FoodSafety magazine

SPECIAL EDITION

Building an Effective Food Safety Plan

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By Kassy Marsh

The Need for a Combined HACCP & HARPC Food Safety Plan

Since the passage of the Food Safety Modernization Act (FSMA) in 2011, there has been a need for a food safety plan that meets the preventive controls for human food and the typical Hazard Analysis and Critical Control Points (HACCP) requirements. Although there are similarities between these requirements, there are fundamental differences that must be fully understood to comply with both HACCP and Hazard Analysis and Risk-Based Preventive Controls (HARPC).

HACCP is a well-established set of principles for the control of food safety and continues to be a requirement in many countries around the world. Particularly where U.S. food facilities are producing food for export, businesses will continue to be required by local law in the countries in which the product is being sold, and by their customers, to comply with HACCP.

Initially, the requirements for HACCP and HARPC seem aimed at the same goals: Both are designed to prevent contamination and control food safety in the supply chain, and both require an Hazard Analysis to determine which elements of the process require control. However, important differences between the rules of the preventive controls regulations and the principles of HACCP make it difficult to meet both sets of requirements.

Many food businesses now face the task of adjusting their typical HACCP systems to meet the HARPC requirements. The requirements of the Preventive Controls rule are clear, but with limited guidance available on how to actually develop a combined HACCP/HARPC plan, this is not an easy undertaking.

Comparing HACCP Principles with HARPC

To establish how to combine a food safety system that meets the requirements for HACCP and HARPC, it is essential to understand the regulations for the Preventive Controls rule and HACCP principles.

HARPC can be broken down into eight main steps:

1. Define the scope of the assessment
2. Identify the hazards
3. Carry out the Hazard Analysis
4. Add Preventive Controls
5. Implement monitoring systems
6. Add corrective actions and corrections
7. Verify the system
8. Reanalyze the system

The key points from each of these steps have been evaluated below.

1. Define the Scope of the Assessment

Although the U.S. Food and Drug Administration (FDA) does not specifically state that a scope is required for the assessment, the agency has detailed the elements that would typically be captured in the scope of a food safety plan:

- The Hazard Analysis must consider known inherent hazards and hazards that could "reasonably occur."
- The hazards from microbiological, chemical, radiological, and physical sources must be included.

FDA also provides guidance as to the manifestation of these hazards:

- They are inherent to the raw material or product.
- They occur through error in the process.
- They may be carried out deliberately for economic gain (for food safety only).

A typical HACCP plan would focus on the food safety errors that may occur during the processing of the product, and this remains a requirement for compliance with HARPC.

New: Economic Gain Hazards:

Hazards that may happen in rare cases, where food safety is put at risk due to fraudulent activity in the supply chain for economic gain, are new to a typical HACCP system and require specific knowledge and focus on the raw material supply chain.

The Global Food Safety Initiative (GFSI) is currently reviewing its benchmarking standard, with the aim of introducing requirements around economic gain, food fraud and food defense. The British Retail Consortium (BRC) Global Standard for Food Safety has already introduced a section into its standard that requires accredited food facilities to carry out a vulnerability assessment on their raw materials. To comply, however, the BRC stan-

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dard requires the inclusion not just of food safety hazards but also those that would compromise the integrity of the product, such as quality or legal issues. FDA is clear that for HARPC, only food safety hazards due to economic gain should be included.

This means, for facilities accredited to the BRC Global Standard for Food Safety, or in the future, to any GFSI-recognized scheme once the GFSI has released its new benchmarking standard, food safety hazards will need to be included in their HARPC plan, plus an additional vulnerability assessment to manage integrity issues due to food fraud.

> "A typical HACCP plan would focus on the food safety errors that may occur during the processing of the product, and this remains a requirement for compliance with HARPC."

Ensuring the Scope Is Clear:

Ensuring that the system has a clear scope is essential to HACCP, and the scope must cover not only the elements of processing but also, for compliance with HARPC, the risks from the supply of raw materials and the inherent risks from those raw materials and the product.

Ensuring that those involved in the creation of the food safety system set out a clear scope is key to ensuring that the team assesses the pertinent hazards.

The scope should include the definition of the start and endpoints of the study, detailing what elements of the supply chain the food business is responsible for. FDA has stated that where a preventive control is required to ensure that the food is safe to consume, and this preventive control is not applied within the business's control but at a later step in the supply chain, then the business in question must still take some responsibility to ensure that the preventive control is applied effectively. An example of this may be where raw meat is processed and packed raw for further cooking by another processor or by the consumer prior to consumption. Therefore, the scope can be used to provide clarity about the boundaries of responsibility and where preventive controls are applied at a later step.

Providing Knowledgeable & Experienced Resources:

Part of the scoping exercise should include consideration of the resources required to carry out the food safety assessment.

To conform to National Advisory Committee on Microbiological Criteria for Foods (NACMCF) and Codex Alimentarius guidance and standards, the system must be developed and implemented by a multidisciplinary team to ensure that the necessary experience and knowledge about the product and process is available to pinpoint the pertinent hazards.

FDA's introduction of the term "Preventive Controls Qualified Individual" (PCQI) reiterates the importance of having the required experience and knowledge of the specific food safety principles relating to the product and processes available. The focus of FDA is that a PCQI must conduct or oversee the development and implementation of the plan. To comply with both elements, both approaches must be taken: a multi-disciplinary team including a PCQI, perhaps as the team leader.

The experience and knowledge of the PCQI is vital. This person can be qualified either by their experience or by training, but they must be able to extract the pertinent hazards from the information defined in the scope and be able to present the plan confidently and competently.

Prerequisites:

Within the scoping element of the system, prerequisites must be defined to comply with HACCP principles. Although FDA does not specifically talk about prerequisites, the agency expects the system to be underpinned by Good Manufacturing Practices (GMPs), which would generally be prerequisites. Prerequisites are the fundamental building blocks of any good manufacturing system; without these, any additional food safety controls that are applied will not be effectively supported.

FDA has improved the original GMPs to make them more robust; in addition, FDA has specified a number of prerequisite-type controls that would need to be included as part of an HARPC system, which are the following:

- Process controls
- Food allergen controls
- Sanitation controls
- Supply chain controls
- Recall plan

A good food safety system should detail the prerequisites, including the GMPs, which support it. It is beneficial to use this list as a reference point to the procedures that provide the detail of these controls.

2 & 3. Identify the Hazards and Perform the Hazard Analysis

The hazard categories that must be assessed are aligned within the HACCP and HARPC requirements and must cover microbiological, physical, chemical (including allergenic), and radiological hazards.

The manifestation sources of the hazards that must be taken into consideration are the following:

- The recipe or formulation (inherent product risks)
- The ingredients (inherent risks and those from economic gain)
- The intended use (and user) of the food
- The product processes, including the equipment and tools used
- The fabrication and facility environment

Inherent Hazards:

Typical HACCP requirements would not specifically state, as FDA has done, that hazards inherent to the raw materials and product must be included.

However, within HACCP, a product description is required that alludes to the fact that hazards from raw materials (through composition and country of origin) and the finished product (from the intrinsic risks and treatment of the product) should be included.

An inherent hazard is something that is characteristic of the ingredient, packaging, or the finished product. Inherent hazards require a very specific and detailed knowl-

edge of the microbiological, chemical, radiological, and physical risks associated with the particular raw materials being used and the products being produced.

Examples of these may be:

- Fragments of bone in meat, such as shredded duck
- The risk of wheat in gluten-free coatings
- Growth of *Listeria monocytogenes* in chilled, ready-to-eat sliced meat
- *Campylobacter* spp. in raw chicken
- *Staphylococcus aureus* in raw milk

Intended Use & User:

To comply with HACCP principles, in addition to the product description, the scope should include a description of the intended use and intended user. The purpose of this is very much in line with FDA's intentions to ensure that the necessary information and understanding are channeled into the Hazard Analysis. By describing the product and what treatments and food safety hurdles make it safe, this focuses the team and the PCQI to take these specific elements into account.

Hazards that may be taken from the intended use or user may include cooking instructions for the consumer, if it is a raw meat product or consumption of the product by vulnerable groups, including those with allergies.

The Product Processes:

As with a conventional HACCP, the hazards applicable to the processing of the product must be included. This should include the assessment of any hazards that may arise from the equipment or tools used. Within an NACMCF or Codex Alimentarius HACCP system, a process flow diagram would be essential. FDA does not make reference to the use of a process flow diagram; however, it is sensible to assume that either a diagram or, for simple processes, a list of steps would be required to ensure that none were missed. For facilities working to HACCP principles, the need for a process flow diagram will remain.

Fabrication & Facility Environment:

FDA has made special reference to the risks associated within the environment, specifically around ready-to-eat products and contamination from pathogens such as *L. monocytogenes*. The process flow diagram can be used to aid this process. While walking the process steps, the team and PCQI should not only assess the food contact elements of the process but also look above and around the process step to establish if there are any environmental hazards that must be included. For example, where clean-as-you-go practices use wet cleaning, perhaps with pressurized water, there may be a risk of *L. monocytogenes* becoming airborne on water droplets, which may contaminate food contact surfaces. For nonfood-contact glass, sensors above open product may need to be considered a risk in case of breakage.

Focusing the Hazards:

A typical HACCP system will include all the hazards that could possibly occur. These hazards would then be mitigated through the risk assessment, due to the controls in place, or the CCP decision tree would be used to determine that they are managed by the prerequisite programs. A HARPC plan requires a much more structured and focused approach to determining which of the hazards are pertinent and should be included in the assessment.

> "To ensure that the food system continues to be effective and meet the HACCP principles and Preventive Control rule for HARPC, it needs to be continually reviewed.

One major fundamental difference between the HACCP principles and the requirements for the Preventive Controls rule for HARPC is that the risk assessment for HACCP should be carried out taking into account any controls, and for HARPC, the risk assessment must be carried out in the absence of any controls.

The risk assessment for both systems requires the severity and likelihood (FDA terms this "occurrence") of the hazard to be assessed to determine significance.

Because a HARPC system expects the likelihood of the hazard occurring to not take into account any of the controls that are currently in place, this will mean the number of significant food safety risks that are determined will be much higher than in a typical HACCP system. If all these significant hazards were then put through a CCP decision tree, the system would generate a large number of CCPs, which would be impractical and probably cause the system to be ineffective.

Therefore, it is vital that only the really pertinent hazards that could reasonably occur be highlighted for risk assessment. This way, the number of significant hazards generated that require preventive controls is focused on the control of the truly important food safety hazards.

4–6. Add Preventive Controls, Monitoring, Correction, & Corrective Actions

A preventive control must prevent the hazard from occurring or provide positive confirmation that the hazard has, or has not, occurred. Where the hazard has occurred, procedures must be in place to correct the hazard to bring it back into control, plus control the affected nonconforming product so that it is not released as good product.

A preventive control requires criteria or critical limits to be applied. Critical limits are objective and based on validation. The validation must provide evidence that the critical limits control the hazard effectively. Preventive controls that may have critical limits are activities such as testing or minimum oxygen values in modified-atmosphere packing.

Where a critical limit cannot be applied, because the preventive control is more subjective, criteria should be applied and these criteria should be justified. The hazard of shards of bone in shredded duck, for example, may be controlled through the application of a preventive control where the ingredient is visually assessed for bones. A 100 percent manual check for bones would not be practical, so a proportion of the ingredient would need to be assessed. The quantity assessed per batch or per delivery would need to justified, and the pass criteria would also need to be set and justified, for example, one bone per set number of

kg of product assessed.

All preventive controls will require a monitoring procedure that details the process of monitoring, the criteria or critical limits, and the action that must be taken when the criteria or critical limits are not met. This can be produced in the form of a procedure, an instruction or a Standard Operating Procedure, depending on what works best for the facility and the preventive control. The key is to ensure that all the necessary information is documented and is set out in a way in which it can be easily understood and distributed to those involved.

