



## Missouri Department of Health and Senior Services

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### Technical Bulletin F1-12

**TO:** Regional EPHS V's  
Local Public Health Administrators  
Local Environmental Public Health Specialists

**FROM:** Mark Jenkerson, Chief  
Bureau of Environmental Health Services

**SUBJECT:** Specialized Process Approval Policy

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[http://health.mo.gov/atoz/ehog/pdf/Ch\\_9.1.pdf](http://health.mo.gov/atoz/ehog/pdf/Ch_9.1.pdf)

#### Introduction

Specific food processes have historically resulted in more foodborne illness than standard processes. They present a significant health risk if not conducted under strict operational procedures. These types of operations may require the person in charge and food employees to use specialized equipment and demonstrate specific competencies. The specialized process approval requirement is designed to ensure that the proposed method of operation is carried out safely. General guidance regarding administrative procedures is given below.

Authority to conduct inspections comes from statute: 196.190 to 196.265 and except where governed by a local ordinance, food safety inspections are currently conducted under a code modeled after the Food and Drug Administration's food code from 1999. Since the adoption and implementation of the food code there has been no process available to address the required VARIANCE in 3.502.11; additionally, there is no statutory authority to approve VARIANCES. Allowing informal approvals of these specialized processes is not wise considering the risk of foodborne illnesses if the processes are not done correctly. The retail food program has two options: pursue changes to the statute or develop a program policy to facilitate the application, review and approval of the specialized process. This technical bulletin outlines the program policy. This method should be used by a local agency when requiring a specialized process approval and the food establishment when compiling the material and information for the approval. The term "special process" was chosen for use because, in addition to reducing confusion regarding VARIANCE authority, is used exclusively in modern FDA codes and more accurately describes the systemic approach. Future Missouri Codes will have updated language to reflect this clarification.

This technical bulletin was developed to outline the written administrative process for submittal and approval of the specialized process requirements in the 1999 Missouri Food Code. Sanitation of Food Establishments 19 CSR 20-1.025(1)(B)(28), and specifically Section 3-502.11, of the 1999 Missouri Food Code where a variance is required for specialized processes in retail food service establishments. This special process application is what

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must be completed and submitted to comply with 3-502.11. A copy of the Specialized Process Application Checklist can be obtained from the Environmental Health Operational Guidelines (EHOG) or from the Department's Food Safety web page. This checklist is to be submitted with the information outlined in this bulletin. The application or proposal must address the five points outlined below.

1) The facility should begin the specialized process application by checking the process for which the application is being submitted. A separate application for each specialized process must be completed.

- Smoking food (for preservation)
- Curing food
- Brewing alcoholic beverages
- Food additives (for preservation or to alter a food to a non-\*PHF)
- Packaging food using Reduced Oxygen Packaging except as specified under 3-502.12\*\*
- Custom Animal Processing (under Missouri Department of Agriculture (MDA) regulation)
- Other (per Regulatory Authority)

\*PHF – potentially hazardous food

\*\*3-502.12 – Reduced Oxygen Packaging may be conducted without having to obtain a “specialized process approval” from the Bureau if when *Clostridium botulinum* is identified as a microbiological hazard in the final packaged form and there are at least two barriers in place to control the growth and toxin formation of *C. botulinum*. The facility must have an approved Hazard Analysis Critical Control Point (HACCP) plan and written proof that the barriers utilized are sufficient to prevent growth of the identified pathogens. This could include scientific documentation along with monitoring records, or independent laboratory analysis as needed. Note: Only Section 4 of the checklist needs to be completed for compliance with this section of the Food Code

2) Information to be submitted includes:

- a) A proposal for the special process to be used including citing the applicable code reference numbers.
- b) A written statement why the proposal should be approved. Include a reference to the section of the code that the proposal is for and why the proposal will not create a potential public health hazard or nuisance.

3) Supporting documentation may include any or all of the following:

- a) Documentation supporting the rationale for the proposal which could include scientific studies, process authority analysis reports, prerequisite programs and HACCP plans. Industry studies already in existence from reliable authorities that address the issues;
- b) Process review by a recognized Process Authority;
- c) Written prerequisite programs (such as maintenance logs, cleaning schedules and policy manuals) and Standard Sanitation Operating Procedures (SSOP);
- d) Checklists and/or verification records on the prerequisite programs and procedures;
- e) Training programs and procedures.

