

Applying HACCP: Guidance and Avoiding Gaps A Practical Guide

Part 1 of a 3-Part Series

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INTRODUCTION BY SARA MORTIMORE AND CAROL WALLACE

The concept of Hazard Analysis Critical Control Point (HACCP) has been available to the food industry as a tool for helping to ensure food safety for over 50 years. Initially used by Pillsbury for the U.S. manned space program, it was shared with the public in the early 1970s. While widespread adoption did not really begin until the HACCP principles had been further developed and codified in the late 1980s and early 1990s, the system has now been used successfully by countless manufacturers, retailers, and regulators worldwide. Despite the widespread use, many organizations struggle to reap the benefits that should come from effective implementation. Why is that? Reasons include inadequate education and training, lack of skill and guidance in specific areas, e.g., hazard analysis, and also, perhaps, the sentiment that HACCP has been “done” and therefore there has been little discussion recently regarding its continued improvement. We still see enormous opportunity to make HACCP more effective and are excited to know that honest discussion is now occurring in many circles. This document is testament to the importance of like minded industry, academic and regulatory professionals coming together under the auspices of the International Association for Food Protection (IAFP) HACCP Professional Development Group (PDG) to consider some of the gaps in HACCP application. The gaps listed here are not a complete list – there will be others – but hopefully it will be helpful to share observations as a means to collectively make food safety failures less likely.

This article is the first in a series that aims to provide a practical guide to applying HACCP through exploring gaps in application effectiveness and suggested tactics for closing or avoiding these gaps. Here the IAFP HACCP PDG Back to Basics working group considers part 1 of the HACCP principle application process – the preliminary steps to HACCP development. For each preliminary step, current guidance is examined alongside gaps that have been identified by experienced practitioners, and additional guidance is provided to help bridge these gaps in practice.

TERMS AND DEFINITIONS

HACCP: A system that identifies, evaluates, and controls hazards that are significant to food safety (1).

HACCP System: The overall HACCP effort at an organization or facility. A HACCP System may include multiple HACCP Programs.

HACCP Program: The application of a HACCP System for a specific product or group of products. A HACCP Program includes documentation of HACCP development, maintenance and records.

HACCP Plan: A document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant to food safety in the segment of the food chain under

consideration (1). “The HACCP Plan summarizes control of significant hazards for a HACCP Program, and includes names of the critical control points, hazards addressed, critical limits, monitoring details, corrective actions, verification activities, and record keeping.”

STEP 1: ASSEMBLE THE HACCP TEAM

General Guidance

The HACCP team should be composed of individuals collectively having multi-disciplinary knowledge and expertise, including a working knowledge of developing and implementing HACCP systems (Fig. 1).



Figure 1. The HACCP team ensures that HACCP is a dynamic, well-executed program.

Appropriate knowledge of regulatory issues, hazards, risks, and processing specific to the products being evaluated must be represented on the team. Subject matter experts on the team can be internal or external. The names of all HACCP team members, a description of their HACCP training, and their role on the HACCP team should be documented.

Highly effective HACCP teams are composed of members having well defined roles to ensure appropriate representation on the team. Members should have technical expertise in the identification and control of biological, chemical or physical hazards.

The HACCP team leader plays a vital part in facilitating the HACCP team. This leader should have a strong technical knowledge as well as the skill and ability to draw input from other functional areas, e.g., maintenance and the impact of equipment condition on HACCP performance.

Example of a HACCP team composition:

- Member of site leadership, e.g., plant manager
- Functional experts, e.g., operators, engineers, maintenance, sanitation, quality assurance, human resources and other technical expertise

When needed, other subject matter experts should be involved in the team, such as:

- Application, e.g., research and development, microbiology, toxicology
- Process Design

- Sales/Marketing
- Supply Chain or Logistics
- Procurement/Sourcing
- Legal/Regulatory
- Consumer Affairs

HACCP TEAM KNOWLEDGE AND TRAINING

The HACCP team will determine products and processes to be included in the HACCP program, document process flows, lead hazard analyses, identify the need to reassess and work collaboratively with all facility employees to ensure that HACCP is a dynamic, well-executed program. The team should also document/record all meeting activities, trainings, decisions and rationale for future reference, and maintain current HACCP documentation (2).

Team member selection is the first step in the HACCP process. At minimum, every member of the HACCP team must have foundational HACCP training, and at least one member must have advanced HACCP training, including how to design, create, and implement HACCP (3–5).

