or wearing gloves for food handling if product is ready to eat and maintaining gloves, if they are used in food handling, in an intact, clean, and sanitary condition. The gloves should be of an impermeable, non-latex material.~~

~~Wearing, where appropriate, in an effective manner, hairnets, headbands, caps, beard covers, or other effective hair restraints.~~

~~Storing clothing or other personal belongings in areas other than where food is exposed or where equipment or utensils are washed.~~

~~Confining the following to areas other than where food may be exposed or where equipment or utensils are washed: eating food, chewing gum, drinking beverages, or using tobacco. Additional restrictions concerning use of tobacco are contained in 18 V.S.A. Chapter 37.~~

~~Taking any other necessary precautions to protect against contamination of food, food contact surfaces, or food packaging materials with microorganisms or foreign substances including, but not limited to, perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.~~

~~Education and Training~~

~~Personnel responsible for identifying sanitation failures or food contamination shall have a background of education or experience, or a combination thereof, to provide a level of competency necessary for production of clean and safe food, when available.~~

~~Food handlers and supervisors shall receive appropriate training in proper food handling techniques and food protection principles and should be informed of the danger of poor personal hygiene and insanitary practices.~~

~~Supervision~~

~~Responsibility for assuring compliance by all personnel with all requirements of these Regulations shall be clearly assigned to supervisory personnel.~~

~~Plants and Grounds~~

~~Grounds—The grounds around a food plant under the control of the operator shall be kept in a condition that will protect against the contamination of food. The methods for adequate maintenance of grounds include, but are not limited to:~~

~~Properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the plant buildings or structures that may constitute an attractant, breeding place, or harborage for pests;~~

~~Maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where food is exposed;~~

~~Adequate draining areas that may contribute contamination to food by seepage, foot borne filth, or providing a breeding place for pests;~~

~~Operating systems for waste treatment and disposal in an adequate manner so that they do not constitute a source of contamination in areas where food is exposed;~~

~~If the plant grounds are bordered by grounds not under the operator's control and not maintained in the manner described in the above sections (9.1.1-9.1.3) of this Rule, care shall be exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth that may be a source of food contamination.~~

~~Plant Construction and Design~~

~~Plant buildings and structures shall be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food manufacturing purposes. The plant and facilities shall:~~

~~Provide sufficient space for such placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations and the production of safe food;~~

~~Permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces, or food packaging materials with microorganisms, chemicals, filth, or other extraneous material. The potential for contamination may be reduced by adequate food safety controls and operating practices or effective design, including the separation of operations in which contamination is likely to occur, by one or more of the following means: location, time, partition, air flow, enclosed systems, or other effective means.~~

~~Permit the taking of proper precautions to protect food in outdoor bulk fermentation vessels by any effective means, including:~~

~~Using protective coverings;~~

~~Controlling areas over and around the vessels to eliminate harborages for pests;~~

~~Checking on a regular basis for pests and pest infestation;~~

~~Skimming the fermentation vessels, as necessary.~~

~~Be constructed in such a manner that floors, walls, and ceilings may be adequately cleaned and kept clean and in good repair; that drip or condensate from fixtures, ducts, and pipes does not contaminate food, food-contact surfaces, or food packaging materials; and that aisles or working spaces are provided between equipment and walls and are adequately unobstructed and of~~

~~adequate width to permit employees to perform their duties and to protect against contaminating food or food contact surfaces with clothing or personal contact.~~

~~Provide adequate lighting in hand washing areas, dressing and locker rooms, and toilet rooms and in all areas where food is examined, processed, or stored and where equipment or utensils are cleaned; and provide safety type light bulbs, fixtures, skylights, or other glass suspended over exposed food in any step of preparation or otherwise protect against food contamination in case of glass breakage.~~

~~Provide adequate ventilation or control equipment to minimize odors and vapors (including steam and noxious fumes) in areas where they may contaminate food; and locate and operate fans and other air blowing equipment in a manner that minimizes the potential for contaminating food, food packaging materials, and food contact surfaces.~~

~~Provide tight fitting doors and outer openings and, where necessary, adequate screening or other protection against pests.~~

~~Sanitary Operations~~

~~General Maintenance—Buildings, fixtures, and other physical facilities of the plant shall be maintained in a sanitary condition and shall be kept in repair sufficient to prevent food from becoming adulterated within the meaning of these Regulations. Cleaning and sanitizing of utensils and equipment shall be conducted in a manner that protects against contamination of food, food contact surfaces, or food packaging materials.~~

~~Substances Used in Cleaning and Sanitizing—Storage of Toxic Materials~~

~~Cleaning compounds and sanitizing agents used in cleaning and sanitizing procedures shall be free from undesirable microorganisms and shall be safe and adequate under the conditions of use. Compliance with this requirement may be verified by any effective means including purchase of these substances under a supplier's guarantee or certification, or examination of these substances for contamination. Only the following toxic materials may be used or stored in a plant where food is processed or exposed:~~

~~Those required to maintain clean and sanitary conditions;~~

~~Those necessary for use in laboratory testing procedures;~~

~~Those necessary for plant and equipment maintenance and operation;~~

~~Those necessary for use in the plant's operations.~~

~~Toxic cleaning compounds, sanitizing agents, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of food, food contact surfaces, or food packaging materials. All relevant regulations promulgated by other Federal, State, and local government agencies for the application, use, or holding of these products shall also be followed.~~