From the preventive controls generated, there now needs to be a new type of assessment to determine which of the preventive controls must be classed as a CCP. Using a typical decision tree will not align, because essentially this will mean that the majority of the preventive controls will become CCPs. There needs to be a structured approach, and the key to applying such a system requires clarity of the difference between a preventive control and a CCP.

FDA defines a preventive control as "risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the Hazard Analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packing, or holding at the time of the analysis."[1]

The above is more of a statement than a definition; however, the key elements can be extracted from it, which are that a preventive control significantly minimizes or prevents a hazard.

FDA refers to the definition of a CCP in the final rule, and this is in line with NACMCF and Codex Alimentarius, as "a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level."

Comparing the definitions, it can be established that both a preventive control and a CCP are designed to prevent a hazard from occurring; therefore, this is not the distinguishing factor. The distinguishing factor is:

- A preventive control is one that significantly minimizes the hazard.
- A CCP is a control that eliminates or reduces the hazard to an acceptable level.

7 & 8. Verify & Reanalyze the System

To ensure that the food system continues to be effective and meet the HACCP principles and Preventive Controls rule for HARPC, it needs to be continually reviewed.

The HACCP principles and HARPC requirements are aligned in their expectations of this. To ensure that the system is effectively maintained, verification activities and regular reviews must be carried out. Verification activities may include:

- Checking and signing off that preventive controls records have been completed correctly
- Testing of raw materials in process materials or finished product
- Verifying the accuracy of monitoring or measuring equipment
- Environmental testing, such as *L. monocytogenes* swabbing
- Reviews, including trending and complaints

FDA has been very clear that part of the ongoing maintenance of the system must be to ensure that records are available to provide evidence that the system is effective. These records must document that verification and review activities are taking place.

Conclusions

In summary, there are parallels between the HACCP principles and the Preventive Controls rule for HARPC, but the key contradictions in the system make their amalgamation difficult. A detailed knowledge of both requirements is essential to ensuring that the system does not become confused or overly cumbersome. ■

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Reference

1. https://www.federalregister.gov/articles/2015/09/17/2015-21920/current-good-manufacturing-practice-hazard-analysis-and-risk-based-preventive-controls-for-human.

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By Bala Kottapalli, Ph.D., CQE, and Loralyn H. Ledenbach, M.Sc.

Essentials of Hazard Analysis for Process Preventive Controls: Part 1

The basic principles of Hazard Analysis and Critical Control Points (HACCP) have been recognized since the 1970s, and more formal programs have been continually evolving since then. Regulatory agencies in the United States [U.S. Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA)] and Canada (Canadian Food Inspection Agency) have each issued their own set of HACCP regulations. Each system follows the concepts of the standard seven principles of HACCP, at times with the use of different terms. At the heart of any HACCP or food safety plan are the documented control measures, which are based on the Hazard Analysis.

Control Measure Concepts in North America

The USDA Food Safety Inspection Service HACCP regulation[1] was the first rule published on HACCP in the United States and requires the use of CCPs to control hazards reasonably likely to occur that were identified during the Hazard Analysis. Prerequisite programs (PRPs) are defined as written procedures that describe specific activities of a plant that can be used to support decisions made in the Hazard Analysis. PRPs do not control food safety hazards. Good Manufacturing Practices (GMPs) or Sanitation Standard Operating Procedures (SSOPs) are examples of PRPs.[2,3] While PRPs are not considered a sufficient control measure for an identified food safety hazard, these programs are considered support for hazards being considered not reasonably likely to occur, and as a justification for not adding a potential hazard to an HACCP plan.

FDA has promulgated three regulations relating to HACCP and food safety, commonly referred to as Juice HACCP,[4] Seafood HACCP[5], and the Preventive Controls rule.[6] Under Juice HACCP, the regulated facility is required to implement control measures for all hazards deemed reasonably likely to occur that were identified during the Hazard Analysis. Control measures can be CCPs or SSOPs. Good Agricultural Practices (GAPs) and Current GMPs (CGMPs) are not considered to be control measures. Seafood HACCP provisions are nearly identical to those in Juice HACCP, except that instead of "control measure," the term "preventive measure" is used. CCPs and SSOPs are the required preventive measures for all hazards deemed

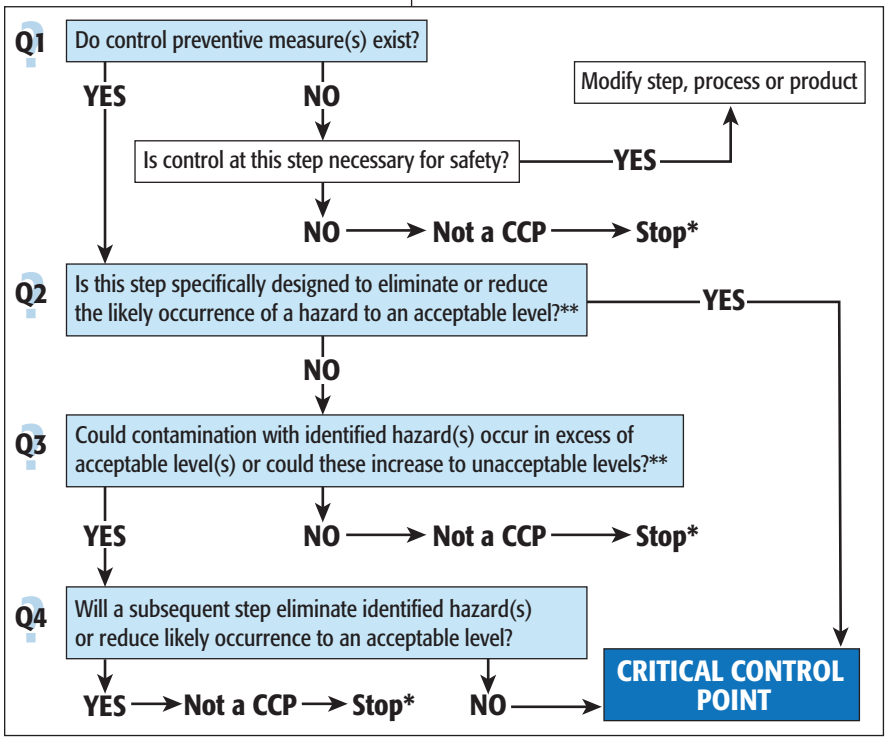

Figure 1. Codex Decision Tree

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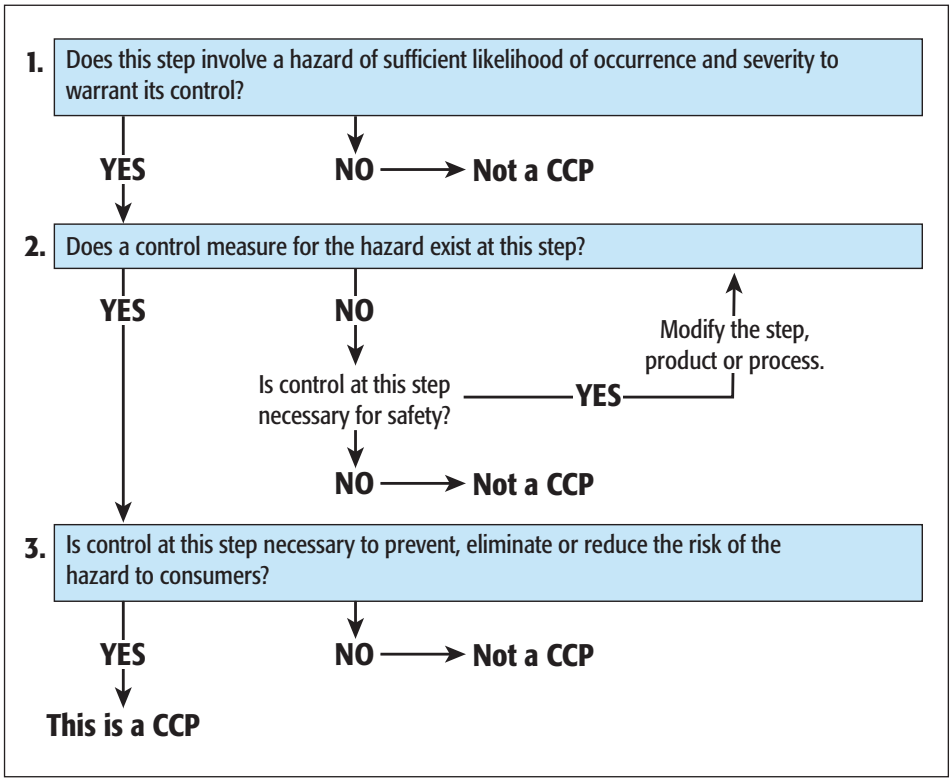

Figure 2. Decision Tree Suggested in the Seafood HACCP Guidance

Using Decision Trees to Determine the Type of Preventive Control

An Internet search for "HACCP decision trees" will result in a hundred types of decision trees, but all of them have common elements, and many relate back to the decision tree listed by Codex Alimentarius.[9] This is often referred to simply as the Codex Decision Tree (Figure 1). To use this decision tree to decide whether a particular preventive control measure should be a CCP at a process step, there are certain pieces of information needed: the process steps where control measures may be applied, the potential control measures, the effectiveness of the control measures and the contamination potential of the product after control steps have been applied. The output from this tree is either that the process step is a CCP or the process step is not a CCP. If the process step is not a CCP, then the assumption is made that the process step does not need to be a preventive measure at all, or that it may need to become a PRP or SSOP.

reasonably likely to occur that were identified during Hazard Analysis.

The Preventive Controls rule is the first regulation that introduces the concept of "preventive controls," which are defined as "(i) Controls at CCPs, if there are any CCPs, or (ii) Controls, other than those at CCPs, that are also appropriate for food safety." This rule does not require use of the terms CCPs, operational PRPs (OPRPs) or PRPs, but rather any control that is appropriate for food safety is considered a preventive control. Decisions on how to choose, verify and validate controls other than CCPs can be difficult, especially for smaller companies. Various terms have been coined to describe controls other than CCPs, such as OPRPs, "specific PRPs," and the more traditional terms PRPs and "universal PRPs."

The Safe Food for Canadians Act[7] refers to the use of the Canadian *Food Safety Enhancement Program Manual* 2014-07-01. Prior to the publication of this act, HACCP systems in Canada were similar to those in the U.S., and Canadian HACCP systems were early adopters of the use of PRPs as control measures in the first edition of the Canadian *Food Safety Enhancement Program Manual*.[8]

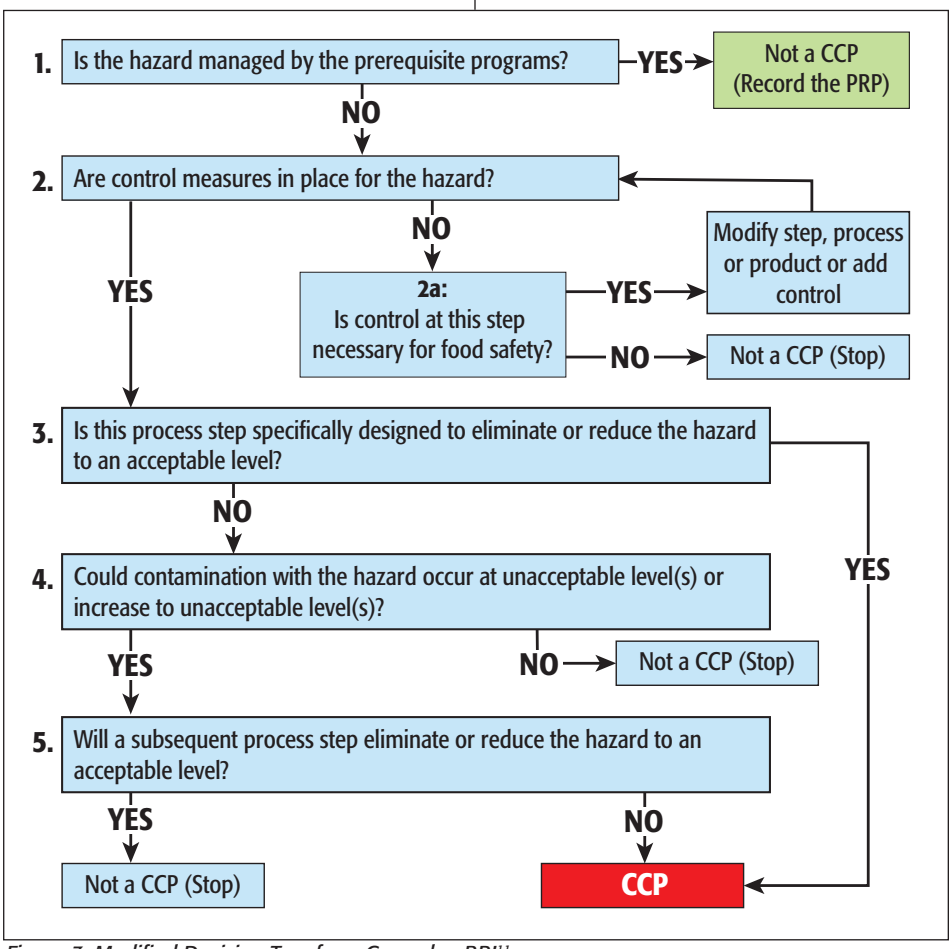

Figure 3. Modified Decision Tree from Campden BRI[11]

