Virginia Cooperative Extension
Virginia Tech • Virginia State University
www.ext.vt.edu

Writing a Food Safety Plan: Resources for Conducting a Hazard Analysis

Authored by Alexis M. Hamilton, Assistant Professor and Extension Specialist, Department of Food Science and Technology, Virginia Tech; and Joell Eifert, Lecturer and Experiential Learning Coordinator, Department of Food Science and Technology, Virginia Tech

What is a hazard?

A "food safety hazard", or "hazard", is defined as any biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control [21 CFR § 120.3(g); Figure 1]. Hazards must be controlled in a food product or the environment where the food is manufactured (i.e., processed), prepared, packed, or held (e.g., stored, transported); otherwise, that product is considered adulterated (or unsafe for consumption) and cannot be sold [21 CFR § 402(a)(3-4)].

Figure 1. Types of food safety hazards.

Under the Food and Drug Administration (FDA) Food Safety Modernization Act Preventive Controls for Human Food (FSMA PCHF) Rule, radiological hazards are classified as chemical hazards and producers must consider if there is an economic motivation for hazards [21 CFR 117.130(b)(1)(ii)].

Who is required to conduct a hazard analysis?

Under the FSMA PCHF Rule, any covered facility must complete and maintain a record of a written hazard analysis as part of the food safety plan. It must be prepared by (or the preparation overseen by) a preventive controls qualified individual [21 CFR 117.126(a)(2)].

What is the purpose of a hazard analysis?

A hazard analysis is the process of collecting and evaluating information about food safety hazards and conditions in the processing environment that may impact the presence of food safety hazards to identify if they should be controlled through a preventive control. It provides a systematic approach identifying hazards that must be controlled to prevent and/or minimize the likelihood of foodborne illness and/or injury from occurring as a result of consuming a food product.

This process focuses on the safety of food products over the quality of the product. It is used to reduce the likelihood of food safety events occurring by prioritizing a facility's efforts to target its greatest vulnerabilities first and is supported by other prerequisite programs (for example, Good Manufacturing Practices, sanitation programs.

Why is conducting a hazard analysis important?

Firstly, a written hazard analysis is required for most covered facilities covered under the FSMA PCHF Rule. It also helps reduce the risk of a hazard entering and/or persisting in a food product, which

further reduces the possibility that a customer will become sick or hurt after eating that product. Conducting a hazard analysis has the additional benefits of helping a facility and its employees know what must be done to keep the product safe. A hazard analysis as part of a written food safety plan provides support for the safety of your product as an ingredient in other food products, may also be a requirement from a buyer prior to contract, and may be required as part of a third-party audit scheme.

What are the parts of a hazard analysis?

A hazard analysis is made up of two parts: hazard identification and hazard evaluation. Hazard identification is about creating a list of all of the potential (foreseeable) hazards that could enter your product or the environment it is produced in. This includes biological, chemical (including radiological), or physical agents and those that may occur through economic motivation. The FDA provides a structured list of questions to help with this part in Chapter 2 of their "Hazard Analysis and Risk-Based Preventive Controls for Human Food" draft guidance (FDA 2018). Hazard evaluation is about determining if a potential hazard is reasonably likely to occur in the product or the environment it is produced in, which is discussed further in the next section. This hazard analysis process is organized in Form 2-B in Appendix 2 of the FDA's draft guidance for the FSMA PCHF Rule (FDA 2018).

What resources exist to help evaluate hazards?

After all potential hazards have been identified, there are many resources available to help a facility with a hazard evaluation to determine if a hazard is reasonably likely to occur in the food product or processing environment and, therefore, needed to be included in the food safety plan. The Hazard Evaluation Decision Tree in Figure 2 is one way to systematically walk through this process. This step-by-step procedure shows a facility how to identify the hazards that must be controlled with a preventive controls (PC) program by asking three questions: (1) is the hazard historically associated with the ingredient or product, (2) would the loss of control of this hazard likely result in illness or injury to the consumer, and (3) is the hazard likely to occur in the ingredient, process (facility), or finished product if not controlled by any other program (such as a prerequisite program)? Resources that help answer these questions are presented in Tables 1-3.

