Applying HACCP: Guidance and Avoiding Gaps A Practical Guide

Part 2 of a 3-Part Series

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CONTENT

INTRODUCTION BY SARA MORTIMORE AND CAROL WALLACE

HACCP systems will be effective only if the HACCP principles are accurately applied in the design, implementation and maintenance of HACCP plans and if these operate within a hygienic environment and a positive food safety culture. Therefore, businesses will experience the full benefits of HACCP only if there is full understanding of the application of HACCP principles as a means to effectively manage food safety risk. Experience tells us that many food companies struggle with HACCP principle application and that further guidance is needed to help HACCP teams in their efforts to design strong HACCP plans. Accuracy in the application of both Principle 1, *Conduct a Hazard Analysis*, and Principle 2, *Establish Critical Control Points*, is paramount to success, it is in regard to these principles that many HACCP teams experience difficulty. Similarly, understanding and effective application of scientific information is crucial to Principle 3, *Establish Critical Limits*. Technical expertise combined with a real understanding of the concept is essential. Poor understanding, often due to inadequate training, education and exposure to what a good system looks like, has been a hindrance to full realization of the benefits of the HACCP approach.

This article builds on the previous work of the IAFP HACCP PDG Back to Basics working group on preliminary steps to HACCP development *(2)*. Readers who have not yet seen the first article in this series are encouraged to go back and read it to obtain the full benefit of this guidance in sequence. This article starts by providing general guidance on application of the key HACCP principles 1, 2, and 3 and then identifies gaps in current knowledge and practice in their application, along with specific guidance to help HACCP teams overcome these potential problems. Understanding of these areas of potential weakness in HACCP principle application will help food businesses take action to review and design more effective HACCP plans, and for those just starting out, to learn from past mistakes.

STEP 6, PRINCIPLE 1: CONDUCT A HAZARD ANALYSIS (TO INCLUDE LISTING ALL POTENTIAL HAZARDS AND CONSIDERATION OF CONTROL MEASURES)

Intent

Effectively identify specific potential hazards associated with each ingredient and processing step, complete hazard analysis considering the severity of hazards, likelihood of occurrence and measures applied to control the identified hazards to an acceptable level, and identify significant hazards. Significant hazards are reasonably likely to cause adverse health effects and are not controlled by prerequisite programs or process steps that do not require control for food safety.

General guidance

It is important to consider and understand the interrelation of the HACCP process steps that are conducted prior to completing a hazard analysis, and understand how they influence the process, particularly with respect to identifying hazards and determining risk levels. As described in the first article in this series *(2)*, Steps 1 – 5 are completed prior to the hazard analysis for specific reasons, as the output should be used to inform the decisions made in completing Step 6.

Potential food safety hazards that are reasonably expected to occur must be identified at each manufacturing process step. Putting the onus solely on the Quality Assurance (QA) function to complete the hazard analysis in isolation, without using a cross-functional group of people who understand the various food safety hazard groupings, will significantly limit the quality and depth of the hazard analysis.

Raw materials, the manufacturing process, equipment, environmental factors, product storage and distribution should all be considered when identifying hazards that may be likely to occur. For a comprehensive study, it is essential that an experienced team conducts the hazard analysis. Using individuals with experience and knowledge from different disciplines provides greater insight into the various activities and processes being carried out at a plant *(Fig. 1)*. This multidisciplinary approach increases awareness of the factors that could result in introduction of food safety hazards into the process steps.

It is important to define the scope of the hazard analysis, which may include outsourced processes and, potentially, steps that precede or follow product manufacturing and have an impact on the safety of the finished product. Not only does constructing and verifying the process steps as a team allows development of a more comprehensive process flow diagram, but the onsite verification helps to ensure the identification of potential hazards that may be introduced into the process from equipment or the environment.

Identification of hazards should be based on the preliminary information collected through assessment of process steps and utilization of external information sources such as scientific journals, regulatory guidance or reported food safety issues.