~~Pest Control—No pests shall be allowed in any area of a food plant. Guard or guide dogs may be allowed in some areas of a plant if the presence of the dogs is unlikely to result in contamination of food, food contact surfaces, or food packaging materials. Effective measures shall be taken to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. The use of insecticides or rodenticides is permitted only under precautions and restrictions that will protect against the contamination of food, food contact surfaces, and food packaging materials.~~

~~Sanitation of Food Contact Surfaces—All food contact surfaces, including utensils and food contact surfaces of equipment, shall be cleaned as frequently as necessary to protect against contamination of food.~~

~~Food contact surfaces used for manufacturing or holding low moisture food shall be in a dry, sanitary condition at the time of use. When the surfaces are wet cleaned, they shall, when necessary, be sanitized and thoroughly dried before subsequent use.~~

~~In wet processing, when cleaning is necessary to protect against the introduction of microorganisms into food, all food contact surfaces shall be cleaned and sanitized before use and after any interruption during which the food contact surfaces may have become contaminated. Where equipment and utensils are used in a continuous production operation, the utensils and food contact surfaces of the equipment shall be cleaned and sanitized as necessary.~~

~~Non food contact surfaces of equipment used in the operation of food plants should be cleaned as frequently as necessary to protect against contamination of food.~~

~~Single service articles (such as utensils intended for one time use, paper cups, and paper towels) should be stored in appropriate containers and shall be handled, dispensed, used, and disposed of in a manner that protects against contamination of food or food contact surfaces.~~

~~Sanitizing agents shall be adequate and safe under conditions of use. Any facility, procedure, or machine is acceptable for cleaning and sanitizing equipment and utensils if it is established that the facility, procedure, or machine will routinely render equipment and utensils clean and provide adequate cleaning and sanitizing treatment.~~

~~Storage and Handling of Cleaned Portable Equipment and Utensils—Cleaned and sanitized portable equipment with food contact surfaces and utensils should be stored in a location and manner that protects food contact surfaces from contamination.~~

Sanitary Facilities and Controls

~~Each plant shall be equipped with adequate sanitary facilities and accommodations including, but not limited to:~~

~~Water Supply—The water supply shall be sufficient for the operations intended and shall be derived from an adequate source. The facility shall comply with requirements regarding water~~

~~quality and the site and location of the source of the water supply will meet criteria as specified in rule by the Vermont Department of Environmental Conservation.~~

~~Any water that contacts food or food contact surfaces shall be safe and of adequate sanitary quality.~~

~~Running water at a suitable temperature, and under pressure as needed, shall be provided in all areas where required for the processing of food, for the cleaning of equipment, utensils, and food packaging materials, or for employee sanitary facilities.~~

~~Plumbing—A plumbing system shall be designed, constructed, and installed according to all applicable federal, state, and local requirements. Plumbing shall be of adequate size and design and adequately installed and maintained to:~~

~~Carry sufficient quantities of water to required locations throughout the plant;~~

~~Properly convey sewage and liquid disposable waste from the plant;~~

~~Avoid constituting a source of contamination to food, water supplies, equipment, or utensils or creating an unsanitary condition;~~

~~Provide adequate floor drainage in all areas where floors are subject to flooding type cleaning or where normal operations release or discharge water or other liquid waste on the floor; and~~

~~Provide that there is not backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing.~~

~~Sewage Disposal—Sewage disposal shall be made into an adequate sewerage system or disposed of through other adequate means and in compliance with requirements as specified in rule by the Vermont Department of Environmental Conservation.~~

~~Toilet Facilities—Each plant shall provide its employees with adequate, readily accessible toilet facilities. Compliance with this requirement shall be accomplished by:~~

~~Maintaining the facilities in a sanitary condition;~~

~~Keeping the facilities in good repair at all times;~~

~~Providing self-closing doors; and~~

~~Providing doors that do not open into areas where food is exposed to airborne contamination, except where alternate means have been taken to protect against such contamination (such as double doors or positive air flow systems).~~

~~Hand Washing Facilities—Hand washing facilities shall be adequate and convenient and be furnished with running water at a temperature of at least 100°F (38°C). Hand washing sinks shall be designated for hand washing only and shall not be used for other purposes. Compliance with this requirement may be accomplished by providing:~~

~~Hand washing and, where appropriate, hand sanitizing facilities at each location in the plant where good sanitary practices require employees to wash and/or sanitize their hands;~~

~~Effective hand cleaning and sanitizing preparations (soap);~~

~~Sanitary towel service or suitable drying devices;~~

~~Devices or fixtures, such as water control valves, so designed and constructed to protect against recontamination of clean, sanitized hands;~~

~~Readily understandable signs directing employees handling unprotected food, unprotected food packaging materials, or food contact surfaces to wash and, where appropriate, sanitize their hands before they start work, after each absence from post of duty, and when their hands may have become soiled or contaminated. These signs may be posted in the processing room(s) and in all other areas where employees may handle such food, materials, or surfaces.~~

~~Refuse receptacles that are constructed and maintained in a manner that protects against contamination of food.~~

~~Rubbish and Offal Disposal—Rubbish and any offal shall be so conveyed, stored, and disposed of as to minimize the development of odor, minimize the potential for the waste becoming an attractant and harborage or breeding place for pests, and protect against contamination of food, food contact surfaces, water supplies, and ground surfaces.~~

Equipment and Utensils

~~All plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable and shall be properly maintained.~~

~~The design, construction, and use of equipment and utensils shall preclude the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.~~

~~All equipment shall be installed and maintained as to facilitate the cleaning of the equipment and of all surrounding spaces.~~