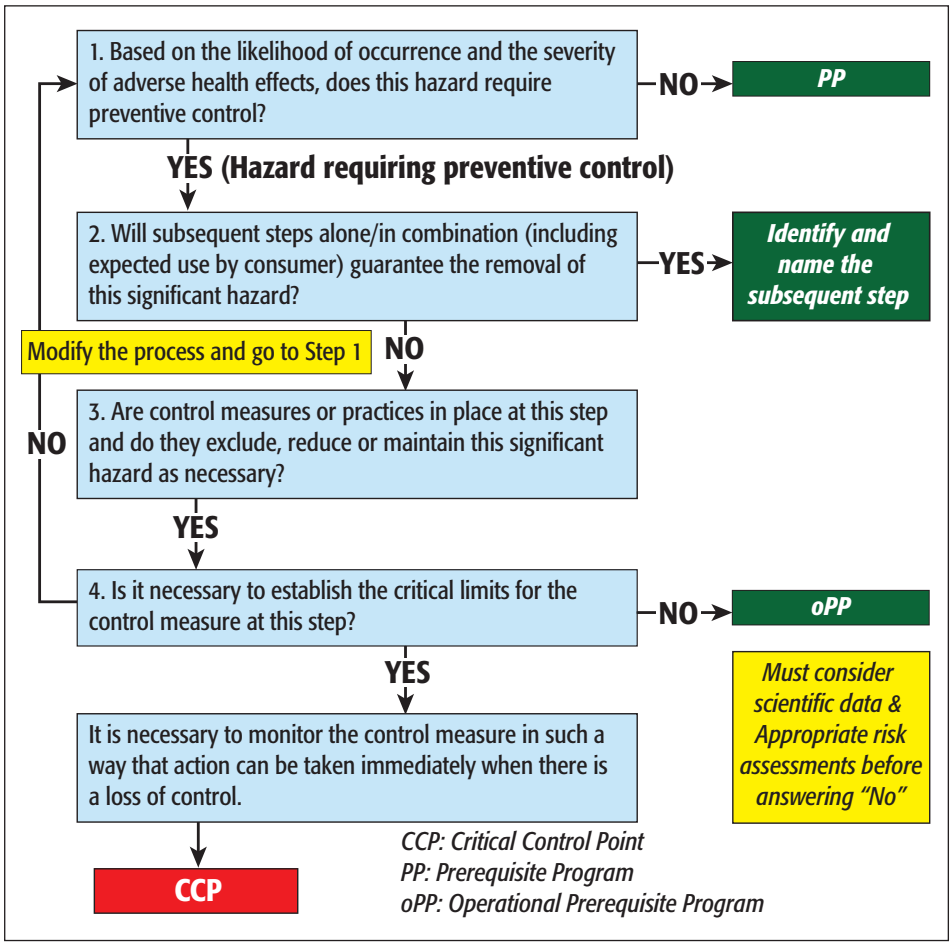

Figure 4. Modified Tree That Allows for OPRPs in the Decision-Making Process

Figure 2 is a similar decision tree suggested in the Seafood HACCP guidance,[10] with fewer questions but similar outputs. Figure 3 is another modified decision tree from Campden BRI[11] that starts with the question about whether the identified hazard is managed by PRPs and stops the process immediately if the answer is yes. This decision tree could possibly be used for USDA, Juice HACCP, and Seafood HACCP plans, but would not be practical for facilities regulated under the FDA Preventive Controls rule. While these trees can be very helpful for determining CCPs, they are not as useful when a facility has "preventive controls other than CCPs" in their HACCP system for certain identified hazards. These preventive controls may still be necessary for food safety but will not meet the criteria for a CCP in these other trees. For those situations, modified Codex decision trees could be more helpful. Figure 4 shows modified trees that allow for the possibility of OPRPs in the decision-making process.

Using Other Tools to Determine the Type of Preventive Control

Another commonly used tool to aid with the determination of type of preventive control is a risk matrix. Typical risk matrices used in the Hazard Analysis combine severity rankings with likelihood of occurrence rankings for a given hazard. Examples are 3 × 3 and 5 × 5 matrices.

Ratings for a 3 × 3 matrix could look like this:

Severity	Likelihood
1: Low or no risk, no proven risk of illness or injury	1: Rare, not known or unlikely to happen
2: Medium risk, harmful with high dose or cumulative dose, or causes discomfort but not injury	2: Frequent, occurs occasionally or spaced
3: High risk, severe illness or injury	3: Recurring, occurs often

Use of the 3 × 3 matrix is illustrated in Figure 5.[12] Hazards rated as 1–3 (indicated in green in the figure) are managed by PRPs, hazards rated as 4–6 (indicated in yellow in the figure) are managed by OPRPs, a combination of OPRPs or CCPs, and hazards rated as 9 (indicated in red in the figure) are managed by CCPs.

Severity - > Likelihood of Occurence (Facility)	1	2	3
1	1	2	3
2	2	4	6
3	3	6	9

Figure 5. Three-by-Three Matrix[12]

Ratings for a 5 × 5 matrix could look like this:

Severity	Likelihood
1: Not significant	1: Practically impossible
2: Consumer discomfort	2: Not expected to occur
3: Illness	3: Could occur
4: Hospitalization	4: Known to occur
5: Fatality	5: Common occurrence

Use of the 5 × 5 matrix is illustrated in Figure 6. Hazards rated in green are managed by PRPs, hazards rated in yellow are managed by OPRPs or a combination of OPRPs, and hazards rated in red are managed by a combination of OPRPs or CCPs.

Severity - > Likelihood	1	2	3	4	5
1	1	2	3	4	5
2	2	4	6	8	10
3	3	6	9	12	15
4	4	8	12	16	20
5	5	10	15	20	25

Figure 6. Five-by-Five Matrix

Summary

Hazard Analysis for food safety is a complex process and is different for every

type of food product and food manufacturing facility. It is easy to get caught up in predetermined schemes and rely on published guidance. Those tools, while an excellent starting point, should not be used "straight from the page" but adapted to each unique manufacturing facility scenario. Employing a combination of expert knowledge, use of decision trees and use of risk matrices is the most effective means of arriving at solid Hazard Analysis and preventive control decisions. ■

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References

1. *Federal Register*, 9 C.F.R. Part 417. January 1, 2012.
2. GMA. *HACCP – A Systematic Approach to Food Safety: A Comprehensive Manual for Developing and Implementing a Hazard Analysis and Critical Control Point Plan*, 5th ed. (2014).
3. NACMCF. 1998. "Hazard Analysis and Critical Control Point Principles and Application Guidelines." *J Food Prot* 61:762–775.
4. *Federal Register*, 21 C.F.R. Part 120. January 19, 2001.
5. *Federal Register*, 21 C.F.R. Part 123. December 19, 1995.
6. *Federal Register*, 21 C.F.R. Part 117. September 17, 2015.
7. Safe Food for Canadians Act S.C. 2012, c.24.
8. Canadian Food Inspection Agency. *Food Safety Enhancement Program Implementation Manual*, Volumes 1 and 2 (Ottawa: Government of Canada, 1993).
9. Codex Alimentarius Commission. 2003. "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for its Application," Annex to CAC/RCP 1-1969 (Rev. 4-2003).
10. *Fish and Fishery Products Hazards and Controls Guidance*, 4th ed. (Department of Health and Human Services, Public Health Service, FDA Center for Food Safety and Applied Nutrition, Office of Food Safety, 2011).
11. Campden BRI. *Guideline 42, HACCP – A Practical Guide*, 5th ed. (2015).
12. CCP/OPPR Decision Tree. 2009. Coca-Cola Company and Michigan State University; www.fskntraining.org, licensed under CC-BY-SA.

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By Bala Kottapalli, Ph.D., CQE, and Loralyn H. Ledenbach, M.Sc.

Essentials of Hazard Analysis for Process Preventive Controls: Part 2

In Part 1 of our article series, we talked about the basic principles of Hazard Analysis and Critical Control Points (HACCP) and the regulations specific to agencies in the United States [U.S. Food and Drug Administration (FDA) and U.S. Department of Agriculture (USDA)] and Canada (Canadian Food Inspection Agency).

An outcome of a manufacturing facility's Hazard Analysis (based on the guidance discussed in Part 1) would include identification of preventive controls that would significantly minimize and prevent the identified reasonably foreseeable hazards. These preventive controls can be broadly classified into process controls, food allergen controls, sanitation controls, and supply chain controls as appropriate to the nature of the facility and the products produced. This article focuses on the requirements for the identification and implementation (specifically the preventive control management components: monitoring, corrective actions, verification, and records) of process preventive controls.

Process Preventive Controls

Per the Food Safety Modernization Act Section 117.135, process preventive controls include "*procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, acidifying, irradiating, and refrigerating foods. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system: (i) Parameters associated with the control of the hazard; and (ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control.*"

Process preventive controls play an important role in a facility's food safety plan since they are considered very critical for food safety. Process preventive controls (e.g., thermal processing, irradiation) result in significant reduction in potential food safety hazards and hence are often deemed CCPs (CCPs require establishment of critical limits) to reinforce the importance of their role in a facility's food safety plan. In some situations, process preventive controls, where the parameters (referred to as quality control points or operational limits) required to produce a saleable acceptable product quality far exceed the established food safety limits, may be managed as an operational prerequisite program (OPRP) in a facility's safety plan. In this situation, the food safety team must perform a scientific risk assessment in conjunction with expert microbiologists and statisticians to justify the decision (Figure 1). One common mistake in determining CCPs/OPRPs for the food safety team is to start with existing controls and determine which of these are CCPs/OPRPs, ignoring the Hazard Analysis. This will probably result in over- or underestimating the reasonably foreseeable hazards, leading to poor identification of preventive controls and thereby resulting in an inadequate food safety plan. Decision trees provide a meaningful and standardized approach to help the manufacturer identify if the specific process preventive control can be managed as a CCP or OPRP. The decision to choose a CCP or OPRP must be science-based and be performed in consultation with a subject matter expert (SME) and not simply refer to past decisions and/or current facility procedures. Following the decision of the choice of CCP or OPRP, the food safety team must then list parameters and critical limits/operational limits (or quality control points, the minimum or maximum values associated with the parameters) for the controls for each hazard.