Clarity of reporting the identified hazards is important and must be specific, including clear reference to the potential physical, chemical, and biological hazards that may be introduced or may survive particular process steps. Providing

Figure 1. Using individuals with experience and knowledge from different disciplines provides greater insight into the various activities and processes being carried out at a plant.

an accurate description of the potential hazards is important to facilitate the hazard analysis process and ultimately the measures that are to be considered to control the identified hazards. Different pathogenic bacteria, for example, have different growth requirements, and their ability to multiply, produce toxins, or grow may be influenced by environmental factors and/or the presence or absence of controls within the manufacturing processes.

Once hazards have been clearly identified, an assessment that considers the severity and likelihood of adverse health effects must be completed in order to identify the controls required to ensure control of identified hazards to an acceptable level *(Fig. 2)*. When completing the hazard analysis, it is important to consider the product description, the intended use (including the entire intended shelf life and storage conditions) and the potential for misuse by the consumer, as mentioned in Part I of this series *(2)*. The intended consumer use (or misuse) of the product should also be considered when determining risk, particularly with respect to individuals within vulnerable groups that may be at unusually great risk from the identified hazards. Understanding the needs of the potential consumer could well influence the stringency of control measures required to maintain control and produce a safe product.

Clear justification should be provided for determining the likelihood and severity of the hazard used to determine the level of significance of the hazard; this influences the measure or combination of measures required to prevent, eliminate, or reduce the food safety hazards to defined acceptable levels. Where possible, consideration within the hazard analysis should include (as applicable):

- the qualitative and/or quantitative evaluation of the presence of hazards;
- survival or multiplication of microorganisms of concern;
- production or persistence in foods of toxins, chemicals or physical agents.

When determining the measures required to control the identified hazards, it is important to recognize that in some circumstances more than one control measure may be required to control a specific hazard(s) and more than one hazard may be controlled by a specified control measure. Metal hazards, for example, may be controlled through a combination of Prerequisite Programs (PRPs) such as knife control, planned maintenance, etc., in addition to subsequently identified steps in the process that are critical in controlling metal contaminants, such as metal detection, x-ray, sieving, filtering, etc.

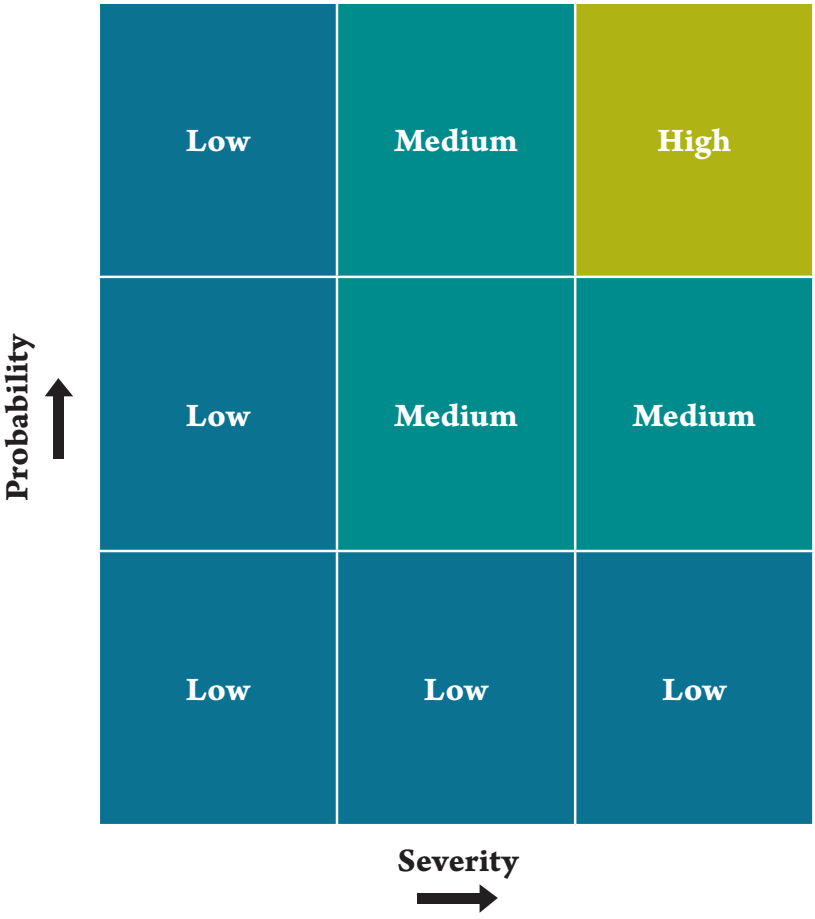


Figure 2. Once hazards have been clearly identified, an assessment that considers the severity and likelihood of adverse health effects must be completed in order to identify the controls required to ensure control of identified hazards are controlled to an acceptable level.