~~Food contact surfaces shall be corrosion resistant when in contact with food. They shall be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food and, if applicable, cleaning compounds and sanitizing agents. Food contact surfaces shall be maintained to protect food from being contaminated by any source, including unlawful indirect food additives.~~

~~Seams on food contact surfaces shall be smoothly bonded or maintained so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms.~~

~~Equipment that is in the manufacturing or food handling area and that does not come into contact with food shall be so constructed that it can be kept in a clean condition.~~

~~Holding, conveying, and manufacturing systems, including gravimetric, pneumatic, closed, and automated systems, shall be of a design and construction that enables them to be maintained in an appropriate sanitary condition.~~

~~Each freezer and cold storage compartment used to store and hold food capable of supporting growth of microorganisms shall be fitted with an indicating thermometer, temperature measuring device, or temperature recording device so installed as to show the temperature accurately within the compartment, and shall be fitted with an automatic control for regulating temperature or with an automatic alarm system to indicate a significant temperature change in a manual operation.~~

~~Instruments and controls used for measuring, regulating, or recording temperatures, pH, acidity, water activity, or other conditions that control or prevent the growth of undesirable microorganisms in food shall be accurate and adequately maintained and adequate in number for their designated uses.~~

~~Compressed air or other gases mechanically introduced into food or used to clean food contact surfaces or equipment shall be treated in such a way that food is not contaminated with unlawful indirect food additives.~~

Production and Process Controls

~~All operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles.~~

~~Appropriate quality control operations shall be employed to ensure that food is suitable for human consumption and that food packaging materials are safe and suitable.~~

~~Overall sanitation of the plant shall be under the supervision of one or more competent individuals assigned responsibility for this function.~~

~~All reasonable precautions shall be taken to ensure that production procedures do not contribute contamination from any source. Chemical, microbial, or extraneous material testing procedures shall be used where necessary to identify sanitation failures or possible food contamination.~~

~~All food that has become contaminated to the extent that it is adulterated as defined in 18 V.S.A. § 4059, shall be rejected or if permissible, treated or processed to eliminate the contamination.~~

Raw Materials and Other Ingredients

~~Raw materials and other ingredients shall be inspected and segregated or otherwise handled as necessary to ascertain that they are clean and suitable for processing into food and shall be stored under conditions that will protect against contamination and minimize deterioration.~~

~~Raw materials shall be washed or cleaned as necessary to remove soil or other contamination.~~

~~Water used for washing, rinsing, or conveying food shall be safe and of adequate sanitary quality.~~

~~Water may be reused for washing, rinsing, or conveying food if it does not increase the level of contamination of the food.~~

~~Containers and carriers of raw materials shall be inspected on receipt to ensure that their condition has not contributed to the contamination or deterioration of food.~~

~~Raw materials and other ingredients shall either not contain levels of microorganisms that may produce food poisoning or other disease in humans, or they shall be pasteurized or otherwise treated during manufacturing operations so that they no longer contain levels that would cause the product to be adulterated within the meaning of these Regulations. Compliance with this requirement may be verified by any effective means, including purchasing raw materials and other ingredients under a supplier's guarantee or certification.~~

~~Raw materials and other ingredients susceptible to contamination with aflatoxin or other natural toxins shall comply with 18 V.S.A. § 4062, this Rule, and applicable action levels/regulations for poisonous or deleterious substances promulgated by the FDA before these materials or ingredients are incorporated into finished food. Compliance with this requirement may be accomplished by purchasing raw materials and other ingredients under a supplier's guarantee or certification or may be verified by analyzing these materials and ingredients for aflatoxins and other natural toxins.~~

~~Raw materials, other ingredients, and rework susceptible to contamination with pests, undesirable microorganisms, or extraneous material shall comply with the provisions of section 13.0 of this Rule regarding defect action levels for natural or unavoidable defects if a manufacturer wishes to use the materials in manufacturing food. Compliance with this requirement may be verified by any effective means, including purchasing the materials under a supplier's guarantee or certification or examination of these materials for contamination.~~

~~Raw materials, other ingredients, and rework shall be held in bulk, or in containers designed and constructed so as to protect against contamination and shall be held at such temperature and relative humidity and in such a manner as to prevent the food from becoming adulterated within the meaning of these Regulations. Material scheduled for rework shall be identified as such.~~

~~Frozen raw materials and other ingredients shall be kept frozen. If thawing is required prior to use, it shall be done in a manner that prevents the raw materials and other ingredients from becoming adulterated within the meaning of these Regulations.~~

~~Liquid or dry raw materials and other ingredients received and stored in bulk form shall be held in a manner that protects against contamination.~~

~~Manufacturing Operations~~

~~Equipment and utensils and finished food containers shall be maintained in an acceptable condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment shall be taken apart for thorough cleaning.~~

~~All food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms or for the contamination of food. One way to comply with this requirement is careful monitoring of physical factors such as time, temperature, humidity, aw, pH, pressure, and flow rate, and manufacturing operations such as freezing, dehydration, heat processing, acidification, and refrigeration to ensure that mechanical breakdowns, time delays, temperature fluctuations, and other factors do not contribute to the decomposition or contamination of food.~~

~~Food that can support the rapid growth of undesirable microorganisms, particularly those of public health significance, shall be held in a manner that prevents the food from becoming adulterated as defined in 18 V.S.A. § 4059. Compliance with this requirement shall be accomplished by any effective means, including:~~