- 4) Hazard Analysis of process and/or specific items including information on ingredients, materials and equipment to be used.
  - a) For a food establishment that is required to have a HACCP plan, the plan and specifications shall indicate:
    - i) A list of the potentially hazardous foods that the establishment intends to use the proposed process for; or other foods that are specified by the regulatory authority;
    - ii) A flow diagram and hazard analysis by specific food or group of foods where the special process is to be used that identifies critical control points and provides information on the following:
      - (1) Ingredients, materials, and equipment used in the preparation of that food, and
      - (2) Formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved;
  - b) Food employee and supervisory training plan that addresses the food safety issues of concern.
  - c) A Critical Control Point plan including clearly identifying:
    - i) Each critical control point;
    - ii) The critical limits for each critical control point;
    - iii) The method and frequency for monitoring and controlling each critical control point by the food employee designated by the person in charge;
    - iv) The method and frequency for the person in charge to routinely verify that the food employee is following standard operating procedures and monitoring critical control points;
    - v) Action to be taken by the person in charge if the critical limits for each critical control point are not met; and,
    - vi) Records to be maintained by the person in charge to demonstrate that the HACCP plan is properly operated and managed.
- 5) Additional scientific data or other information, as required by the regulatory authority, supporting the determination that food safety is not compromised by the proposal.
  - a) Examples of labeling and lot identification system including an explanation of the code and recordkeeping system.
  - b) Layout of the area showing all equipment where the operation will take place and an explanation of the physical/scheduling barriers between this area and other parts of the operation.
  - c) Information on prerequisite programs to include:

- i) Safety of water;
- ii) Cleaning and maintenance of equipment and facilities;
- iii) Methods of prevention of cross-contamination;
- iv) Use, storage and labeling of toxics;
- v) Personnel health and hygiene policies;
- vi) Pest control program;
- vii) List of job descriptions of personnel involved in the process;
- viii) Written use procedures and calibration steps for all measuring devices such as thermometers and pH meters.

HACCP plans and special process proposals are not transferable from process to process or place to place. Any significant changes in the process or HACCP plan will require resubmission of the updated information for review.