HAZARD IDENTIFICATION GAPS

Gap A: The identification of hazards is not specific or detailed enough.

Gap B: New or changed hazards are not identified due to failure to update the process flow diagram.

Gap C: Assumptions are made about the hazards associated with a particular product without full reference to and understanding of potential new inputs.

Gap D: The rationale behind the identification of hazards is not fully explained and justified.

Gap A: The identification of hazards is not specific or detailed enough. When identifying hazards, several key aspects may often be taken for granted or overlooked. On occasion, identified hazards may be referred to in a generic manner, e.g., *"pathogens"* instead of the actual organism of concern, without understanding the growth characteristics of the organism associated with the product or ingredient. As a result, it is not always possible to accurately complete the hazard analysis or determine the relevancy of the controls in place required to manage the hazard that has been identified. For example, various microbial pathogens have different responses to potential control mechanisms. Notably, the heat resistance of spores is much greater than that of most vegetative pathogens; therefore, different thermal processes will be required to control to acceptable levels. Likewise, different chemical hazards, such as allergens, have different source attribution. In this case, an understanding of the specific allergen and its likely sources will assist in identification of the most appropriate control measures. Last, different physical hazards can be controlled by use of appropriate sized screens and filters, and various metallic hazards (e.g., ferrous versus non-ferrous) can be detected at different sensitivities by a metal detector. Here again, identification and description of the exact nature of the contaminating material helps direct the team to the most appropriate control options. Therefore, there is a need to brainstorm the entire list of potential hazards in as much detail as possible in order to identify those that may subsequently be determined to be significant and therefore will need to be controlled.

Gap B: New or changed hazards are not identified as a result of failure to update the process flow diagram. Processes are often revised within a manufacturing environment. However, this may not always be captured in a timely manner within the process flow diagram. Failure to update or accurately validate the process flow diagram through a team-based approach could result in hazards not being identified at the appropriate process step, making it impossible to complete an effective hazard analysis. Undocumented changes to raw materials, plant layout, equipment modifications, processing parameters or new packaging operations could all lead to failure to consider new or different hazards. For example, changes in equipment placement could alter the flow of product, people or air within a facility, all or any of which changes could introduce hazards not previously considered. Likewise, change to a different raw material supply could easily introduce new or different levels of hazards if the specification for the new material is not somehow vetted to match the original exactly. Changes to processing parameters or packaging method could readily change the conditions affecting survival of different pathogens. Appropriate review and modification of the process flow diagram as necessary therefore becomes the starting point for re-evaluation of potential new or altered conditions affecting the potential for new or altered hazards to manifest.

Gap C: Assumptions are made about the hazards associated with a particular product without full reference to and understanding of potential new inputs. Without understanding the key attributes of the product, including the intended shelf life or the vulnerability of the consumer, it is difficult to ascertain the true nature of the hazards and their potential effect on the finished product and, ultimately, to the consumer. It is important to be accurate, factual and realistic when identifying food safety hazards from inputs associated with raw materials, utilities and even food contact materials that may affect the safety of the product. As knowledge of foodborne hazards grows, either through adverse events and their respective investigations (e.g., foodborne illness and associated product recalls) or through new discoveries from scientific research, the documentary record increases. Hence, consideration must be given to relevant scientific literature, particularly regarding emerging issues and acceptable limits that might be unknown or overlooked in favor of tribal knowledge or previous assumptions used in defining risk levels. A clear rationale as to how decisions are made, based on awareness and understanding of any new inputs, is required.