Collectively, the following skills, experiences and expertise must also be represented on the HACCP team:

- Ability to identify and analyze the production process under consideration and the facility for potential hazards
- Ability to describe the product being produced, including intended use

- Ability to identify potential food safety hazards (biological, chemical and physical) associated with production of the product under consideration, including control to reduce risks
- Ability to identify and analyze the production flow, from incoming raw materials to how the consumer uses the final product
- Understanding of, and ability to explain to others, the regulations of the production country and any export countries
- Ability to identify and analyze food safety hazards associated with the raw materials

HACCP TEAM GAPS

- Gap A: The plant's food safety culture does not support an effective HACCP program.
- Gap B: HACCP teams operate in a regulatory-driven culture, and the development and maintenance of HACCP becomes a compliance activity only.
- Gap C: HACCP team members lack technical expertise and/or functional experience.
- Gap D: The defined scope for the HACCP team is too broad and general.
- Gap E: The HACCP team does not meet on a regular basis or is unable to complete, review, and update a HACCP plan as needed.
- Gap F: HACCP team documentation is lacking.

Gap A: The plant's food safety culture does not support an effective HACCP program. An effective HACCP team is an integrated structure of a food-manufacturing site. As stated by Mortimore and Wallace, *Early involvement of senior management is fundamental to the effective implementation of HACCP.* One proof point for this is that new members of the site know they are active members of the HACCP team and that time is invested to train on not just the standard principles of HACCP, but also on the specific rhythms and expectations of the manufacturing site. This ensures active involvement of new members in the HACCP team and a solid, sustainable integration of HACCP into the site's food safety culture.

Gap B: HACCP teams operate in a regulatory-driven culture, and the development and maintenance of HACCP becomes a compliance activity only. It is essential that HACCP team members understand what a significant hazard is, as well as where hazards may occur in raw materials, production processes and finished product (6). The product of a HACCP team is only as good as the culture it operates within and the knowledge and experience of the cross functional team. Troubleshooting and continuous improvement of a HACCP system requires cognitive skills beyond understanding basic concepts. Teams must be competent in analyzing, distilling, and evaluating the performance of their HACCP system to truly and proactively avoid hazards from reaching the consumer.

Gap C: HACCP team members lack technical expertise and/or functional experience. The HACCP team leader is responsible for ensuring that training and expertise of team members are sufficient. Identified gaps in knowledge and/or experience must be addressed either by adding additional team members possessing the needed expertise or by leveraging external sources. This could be accomplished by having clearly defined competencies for the team and reviewing them regularly. For example, a facility that produces shelf-stable peanut butter spread will be introducing a line extension of "gently roasted" nut butters that will meet the emerging consumer demand for minimally processed foods. The "gently roasted" nut butter line extension will be run on the same processing line as the current product portfolio. The HACCP team will need to include team members (internal or external) who have experience specific to understanding the food safety risks of "gently roasted" nut butters, validation of the new roasting process and assessment of potential cross contamination concerns. If a team member leaves, a replacement must be available to ensure the team maintains the needed expertise.

Gap D: The defined scope for the HACCP team is too broad and general. One of the primary functions of the HACCP team is to clearly define the scope so that the team is on track to work on the right priorities. A thorough understanding of the production process and products is important to ensure that the scope of the HACCP program is reasonable and adequate. It is common for new HACCP teams to struggle to determine which elements of the supply chain are to be included in the HACCP plan. For example, a single HACCP plan for a facility that produces a wide variety of products may not be appropriate. The HACCP team should evaluate products having similar inherent characteristics and processing systems and focus accordingly, if needed, using multiple HACCP plans to cover the entire facility.

Gap E: The HACCP leader does not facilitate the HACCP team effectively. The HACCP team leader should possess demonstrated leadership skills and the ability to effectively facilitate meetings in order to maximize success. The HACCP team leader plays a key role in ensuring that the HACCP team assembles on a regular basis, verifies that HACCP plan(s) are reviewed comprehensively and updates are handled as needed, to ensure that the HACCP plan is maintained accurately and comprehensively. Support from senior management must be demonstrated and visible for the team members to make their role a priority and meet as often as needed to complete HACCP tasks in a timely manner. In addition, the HACCP team must be aligned with goals and expectations of the HACCP program to ensure productivity and effectiveness. Team effectiveness is optimal when all team members understand their role on the team as individual subject matter experts, when all team members clearly understand the food safety goals, when teams are engaged with their internal and external partners on the HACCP inputs and outputs,

when clear ground rules are established and followed, when team successes are celebrated and, finally, when all team activities are documented.