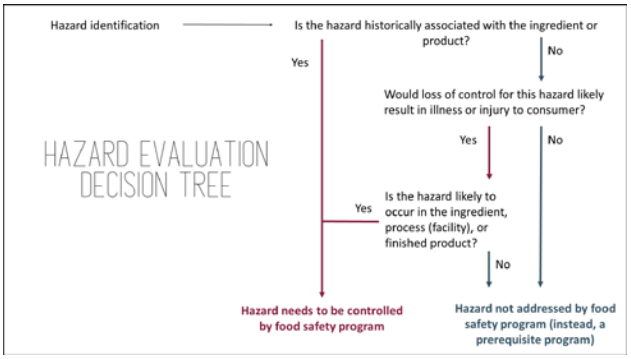

Figure 2. Hazard evaluation decision tree.

Is the hazard historically associated with the ingredient or product?

This question evaluates recall and outbreak data related to an ingredient or product. A hazard is considered to have a historical association with a product if (1) recalls frequently occur or (2) an outbreak has occurred in the product as a result of the presence of the hazard. In the event that the FDA conducts a separate investigation about a type of product (termed a "sampling assignment", such as that begun by FDA with respect to fresh herbs, guacamole, and processed avocado in 2018), this may also be considered. Resources to help answer this question are provided in Figure 3. If facilities need assistance beyond these resources, they are encouraged to consult with outside experts.

Food recall databases
FDA Recalls, Market Withdrawals, & Safety Alerts
FDA Reportable Food Registry
USDA Recalls & Public Health Alerts
Food safety organizations
Association of Food and Drug Officials (AFDO)
Safefood 360°
Government resources
Canadian Health Pathogen Safety Data Sheets
CDC lists of multistate outbreaks
FDA "Hazard Analysis and Risk-Based Preventive Controls for Human Food" Guidance, Chapter 3 in Hazard Guide
FDA reports on outbreak investigations
FDA sampling assignments
FoodSafety.gov
Morbidity and Mortality Weekly Report
Internet searches
Search [ingredient] + "food safety"
Search [food product] + "food safety"
Trade organizations
Center for Science in the Public Interest
Commodity trade organizations, such as International Bottled Water Association

Figure 3. Example resources for determining if there is a historical association of a hazard with an ingredient or food product.

Would loss of control for this hazard likely result in illness or injury to a consumer?

This question evaluates the severity of the hazard. A facility should consider the susceptibility of the product's consumers to foodborne illnesses, how serious or long the illness would be, and the impact of secondary problems or infections as a result of foodborne illness. A hazard is considered severe if (1) the product is intended to be eaten by infants, small children, the elderly, and those whose immune systems are impacted due to other illnesses or life events (for example, pregnancy), (2) the hazard will make someone sick for an extended period of time or if the illness commonly results in hospitalization or death, or (3) secondary infections or injuries are common after recovery from a foodborne illness (such as kidney problems). Resources to help answer this question are provided in Figure 4. If facilities need assistance beyond these resources, they are encouraged to consult with outside experts.

Government resources
FDA Chemical, Metals, Natural Toxins & Pesticides Guidance Documents and Regulations
FDA Defect Action Levels
FDA Food Safety Plan Builder
FDA Pesticide Residue Monitoring Program data
Guidebook for the Preparation of HACCP Plans
USDA Meat and Poultry Hazards and Controls Guide
Trade groups
Food Safety Preventive Controls Alliance (FSPCA)
Universities
Virginia Cooperative Extension
Virginia Tech trainings and resources
Cornell Dairy Foods Extension
Other Extension fact sheets and workshops

Figure 4. Example resources for determining if loss of control of a hazard will likely result in illness or injury to a consumer.

Is the hazard likely to occur in the ingredient, process (facility), or finished product in lieu of any other control (prerequisite program)?