Gap D: The rationale behind the identification of hazards is not fully explained. Justification must be provided to support the likely occurrence of potential hazards; the recording of hazards without appropriate supporting rationale may raise doubt about the validity of the hazard identification process. The rationale is usually supported by recorded experiential evidence, recourse to and complete understanding of external information, and/or the external advice of a reputable subject matter expert (i.e., a consultant). If the latter, the HACCP plan developers must fully understand the given advice. It is insufficient to simply quote the consultant. It is also important to be able to explain (and document) why certain hazards are considered and retained for consideration whereas others may not be.

HAZARD ANALYSIS GAPS

Gap A: Failure to fully explain and justify the rationale behind the hazard analysis.

Gap B: Lack of understating of the severity of a particular hazard should it not be controlled.

Gap C: Failure to fully document decisions relating to the hazard analysis.
Gap D: Premature identification of Critical Control Points (CCPs) at the hazard analysis stage, prior to following the established procedure (e.g., decision tree approach).
Gap E: Failure to identify a CCP to control a known significant hazard.

Gap A: Failure to fully explain and justify the rationale behind the hazard analysis. When completing a hazard analysis and determining a risk rating for the hazards that have been identified, it is important to justify the likelihood and severity ratings that have been determined in order to establish the significance of the hazard. Attributing a hazard score based on a numbering system, without appropriate explanation or justification, makes it difficult to explain the significance of the hazard. Utilizing the experience and knowledge of a multidisciplinary team allows for a greater depth of analytical assessment of each of the process steps. The hazard analysis process can often be resource intensive, which can lead to the practice being completed in isolation, often by the QA department alone. Such an approach to hazard analysis limits the quality of the output but also casts doubt as to the actual engagement of the HACCP team and, ultimately, their ownership of the HACCP program.

Gap B: Lack of understanding of the severity of a particular hazard should it not be controlled. Defining the level of severity can often be confusing for HACCP teams that do not have appropriate knowledge of the hazards. The severity rating must be based on the potential public health outcome. For example, if not properly controlled, the presence of a large number of virulent *Listeria monocytogenes* in a ready-to-eat product, could have potentially life-threatening consequences to a susceptible individual. Hence, in such situations the hazard would rank as high severity. Often, without technical or scientific support, likelihood and severity ratings are randomly assigned, leading to an inappropriate risk rating and apportion of significance, resulting in elevated risk ratings or, worse, a lower risk rating than the actual situation calls for. The key to closing this gap is involvement of subject matter experts who have broad knowledge of hazards and their likely public health consequences if unmitigated.

Gap C: Failure to fully document decisions relating to the hazard analysis. Clarity in the justification of decisions that have been made can sometimes either lack detail or be inappropriately documented, making it difficult to decipher how the risk levels were actually determined. Care is also required when documenting the output from the hazard analysis, occasionally because of the vast number of process steps within a HACCP plan that require evaluation. A tendency to "copy and paste" information across a number of process steps can lead to incorrect information being applied within the HACCP plan. It is important that the foundation for any decisions be recorded in order to provide a base for future discussions and prevent unnecessary repetition and redundancy should HACCP requirements change. All changes to decisions affecting the hazard analysis must be recorded in the HACCP plan files.

Gap D: Premature identification of Critical Control Points (CCPs) at the hazard analysis stage, prior to following the established procedure (e.g., the decision tree approach). CCPs are sometimes determined before the assessment is fully completed or even started. When completing the hazard analysis, consideration of the existing control measures are sometimes allowed to influence the decision-making; this approach can potentially impact the risk rating. Although it may be tempting to identify CCPs prematurely on the basis of prior knowledge or experience, such temptation must be resisted. The subsequent steps of determining CCPs and assigning control measures must be allowed to occur in the structured and systematic manner that good HACCP planning demands. It is important that the capabilities as well as the interrelations between various measures employed to control hazards are fully understood. For example, a large number of programs may be in place to manage microbiological hazards, including sanitation activities, good manufacturing practices, supplier approval, monitoring of raw materials, etc. In isolation, these may present limitations to managing microbiological hazards. However, the effectiveness of these controls in totality and their influence in supporting the effectiveness of a step such as cooking within a manufacturing process is sometimes overlooked.

The justification for proposing control measures must be supported by scientific evidence, program review data, process validation information, etc., and/or information recognized as meeting requirements mandated by regulators *(Fig. 3)*.