~~Maintaining refrigerated foods at 41°F (5°C) or below as appropriate for the particular food involved;~~

~~Maintaining frozen foods in a frozen state;~~

~~Maintaining hot foods at 135°F (57°C) or above;~~

~~Heat treating acid or acidified foods to destroy mesophilic microorganisms when those foods are to be held in hermetically sealed containers at ambient temperatures;~~

~~Any other acceptable method approved by the Vermont Department of Health Food and Lodging Program.~~

~~Measures such as sterilizing, irradiating, pasteurizing, freezing, refrigerating, controlling pH, or controlling aw that are taken to destroy or prevent the growth of undesirable microorganisms, particularly those of public health significance, shall be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated within the meaning of these Regulations.~~

~~Work in process shall be handled in a manner that protects against contamination.~~

~~Effective measures shall be taken to protect finished food from contamination by raw materials, other ingredients, or refuse.~~

~~When raw materials, other ingredients, or refuse are unprotected, they shall not be handled simultaneously in a receiving, loading, or shipping area if that handling could result in contaminated food.~~

~~Food transported by conveyor shall be protected against contamination as necessary.~~

~~Equipment, containers, and utensils used to convey, hold, or store raw materials, work in process, rework, or food shall be constructed, handled, and maintained during manufacturing or storage in a manner that protects against contamination.~~

~~Effective measures shall be taken to protect against the inclusion of metal or other extraneous material in food. Compliance with this requirement may be accomplished by using sieves, traps, magnets, electronic metal detectors, or other suitable effective means.~~

~~Food, raw materials, and other ingredients that are adulterated within the meaning of these Regulations shall be disposed of in a manner that protects against the contamination of other food. If the adulterated food is capable of being reconditioned, it shall be reconditioned using a method that has been proven to be effective or it shall be reexamined and found not to be adulterated within the meaning of these Regulations before being incorporated into other food.~~

~~Mechanical manufacturing steps such as washing, peeling, trimming, cutting, sorting and inspecting, mashing, dewatering, cooling, shredding, extruding, drying, whipping, defatting, and forming shall be performed so as to protect food against contamination. Compliance with this requirement may be accomplished by providing adequate physical protection of food from contaminants that may drip, drain, or be drawn into the food. Protection may be provided by adequate cleaning and sanitizing of all food contact surfaces and by using time and temperature controls at and between each manufacturing step.~~

~~Heat blanching, when required in the preparation of food, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent manufacturing without delay.~~

~~Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by periodic cleaning.~~

~~Where the blanched food is washed prior to filling, water used shall be safe and of adequate sanitary quality.~~

~~Batters, breading, sauces, gravies, dressings, spices, and other similar preparations shall be treated or maintained in such a manner that they are safe and protected against contamination. Compliance with this requirement shall be accomplished by any effective means, including one or more of the following:~~

~~Using ingredients free of contamination and verified by testing;~~

~~Employing adequate heat processes where applicable;~~

~~Using adequate time and temperature controls minimizing time food is in temperature danger zone of 41°F (5°C) to 135°F (57°C);~~

~~Providing adequate physical protection of components from contaminants that may drip, drain, or be drawn into them;~~

~~Cooling to an adequate temperature during manufacturing;~~

~~Disposing of batters at appropriate intervals to protect against the growth of micro organisms;~~
~~Any other acceptable method approved by the Vermont Department of Health Food and Lodging Program;~~

~~Filling, assembling, packaging, and other operations shall be performed in such a way that the food is protected against contamination. Compliance with this requirement shall be accomplished by any effective means, including:~~

~~Use of a quality control operation in which the critical control points are identified and controlled during manufacturing;~~

~~Adequate cleaning and sanitizing of all food contact surfaces and food containers;~~

~~Using materials for food containers and food packaging materials that are safe and suitable, as defined in these Regulations;~~

~~Providing physical protection from contamination, particularly airborne contamination;~~

~~Using sanitary handling procedures;~~

~~Any other acceptable method approved by the Vermont Department of Health Food and Lodging Program;~~

~~Food such as, but not limited to, dry mixes, nuts, intermediate moisture food, and dehydrated food, that relies on the control of a_w for preventing the growth of undesirable microorganisms shall be processed to and maintained at a safe moisture level. Compliance with this requirement shall be accomplished by any effective means, including employment of one or more of the following practices:~~

~~Monitoring the a_w of food;~~

~~Controlling the soluble solids water ratio in finished food;~~

~~Protecting finished food from moisture pickup, by use of a moisture barrier or by other means, so that the a_w of the food does not increase to an unsafe level;~~

~~Any other acceptable method approved by the Vermont Department of Health Food and Lodging Program;~~

~~Food such as, but not limited to, acid and acidified food, that relies principally on the control of pH for preventing the growth of undesirable microorganisms shall be monitored and maintained at a pH of 4.6 or below. Compliance with this requirement shall be accomplished by any effective means, including employment of one or more of the following practices:~~

~~Monitoring the pH of raw materials, food in process, and finished food;~~

~~Controlling the amount of acid or acidified food added to low acid food;~~

~~Any other acceptable method approved by the Vermont Department of Health Food and Lodging Program.~~

~~When ice is used in contact with food, it shall be made from water that is safe and of adequate sanitary quality and shall be used only if it has been manufactured in accordance with current good manufacturing practice as outlined in these Regulations.~~

~~Food manufacturing areas and equipment used for manufacturing human food shall not be used to manufacture nonhuman food grade animal feed or inedible products, unless there is no reasonable possibility for the contamination of the human food.~~