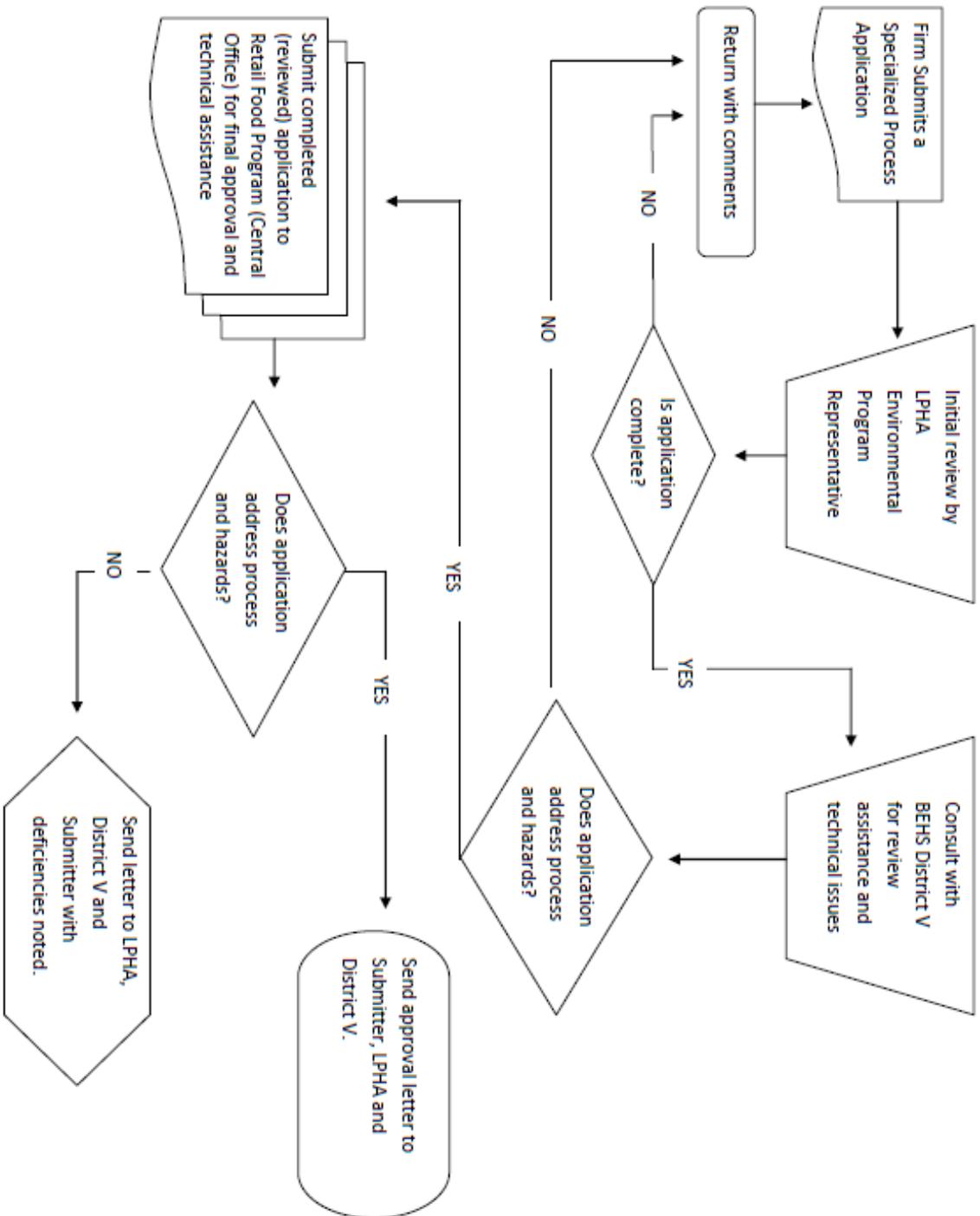
**Duties of BEHS Staff:**

1. Assess needs and develop guidelines and policies.
2. Assist District staff and Local Public Health Agency (LPHA) staff with specialized process application. See the Specialized Process Approval Application Submission Flow Chart.
3. Act as a liaison between DHSS and other government agencies.
4. Provide training to LPHA staff and industry.
5. Review and approve completed specialized process application and HACCP plans.

**Common Responsibilities of LPHA**

1. Perform routine food safety and sanitation inspections under DHSS authority 19 CSR20-1.025. Noting during inspections where specialized processes are performed.
2. Provide facilities with specialized process application.
3. Provide technical assistance to facility management.
4. Perform preliminary review of application and HACCP plan.
5. Work with District staff to assure the application accurately reflects the process and is complete. Submit completed application packet to Food Program staff for review and approval.

Specialized Process Approval Application Submission Flow Chart



## Resources:

### HACCP Resource Web links

United States Department of Agriculture:

[http://www.fsis.usda.gov/Science/Generic\\_HACCP\\_Models/index.asp](http://www.fsis.usda.gov/Science/Generic_HACCP_Models/index.asp)

Iowa State University Extension: <http://www.extension.iastate.edu/HRIM/HACCP>

Food and Drug Administration HACCP:

<http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/JuiceHACCP/ucm073594.htm>

Food and Drug Administration Food Safety:

<http://www.fda.gov/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/default.htm>

National Food Service Management Institute <http://sop.nfsmi.org/HACCPBasedSOPs.php>

Association of Food and Drug Officials:

<http://www.afdo.org/Training/HACCP/SevenHACCPPrinciples.cfm>

Food and Drug Administration Food Safety Management Manual:

<http://www.fda.gov/downloads/Food/FoodSafety/RetailFoodProtection/ManagingFoodSafetyHACCPPrinciples/Operators/UCM077957.pdf>

Food and Drug Administration Food Safety HACCP Application Guidelines:

<http://www.fda.gov/Food/FoodSafety/HazardAnalysisCriticalControlPointsHACCP/HACCPPrinciplesApplicationGuidelines/default.htm>

Seafood Network Information Center: <http://seafood.ucdavis.edu/haccp/ha.htm>

University of Nebraska – Lincoln - Meat Products:

<http://food.unl.edu/web/meatproducts/introduction-to-haccp-training>

University of Nebraska – Lincoln - Meat Products HACCP:

<http://food.unl.edu/web/meatproducts/haccpdocandlink>

University of Nebraska – Lincoln – Meat Products SSOP:

<http://food.unl.edu/web/meatproducts/haccpsop#ssop>

Iowa State University online HACCP Course:

<http://www.ucs.iastate.edu/mnet/haccpretail/home.html>