Gap E: Failure to identify a CCP to control a known significant hazard. CCPs are product- and process-specific and may change as a result of unanticipated changes. When determining the CCPs for your HACCP plan, the hazard assessment must include evaluating the ingredients, the process, the identified hazard and the necessary measure to control the hazard. If a full risk assessment is not conducted, a known hazard may be overlooked. For example, overlooking review of maintenance logs may result in overlooking the fact that the manufacturing line stops, resulting in extended down time periods that introduce the risk of temperature abuse of in-process product and thus the hazard of pathogenic growth. Therefore, the hazard assessment should include review of the expected number and time length of line stoppages and the potential for the in-process product to support growth of pathogens.

Recommended Hazard Analysis focus areas:

- Consideration and reference to preceding HACCP steps;
- Utilization of a multidisciplinary team approach and its importance;

Figure 3. The justification for proposing control measures must be supported by scientific evidence, program review data, process validation information, etc.

- Correct use of risk assessment tools;
- Importance of identification of all relevant hazards;
- Being specific about the hazard and source;
- Documentation of justification for each assessment and decision;
- Reference to credible information to support decisions.

STEP 7, PRINCIPLE 2: ESTABLISH CRITICAL CONTROL POINTS (CCPs)

Intent

For each significant hazard, determine the appropriate critical control point to eliminate or reduce the hazard to an acceptable level. All significant hazards require determination of a CCP for producing safe product.