Gap F: HACCP team documentation is lacking. HACCP teams should designate a team member as recording secretary/scribe to ensure that team activities are accurately and adequately documented. Documentation should include training records, qualification/certification records, meeting dates, meeting participants, meeting agendas, activities, decisions, justification for information (including references), external partner assessments, revisions to HACCP plan documents and any other pertinent information. Records of HACCP training should include name of training course, trainer credentials, date(s) including expiry date, and description of training, including any certification.

STEP 2: DESCRIBE THE PRODUCT

General Guidance

Product description should include all general information for product(s) included in the HACCP system, such as:

- List of ingredient types used to manufacture products included in the HACCP plan, including information such as origination/origin.
- For example, “peanuts (U.S.), sugar (U.S.), molasses (Mexico), honey (China), vegetable oils (U.S.), salt (U.S.)”
- Additional detail on ingredients should be addressed in the hazard analysis.
- General description of production method, nature of the product, and packaging utilizing varying amounts of detail sufficient to understand the type of product.
- For example, “Pasteurized, processed cheese spread packaged in sealed plastic jars for retail sale.”
- For example, “Peanut butter product made from roasted peanuts using the following process: cleaning the peanuts, shelling, dry roasting, cooling, blanching, grinding with added ingredients, ing, and packaging in sealed plastic jars for retail sale or in fiber drums for use as ingredient by manufacturers of other products.”
- For example “Smooth Peanut Butter #257, Chunky Peanut Butter #357, Unsalted Peanut Butter #157, Reduced Salt Peanut Butter #457.”
- Intended distribution and storage conditions and shelf life limitations.
- For example, “Intended for distribution and storage under ambient temperature conditions.”
- For example, “Best Used By date printed on the package indicates shelf life limitation of 1 year to maintain acceptable product quality.”
- Factors that may potentially influence food safety risk.

- For example, any use of microbial reduction steps during production, packaging, storage, and preparation and/or handling before consumption or processing.
- Requirements for any treatment before consumption to reduce food safety risk.
- For example, “Heat to 160°F before consuming,” or “Safe to eat without further heating or other preparation before consumption.”
- Statutory and Regulatory Food Safety requirements.
- For example, “Meet statutory and regulatory food safety requirements as set out by the United States Department of Agriculture – Food Safety Inspection Service (USDA-FSIS).”
- List of all products covered by the HACCP plan. Each of these products may be a product family having similar ingredients. Individual stock keeping units (SKUs) need not be listed in HACCP documentation; however, a method of cross-referencing products listed in the HACCP plan with SKUs must be readily available.

PRODUCT DESCRIPTION GAPS

Gap A: Products included in the HACCP plan are too diverse.

Gap B: Product description is not reviewed and updated when changes are implemented.

Gap A: Products included in the HACCP plan are too diverse. Group products into a HACCP plan according to similarity of processing steps, food safety controls, and the composition and nature of finished products. If this grouping is not done, the HACCP plan will be very difficult to complete accurately to help the plant be successful at making safe products. Peanut butter could include several different types/flavors, but each has similar processing steps, food safety controls, and nature of finished product, so they can be addressed under one HACCP plan. New products to be included in a HACCP plan must be reviewed for compatibility with the plan before production and, if compatible, should be added to the product list in HACCP documentation before production. Obsolete products should be taken off the list as soon as practical. For example, a HACCP plan includes shredded baked cereal products and extruded cereal products. Although all the products are breakfast cereals, the processing steps and associated controls are very different. A separate HACCP plan should be developed for the extruded products instead of including them in a single HACCP plan with the shredded baked products.

Gap B: Product description is not reviewed and updated when changes are implemented. The product description (in addition to other sections of HACCP documentation) must be revised in a timely manner to maintain accuracy, including ingredient types, production method and factors that may influence food safety risk.

Several cheese spread products are reformulated to improve flavor and nutritional value. A system should be used to collect, maintain, and review changes. For example, instead of roasting raw peanuts, pre-roasted peanuts are purchased from a supplier to manufacture peanut butter.

STEP 3: IDENTIFY INTENDED USE

General Guidance

Describe for each product the intended and any known unintended use(s) of the finished product(s) by customers or consumers, as well as the intended and any known unintended consumer group(s) that may be adversely affected. Intended use should be examined throughout the supply chain, including further manufacturing, food service, and use by the final food preparer and consumer. This includes all reasonably expected handling of the end product, including mishandling and misuse of the end product by the customer or consumer. Consumer groups known to be especially vulnerable to specific food safety hazards must be considered (Fig. 2).

A table can be used to provide information on product use (Table 1).