Validation is a key component in the design of critical/operational limits for process preventive controls. In recent years, the requirement for thermal process validations has received significant attention owing to several recalls of low- moisture foods.[1–6] Thermal process validation approaches may typically be classified into three categories:[7]

1. Measurement of the physical delivery of the process and comparison with published data
2. A microbiological challenge study of the process with pathogen strains or a valid surrogate organism, to demonstrate a

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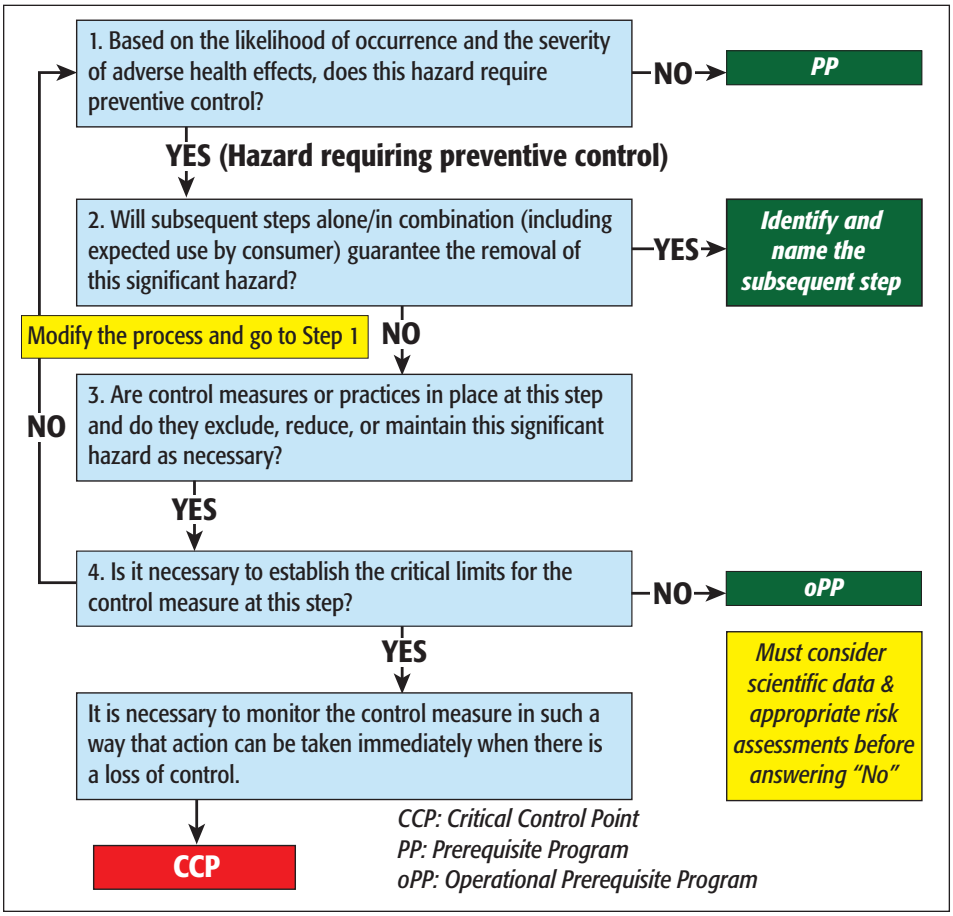

Figure 1. Modified Tree That Allows for OPRPs in the Decision-Making Process

desired reduction

3. Process modeling with data from thermal-death time studies, using data either from the literature or from experiments conducted by the processor

Similar approaches can be applied for other process preventive controls such as irradiation, acidification, and refrigeration of foods. There is a plethora of information regarding how to perform validation studies for different types of process preventive controls from several credible resources.[8–12]

Finally, the elements of monitoring, corrective actions to be taken when deviations from the critical/operational limits occur, verification procedures, and records must also be documented as part of the food safety plan.

Monitoring: Monitoring is defined as "the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control" (21 C.F.R. 117.3, Definitions).

Monitoring of CCPs/OPRPs must be routinely conducted to determine whether the process is operating within the critical/operational limits. Appropriate corrective actions must be taken when deviations relating to critical/operational limits are encountered. Monitoring activities should be designed to alert the designated employee/qualified individual conducting the monitoring activities in the event of a deviation. As outlined by the National Advisory Committee on Microbiological Criteria for Foods (NACMCF),[9] monitoring serves three main purposes: 1) tracking of the operation; 2) determining when there is a loss of control or when a deviation from a critical/operational limit occurs; and 3) monitoring activities that involve measurement and/observation. Monitoring differs from verification in that it is intended to provide real-time data on whether a CCP/OPRP is implemented properly. There are four elements of monitoring: 1) what will be monitored; 2) how it will be monitored; 3) when it will be monitored; and 4) who will perform the monitoring.

What will be monitored: Depending on the nature of the control measure, monitoring activities may include (but are not limited to) measurement of pH, temperature, time, volume/weight, flow rate, acid addition, water activity, chemical concentration, appearance, process performance, and other relevant factors as appropriate to the control measure.

How it will be monitored: Selecting an appropriate monitoring device should be the first order of business when designing monitoring activities. Monitoring activities are expected to produce an accurate record for future use in verification; hence, the measurement monitoring devices should be calibrated and deliver highly sensitive and accurate measurements.

When it will be monitored: Monitoring activities may be classified into continuous or noncontinuous. For noncontinuous monitoring activities, it is important to perform at a frequency sufficient to establish process control. Process capability studies may be considered to determine the appropriate frequency. Continuous monitoring at a CCP/OPRP is preferred but may not always be practical or necessary. Continuous monitoring becomes more of a critical requirement if minor variations/deviations in the critical limits may otherwise go unnoticed. Automatic and continuous monitoring is possible with many types of physical (temperature, time) and chemical measurements (pH, chlorine concentration). In some cases, modern technology has made it possible to continuously monitor variables like temperatures on statistical process control charts and electronically communicate (email alerts) to designated employee(s)/qualified individual(s) where deviations from critical/operational limits are encountered. This will not only facilitate real-time verification of a facility's food safety system but also trigger corrective actions in a timely manner.[13]

Who will perform the monitoring: Qualified individuals assigned to preventive controls monitoring activities must receive appropriate training for the tasks.

Corrective actions: An important purpose of corrective actions is to prevent adulterated foods from entering commerce. Where there is a deviation from established critical/operational limits, corrective actions are necessary. Therefore, corrective actions should a) identify the problem; b) correct or contain the problem; c) eval-

uate affected food for safety and prevent it from entering commerce if you cannot ensure (prove and document) the affected food is not adulterated or misbranded; d) determine the root cause of the nonconformance; e) take corrective action to prevent its recurrence; f) identify and initiate preventive actions to eliminate the cause for the future (i.e., proactive procedure); g) review and approve the corrective and preventive action report; h) monitor and evaluate the corrective and preventive actions to ensure that they are effective; i) when appropriate, reanalyze the food safety plan to determine whether modification of the plan is required; and j) document all actions performed. Specific corrective actions should be developed in advance for each CCP/OPRP and included in the facility's food safety plan. At a minimum, the food safety plan should identify what was done in the event of deviation and identify the role and responsibility of the person performing the activity. Individuals who have thorough understanding of the process, product, and food safety plan should be assigned the responsibility for oversight of corrective actions. As appropriate, SMEs may be consulted to perform a scientific evaluation to determine the disposition of the nonconforming product.[13]

Verification: The primary purpose of the verification activity is to evaluate if a facility's food safety system is effectively functioning as intended. An effective food safety system may require little product testing, since it relies on frequent reviews of their food safety plan, effective management of preventive controls, and foundational food safety programs (PRPs). Another aspect of verification is the initial validation of the food safety plan to determine that the plan is scientifically and technically sound, that all hazards have been identified, and that if the food safety plan is properly implemented, these hazards will be effectively controlled. Information needed to validate the food safety plan often includes expert advice and scientific studies, and in-plant observations, measurements, and evaluations. For example, validation of the roasting process of peanuts must include the scientific justification of the heating times and temperatures needed to obtain an appropriate destruction of pathogenic microorganisms (e.g., *Salmonella*) and studies to confirm that the conditions of roasting will deliver the required time and temperature to each peanut. Subsequent validations are triggered by major changes to the food safety plan (e.g., change of process, use of new raw material supplier, emergence of new hazards, installation of new equipment).[13]

Records: Records maintained for the food safety system should include the following: 1) a summary of the Hazard Analysis, including the rationale for determining hazards and control measures, and 2) CCP/OPRP summary tables identifying hazards of concern, critical/operational limits, monitoring, corrective actions, verification procedures, and record-keeping procedures.

Considerations for Decision Making	Rationale
Is it reasonably foreseeable that *Clostridium botulinum* will grow and produce toxin during finished product storage at the manufacturing facility if temperature is not controlled?	Yes. These products contain no barriers (other than refrigeration) to toxin formation by *C. botulinum* type E and nonproteolytic types B and F during finished product storage and distribution.
Can growth and toxin formation by *C. botulinum* that is reasonably foreseeable be eliminated or reduced to an acceptable level based on intended use?	No, because of the extremely toxic nature of *C. botulinum* toxin, it is unlikely that the significance of the hazard will be affected by the intended use of the product.
Is it necessary to establish critical limits for control of the identified hazard?	Yes. Refrigerated finished product storage is critical to the safety of all products in this category and must be identified as a CCP.
What are the critical limits?	The product is held at a cooler temperature of 40 °F or below. Note that allowance for routine refrigeration defrost cycles may be necessary. Also, note that you may choose to set a critical limit that specifies a time and temperature of exposure to temperatures above 40 °F.
What are the monitoring procedures?	What: The temperature of the cooler How: Use a continuous temperature-recording device (e.g., a recording thermometer) When: Continuous monitoring by the device itself, with a visual check of the recorded data at least once per day Who: Monitoring is performed by the device itself. The visual check of the data generated by the device, to ensure that the critical limits have been met consistently, may be performed by any designated employee who understands the nature of the controls.
What are the corrective actions?	Chill and hold the affected product until an evaluation (including root-cause analysis) of the total time and temperature exposure is performed (OR) destroy the product (OR) divert product for nonfood use.
What are the record-keeping practices?	Printouts, charts or readings from continuous temperature-recording devices (AND) record of visual checks of recorded data.
What are the verification procedures?	Comparing the temperature reading on the device with known accurate reference device [e.g., a National Institute of Standards and Technology (NIST)-certified thermometer] under conditions that are similar to how it will be used (e.g., air temperature) (AND) check temperature records daily (AND) calibrate thermometers (AND) review monitoring, corrective action and verification records within 1 week of preparation to ensure they are complete and any critical limit deviations that occurred were appropriately addressed.

Example 1.

In this article, we describe two examples to illustrate how Hazard Analysis drives the decision to choose a CCP/OPRP and eventually develop preventive control management components (monitoring, verification, corrective actions, and record keeping).

Example 1: High-moisture fishery products in which temperature is the sole requirement to prevent toxin formation and is managed as a CCP in a facility's food safety plan.

Note: Example 1 is provided for illustration purposes only based on the guidance published in *Fish and Fishery Products Hazards and Controls Guidance*.[14] Manufacturing facilities must perform Hazard Analysis and identify preventive controls as appropriate to the nature of the applicable control and its role in the facility's food safety system.

Example 2: Frozen bakery products in which a cooking process is used to significantly minimize or prevent *Salmonella* spp. survival and is managed as an OPRP in a facility's food safety plan.

Note: The above example is provided for illustration purposes only based on the International Association for Food Protection (IAFP) poster presentations by Kottapalli et al.[15] and Kottapalli and Schaffner.[16] Manufacturing facilities must perform Hazard Analysis and identify preventive controls as appropriate to the nature of the applicable control and its role in the facility's food safety system.

Advantages, Disadvantages, and Limitations of Tools

The main advantage of using decision trees and/or risk matrices is that they provide a straightforward, easily documented approach to determining the type of control measure needed to address an identified hazard during risk analysis. For larger companies with multiple facilities, these tools are a good way to standardize the Hazard Analysis approach across the company. Codex Alimentarius recommends training in the use of the decision tree,[17] and in the Seafood HACCP guidance, FDA recommends that users "not rely exclusively on the decision tree, because error may result."[14] Each facility and food safety plan is different and requires expert review to ensure the decision tree results are, in fact, appropriate to the Hazard Analysis. Some examples of this limitation are described below.