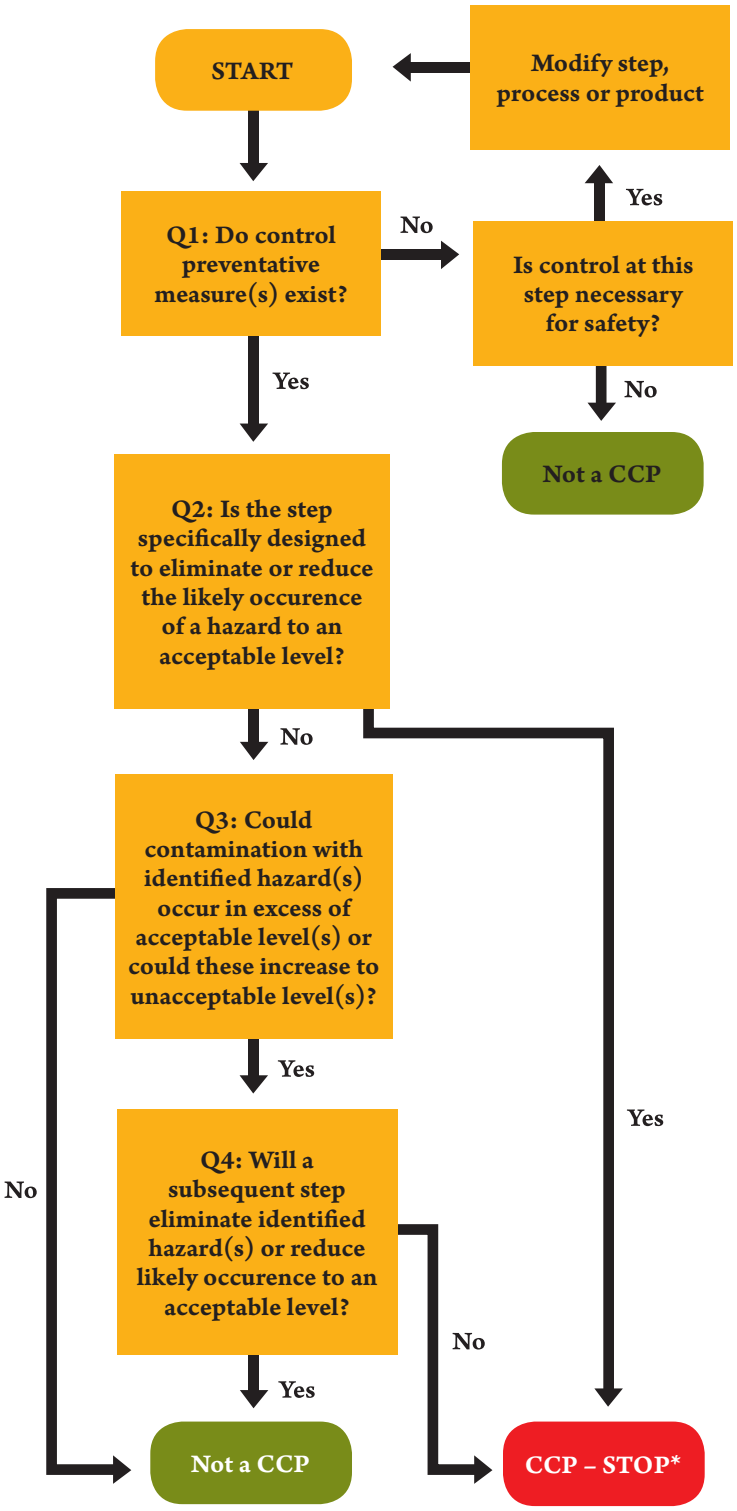
General guidance

To determine the CCPs, a logical reasoning approach must be used. It is important to remember that established control measures are specific for each hazard. Utilizing the full HACCP team helps ensure availability of the essential knowledge and skills needed to account for the ingredients, the process, the identified hazard and the necessary measure to control the hazard *(4)*. The point is considered critical if failing to control said measure results in a significant public health risk to consumers. To help guide the decision in establishing a CCP, there are many different tools, such as a decision tree or score cards, to help assess the hazards. The Codex CCP decision tree (CAC, 1969) example is given in *Fig. 4*.

However, it is worth noting that any scoring assessment tool is useful only if used appropriately and utilized after the completion of the hazard analysis.

If the team does not have the expertise for the hazard assessment or does not know how to use the assessment tools, it is highly recommended that the HACCP team seek the assistance of internal or external subject matter experts

CCP Decision Tree
(source: codex CAC/RCP 1-1969, Rev 4-2003



***Proceed to the next identified hazard in the described process.**

Figure 4. CCP Decision tree (CAC/RCP 1–1969, Rev. 4 –2003)

for guidance. If a significant hazard has been identified, but no control measure exists, then the process or product must be modified to include a control measure, or the product cannot be made safely.

CRITICAL CONTROL POINT (CCP) GAPS

Gap A: The CCP is identified, assumed or mandated before the hazard analysis is completed.
Gap B: The CCP identified does not or may not control the hazard.
Gap C: More than one preventative control may be needed to control a hazard that occurs at different stages of a process.
Gap D: Training on use of CCP decision tools is inadequate.
Gap E: The approach used is not documented with scientific justification or rationale as to why it is a CCP (significant hazard).
Gap F: Everything is considered a CCP — Confusion between Control Points (CP) and true CCPs.

Gap A: The CCP is identified, assumed or mandated before the hazard analysis is completed. When preparing a HACCP plan, it can be easy to identify a CCP that is routinely used for a specified product without following the HACCP process. CCPs can be assumed or mandated to appear in HACCP plans, regardless of the HACCP analysis, based on team bias, historical practices, audit results, customer specification, or regulatory guidance. The perceived risk is assumed to be universal to all product and process combinations, resulting in an artificially inflated likelihood and severity score to justify the CCP status. This can result in a devaluation of the HACCP process and confusion within the HACCP team.

To implement a HACCP plan properly, it is important to assess the entire process critically. For example, in an 8-oz single package size, cheese spread process, the finished product label verification at the label step is identified as a CCP because of the presence of milk allergen (dairy) in the product. However, the manufacturing line runs this product and formula in only this size package, and no other product is run on the line. A Control Point (CP) rather than a CCP may be sufficient to manage the hazard because there is only a single allergen and package run on the line and it is present in every production run. If another product formulation is added to this manufacturing line, the rationale for no CCP (management as a CP) should be revisited to determine if the significance of the risk has changed. The HACCP team is responsible for ensuring that there is a comprehensive assessment of all other potential processing controls that may be in place, either through prerequisite programs, equipment design, supplier ingredient programs, upstream process steps or additional upstream controls, or other manufacturing controls when evaluating hazards.