Warehousing and Distribution

~~Storage and transportation of finished food shall be under conditions that will protect food against physical, chemical, and microbial contamination as well as against deterioration of the food and the container.~~

Defect Action Levels

~~Some foods, even when produced under current good manufacturing practice, contain natural or unavoidable defects that at low levels are not hazardous to health. The FDA establishes maximum levels for these defects in foods produced under current good manufacturing practice and uses these levels in deciding whether to recommend regulatory action.~~

~~Defect action levels are established by the FDA for foods whenever it is necessary and feasible to do so. These levels are subject to change upon the development of new technology or the availability of new information. The current Defect Action Levels handbook may be downloaded from the FDA website through: <http://www.fda.gov/>.~~

~~Food that has been adulterated as defined in 18 V.S.A. § 4059 shall still be in violation of this Rule even if the food manufacturer is in compliance with defect action levels.~~

~~The mixing of a food containing defects above the current defect action level with another lot of food is not permitted and renders the final food adulterated within the meaning of these Regulations, regardless of the defect level of the final food.~~

~~Compliance with defect action levels does not excuse violation of the requirement of 18 V.S.A. Chapter 85 that food not be prepared, packed, or held under unsanitary conditions or the requirements of this Part that food manufacturers, distributors, and holders shall observe current good manufacturing practice. Evidence indicating that such a violation exists causes the food to be adulterated within the meaning of this Part, even though the amounts of natural or unavoidable defects are lower than the currently established defect action levels. The manufacturer, distributor, and holder of food shall always utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible.~~

7.0 Adoption by Reference-Incorporation by Reference

~~3.8 Federal Food, Drug, and Cosmetic Act: §201(m) [21 USC §321 Definitions], §301(e), (f), (k), (v) [21 USC §331 Prohibited Acts], and §703 [21 USC §373 Records of Interstate Shipment] are adopted by reference.~~

~~3.9 Code of Federal Regulations: 21 CFR Parts 70.20 70.25, 73.1 73.615, 74.101 706, 81, 82.3 82.706, 100.155, 101 (except 101.69 and 101.108), 102 (except 102.19), 104, 105, 106 (except 106.120), 107 (except 107.200 107.280), 108.25 108.35, 109, 113, 114, 118, 120, 123, 129 130 (except 130.5 130.6 and 130.17), 136 170 (except 168.140, 170.6, 170.15, and 170.17), 172 178, and 180 189 are adopted by reference.~~

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

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

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

7.4 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 but are not necessarily limited to the following:

7.4.1 Food Processing

~~3.9.1.1 21 C.F.R. Part 106 (except § 106.120): Infant Formula Quality Control Procedures;~~

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

~~3.9.1.2~~ ~~21 C.F.R. Part 110: Current Good Manufacturing Practice in Manufacturing, Packing or Holding Human Food;~~

~~3.9.1.3~~ ~~21 C.F.R. Part 111: Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling or Holding Operations for Dietary Supplements;~~

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

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

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

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

~~3.9.1.4~~ ~~21 C.F.R. Part 115: Shell Eggs;~~

~~3.9.1.5~~ 7.4.1.6 21 C.F.R. Part 117: Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food;

~~3.9.1.6~~ ~~21 C.F.R. Part 118: Production, Storage and Transportation of Shell Eggs;~~

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

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

~~3.9.1.7~~ ~~21 C.F.R. Part 129: Processing and Bottling of Bottled Drinking Water.~~

7.4.2 Food Labeling

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

~~Subpart OB (§1.900-1.934): General Labelling Requirements;~~

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

~~3.9.1.7.1 Subpart G: Specific Administrative Rulings and Decisions;~~

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

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

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

~~3.9.1.8 21 C.F.R. Part 105: Foods for Special Dietary Use;~~

~~3.9.1.9 21 C.F.R. Part 107 (except § 107.200-107.280): Infant Formula;~~

~~3.9.1.10 9 C.F.R. Part 317: Labeling, Marking Devices and Containers.~~

7.4.3 Standards of Identity

~~3.9.1.11~~ 21 C.F.R. Part 130: Food Standards: General (except 130.5-6, 130.17);

~~3.9.1.12 21 C.F.R. Part 131: Milk and Cream;~~

~~21 C.F.R. Part 133: Cheeses and Related Cheese Products;~~

~~3.9.1.13 7.4.3.121 C.F.R. Part 135: Frozen Desserts;~~

~~3.9.1.14 7.4.3.221 C.F.R. Part 136: Bakery Products;~~

~~3.9.1.15 7.4.3.321 C.F.R. Part 137: Cereal Flours and Related Products;~~

~~3.9.1.16 7.4.3.421 C.F.R. Part 139: Macaroni and Noodle Products;~~

~~3.9.1.17 7.4.3.521 C.F.R. Part 145: Canned Fruits;~~

~~3.9.1.18 7.4.3.621 C.F.R. Part 146: Canned Fruit Juices;~~

~~3.9.1.19~~7.4.3.721 C.F.R. Part 150: Fruit Butters, Jellies, Preserves and Related Products;

~~3.9.1.20~~7.4.3.821 C.F.R. Part 152: Fruit Pies;

~~3.9.1.21~~7.4.3.921 C.F.R. Part 155: Canned Vegetables;

~~3.9.1.22~~7.4.3.10 21 C.F.R. Part 156: Vegetable Juice;

~~3.9.1.23~~7.4.3.11 21 C.F.R. Part 158: Frozen Vegetables;