Earlier decision trees developed prior to the introduction of the preventive control concept have an inherently limited flexibility to consider OPRPs. These early trees have only "CCP" and "Not a CCP" options and do not describe what needs to happen for those control measures deemed "Not a CCP." While the assumption is that the "Not a CCP" measure will be maintained as a Good Hygiene Practice (GHP) or PRP, this is not explicitly stated within the decision trees themselves. Use of the modified decision trees in Figure 1 could be more helpful to facilities that have preventive controls to be managed as OPRPs.

Considerations for Decision Making	Rationale
What is the hazard of concern for this type of product?	*Salmonella* spp., based on scientific literature and epidemiology data.
Based on the likelihood of occurrence and the severity of the adverse health effects, is this a hazard requiring preventive control?	Yes. *Salmonella* is a reasonably foreseeable hazard in raw flour. Consumption of food contaminated with *Salmonella* can cause salmonellosis, one of the most common bacterial foodborne illnesses.
Will subsequent steps alone/in combination (including expected use by consumer) guarantee the removal of this significant hazard?	No. Cooking is the only step in the process that will effectively reduce *Salmonella* that is present in the dough.
Are control measures or practices in place at this step and do they exclude, reduce or maintain this significant hazard as necessary?	Yes. Cooking temperatures and times required to produce a saleable product. Exit product temperatures greater than 167 °F ensure at least a 5-log reduction in *Salmonella* spp.[15]
Is it necessary to establish the critical limits for the control measure at this step (consider scientific data and risk assessment, involve SMEs and expert statisticians as appropriate)?	No. Exit product temperatures required for saleable product are typically greater than 180 °F. Quantitative microbial risk assessment estimations indicate that the risk of salmonellosis from the proper cooking of raw flour-based batters (where "proper" is defined as an average internal temperature of 176 °F or above, and no longer a slurry and suitable for sale) is extremely low (99th percentile: one illness in every 312 years).[16] So, operational limits (176 °F) required to produce a saleable product can be used to manage the food safety risk. Hence, critical limits are not required.
What are the operational limits?	Products must be heated to minimum internal temperature of 176 °F or more.
What are the monitoring procedures?	What: Exit product temperatures How: Temperature-indicating device (e.g., a recording thermometer) When: Every 4 hours Who: Performed by any designated employee who understands the nature of the controls
What are the corrective actions?	Hold the affected product until an evaluation (including root-cause analysis) of the total time and temperature exposure is performed (OR) destroy the product (OR) divert product for nonfood use.
What are the record-keeping practices?	Temperature charts, hold-and-release records, corrective action records, verification records, traceability records.
What are the verification procedures?	Preshipment review of internal temperature data, designated plant employee reviews all disrupted process records, verification of temperature readout devices shall be verified weekly (when production is running) against a NIST-certified thermometer.

Example 2.

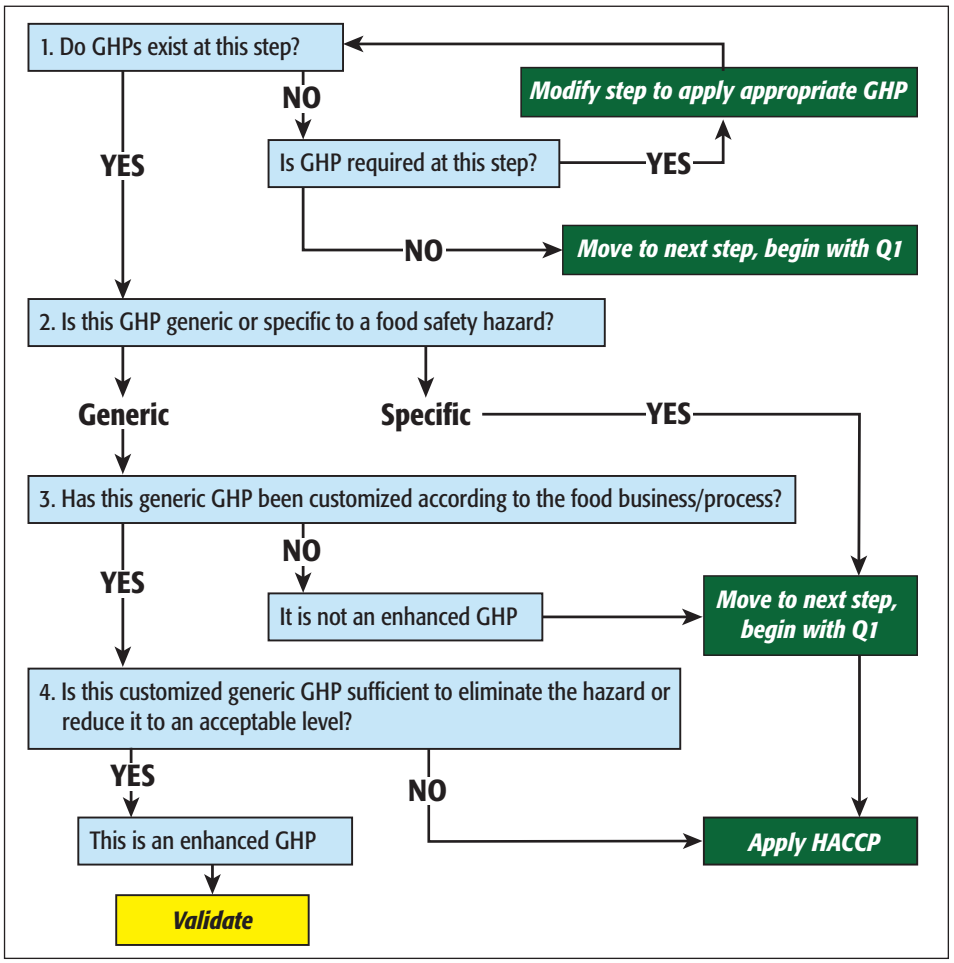

Figure 2. Proposed Decision Tree to Accompany the Codex Alimentarius Commission on Food Hygiene's Revisions for Enhanced GHPs

The Codex Committee on Food Hygiene is considering adding the concept of "Control Measures at Places other than CCPs" or "Enhanced GHPs," but this terminology has not yet been finalized.[18] There is a proposed decision tree (Figure 2) that accompanies this revision.

While the risk matrix approach may seem a good quantitative technique, the Hazard Analysis becomes more difficult when it gets to the point of assigning number rankings to certain hazards. Questions can arise on how much of a dose is considered a high dose, what is really the difference between a consumer who is ill and one who goes to the hospital, and what is the difference between something that occurs occasionally, occurs often, or is a common occurrence? Another option could be to take a more conservative approach to risk analysis, and instead of assigning number rankings to severity and likelihood, the decisions are made as to whether the hazard is or isn't severe, and whether the hazard is or isn't likely to occur. In this case, severity and likelihood rankings are listed simply as Yes or No. Combinations of Yes and No will determine whether the hazard is one that needs a preventive control and what type of preventive control it should be (Table 1).

Likelihood	Severity	Hazard Requiring Preventive Control	Rationale
Yes	Yes	Yes	Include the rationale for this analysis and manage the risk by CCP or OPRP (at a minimum)
No	No	No	Include the rationale for this analysis
No	Yes	No	Include the rationale behind why the likelihood of occurrence is a "No" (support the decision by referring to appropriate PRPs)
Yes	No	No	Include the rationale behind why the severity of the hazard is a "No" (support the decision by referring to appropriate PRPs)

Table 1. Risk Matrix

Depending on the situation at the individual facility, there are additional things to consider when determining the type of preventive control. The company or manufacturing facility food safety culture may be such that employees are biased toward "CCP thinking" and "prerequisite thinking." In these situations, operators are used to managing only two types of controls– either it is critical or it is not. Without intensive and appropriate training, having an OPRP control could cause confusion and result in less-than-optimal monitoring and verification of the control, since operators may not be able to discern the difference between an OPRP and the PRPs they are used to implementing. For facilities that operate under multiple regulatory jurisdictions, again there are opportunities for confusion among floor operators. For example, in a facility that makes snack kits, some of which contain meat and some that do not, a particular preventive control needs to be an OPRP in the FDA HACCP plan for the meatless snack kits, and a PRP in the USDA plan for the meat-containing snack kits. The monitoring and verification activities could be performed at different frequencies, and corrective actions could be different. Facilities that are audited under any of the various Global Food Safety Initiative auditing schemes will need to justify their decision-making process for the choice of preventive controls, so a well-documented procedure to follow when making these decisions is a necessary component of an HACCP/food safety plan. Facility personnel will need to understand and be able to explain any and all tools that were used to determine the type of preventive control.

Summary

Hazard Analysis for food safety is a complex process and is different for every

type of food product and food manufacturing facility. It is easy to get caught up in predetermined schemes and rely on published guidance documents. Those tools, while an excellent starting point, should not be used "straight from the page" but adapted to each unique manufacturing facility scenario. Employing a combination of expert knowledge, use of decision trees and use of risk matrices is the most effective means of arriving at solid Hazard Analysis and preventive control decisions. ■

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References

1. Almond Board of California. 2007. *Considerations for Proprietary Processes for Almond Pasteurization and Treatment*, v1.0.
2. Almond Board of California. 2007. *Guidelines for Process Validation Using* Enterococcus faecium *NRRL B-2354*, v1.2.
3. Almond Board of California. 2007. *Guidelines for Validation of Blanching Processes*, v1.0.
4. Almond Board of California. 2007. *Guidelines for Validation of Dry Roasting Processes*. *Guidelines for Validation of Oil Roasting Processes*.
5. Grocery Manufacturers Association. 2009. *Control of* Salmonella *in Low-Moisture Foods*.
6. Grocery Manufacturers Association. 2010. *Industry Handbook for Safe Processing of Nuts*.
7. Anderson, DG and LA Lucore. *Validating the Reduction of* Salmonella *and Other Pathogens in Heat Processed Low-Moisture Foods* (Alexandria, VA: Alliance for Innovation & Operational Excellence, 2012).
8. Codex Alimentarius Commission. *Guideline for the Validation of Food Safety Control Measures (CAC/GL 69-2008)* (Rome: Joint FAO/WHO Food Standards Program, 2008).
9. NACMCF. 1998. "Hazard Analysis and Critical Control Point Principles and Application Guidelines." *J Food Prot* 61:762–775.
10. NACMCF. 2006. "Requisite Scientific Parameters for Establishing the Equivalence of Alternative Methods of Pasteurization." *J Food Prot* 69:1190–1216.
11. NACMCF. 2010. "Parameters for Determining Inoculated Pack/Challenge Study Protocols." *J Food Prot* 73:140–202.
12. Scott, VN et al. 2005. "Guidelines for Conducting *Listeria monocytogenes* Challenge Testing of Foods." *Food Prot Trends* 25:818–825.
13. GMA. *HACCP – A Systematic Approach to Food Safety: A Comprehensive Manual for Developing and Implementing a Hazard Analysis and Critical Control Point Plan*, fifth ed. (2014).
14. Department of Health and Human Services, Public Health Service, Food and Drug Administration Center for Food Safety and Applied Nutrition, Office of Food Safety. *Fish and Fishery Products Hazards and Controls Guidance*, fourth ed. (2011).
15. Kottapalli, B, A Cunningham, Y Huang, E Akins and SJ Hermansky. "Survival of *Salmonella* spp. and *L. monocytogenes* during Pancake Cooking Process." Poster presentation at IAFP 2015 Annual Conference, Portland, OR.
16. Kottapalli, B and DW Schaffner. "Modeling the Risk of Salmonellosis Associated with Consumption of Frozen Precooked Pancakes." Poster presentation at IAFP 2016 Annual Conference, St. Louis, MO.
17. Codex Alimentarius Commission. 2003. "Hazard Analysis and Critical Control Point (HACCP) System and Guidelines for Its Application." Annex to CAC/RCP 1-1969 (Rev. 4-2003).
18. Codex Alimentarius Commission. *CX/FH 17/49/5 Proposed Draft Revision of the General Principles of Food Hygiene (CAC/RCP 1-1969) and its HACCP Annex*.