Similarly, some CCPs are implemented because of the perceived risk assumed prior to assessment of all of the other controls that may be in place. For example, a puffed dry cereal packaged in a 15-oz paperboard carton has metal detection as a CCP because of corporate policy. It is an effective practice to have an established team in place that can assess and review prerequisite programs, equipment design, supplier ingredient programs, upstream process steps or additional upstream controls, other manufacturing controls and historical consumer complaints to determine if there is a warranted hazard that needs to be controlled.

Gap B: The CCP identified does not or may not control the hazard. As the business and processing needs change for the product, it is important to be mindful of the potential impact these changes may have on the HACCP plan. For example, in a dry granola cereal product, a flavored honey slurry with water activity of 0.68 is sprayed on the granola just prior to the final blending and drying step by conveyance through a 20 feet long, forced-air oven at 183°F set point, and with a belt speed of 1 in/sec. This combination of oven temperature and belt speed to control the identified *Salmonella* risk was determined and confirmed through validation. The honey slurry is not pretreated for pathogen reduction by the supplier. If a new flavor of slurry is run with the same process conditions (oven temperature and belt speed) but the new honey slurry has a water activity of 0.71, the impact of the increased water activity of the new honey slurry can often be overlooked, with the assumption that the original belt speed and oven temperatures would be adequate to control the same *Salmonella* hazard. Ingredient changes such as these require a validation study performed to determine if the oven temperature and belt speed are adequate to eliminate the *Salmonella* risk with the new honey slurry with water activity of 0.71.

Gap C: More than one preventive control may be needed to control a hazard that occurs at different stages of a process. Prerequisite/preventive controls provide a foundation for the HACCP system, as they can help to reduce the likelihood of certain hazards from occurring. Often, managing more than one preventive control can support the justification for hazards not occurring. For example, in a peanut butter manufacturing process, a control for *Salmonella* contamination is needed at a validated roasting step for incoming raw nuts to eliminate the pathogen and also further downstream in the process, at the peanut grinding step, for paste production to control post roasting environmental re-contamination with *Salmonella* prior to packaging. These additional controls should consider the existing prerequisite programs, such as environmental monitoring programs, employee behaviors and training, product and personnel traffic through the facility, and GMPs to help determine the CCPs for this operation.

Gap D: Training on use of CCP decision tools is inadequate. Resource tools such as decision trees or grids are effective in determining CCPs for hazard management. However, it is important that the user be trained in how to use the tool and

has the knowledge regarding the hazard implications. Making use of a tool such as the Codex Decision Tree requires skill in understanding the specific product, the specific process and the risks associated with it. If the HACCP team does not have the appropriate training or skills, the determined CCP may not be properly identified or a CCP may be identified for a non-significant hazard that could be managed by another step. It is important to understand that decision tools are used only for hazards that are determined to be significant. If there is uncertainty, it is recommended that the HACCP team seek expert advice (internal or external) before making the decision on a significant hazard. Exploring several tools may be necessary to determine which tool best suits the needs of the team, product and process.

Gap E: The approach used is not documented with scientific justification or rationale as to why it is a CCP (significant hazard). Without sufficient documentation of the scientific rationale, the significance of the risk and controls needed to ensure safe product may not be understood by new HACCP team members, or may be lost when new products are added or existing product formulas or process steps are changed, when new equipment is added to the line, or during annual review of the HACCP plan. Additionally, documentation of the scientific justification is helpful during third-party audits or regulatory visits. A best practice is to include the CCP justification documentation in the HACCP plan for easy access and historical record.

Gap F: Everything is considered a CCP — Confusion between Control Points (CP) and true CCPs. Some HACCP teams go through the process and determine that a substantial number of steps are deemed critical. Careful consideration should be given to the criticality and feasibility of monitoring the CCPs. It is also important to consider the other measures that may already be in place that can help control a hazard. Prerequisite Programs (PRP), Good Manufacturing Practice (GMP), supplier control programs, environmental monitoring, and thermal process programs are supplemental programs that can help manage hazards. It is important to consider these measures to determine if they are sufficient in controlling a hazard. Furthermore, every CCP must be considered critical and therefore necessary to control throughout the process.