INTENDED USE GAPS

- Gap A: Not including unintended use
- Gap B: If producing ingredients, not understanding how they are further processed and handled
- Gap C: Unintended users are not addressed

Gap A: Not including unintended use. An industry Gap that needs to be addressed is not including the known unintended use of their finished products. This gap can occur because there is little or no information on how the consumer is interacting with the product when the product is launched. As consumer usage of the finished product evolves over time, this section in the HACCP plan is not updated. HACCP teams may also minimize the significance of the data they have on their products. An example of not including unintended use would be a non-ready-to-eat product that is also used as a ready-to-eat product. For example, a dry seasoning mix that is intended to be prepared by following the directions on the package, which include a cook step, could be used as a ready-to-eat dip. The hazards associated with a ready-to-eat product versus a non-Ready-to-Eat (RTE) product will be addressed differently in the design phase of a new product. The microbiological hazards would also be mitigated in different ways.

One way to address this is to ensure the team is including the potential unintended usage in their assessment and that they understand the RTE status of the products and how the consumer/customer is using the products. Sources of data that will help the HACCP team would include consumer data (consumer insight data, consumer contact information and social media data). Activities may include review of company recipes and social media recipes, review and assessment of illness outbreaks or pathogen contamination events that the products have experienced, and review of how the company is marketing the products.



Figure 2. Consumer groups known to be especially vulnerable to specific food safety hazards must be considered.

TABLE 1. PRODUCT USE

Use by Consumers (keeping in mind various use situations such as food service, convenience stores, camping, driving, etc.)

| | |
|---|---|
| Intended Use | This product is designed for the general population which may include high-risk groups. |
| Unintended Use | Susceptible individuals may consume some products containing allergens. All allergens are stated on the package and all packages carry the relevant warnings. |
| | Some products requiring cooking for safety may be consumed without cooking. Preparation instructions are clearly stated on each package. |
| Reasonably expected mishandling and misuse | Some products requiring cold temperatures during storage for safety may be stored improperly at elevated temperatures. Storage requirements for food safety are clearly stated on each package. |
| | Some products requiring limited shelf life for safety may be consumed after excessive storage time. "Use by date" for food safety is clearly stated on each package. |
| | Some products requiring cooking for safety may be consumed without adequate cooking. Cooking instructions for food safety are clearly stated on each package. |

Gap B: If producing ingredients, not understanding how they are further processed and handled. The HACCP team needs to understand how their customers are using and further processing their ingredients. In this review, the HACCP team must understand how their ingredient is being used and further processed. The ingredient manufacturer can then communicate known hazards to the customer so that appropriate controls can be put in place. For example, cereal particulate is an example in which further processing could occur or the ingredient could be added directly to a product intended to be RTE.

Gap C: Unintended users are not addressed. To help HACCP teams identify unintended consumer users, the team can ask several questions during this review. What population is this product targeted for? Do they include higher risk groups like babies, children, or the elderly? Does your product have allergens? How is your product marketed. Is it for kids? If HACCP teams are using a standard table similar to the one discussed previously for reporting this information in the plan and utilizing guidance, this step should be addressed.

STEPS 4 AND 5: CONSTRUCT AND CONFIRM PROCESS FLOW DIAGRAM

General Guidance

The Process Flow Diagram is a representation of all steps and their interactions used to manufacture products included in the HACCP Program. A single flow diagram may be used for several products manufactured using similar steps. Differences in steps among products may be shown by using labeling with text or color that applies to specific products. Alternatively, modular diagrams similar to those described may be used to show groups of process

steps unique to specific products (6). Current accuracy and completeness of the Process Flow Diagram is very important since it is used as a resource for understanding the process, and hazards and controls associated with the process and is enhanced by on-site confirmation of each step of the diagram (Fig. 3).

The Process Flow Diagram is an important tool used for facilitating an effective Hazard Analysis. It should be constructed by HACCP Team members using guidelines established by the company. This facilitates accuracy, ease of understanding, and ease of revision. Some general guidelines for effective Process Flow Diagrams are listed below:

- Show all steps sequentially in text boxes, with arrows between steps indicating interactions and direction of all process flow from inputs to outputs.
- Label each step with a concise name describing activity at the step. Use names of equipment only when descriptive of the activity (e.g., oven, extruder, metal detector) or if activity at the step is described separately. A Process Flow Description document can be used to provide detail about activity associated with each step. This can enhance understanding of potential hazards and controls.
- Some step labels may include specific control information, especially for steps that are Critical Control Points (CCP).
- Show all transfer steps (e.g., conveyor, cart, and tote). Identify type of conveyance (belt, vibratory, pneumatic).
- Label each step with a unique number to relate to other documents (i.e., process hazard analysis) and help understanding of the flow.