Food Safety can be overwhelming, but it doesn't have to be

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By Robert A. LaBudde, Ph.D.

The 7 Deadly Sins and 7 Heavenly Virtues of Food Safety: A Catechism of HACCP

Most discussions about food safety approach the subject from a scientific or managerial point of view. The dispassionate, scientific tone of these discussions leads to varying points of view and varying systems of prioritization. What is missing from these discussions is the realization that food safety is not simply another aspect of food quality. Instead, it is an issue of human morality: People die or become seriously ill from lapses in discipline.

In what follows, the sense of "right" and "wrong" in the practice of food safety is discussed, perhaps for the first time in print. The "Seven Deadly Sins" and "Seven Heavenly Virtues" of food safety are approached, not from just lists of seven items, but from the traditional foundations of human morality and ethics. It is hoped that by portraying the ethical problems of food safety in this manner, you will recognize the patterns of human behavior as the symptoms of the moral issues that underlie them.

Why "Sins" And "Virtues"?

Many experts consider "food safety" to be just one aspect of "food quality." However, there are several key differences. "Quality" is a vague and all- encompassing term and is assessed from a standpoint of economics. It is measured on at least an ordinal scale, so the level of quality can be defined as "better" or "worse" than another level, based on some figure of merit, such as dollars of profit or cost. "Safety" involves the lives of real people. It is assessed from a standpoint of the nominal scale of "right" vs. "wrong," not just economics.

Most people don't realize that when a widespread multistate outbreak of food- borne illness with deaths occurs, the U.S. Department of Agriculture (USDA) or the U.S. Food and Drug Administration (FDA) automatically convenes a federal grand jury that can issue indictments related to the episode. "Criminal intent" is a term judged on the basis of "right" vs. "wrong."

Righteousness, Sin And Virtue Defined

Before actions taken or omitted in food safety can be judged, a sense of "right" must be agreed upon. Although hundreds, if not thousands, of books and articles have been published on food safety and its current vogue methodology Hazard Analysis & Critical Control Points (HACCP), the overriding goal of food safety is never or rarely articulated. How can you steer a ship, if you have no compass?

Here is our mission statement for our food safety activities: "We will try, as far as is reasonably possible, to make sure every unit of food produced is safe for the consumer to eat." The word "reasonably" will depend on current knowledge and available technology. It is well-understood by the courts, where it is the basis of defining the crime and tort of negligence. For our purposes, it means the judgment expressed by a jury of our peers in reviewing our actions after the fact. It also means the judgment inflicted upon ourselves by our consciences when we review "what might have been." "Righteousness" is the performing of the duties implied by the mission statement for our food safety activities.

What are "sin" and "virtue"? Sin is defined as any willful thought, desire, word, action, omission, or commission contrary to righteousness. To the U.S. Attorney investigating a mortal outbreak, sin is defined as "criminal intent," "negligence," or "malfeasance." To your peers, it is "unprofessional" or "irresponsible" conduct. Virtue is defined as a habitual and firm disposition to act righteously. It is pro-activism in the pursuit of "professional" or "responsible" behavior.

The "Axis of Evil" in food safety is: Money-Guilt–Fear. The problem with ethics in food safety is the obvious and overriding importance of economics to commercial activities. The issue of loss of profits typically corrupts professional standards and leads to "sinful" behavior. After the fact, fear of losing one's job or other repercussions leads to cover-ups or further transgressions.

In addition to one's own commission of sins, there are nine ways of being accessory to another's sin. Part of righteous behavior is knowing how you can be tricked off the "straight and narrow path." This happens: (1) by counsel (i.e., participation in the

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making of a decision); (2) by command (i.e., making the decision); (3) by consent; (4) by provocation (i.e., coercion into a wrong decision); (5) by praise or flattery (i.e., in support of a wrong decision); (6) by concealment; (7) by partaking; (8) by silence; and (9) by defense of the ill done.

When a new duty is imposed upon you (e.g., by regulation), the following stages of thinking are typical before acceptance of the duty is attained: (1) shock (when the duty is imposed); (2) denial (that the new duty is necessary); (3) anger (that the burden was placed); (4) depression (in shouldering the burden); (5) bargaining (to reduce the burden); (6) sadness (that the burden cannot be escaped); and (7) acceptance of duty. In each stage but the last, the opportunity for wrong actions is possible.

> "Envy results in theft of a safety system design from prestigious sources, rather than designing one tailored to your own operations."

The 7 Deadly Sins

Human morals have been studied for thousands of years. Western civilization, at least, has codified wrong actions into seven categories:

Deadly Sin # 1: Pride or Arrogance. The Book of Proverbs cautions: "Pride goes before destruction, a haughty spirit before a fall." The Greeks had a saying: "Whom the Gods destroy, they first make mad." The sin of Pride evidences itself in food safety by a belief that can be summed up as, "It can't happen to me," "I know better than everyone else," or "I want to do it myself in my own way." Prideful behavior results in a NIH ("not-invented-here") attitude. You worry about who "owns" specifications and the power of control, not about what results occur. You don't fulfill your duties to food safety, because you "know" that they don't matter and are just "make-work."

Deadly Sin #2: Avarice or Greed. As is oft-quoted from the Book of Timothy, "The love of money is the root of all evil." The sin of Avarice is a common one in food safety. A company is in business, after all, for the purpose of making money. Its management begrudges every dollar of profit lost to avoidable costs. Excessive attention to food safety is often viewed as an avoidable cost. Greedy behavior results in an attempt to salvage every unit of production, even if the sublot is suspect for safety reasons. You are unwilling to accept the loss as the price of doing your duty to food safety and try contorted means to justify avoiding it. Greedy behavior is recognized by its arguments after the fact, which stand out in a system of food safety that is supposed to be pre-planned. The sin of Avarice is the unwillingness to commit to the importance of safety over cost.

Deadly Sin #3: Lust or Unnatural Desire. The sin of Lust is the unnatural and self-destructive desire for goals in conflict with your duties. It occurs in food safety when you strive to build a system for its own sake, not that of safety. Lustful behavior is evidenced by an overly complex implementation, or a love of technology over effectiveness. Common sense is overridden for the sake of "bells and whistles." The sin of Lust also can occur by its "flip-side": the fear of the pain of duty, an unwillingness to face hard issues and make hard decisions.

Deadly Sin #4: Anger or Wrath. The sin of Anger is the ire raised against those who impose your rightful duties upon you. Wrathful behavior shows itself sometimes as defensiveness. You won't brook criticism or learn from it. Wrathful behavior also appears as rebellion against duties and regulations instead of embracing them. You will recognize the sin of Anger when you hear arguments against duties, a refusal to take them seriously in a scoffing tone, and statements that the duties are burdensome or inconsequential.

Deadly Sin #5: Gluttony. The sin of Gluttony is an insatiable appetite that conflicts with the fulfillment of duties. In food safety, gluttonous behavior is the appetite for "bells and whistles" in the HACCP plan that diminish its effectiveness. It is the attempt to fold all of the quality and safety goals into one system, even though their goals conflict. Gluttonous behavior ignores the special importance of safety and considers safety is just one facet of quality. Gluttonous behavior is also marked by over-testing and inclusion of all control points as CCPs. You can recognize Gluttony in action when you see a refusal to discriminate and prioritize.

Deadly Sin #6: Envy. The sin of Envy is resentment against the good or approbation that others might receive. It is coupled frequently to the sin of Pride, and both are common to trained professionals. In food safety, Envy is evidenced by a NIH attitude, a refusal to allow other input into the safety plan or its implementation. Envy results in theft of a safety system design from prestigious sources, rather than designing one tailored to your own operations. Because of Envy, you begrudge the consumer his due, and fail to commit to the importance of safety above all else.

Deadly Sin #7: Sloth or Laziness. The sin of Sloth is a failure to take action when it is required, a lack of zeal or a drift into complacency. Sloth is common in food safety. You have a "paper" plan, not one that works. You don't bother to validate your interventions to make sure they really work. You are too lazy to characterize variability and take it into account. You are too lazy to analyze for special hazards and risks. You are too lazy to figure out interventions that work, so you use one that you know doesn't.

Sloth is evidenced a failure to "do." You know you should do something, you know that it's the right thing to do, but you don't do it because it's difficult or too much work. At a higher level, Sloth is spiritual laziness: You don't commit or act when you know you should, just because you don't bother to.

The 7 Heavenly Virtues

Corresponding to the classification of wrongful actions into Deadly Sins, rightful actions have also been classified into Heavenly Virtues:

Heavenly Virtue #1: Faith. The virtue of Faith is the belief that doing right is worth doing for its own sake. In food safety, Faith is evidenced by a belief in scientific principles and trust in cause-and-effect relations. Faith is commitment to safety above all else and the belief this will be rewarded over the long run.

Heavenly Virtue #2: Hope. The virtue

of Hope is the focus on good results in times of adversity. Hope reinforces Faith by trusting that all will turn out right in the end, if we just do our duty. Hope is waiting out the "learning curve" without getting discouraged and giving up our principles too soon.

Heavenly Virtue #3: Charity. The virtue of Charity is allowing others to have their due. Charity is keeping the consumer's safety at the forefront instead of other, secondary priorities. Charity is allowing others' input into planning, design and ownership of safety systems. Charity is placing the consumer's needs above your own.

Heavenly Virtue #4: Prudence. The virtue of Prudence in discerning in every instance the right goal and the right means for achieving it. In food safety, Prudence is evidenced in the use of validation and verification, and in having an error budget to ensure correct results. Prudence is multiple CCPs for serious hazards and periodic reviews to ensure all is working correctly. Prudence is deciding conservatively when it comes to safety.

Heavenly Virtue #5: Justice. The virtue of Justice is the firm and constant will to give others their due. In food safety, Justice is taking your duties seriously, giving consumer safety the priority it deserves, and always focusing on what you owe as a duty and how to meet it. Acting justly means not corrupting a system designed to work right in order to satisfy conflicting goals.

Heavenly Virtue #6: Fortitude. The virtue of Fortitude is firmness or courage in the face of adversity and constancy in the pursuit of righteousness. Fortitude means standing by your convictions and commitments, waiting out the "learning curve," and withstanding criticism and pressure. Fortitude is the moral courage to avoid "backsliding" when times get tough. Fortitude is needed to announce a recall, when you know the product may be unsafe.

Heavenly Virtue #7: Temperance. The virtue of Temperance is that of keeping a proper balance and the use of "common sense." Temperate action keeps things simple and focuses on results in meeting one's duties. It involves common sense to achieve workability, and it focuses on safety without trying to include subsidiary issues with competing priorities.

Just as in historical human morality, the Deadly Sins and Heavenly Virtues can be easily summarized by simple "Golden Rules" that are short statements of the philosophical goals behind "right" and "wrong." To paraphrase a few:

- Love thy consumer as thyself
- Serve food unto others as you would have them serve unto you.
- First, do no wrong.

7 Ways To Fail In Food Safety

Ultimately, there are seven ways to fail in ensuring safe food production:

1. Failure to consider a hazard
2. Failure to include all CCPs needed
3. Failure to validate interventions and plan
4. Failure to monitor
5. Failure to verify
6. Failure to take corrective action
7. Failure to recall

> Prudence is evidenced in the use of validation and verification, and in having an error budget to ensure correct results.

When considering a few cases involving food safety failures in terms of the Deadly Sins and Heavenly Virtues, one can see that such failures have a significant impact on more than the technicalities of food safety measures.