STEP 8, PRINCIPLE 3: ESTABLISH CRITICAL LIMITS FOR EACH CCP

Intent

Identify the critical limits or absolute values for each CCP that must be achieved in those specific process steps to ensure the finished product will be safe.

General guidance

Once all CCPs have been identified for the process, the next step is to establish critical limits. A critical limit is a criterion that separates safe and unsafe product and ensures that the CCP is managing the risk *(3)*. All critical control points need defined and documented critical limits to ensure the identified acceptable level of the hazard in the end product is not exceeded. Critical limits must be specific, with a measurable factor that can be monitored by a test or observation, such as time or temperature. Critical limits for each CCP need to be validated as well.

The critical limits define the boundaries between safe and potentially unsafe product. Therefore, the team needs to make sure the critical limits are appropriate to the hazard and that all factors associated with food safety have been identified. The entire HACCP team needs to be involved to ensure that the plant is capable of meeting these critical limits. The team may need to collaborate with resources such as R & D, QA, Statistics, or external consultants as needed to conduct scientifically sound studies. The output should be used to determine the critical limits. Validation is the final step to ensure the system is capable of meeting these critical limits.

CRITICAL LIMITS GAPS

Gap A: Technical expertise is not leveraged for validation of critical limits.
Gap B: Critical limits are not adequate to reduce or eliminate the hazard.
Gap C: Critical limits must be established for hazards that are challenging to monitor.
Gap D: The process cannot consistently be maintained within the defined critical limits.

Gap A: Technical expertise is not leveraged for validation of critical limits. Many companies, both small and large, do not have access to the level of technical expertise required to conduct validation of critical limits. If the necessary resources are not available, sources of information should be leveraged, as described by Mortimore and Wallace in *HACCP: A Practical Approach (5)*.

- Published data — Information in scientific literature, the Internet, in-house and supplier records, industry and regulatory guidelines (e.g., Codex, International Commission on Microbiological Specifications for Foods — The International Commission on Microbiological Specifications for Foods (ICMSF), US FDA, International Dairy Federation — IDF), and trade associations
- Expert advice — From universities, consultants, research associations, plant and equipment manufacturers, cleaning chemical suppliers, microbiologists, toxicologists, and process engineers
- Experimental data — Likely to support critical limits for microbiological hazards and may come from planned experiments, from challenge studies in which product is inoculated, or from specific microbiological examination of the product and its ingredients

Mathematical modeling — Computer simulation of the survival and growth characteristics of microbiological hazards in food systems *(5)*

Gap B: Critical limits are not adequate to reduce or eliminate the hazard. A CCP may not be capable of reaching the critical limit or may have several parameters that need to be controlled, all of which may not be taken into account. Validation of system capability is important to demonstrate that the control measure is capable of meeting these limits. An example of this is in processed cheese. If the product is not allowed to cool in the specified time, additional bacterial growth can occur.

Gap C: A critical limit must be established for hazards that are challenging to monitor. A critical limit must be specific and must be able to be measured through some monitoring procedures. Tests and observations on conditions such as time and temperature may be challenging to measure for each internal piece of baked chicken or hamburger patty. Instead, a team can validate that a belt speed at a certain oven temperature will ensure that the internal temperature to eliminate the hazard is achieved.

Gap D: The process cannot consistently be maintained within the defined critical limits. Each CCP needs to be validated so that, under normal operating conditions, the process can be realistically and consistently maintained within the defined critical limits. Process variations, including product size differences, humidity and temperature fluctuations, and differences in dwell time are examples of factors that need to be controlled to ensure that critical limits are not exceeded. One way of assessing whether a process is capable of being maintained is to use statistical analysis. Such statistical techniques have been developed and used for many years, predominantly for process monitoring and control in the engineering industry.

ACKNOWLEDGMENTS

The Back to Basics Working Group of the HACCP PDG are acknowledged for their contribution to the framework and content: Gary Acuff, Jean Anderson, Andrew Clarke, Rocelle Clavero, Fred Cook, Lone Jespersen, Amy Kramer, Chantal Nde, John Weisberger and Pamela Wilger.

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