Figure 3. Completeness and accuracy of the Process Flow Diagram is greatly enhanced by periodic physical on-site confirmation of each step of the diagram.

- Show all product inputs (i.e., ingredients, Work In Progress (WIP), packaging, rework, recycling).
- Show all other process inputs (i.e., water, steam, air, other gasses, processing aids).
- Show all process outputs (i.e., end products, intermediate products, rework, recycling, by-products, waste).
- Show alternate paths of the product stream (e.g., temporary holding).
- Show alternate process flow during unusual circumstances (e.g., process delays, downtime, seasonal). A separate Process Flow Description document can be helpful for describing this detail).
- Include identification of external process steps (e.g., freezing at distribution facility, contact packaging).
- A plant schematic can be a valuable addition to the Process Flow Diagram and the Process Flow Description to clearly identify flows of people, product, and waste; points of potential cross-contamination; and segregation between high and low risk areas.

PROCESS FLOW DIAGRAM GAPS

Gap A: Process Flow Diagram not complete or accurate

Gap B: Process Flow Diagram not current with changes to process

Gap C: Process Flow Diagram not easy to understand or use

Gap A: Process Flow Diagram not complete or accurate. The Process Flow Diagram is an essential resource used during Hazard Analysis, since it provides information on hazards and controls that exist in the process. Missing steps or inaccurate information in the Process Flow Diagram can cause hazards to be unrecognized or poorly understood, or controls to be mistakenly considered. For example, a Process Flow Diagram for peanut butter production does not include rework, but in the actual process peanut butter from under-filled jars is scraped out and put into a vessel that is used for filling additional jars of peanut butter. Because this step is missing from the Process Flow Diagram, the HACCP Team misses it when conducting the Hazard Analysis. As a result, risks associated with the peanut butter rework practice are unrecognized, compromising effectiveness of the HACCP system for ensuring that controls are in place for the production of safe food. Completeness and accuracy of the Process Flow Diagram are greatly enhanced by periodic physical on-site confirmation of each step of the diagram and interactions between these steps, during development and reassessments of the HACCP Program. This is best done by persons having sufficient knowledge of the processing operation. Results of confirmation may reveal need for revisions to achieve current accuracy and completeness.

Gap B: Process Flow Diagram not current with changes to process. Changes to the way product is made can affect food safety and are therefore important to include in updates of the Process Flow Diagram and other HACCP documents. For example, ingredient

addition for processed cheese spread was changed such that spices are added after a thermal treatment instead of before. The Process Flow Diagram was not updated, and erroneously shows spices are added before the thermal treatment. This inaccuracy may cause understated microbiological risk associated with new ingredients (oregano and nutmeg) in the product. To keep Process Flow Diagrams up to date, a mechanism must be in place to inform the HACCP Team of any changes to ingredients, facility, equipment and processes. The team should review this information, update the Process Flow Diagram and other HACCP documents if needed, and determine if the change is likely to affect food safety. If the change may affect food safety, the HACCP plan should be reassessed, with the Process Flow Diagram used to support repeat of hazard analysis. Reassessments should be done periodically to confirm accuracy and completeness of HACCP plan documents, including Process Flow Diagrams.

Gap C: Process Flow Diagram not easy to understand or use. Process Flow Diagrams must be constructed in a way that can be easily understood to recognize flow among process steps

and their associated hazards and controls. If the sequence of steps is not correctly determined from the diagram, hazards may not be recognized. This can reduce effectiveness of the HACCP system. For example, a Process Flow Diagram for breakfast cereal products indicates metal detection is used. In the sequence of production, it is located immediately before the last blender but, because of nonspecific representation in the Process Flow Diagram, the HACCP Team mistakenly believes it is located after the blender. This situation may cause the HACCP Team to mistakenly believe the metal detector reduces risk of metal hazard from the blender. To prevent misinterpretation of the Process Flow Diagram, standard guidelines should be followed during construction and revision of the diagram, such as those described above. Someone not familiar with the process should review the diagram and be able to fully understand the flow without uncertainty. The diagram must clearly show the sequential order of process steps and their interrelationships.

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In Memory

Donald G. Lane

We extend our deepest sympathy to the family of Donald Lane who recently passed away. Mr. Lane was a member of the Association since 2005. IAFP will always have sincere gratitude for his contribution to the Association and the profession.