Case Study: Hudson Foods* E. coli *O157:H7 Outbreak. In the summer of 1997, 15 cases of *E. coli* O157:H7 were traced to frozen ground beef patties produced by a Hudson Foods plant. During the resulting political fallout, Hudson Foods ceased to exist as a company. The Hudson Foods plant was operating under a self-imposed HACCP plan. The plant general manager and top technical manager were indicted and tried in federal district court for criminal negligence, obstruction and conspiracy. (They were both acquitted.)

Deadly Sin/Heavenly Virtue tally:

1. The sins of Pride and Avarice in not testing its own brand name products for *E. Coli* O157:H7, when the franchise-chain product had required such testing. (No outbreak of EHEC has been documented as occurring from tested ground beef.)
2. The absence of the virtues of Faith, Prudence, and Justice.

Case Study: Snow Brand Company in Japan. In the summer of 2000, more than 15,000 cases of staphylococcal intoxications occurred throughout the Japanese school population as a result of milk products sold by Snow Brand. Pipes had been added to the producing plant's system, but were not documented on blueprints or approved by inspectors. As a result, the plant's own sanitation work- force failed to clean the new pipes for months.

According to the Corporate Social Responsibility website (www.mallenbaker.net/csr/index.html): "By all account, it [Snow Brand] initially sought to downplay the incident, and gave the impression of being more concerned for its reputation and standing than it was for the victims of the outbreak. The overall impression—as judiciously reported by the media at the time—was that the poisoning was the end-product of a company rife with corporate arrogance. The [company president] Tetsuro Ishikawa tried in vain to win support, and was eventually admitted to hospital suffering from the stress of the incident. The end result was that he, and seven executives, resigned in atonement for what had happened."

In 2001, the same company was caught repackaging Australian beef as Japanese in order to fraudulently claim compensation for condemned BSE product. The company's new president was again forced to resign. In 2002, Snow Brands was discovered repackaging frozen butter after its shelf-life had elapsed in order to extend the life by an additional year. Though not currently an illegal practice in Japan, it is an interesting footnote to Snow Brand's recent history.

Deadly Sin/Heavenly Virtue tally:

1. The sin of Pride is placing its image above its duties to consumers.
2. The sin of Avarice in choosing product cost above all else.
3. The sin of Sloth in failing to test its products for known pathogens.
4. The complete absence of all 7 Heavenly Virtues.

Case Study: Alfalfa and Other Sprouts. There have been numerous large-scale outbreaks of *Salmonella* and EHEC due to alfalfa and other types of sprouts sold to consumers. The problem has been traced to contamination of seeds used by growers, and research is still underway as to how these are contaminated. One of the outbreaks associated with sprouts occurred in Japan, where more than 3,000 cases of *E. coli* O157:H7 were attributed to radish sprout consumption. The sprout industry was decimated by the outbreak and has yet to frill recover after 5 years. In another large outbreak, more than 100 cases of *E. coli* O157:H7 occurred in multiple U.S. states due to alfalfa sprouts in 1997. After numerous outbreaks associated with sprouts, it is amazing that they still continue to occur.

In the latest instance of a *Salmonella* Kotbus outbreak in early 2001, the U.S. Centers for Disease Control and Prevention states: "Review of decontamination and distribution records indicated that at least some seeds underwent heat treatment followed by a 2,000-ppm sodium hypochlorite treatment for 15 minutes. FDA recommends decontamination of seeds with one or more treatments (e.g., soaking in a 20,000-ppm calcium hypochlorite for 15 mm) that have been approved for reduction of pathogens in seeds. The effectiveness of alternative seed decontamination has not been established. The sprout producers subsequently agreed to use only the FDA-recommended 20,000-ppm soak when sprout production resumed."

Deadly Sin/Heavenly Virtue tally:

1. The sin of Pride in choosing an unvalidated method of decontamination instead of the accepted method.
2. The sin of Sloth in not validating the method chosen and in not testing outgoing product.
3. The absence of the virtues of Justice and Prudence.

The point has been made that food safety is not just a technical discipline, it is an activity that deals with people's lives and implies moral duties for right and wrong behavior. "Righteousness" means never having to say "I'm sorry!" to a CNN news camera, or "I invoke my rights under the 5th Amendment to the U.S. Constitution" to a U.S. Attorney. ■

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By Brent L. Reichert

Listeria, *Salmonella*, and *Escherichia coli*: Oh My!

Despite a food manufacturer and retailer's best efforts, contamination can happen. If your company should get that dreaded phone call, you need to know what to do to overcome your fears and take care of your business and consumers. Your company can survive and thrive, as long as you accurately handle all steps of the recovery process: sending out the initial food recall notice, working with your crisis management team, reevaluating your prevention procedures and recovering your losses.

The Goals of Proper Food Recall Crisis Management

There are three important goals that your company must work toward in the event of a foodborne illness outbreak:

1. Protect consumers. You must do everything reasonably possible to limit the public's exposure to the contaminated product. Quickly assess the product involved, recall the product, identify the origin and cause of the contamination, and prevent future contamination.

2. Maintain your company's reputation. Protecting and maintaining the good name, reputation, and viability of your company is second only to ensuring the health and safety of your consumers. You must commit to maintaining customer confidence in your brand both during and after the recall.

3. Recover any losses. For years, food manufacturers suffered all the financial losses related to a food recall. This is no longer necessary. With the right legal counsel by your side, you can recoup the money you lost due to the recall and the fault of others.

All three goals should help determine the actions you take throughout the recall process.

The 10-Step Guide to Managing a Food Recall

When presented with a food contamination incident, you must work closely with your regulatory counsel to determine whether a recall is necessary. If the answer is "yes," you must work quickly and accurately to address the situation, manage the logistics, create a recall plan, and take appropriate precautionary actions to prevent future foodborne illness outbreaks.

1. Meet immediately with your crisis management team. Include on this team your regulatory affairs specialist, director of public relations/communications, director of quality assurance and food safety, sanitation manager, procurement manager, production manager, risk/insurance manager, in-house counsel, and appropriate outside counsel and external consultants. This team should be determined as part of crisis management planning, well in advance of any pending crisis.

2. Provide public notice of the issue and recall. To prevent further illness and capture the suspect product, you must determine how wide a net to cast on your recall so consumers know which products to avoid and return. Your recall notice should include detailed product identification information along with a mechanism for concerned individuals to contact your company and return the product.

3. Determine the source and cause of the foodborne illness. You must find the origin and cause of the contamination and related illnesses. You must also determine the best way to isolate and prevent that cause as you do not want to have the same issue happen again. While the regulatory officials will investigate the contamination incident, you must conduct your own investigation with the assistance of outside counsel and outside consultants. This is necessary in order to keep and maintain the critical work product and attorney-client privileges.

4. Collect all contracts and indemnification agreements related to the ingredient and product suppliers. This documentation will become integral to any legal action stemming from the contamination, as well as to planning how your company will move forward after the incident is closed. As part of your Hazard Analysis and Critical Control Points (HACCP) plan, you should already have the agreed upon purity and quality assurance standards and continuing food guaranties signed by your suppliers. The government investigators will inquire about this paperwork and you should present it to prevent the assessment of any penalties under the Federal Food, Drug and Cosmet-

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ic Act.

5. Notify the appropriate suppliers in the food chain. Sometimes you will not know exactly what the contaminant is or where it came from. In that case, you must notify all potential suppliers and transporters along the distribution chain to preserve your claims.

6. Collect, preserve and test food samples. Create a plan for which product and ingredients to collect, keep, test and ultimately destroy. Keep detailed records and identify where and how long you will store your samples.

7. Notify your insurance carriers and collect and document your financial costs and losses. In order to fully collect your losses, immediately begin keeping records of lost sales as well as the time spent and costs incurred while dealing with all of the necessary tasks to notify consumers and collect, test, store, and ultimately destroy the product pursuant to regulatory requirements.

8. Review your HACCP Plan, Good Manufacturing Processes, Standard Operating Procedures (SOPs), Sanitation SOPs, and Supplier Audits. You may need to review one or all of these based on the source and cause of the contamination. In many cases, you may find that your issue is not with the procedures themselves but with the suppliers' handling of those procedures or the fault of other parties. During this process, work with your outside counsel to maintain your attorney-client and work product privileges.

9. Coordinate legal actions. You will need to coordinate both the defense of the contamination and illness claims, and recovery from your insurance carriers and against the at-fault suppliers, transporters, or other parties. Be sure to hire outside counsel that has experience with both food contamination issues and insurance.

10. After the recall is over, reevaluate your preventions plans and procedures. Review each aspect of these plans and procedures to identify options for tightening up your processes or the processes of suppliers. This will improve avoidance of future contamination and foodborne illnesses. Based on this review, you may have to make the decision to change product ingredients or change suppliers.

Conclusion

Food manufacturers must tread carefully in the wake of a food recall. With this guide in hand, you can do just that. To ensure that you follow all aspects of this process correctly and that your company is well-protected throughout, work with attorneys and consultants who are knowledgeable, responsible, and tough enough to handle the situation at hand. ■

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By Joe Stout, R.S.

Principles of Environmental Pathogen Control

Before discussing focused pathogen environmental hygiene programs, I want to share a few key points about the two pathogen incidents in which I had a concentrated level of involvement. The first incident occurred December 24, 1986, when Nabisco Brands announced a full recall of all Baby Ruth candy bars manufactured at its Franklin Park, IL, plant due to *Salmonella* contamination. For the company and for me as a Nabisco sanitarian, this was a painful experience, as the nationwide recall required significant follow-up visits at the plant location. Fortunately, no illnesses were linked to this incident. However, the product was off-shelf for months, as a hygienic restoration of the facility was planned and executed. This came at a significant cost to the company and consumed months of time from internal resources, as the plant was prepared for a restart. The second incident was in the late 1990s when the meat industry had several ready-to-eat (RTE) *Listeria monocytogenes* product contamination issues that generated recalls, including Thorn Apple Valley, Sabrett hot dogs, Gaspar's sausage, Dearborn sausage, Bilmar Foods, and Oscar Mayer. These were each serious events, given that they occurred close in time and had significant impacts on the health of consumers, on the sales of RTE meat products, and on the RTE meat industry's credibility with consumers.

Two of the RTE meat recalls that had more impact to me were Bilmar Foods (latter part of 1998) and Oscar Mayer (January 1999). The consumer impact from the Bilmar incident comprised 15 deaths and 6 miscarriages. This was devastating for those consumers and their families. The most memorable to me was the loss of Helen Bodnar, who was in her 70s. Her husband of 53 years, John Bodnar, appeared in a *20/20* episode with Arnold Diaz and shared his heart-wrenching story. This was memorable to me, for in John and Helen I saw my parents, who were in a similar place in their lives and marriage. It was a powerful and unforgettable connection and taught me the critical responsibilities that we in food safety and the industry have for protecting the health of consumers. At the time, I worked at Kraft (Oscar Mayer's parent company) and was heavily involved in remediation; I led an initiative called Project Forward whose mission was to drive improvements in preventive plans across Oscar Mayer initially and then across other microsensitive product categories at Kraft.

What Can We Learn?

These events provided an unfortunate but rich learning experience that helped shape my perspective on pathogen control, which, when implemented, provides a holistic and disciplined approach to model a combination of preventive plans that reduce risk. Ultimately, this approach helps avoid failures in environmental programs that otherwise could result in pathogen-related recalls and potential outbreaks.

Another learning opportunity from these pathogen-related events in a short period was the sales impact to RTE meat products across the industry. The largest sales losses were to hot dogs and lunchmeat, and not just with Bilmar and Oscar Mayer, but with all processors and brands of hot dogs and lunchmeat. It took 18 months for sales to recover and return to normal growth levels typical for that time. The key lesson was that the meat industry at the time was known to produce unsafe foods. As a result, the meat industry needed to change. It did just that, with companies working precompetitively to improve food safety for the betterment of both the industry and consumers. Best practices, shared learnings and product reformulation began to reshape the industry. Looking back, this was a phenomenon that other food industry segments later emulated.