~~3.9.1.24~~7.4.3.12 21 C.F.R. Part 160: Eggs and Egg Products;

~~3.9.1.25~~7.4.3.13 21 C.F.R. Part 161: Fish and Shellfish;

~~3.9.1.26~~7.4.3.14 21 C.F.R. Part 163: Cacao Products;

~~3.9.1.27~~7.4.3.15 21 C.F.R. Part 164: Tree Nut and Peanut Products;

~~3.9.1.28~~7.4.3.16 21 C.F.R. Part 165: Beverages;

~~3.9.1.29~~7.4.3.17 21 C.F.R. Part 166: Margarine;

~~3.9.1.30~~7.4.3.18 21 C.F.R. Part 168: Sweeteners and Table Syrups
(except 168.140);

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

~~3.9.1.31~~ ~~9 C.F.R. Part 319: Definitions and Standards of Identity or Composition.~~

7.4.4 Food Additives

~~3.9.1.32~~7.4.4.121 C.F.R. Part 170: Food Additives (except § 170.6, 170.15, 170.17);

~~3.9.1.33~~7.4.4.221 C.F.R. Part 172: Food Additives Permitted for Direct Addition to Food for Human Consumption;

~~3.9.1.34~~7.4.4.321 C.F.R. Part 173: Secondary Direct Food Additives Permitted in Food for Human Consumption;

~~3.9.1.35~~7.4.4.421 C.F.R. Part 174: Indirect Food Additives: General;

~~3.9.1.36~~7.4.4.521 C.F.R. Part 175: Indirect Food Additives: Adhesives and Components of Coatings;

~~3.9.1.37~~7.4.4.621 C.F.R. Part 176: Indirect Food Additives: Paper and Paperboard Components;

7.4.4.7 21 C.F.R. Part 177: Indirect Food Additives: Polymers;

~~3.9.1.38~~7.4.4.8

~~3.9.1.39~~7.4.4.921 C.F.R. Part 178: Indirect Food Additives: Adjuvants, Production Aids and Sanitizers;

~~3.9.1.40~~7.4.4.10 21 C.F.R. Part 180: Food Additives Permitted in Food or in Contact with Food on an Interim Basis Pending Additional Study;

~~3.9.1.41~~7.4.4.11 21 C.F.R. Part 181: Prior-Sanctioned Food Ingredients;

~~3.9.1.42~~7.4.4.12 21 C.F.R. Part 182: Substances Generally Recognized as Safe;

~~3.9.1.43~~7.4.4.13 21 C.F.R. Part 184: Direct Food Substances Affirmed as Generally Recognized as Safe;

~~3.9.1.44~~7.4.4.14 21 C.F.R. Part 186: Indirect Food Substances Affirmed as Generally Recognized as Safe;

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

7.4.5 Color Additives

~~3.9.1.45~~7.4.5.121 C.F.R. Part 70: Color Additives (only § 70.20-70.25);

~~3.9.1.46~~7.4.5.221 C.F.R. Part 73: Listing of Colors Exempt from Certification (only § 73.1-73.615);

~~3.9.1.47~~7.4.5.321 C.F.R. Part 74: Listing of Color Additives Subject to Certification (only § 74.101-706);

~~3.9.1.4~~7.4.5 21 C.F.R. Part 81: General Restrictions for Provisional Color Additives for Use in Foods, Drugs and Cosmetics;

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

~~3.9.2~~ ~~Sanitary Transportation~~

~~3.9.2.1~~ ~~21 C.F.R. Part 1: Subpart O: Sanitary Transportation of Human and Animal Food;~~

~~3.9.2.2~~ ~~21 C.F.R. Part 11: Electronic Records; Electronic Signatures.~~

7.4.6 Intentional Adulteration

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

7.4.7 Federal Food, Drug and Cosmetic Act

~~3.9.2.3~~7.4.7.1 Definitions: 21 U.S.C. § 321(f), (k), (m) ~~and (ff)~~;

~~3.9.2.4~~7.4.7.2 Prohibited Acts: 21 U.S.C. § 331 ~~(a), (b), (c), (d),~~ (e), (f), (k) ~~and (v)~~;

~~3.9.2.5~~ Penalties: 21 U.S.C. § 333;

~~3.9.2.6~~ Seizure: 21 U.S.C. § 334;

~~3.9.2.7~~ Definitions and Standards for Food: 21 U.S.C. § 341;

~~3.9.2.8~~ Adulterated Food: 21 U.S.C. § 342;

~~3.9.2.9~~ Misbranded Food: 21 U.S.C. § 343;

~~3.9.2.10~~ New Dietary Ingredients: 21 U.S.C. § 350(b);

~~3.9.2.11~~ Regulations and Hearings: 21 U.S.C. § 371;

~~3.9.2.12~~7.4.7.3 Records of Interstate Shipments: 21 U.S.C. § 373;

~~Factory Inspection: 21 U.S.C. § 374.~~

Governing Authority

~~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 1 of the C.F.R. In the event of inconsistency between meanings given in Chapter 85 and the Code of Federal Regulations Title 21 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.~~

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). Requirements do not pertain to food service establishments as defined by 18 V.S.A. § 4301(a)(8), or 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 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, the Code of Federal Regulations Title 21 Chapter I 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 “CFR” 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 “Department” means the Vermont Department of Health.
- 4.1.5 “FDA” means the U.S. Food and Drug Administration.
- 4.1.6 “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 “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, distributors, 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 “Isolated” means enclosed such that cross-contamination via air-to-surface or surface-to-surface is not possible.
- 4.1.9 “License” means the document issued by the Department of Health that authorizes a person to operate a food manufacturing establishment.
- 4.1.10 “License exemption” and “license exempt” means a food manufacturing establishment that is exempt from the licensing fee. An establishment is exempt from licensure only after the Department has acknowledged, in writing, the receipt of the Self-Certification of Licensing Exemption form.
- 4.1.11 “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.
- 4.1.12 “Plan review” means the submission of blueprints, drawings, or plans for proposed new construction, renovation, or remodeling of a food processing facility.
- 4.1.13 “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.

