



HACCP/Variance Guide

Many specialized food processing methods require a Hazard Analysis Critical Control Point (HACCP) plan and may also require a variance be submitted and approved by the Department prior to implementation. These specialized operations may require the person in charge and food employees to use specialized equipment and demonstrate specific competencies. No person or establishment shall conduct a specialized food process without prior authorization. It shall be the full responsibility of said person or establishment that a specialized operation shall be in full conformance with approved plans and specifications.

Establishments may apply to the regulatory authority (Department) for a variance or exemption to use a specific food safety performance standard for a product or a process in lieu of compliance with otherwise applicable specifications in the food code. However, to show compliance with the performance standard, the establishment shall demonstrate that processing controls are in place to ensure that the standard is being met, and demonstrates that the hazard, risk, or nuisance associated with the code has been abated or controlled.

Establishments seeking approval for a HACCP plan or variance shall submit an application and supporting documentation for each separate specialized process consistent with the criteria provided in the Maricopa County Environmental Health Code. The list of required supporting documents can be found on the HACCP/Variance application: <http://www.maricopa.gov/DocumentCenter/Home/View/5805>.

A food establishment shall obtain a variance from the Department as specified in §8-103.10 and under §8-103.11 (U.S. Food and Drug Administration 2013 Food Code) before the establishment performs the specified operations in accordance with approved plans pursuant to §8-103.12. A variance is required for each separate physical location and process.

If a submitted variance application, supplemental documentation, procedures, and verification have been found to meet the minimum requirements as specified under code, it may be subsequently approved with stipulations.

An approval of a variance submittal by the Department does not indicate compliance with any other code, law or regulation that may be required - federal, state, or local.



HACCP/Variance Guide (continued)

HACCP (Hazard Analysis Critical Control Point) Plan

A HACCP Plan is a written document that formally reviews the hazards and risks associated with a process, and specifically addresses these hazards and risks with explicit procedures and monitoring to ensure the hazard or risk has been not created. The plan shall be developed and incorporate the HACCP Principles. It should list all relevant food code sections that would be affected by the issuance of a variance. Provide an analysis of what hazards/risks/nuisances that may be created by the issuance of this variance and how these hazards/risks/nuisances will be abated. A HACCP plan with detailed specifications should include flow diagrams, if applicable.

The concept of HACCP (Hazard Analysis Critical Control Point) was first created when the National Aeronautics and Space Administration (NASA) first asked the Pillsbury Company to ensure a safe food safety system in order to avoid foodborne illness for U.S. manned space flights. Internationally, HACCP is recognized as a proactive science based risk management tool to prevent hazards in food safety systems. A HACCP system focuses on three areas of food safety hazards: physical, biological, and chemical. Regulations and recommendations have been developed for safe food practices relating to personnel, buildings and facilities, equipment, production, and process controls.

HACCP is considered a vital component in proper food establishment design. However, the risk management tool is not considered a “stand-alone” food safety system. Design and construction are essential prerequisites and must be put in place prior to the implementation and operation of effective food production practices. The purpose of quality plan review is to ensure that food establishments are safe, sanitary, and efficient. Proper design, construction, and HACCP principles work to achieve these purposes and minimize the aforementioned hazards.

Effective HACCP principles are essential to a successful food establishment and begin with the design and layout of the facility, monitoring the food flow through the establishment, from delivery, storage, preparation, cooking, service and consumption. A well-designed progressive straight-food flow system will minimize cross-contamination and maximize efficiency in an establishment.



HACCP/Variance Guide (continued)

HACCP (Hazard Analysis Critical Control Point) Plan (continued)

Good manufacturing policies or practices, standard operating procedures (SOPs), and documentation are essential to an establishment's HACCP-based food safety program and control over potential hazards. HACCP policies specifically address requirements set out in the FDA Food Code. Additional standards or good retail practices are required as foundation for food safety and are detailed in the FDA Food Code. Examples include employee hygiene, employee restriction or exclusion, general sanitation, design, etc.