With the leadership and support of the American Meat Institute (AMI), companies worked together to share critical learnings about *Listeria* in the environment, methods of control in processing plants, and food safety-related product formulation. AMI was visionary in working with processors and suppliers for the common good. A good example is the AMI *Listeria* Intervention Course that started in 2002 and is still offered today at regular intervals. This course looks at all principles of the *Listeria* control equation, with hands-on workshop activities to help develop a comprehensive environmental monitoring program, in addition to learning about sanitation and sanitary design. Another major AMI initiative

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was to develop an industry team (which I had the privilege to lead) that focused on sanitary equipment design. Later, another AMI team focused on facility design.

Equipment suppliers, engineering firms that designed food plants, and quality and sanitation managers worked together. It was a perfect time for all of us to share what we knew precompetitively. Sometimes, it takes a storm or crisis to elevate expectations and cause rapid evolution. The pathogen concerns did just that and the industry responded with the needed changes. Today, the meat industry is in a better place for it, and fortunately, many of these learnings have spilled over into other food industry segments, such as low-moisture foods, dairy, and produce, reaching original equipment suppliers for all industry segments.

Where to Begin?

When first confronted with a pathogen problem in a facility, it is hard to pinpoint an exact root cause from so many potential sources. At the time, it was necessary to take a holistic view of all conditions and to communicate these to the Oscar Mayer team: putting potential sources into perspective with the ability to zero in on program improvements while keeping it simple and understandable. The approach taken was to put the control components in the form of an equation equaling pathogen control. When I presented this equation to the Oscar Mayer team, it was seen as a practical, true and easy way to communicate. Later with AMI, this equation was used in the *Listeria* Intervention Course and by other companies who partnered with AMI to share information on *Listeria* control. This approach helped the industry understand what was important and where to focus efforts. It enabled an understanding of diverse risks that needed to be controlled and the solutions needed to obtain that control. Since then, the approach continues to be used in many food industry segments. The principles and the equation remain consistently applicable across all categories; most importantly, it is a road map to control pathogens in the plant environment.

The equation is presented in Figure 1.

Let's take a look at each of the six components of the pathogen control equation,

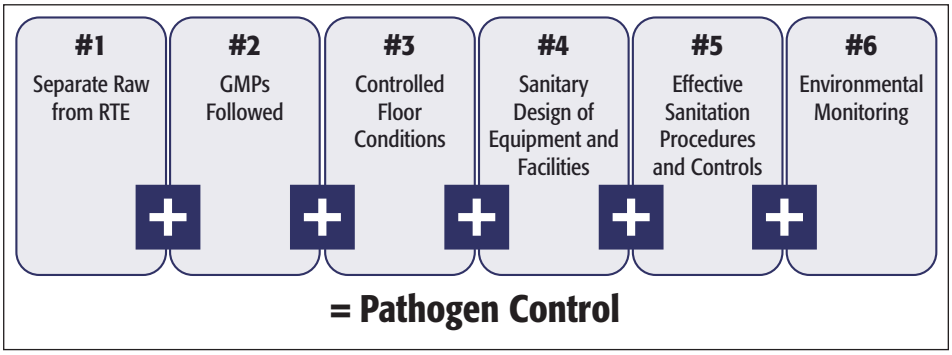

Figure 1: The Pathogen Control Equation

review the importance of each, and assess how each component helps eliminate/control the presence of pathogens. It is also important to look at each of these principles to help compensate for the weaknesses of any one component. For example, we know that equipment design is not perfect in the meat or other food industries; in fact, in some cases, it is quite poor. In the case of poor equipment design (Principle 4) where the defects might not be repairable in the near term, you could enhance the sanitation procedure (Principle 5) and the tear-down frequency, yielding control of pathogens. This example illustrates how the principles can work together to maintain control of equipment or the environment regardless of design flaws. This allows for a holistic approach and focuses on getting the right solution while engaging all control principles.

The Pathogen Control Equation Principles

Principle 1: Separate Raw from RTE

History shows that there is a greater likelihood of finding spoilage organisms or pathogens in uncontrolled plant areas. By *controlled*, I mean maintaining a clean, pathogen-free environment. Maintaining control could require placing restrictions on who can enter or implementing traffic hurdles for people as they come into the area, or separation by walls from one area to the next if they have different hygiene levels. Finally, there could be a benefit to having separate air controls that provide positive air pressure in a higher hygienic zone, thereby forcing undesirable bacteria or dust from the high-hygiene to the low-hygiene care areas.

Let's review a few of the key thoughts from above. First, what is a hurdle? This is a procedure/intervention that reduces the possibility that bacteria present in a lower-hygiene plant area will be carried into a higher-hygiene area. For example, in a meat or dairy plant, there are raw materials present prior to processing. To keep pathogens from infecting the high-hygiene area, we expect to see a hurdle, such as a wet or dry foot bath,[1] so employees can sanitize footwear before entering a more sensitive area. If this were a dry plant, a dry foot bath or a change in footwear would be expected. Dry areas should remain as dry as possible. Another expected hurdle in a wet or low-moisture food facility would be for the employees to be hygienically prepared by wearing proper clothing, washing and sanitizing hands, and wearing sleeves, aprons, etc. If you are aware of pathogen contamination in a high-hygiene area through your monitoring program, you may need to think about decontamination as you exit the same area to avoid contaminating another area.

Principle 2: Follow GMPs

Following Good Manufacturing Practices (GMPs) is one of the most fundamental expectations in the food industry. GMP regulations 21 C.F.R. 210–211 have been part of the tenets of quality and safety over the years. These are practices that are or could be likely cross-contamination points if not followed. GMPs apply not only to personnel practices, which are the most commonly thought of when referenced, but equally to the many production practices that must be in compliance with a plant's GMP program. Here are some examples: From a personnel perspective, it is critical to control and prevent pathogen spread in the facility by unclean hands. This is where the basics kick in–handwashing and wearing hairnets/beard nets, ensuring that we don't cross-contaminate from a zone 3 (non-food contact) to a zone

1 (food contact) area. From a production GMP perspective, practices such as using specific tools in a high-hygiene area versus in a raw area are very important. For example, in raw areas, red totes and red shovels are normally used, whereas in a high-hygiene area, white totes or scrapers would be used. It is critical that both personnel and production practices work hand in hand to ensure an environment that minimizes cross-contamination from a raw to an RTE area, or from a cross-zone situation such as a zone 3 to zone 1. At times, we take these things for granted, but we shouldn't. The best way to see good or bad practices and behaviors is to spend several hours on the production floor observing GMPs and production practices. Sanitation practices during the cleaning process are critical to prevent cross-contamination from zone to zone and must be monitored. A good example with sanitation is to see whether your cleaning practices are in sequence; if you use high-pressure water late in the cleaning cycle after equipment has been cleaned and sanitized, that would be another opportunity for cross-contamination. It is time well spent to observe sanitation operational practices during production. At times, you will be surprised by what you see. I have been doing this for 35 years and I am still frequently surprised!

> "When first confronted with a pathogen problem in a facility, it is hard to pinpoint an exact root cause from so many potential sources."

Principle 3: Controlled Floor Conditions

Floors are generally considered a zone 3 area in a manufacturing plant environment, both in RTE and high-hygiene areas. In some cases, meat, produce, and potentially dairy floors are moist, damp, or just plain wet from manufacturing conditions. Given that moisture is needed to support the growth of pathogens of concern in the food industry, these areas become an ideal environment for microbial growth. Additionally, there tend to be many niche areas on the floors with dairy brick, epoxy, or tile where organisms can harbor and grow. These can be source points for positive pathogen findings that could eventually migrate to zone 2 and zone 1 areas. Therefore, it becomes critical to maintain floors in a condition that can be cleaned and sanitized effectively and efficiently. This means a smooth surface with zero or, at worst, a minimal number of niches at joint areas, no spalled concrete, and no cracked epoxy/urethane coatings where moisture could penetrate and resurface when pressure is applied to the material. Equally important is the need to monitor the microbial environment of floors and drains for pathogen activity. We will cover this in more detail with Principle 6: Environmental Monitoring.

Principle 4: Sanitary Design of Equipment and Facilities

Sanitary design of equipment and facilities is one of the most important principles from a strategic perspective. If we encourage processors to work with original equipment suppliers, we could change the future of sanitation and food safety in the industry. If possible and time permitting, I would recommend that all quality and food safety professionals and engineers who design equipment and facilities spend time during the sanitation process observing the challenges that sanitarians and sanitors face cleaning equipment that is not optimally designed for cleaning. This is an eye-opening experience, especially if you not only observe it but also try to clean it yourself. It also gives one the opportunity to understand the challenges that sanitors experience every day when a line goes down to be cleaned. That's the best way to understand sanitary design and the benefits of an optimized design.

There are many sanitary design standards available today, some better than others, but in most cases, if you follow one standard and use it with the full understanding of sanitation and food safety risks after talking with the maintenance, engineering, sanitation, quality, food safety, and production teams, you will be in a good position to have discussions with your equipment suppliers. Excellent partnerships and communication between processors and equipment suppliers can be the defining factor in the best designs.

Principle 5: Effective Sanitation Procedures and Controls

This is a critical area to focus on as you look at the total equation. All of the principles work together and establish a balance for the other principles, which may otherwise fall short of expectations. As an example, if you have a weakness in sanitary design (all facilities and equipment do), you need to compensate for substandard designs with enhanced cleaning procedures to ensure you clean hard-to-reach areas. This may need to be done daily or periodically–nonetheless, this offers a balance to deliver microbial control of pathogens and spoilage organisms. Likewise with separation concerns, if you have an issue with the separation of raw from RTE or high-hygiene areas, you may need to enhance the hurdle requirements at entry points and increase the frequency of deep cleaning or sanitizing of the floors to eliminate any contamination that may enter a room from poor separation of areas until you are able to provide complete separation.

The fundamental approach we use for sanitation procedures and controls is the "Seven Steps of Sanitation" for wet cleaning and a similar approach with different science for dry cleaning. These are both well-disciplined and thorough procedures that prevent potential cross-contamination from nonproduct zones to product contact zones. Without a disciplined approach, there would be much more cross-contamination in the industry.

Principle 6: Environmental Monitoring

This principle helps us measure how well we're monitoring the facility environment. Call it our measurement meter for pathogen control. It lets us know whether each of our pathogen-prevention programs is effective. Furthermore, the goal of an environmental monitoring program is to get to know your environment. I typically recommend an aggressive program for all areas of the plant for at least 2 years. This provides a profile of what to expect at different times of the year, with different staffing, different weather conditions, during an adverse event (e.g., roof leak, drain backup) or during construction.

Once through the 2-year period, you will know when a pathogen infection occurs that needs your immediate attention. Then, if you find a positive in a new area or are uncertain of the root cause, history can help initiate the best investigation and corrective-action techniques as well as pinpoint the potential source.

Monitoring is one aspect of the program; the other is corrective and preventive actions. When a positive is detected, actions must be taken in a timely manner to prevent the creation of a biofilm or niche that would be harder to eliminate. The effectiveness of the actions taken must be verified. If another positive is detected in the same area, corrective actions must be escalated to ensure the elimination of the pathogen *and* the conditions that allowed its presence.

Summary

Pathogens occur naturally in the environment and can easily infect and populate in food plants. The pathogen control equation provides a holistic approach to preventive controls and its use has endured the test of time in the food industry segments where it has been applied.

An interesting and significant learning opportunity from the pathogen control equation, when fully implemented, is that in addition to controlling pathogens, it is good for quality and business. Experience shows that the shelf life of many microsensitive products has significantly increased, indicating that this process controls not only pathogens but also spoilage organisms. This process leads to satisfied customers with higher-quality products and reduced spoilage: a win-win for the processors and consumers! ■

***Joe Stout, R.S.**, is president of Commercial Food Sanitation LLC. He is known in the industry for his work in sanitation and hygienic design as the former director of global product protection, sanitation and hygienic design for Kraft Foods.*

Reference

1. www.amif.org/wp-content/uploads/09-416.pdf.