4.1.14 “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.

4.1.15 “Significant renovation” means a physical change to a facility or portion of a facility, including the following:

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

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

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

4.1.16 “THC” means tetrahydrocannabinol.

4.1.17 “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 “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 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 determined in 18 V.S.A. §4353.

5.2.2 Additional documentation shall be submitted when applicable and upon request by the Department, including but not limited to:

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, a food manufacturing establishment claiming a license exemption shall submit the Department's Self-Certification of Licensing Exemption form to the Department. The manufacturer is exempt from licensure once the Department confirms, in writing, the receipt of the Self-Certification of Licensing Exemption form.
- 6.1.1 The following food manufacturing establishments are exempt from the licensing requirement described in 18 V.S.A. § § 4353 and 4358:
- 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.
- 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.
- 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.”

7.0 Incorporation by Reference

- 7.1 These regulations hereby adopt and incorporate the FDA Food Safety Modernization Act (FSMA) Final Rule on Preventive Controls for Human Food 21 C.F.R. § 117 (2015) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.
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- 7.4 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 but are not necessarily limited to the following:

7.4.1 Food Processing

- 7.4.1.1 21 C.F.R. Part 109: Unavoidable Contaminants in Food for Human Consumption and Food-Packaging Materials;
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- 7.4.1.3 21 C.F.R. 108.35: Emergency Permit Control - Thermal Processing of Low-Acid Foods Packaged in Hermetically Sealed Containers;
- 7.4.1.4 21 C.F.R. Part 114: Acidified Foods;
- 7.4.1.5 21 C.F.R. 108.25: Emergency Permit Control - Acidified Foods;
- 7.4.1.6 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 21 C.F.R. Part 120: Hazard Analysis and Critical Control Point (HACCP) Systems;
- 7.4.1.8 21 C.F.R. Part 123: Fish and Fishery Products;

7.4.2 Food Labeling

- 7.4.2.1 21 C.F.R. Part 1: General Enforcement Regulations (§1.20-1.24): Subpart O (§1.900-1.934);
- 7.4.2.2 21 C.F.R. Part 100: General (ONLY § 100.155);
- 7.4.2.3 21 C.F.R. Part 101: Food Labeling (except § 101.69 and § 101.108);
- 7.4.2.4 21 C.F.R. Part 102 (except § 102.19): Common or Usual Name for Non-standardized Foods;
- 7.4.2.5 21 C.F.R. Part 104: Nutritional Quality Guidelines for Foods;

7.4.3 Standards of Identity

- 7.4.3.1 21 C.F.R. Part 130: Food Standards: General (except 130.5-6, 130.17);
- 7.4.3.2 21 C.F.R. Part 136: Bakery Products;
- 7.4.3.3 21 C.F.R. Part 137: Cereal Flours and Related Products;
- 7.4.3.4 21 C.F.R. Part 139: Macaroni and Noodle Products;
- 7.4.3.5 21 C.F.R. Part 145: Canned Fruits;
- 7.4.3.6 21 C.F.R. Part 146: Canned Fruit Juices;
- 7.4.3.7 21 C.F.R. Part 150: Fruit Butters, Jellies, Preserves and Related Products;
- 7.4.3.8 21 C.F.R. Part 152: Fruit Pies;
- 7.4.3.9 21 C.F.R. Part 155: Canned Vegetables;
- 7.4.3.10 21 C.F.R. Part 156: Vegetable Juice;
- 7.4.3.11 21 C.F.R. Part 158: Frozen Vegetables;
- 7.4.3.12 21 C.F.R. Part 160: Eggs and Egg Products;
- 7.4.3.13 21 C.F.R. Part 161: Fish and Shellfish;
- 7.4.3.14 21 C.F.R. Part 163: Cacao Products;
- 7.4.3.15 21 C.F.R. Part 164: Tree Nut and Peanut Products;
- 7.4.3.16 21 C.F.R. Part 165: Beverages;
- 7.4.3.17 21 C.F.R. Part 166: Margarine;
- 7.4.3.18 21 C.F.R. Part 168: Sweeteners and Table Syrups (except 168.140);
- 7.4.3.19 21 C.F.R. Part 169: Food Dressings and Flavorings;