The FDA Food Code §8-201.14(B) (2) requires that an establishment utilizing a HACCP-based food safety program provide a food flow diagram by specific food or category and information on the following: ingredients, materials, equipment, formulations or recipes that delineate methods and procedural control measures that address the food safety concerns involved. An establishment shall provide as much information as required to inform this regulatory authority that the equipment or supplies will not increase the hazards and, in fact, will function to minimize hazards.

HACCP Principles

A series of steps that should be followed to develop and implement a HACCP plan:

1. Conduct a hazard analysis.
2. Identify the Critical Control Points (CCPs) in the process.
3. Establish critical limits for preventative measures associated with each identified CCP.
4. Establish CCP monitoring requirements.
5. Establish corrective action to be taken when monitoring indicates that there is a deviation from the established critical limit.
6. Establish procedures for verification that the HACCP system is working correctly; and
7. Establish effective recordkeeping procedures that document the HACCP system.

For further guidance on developing a HACCP Plan, please visit the U.S. Food & Drug Administration page on HACCP Principles & Application Guidelines:

<https://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006801.htm#app-b>



HACCP/Variance Guide (continued)

Variance

“**Variance**” means a written document issued by the Department that authorizes a modification or waiver of one or more code requirements, if in the opinion of the regulatory authority, a health hazard, risk, or nuisance will not result from the modification or waiver. Before a variance from a requirement of code is approved, documentation and justification of the proposed variance shall be provided by the establishment requesting the variance. If a variance is granted, the Department shall retain the information specified under §8-103.11 in its records for the establishment. The establishment shall perform the specified operations in accordance with approved plans pursuant to §8-103.12 and shall provide records upon request to the Department or its representatives pursuant to §8-103.12.

Variance Required: variances are required for any establishment that performs one or more of the following procedures listed under §3-502.11 and 3-502.12 of the 2013 FDA Food Code including:

1. Smoking food as a method of food preservation rather than as a method of flavor enhancement;
2. Curing food using nitrates or nitrites;
3. Using food additives or adding components such as vinegar as a method of food preservation rather than as a method of flavor enhancement, or to render a TCS food so that it is not non-TCS;
4. Packaging TCS foods using a reduced oxygen packaging method, except where the growth of and toxin formation by *Clostridium botulinum* and the growth of *Listeria monocytogenes* are controlled as specified under § 3-502.12;
5. Operating a molluscan shellfish life-support system display tank used to store or display shellfish that are offered for human consumption;
6. Sprouting seeds or beans;
7. Preparing food by another method that is determined by the Department to require a variance, including but not limited to on-site fish slaughtering, or repackaging of shellfish from containers bearing legible source identification tags or labels that are affixed by the harvester, or dealer that depurates, ships, or reships the shellstock, as specified in the National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish, etc.



HACCP/Variance Guide (continued)

Variance Verification and Validation

Once a variance application or exemption has been approved, the Department expects that the process and procedures that have been submitted and approved shall be conducted in accordance with the submitted request, as required by §8-103.12 of the 2013 FDA Food Code. Department staff shall verify that the process and procedures are being maintained in accordance with the stipulated approval that was issued. Personnel in Environmental Health Programs shall verify that a copy of the establishment's reviewed and approved variance or exemption packet is maintained onsite. This packet shall include:

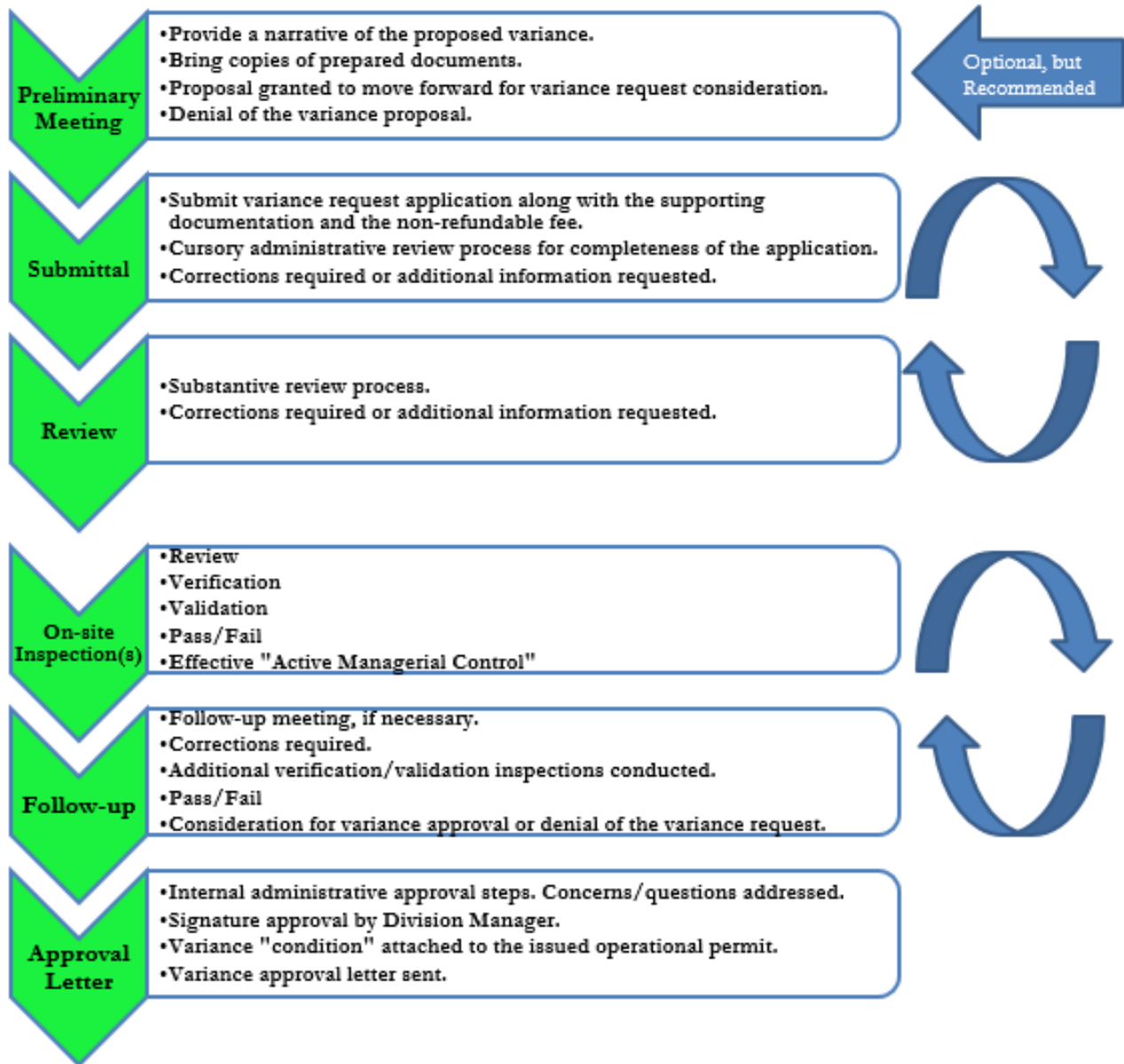
1. A copy of the variance approval letter, which lists the stipulation items that must be followed to maintain approval.
2. A copy of the Department approved HACCP Plan, if a HACCP Plan is required.
3. The last 6 months of logs used for monitoring critical control points, if required by the stipulated approval.

Personnel shall review records and documents as required by the stipulated variance approval. These documents must be readily available and presented for inspection upon request by Environmental Health personnel. Personnel shall verify that the establishment is not deviating from the approved HACCP Plan without prior Department approval. To obtain prior Department approval resubmittal of the variance or exemption request may be required. If during an inspection by Environmental Health personnel any deviation from the approved HACCP Plan or procedure is observed, then a violation may be documented and legal action may be initiated.



HACCP/Variance Guide (continued)

Variance Submittal | Review Process



HACCP | Variance Program

(602)506-6824

esplanreview@mail.maricopa

esd.maricopa.gov

Page 6



Working with our community
to ensure a safe and healthy environment