This question evaluates the likelihood of occurrence of the hazard. A hazard is considered likely to occur if (1) scientific studies show that the hazard is common in the food, its ingredient, or the environment the food is produced in or (2) the hazard has consistently or regularly been encountered in the facility. Prerequisite programs include programming in an operation that provides the foundation for safe food to be made, such as through employee health and hygiene programs or Good Manufacturing Practices. Prerequisite programs can be effective ways to reduce the likelihood that a hazard will occur, which will not require the hazard to be controlled with a preventive control in the food safety plan, as shown in Figure 2. Resources to help answer this question are provided in Figure 5. If facilities need assistance beyond these resources, they are encouraged to consult with outside experts.

Figure 5. Example resources for determining if a hazard is likely to occur if not controlled by a prerequisite program.

Justifying your decision

Regardless of how an operation identifies a hazard or decides how it will be effectively controlled, a justification is required for each food safety hazard considered. For hazards that require a preventive control to produce a safe product, the justification explains how the hazard will be controlled and includes evidence that supports this decision. An example of how an operation may choose to word this justification is included below.

Example: *Listeria monocytogenes is controlled by the food safety plan because it is federally relevant, as shown by FDA's zero tolerance policy for the foodborne pathogen in ready-to-eat foods.*

For hazards that do not require a preventive control to produce a safe food because a prerequisite program sufficiently minimizes the likelihood that the hazard will occur, the justification includes evidence that supports this decision. An example of how an operation may choose to word this justification is included below.

Example: *Glass pieces in the product are adequately controlled by the glass policy, which makes them not likely to occur, as shown by the absence of glass-related consumer complaints.*

It is recommended that potential hazards that are considered and deemed non-hazardous should also include a justification to support the written hazard analysis record and inform future reviews of the hazard analysis. An example of how an operation may choose to word this justification is included below.

Example: *Oxidation of frying oil is not a food safety hazard requiring a preventive control because this quality defect is not likely to result in illness or injury after consumption.*

Using the "Hazard Analysis Worksheet"

To assist an operation in conducting a hazard analysis, the attached "Hazard Analysis Worksheet" was created. The document addresses hazard identification, hazard evaluation, and writing a justification through eight questions discussed below.

Under the "Hazard Identification" section, an operation is first asked to write in the "1. Potential hazard" by name, such as "metal fragments sizes 7-25mm". Next, the operation should identify the "2. Type of hazard" as biological, chemical, or physical. Economically motivated hazards should also be considered as appropriate. Third, the operation is asked to identify how the hazard enters the food ("3. Vehicle for hazard"), such as through an ingredient, the production environment, an employee, or other means.

Under the "Hazard Evaluation" section, the fourth step involves using the hazard evaluation decision tree to determine if the food safety hazard will be controlled by the food safety program or a prerequisite program.

Under the "Justification" section, the result of using the flow diagram is circled under question "5. How controlled". The operation is then asked to circle why that method of control was decided upon ("6. Why"), such as because a food safety hazard was deemed severe and likely to occur. Lastly, the operation is asked to identify "7. Support" for that decision, which may include previous outbreaks, facility logs, scientific studies, or any other documentation that may be relevant.

Finally, an operation is asked to combine all of this information to "8. Put it all together" into one cohesive sentence that could be included as the justification in a written hazard analysis. This question draws upon the information presented in

questions “1. Potential hazard”, “5. How controlled”, “6. Why”, and “7. Support”.

There are many ways to conduct a valid hazard analysis. The attached worksheet is intended to provide one method food producers may use to help organize and systematically carry out this process, in addition to facilitating discussions among food safety teams when deciding how to manage food safety hazards.

Next steps

If after using the Hazard Evaluation Decision Tree hazards are identified that result in a final “Yes”, these hazards require a preventive control. You must then comply with all components of the PCHF Rule related to preventive controls, including (1) developing and validating the preventive control and (2) conducting and recording monitoring, corrective action, and verification activities for that hazard.