7.4.4 Food Additives

- 7.4.4.1 21 C.F.R. Part 170: Food Additives (except § 170.6, 170.15, 170.17);
- 7.4.4.2 21 C.F.R. Part 172: Food Additives Permitted for Direct Addition to Food for Human Consumption;
- 7.4.4.3 21 C.F.R. Part 173: Secondary Direct Food Additives Permitted in Food for Human Consumption;
- 7.4.4.4 21 C.F.R. Part 174: Indirect Food Additives: General;
- 7.4.4.5 21 C.F.R. Part 175: Indirect Food Additives: Adhesives and Components of Coatings;
- 7.4.4.6 21 C.F.R. Part 176: Indirect Food Additives: Paper and Paperboard Components;
- 7.4.4.7 21 C.F.R. Part 177: Indirect Food Additives: Polymers;
- 7.4.4.8 21 C.F.R. Part 178: Indirect Food Additives: Adjuvants, Production Aids and Sanitizers;
- 7.4.4.9
- 7.4.4.10 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 21 C.F.R. Part 181: Prior-Sanctioned Food Ingredients;
- 7.4.4.12 21 C.F.R. Part 182: Substances Generally Recognized as Safe;
- 7.4.4.13 21 C.F.R. Part 184: Direct Food Substances Affirmed as Generally Recognized as Safe;
- 7.4.4.14 21 C.F.R. Part 186: Indirect Food Substances Affirmed as Generally Recognized as Safe;
- 7.4.4.15 21 C.F.R. Part 189: Substances Prohibited from Use in Human Food.

7.4.5 Color Additives

- 7.4.5.1 21 C.F.R. Part 70: Color Additives (only § 70.20-70.25);
- 7.4.5.2 21 C.F.R. Part 73: Listing of Colors Exempt from Certification (only § 73.1-73.615);
- 7.4.5.3 21 C.F.R. Part 74: Listing of Color Additives Subject to Certification (only § 74.101-706);
- 7.4.5.4 21 C.F.R. Part 81: General Restrictions for Provisional Color Additives for Use in Foods, Drugs and Cosmetics;
- 7.4.5.5 21 C.F.R. Part 82: Listing of Certified Provisionally Listed Colors and Specifications (only § 82.3-82.706).
- 7.4.6 Intentional Adulteration
 - 7.4.6.1 21 C.F.R. 121: Mitigation Strategies to Protect Food Against Intentional Adulteration.
- 7.4.7 Federal Food, Drug and Cosmetic Act
 - 7.4.7.1 Definitions: 21 U.S.C. § 321(f), (k), (m);
 - 7.4.7.2 Prohibited Acts: 21 U.S.C. § 331(e), (f), (k);
 - 7.4.7.3 Records of Interstate Shipments: 21 U.S.C. § 373;



INTERAGENCY COMMITTEE ON ADMINISTRATIVE RULES (ICAR) MINUTES

Meeting Date/Location: Monday, March 13, 2023, virtually via Microsoft Teams

Members Present: Chair Sean Brown, Brendan Atwood, Jared Adler, John Kessler, Diane Sherman, Michael Obuchowski, Donna Russo-Savage and Nicole Dubuque

Members Absent: Jennifer Mojo

Minutes By: Melissa Mazza-Paquette

- 2:00 p.m. meeting called to order, welcome and introductions.
- Review and approval of [minutes](#) from the February 22, 2023 meeting.
- No additions/deletions to agenda. Agenda approved as drafted.
- Note: An emergency rule titled 'Emergency Administrative Rules for Notaries Public Remote Notarization', by the Office of Professional Regulation was supported by ICAR Chair Brown on 03/09/23
 - These Emergency Rules allow an individual to satisfy the "personal appearance" requirement for the performance of notarial acts by appearing before a notary public through a secure communication link using specific protocols and standards.
 - If these Emergency Rules expire before rules are adopted to implement Act 171, Vermont notaries public will no longer be permitted to perform remote notarial acts, thus hampering the performance of crucial transactions.
- No public comments made.
- Presentation of Proposed Rules on pages 2-4 to follow.
 1. 10 V.S.A. App. § 141 Baitfish Regulation, Vermont Fish and Wildlife Board, page 2
 2. Manufactured Food Rule, Vermont Department of Health, page 3
 3. Rule Governing Outage Reporting Requirements for Originating Carriers and Electric Power Companies, Vermont Enhanced 911 Board, page 4
- Next scheduled meeting is Monday, April 10, 2023 at 2:00 p.m.
- 2:50 p.m. meeting adjourned

Proposed Rule: Manufactured Food Rule, Vermont Department of Health

Presented By: Natalie Weill

Motion made to accept the rule by Diane Sherman, seconded by Jared Adler, and passed unanimously except for Brendan Atwood who abstained, with the following recommendations:

1. Proposed Rule – Coversheet
 - a. #8: Include a statement as to what the rule does overall. Consider adding a hyphen between ‘license’ and ‘exempt’ in (4).
 - b. #8 and #9: State the reasoning for the rule.
 - c. #12: Check in with the Agency of Agriculture, Food & Markets and the Attorney General’s Office, as they were involved with the Vermont Origins Rule adopted, as small businesses might be affected by this with labeling. Reference that 1, 2, 3, and 5 in #8 doesn’t have any economic impact.
 - d. #16: Add Food Label
2. Economic Impact Analysis
 - a. Clarify what the economic impacts are other than the label changes per the four other categories listed in #8 of the Proposed Coversheet.
3. Public Input Maximization Plan
4. #4: Define ‘will work’ by including a timeline and action steps. Consider groups that work with individuals selling food that should be informed.



STATE OF VERMONT
AGENCY OF HUMAN SERVICES

MEMORANDUM

TO: Sarah Copeland Hanzas, Secretary of State

FROM: Jenney Samuelson, Secretary, Agency of Human Services

A handwritten signature in blue ink, appearing to be "Jenney Samuelson".

DATE: January 31, 2023

SUBJECT: Signatory Authority for Purposes of Authorizing Administrative Rules

I hereby designate Deputy Secretary of Human Services Todd W. Daloz 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 Procedure Act, 3. V.S.A § 801 et seq.

Cc: Todd W. Daloz