References

Almond Board of California. 2023. “Food Safety & Quality Tools”. https://www.almonds.com/tools-and-resources/food-safety-and-quality

Association of Food and Drug Officials (AFDO). 2023. https://www.afdo.org/

Centers for Disease Control and Prevention (CDC). 222. “Current and Past Outbreaks”. https://www.cdc.gov/foodsafety/outbreaks/lists/index.html

Centers for Disease Control and Prevention. 2023. “Morbidity and Mortality Weekly Report”. https://www.cdc.gov/mmwr/index.html

Center for Science in the Public Interest. 2023. https://www.cspinet.org/

Cornell CALS. “Dairy Foods Extension”. https://cals.cornell.edu/dairy-extension

Department of Health and Human Services. https://www.foodsafety.gov/

Food and Drug Administration (FDA). 2018. “Food Defect Levels Handbook”. https://www.fda.gov/food/ingredients-additives-gras-packaging-guidance-documents-regulatory-information/food-defect-levels-handbook

Food and Drug Administration. 2018. “Hazard Analysis and Risk-Based Preventive Controls for Human Food: Guidance for Industry”. https://www.fda.gov/media/100002/download

Food and Drug Administration. 2020. “FDA Sampling Fresh Herbs, Guacamole and Processed Avocado”. https://www.fda.gov/food/cfsan-constituent-updates/fda-sampling-fresh-herbs-guacamole-and-processed-avocado

Food and Drug Administration. 2020. “Food Safety Plan Builder”. https://www.fda.gov/food/food-safety-modernization-act-fsma/food-safety-plan-builder

Food and Drug Administration. 2022. “FSMA Technical Assistance Network (TAN)”. https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-technical-assistance-network-tan

Food and Drug Administration. 2022. “Pesticide Residue Monitoring Program Reports and Data”. https://www.fda.gov/food/pesticides/pesticide-residue-monitoring-program-reports-and-data

Food and Drug Administration. 2022. “Reportable Food Registry for Industry”. https://www.fda.gov/food/compliance-enforcement-food/reportable-food-registry-industry

Food and Drug Administration. 2023. “Chemicals, Metals, Natural Toxins & Pesticides Guidance Documents and Regulations”. https://www.fda.gov/food/guidance-documents-regulatory-information-topic-food-and-dietary-supplements/chemical-metals-natural-toxins-pesticides-guidance-documents-regulations

Food and Drug Administration. 2023. “Investigations of Foodborne Illness Outbreaks”. https://www.fda.gov/food/outbreaks-foodborne-illness/investigations-foodborne-illness-outbreaks

Food and Drug Administration. 2023. “Recalls, Market Withdrawals, & Safety Alerts”. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts

Food Safety Preventive Controls Alliance (FSPCA). https://www.ifsh.iit.edu/fspca

Government of Canada. 2023. “Pathogen Safety Data Sheets”. https://www.canada.ca/en/public-health/services/laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html

International Bottled Water Association. 2023. https://bottledwater.org/

Safefood 360°. https://safefood360.com/

U.S. Department of Agriculture (USDA). 2020. “Guidebook for the Preparation of HACCP Plans”. https://www.fsis.usda.gov/guidelines/2020-0008

U.S. Department of Agriculture (USDA). 2018.

Virginia Cooperative Extension (VCE). 2023. “Resources for Food Safety”. https://www.pubs.ext.vt.edu/tags.resource.html/pubs_ext_vt_edu:food-safety

Virginia Tech Department of Food Science and Technology Extension Wheel under the “Have Questions? Who to contact” tab. 2024. https://www.fst.vt.edu/partnerships-and-learning.html?_gl=1*zpkhd9*_ga*MTA1NjkyNjM2MS4xNzA3NDkyNjMz*_ga_Q6KFVTQ08S*MTcxMjIzNjc0MC4xNC4wLjE3MTIyMzY3NDAuMC4wLjA.#vt-item-vtmultitab_copy_2088765639-5

Virginia Tech Food Producer Technical Assistance Network. 2023. https://www.fst.vt.edu/extension/foodbiz.html

Virginia Tech Food Science Extension. 2023. https://www.fst.vt.edu/extension.html

Visit Virginia Cooperative Extension: ext.vt.edu

2024 FST-474NP