"HACCP Steps: Principles, Content, and Industry Gaps"

A practical guide developed by industry for industry

Developed by the IAFP HACCP PDG – Back to Basics working group

Draft 1.0 July 15, 2014

Contents

Step 1: Assemble the HACCP team

General Guidance:

The HACCP team should have a combination of multi-disciplinary knowledge and expertise in developing and implementing HACCP systems. Appropriate product and process specific knowledge and expertise must be on the team or brought in as a subject matter expert. These experts can be internal or external. The names of each HACCP team member, their HACCP training and their role on the HACCP team shall be documented.

Highly effective HACCP teams have well defined role clarity and ensure appropriate representation on the team. Example of HACCP team composition;

- Designated HACCP team leader
- Member of site leadership
- Person(s) with technical expertise in the identification of biological, chemical or physical hazards.
- Operators, engineers, sanitation and other technical expertise

HACCP Team Knowledge and Training:

It is expected that the HACCP team will define the scope of activity, lead hazard analysis, be called upon when re-evaluation is necessary and will work collaboratively with all facility employees to ensure that the HACCP is a living well executed program. Another important activity of this team is to document all meeting activities, training and decisions for future reference.

An effective HACCP team is empowered by management, multidisciplinary and knowledgeable of their product and process being evaluated. Appropriate multidisciplinary team member selection is the first step in the process. Once selected, team members must receive foundational HACCP training. Additionally, it is important that the team have a depth and breadth of knowledge of the product being produced and the specific production system. Collectively, the following skills, experiences and expertise must also be represented on the HACCP team:

- Knowledge of the production process under consideration
- Knowledge of the product being produced
- Knowledge of the food safety risks (biological, chemical and physical) associated with production of the product under consideration
    - External expertise can be leveraged as part of the HACCP team
    - External expertise must be leveraged with person(s) knowledgeable with the product being produced

- Knowledge of the production flow from incoming raw materials to how consumer uses the final product
    - Includes knowledge of how processes are controlled and monitored
    - Understanding of facility sanitation processes
    - Understanding of site maintenance practices

Industry Gaps:

It is essential that HACCP team members are able to understand what a significant hazard is, where hazards may occur in raw materials, production processes and finished product. (Mortimore and Wallace). The end product of a HACCP team is only as good as the knowledge and experience of the cross functional team. The team must also be able to recognize when external expertise is necessary to ensure a reasonable assessment of the hazards and risks. When external expertise is leveraged, it is important to understand that the HACCP team members have the ultimate responsibility for understanding, implementing and ensuring proper execution of the HACCP plan and food safety system.

Gap: HACCP Team Members lack technical expertise and or / functional experience: The HACCP team leader is responsible for ensuring that the HACCP team training and expertise meets minimum standards. Identified gaps in knowledge and / or experience must be addressed by either adding additional team members with the functional expertise or by leveraging external sources. Functional expertise includes expert knowledge specific to the product being produced and the facility that it is produced in. 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) that have experience specific to understanding the food safety risks of "gently roasted" nut butters, validation of the new roasting process and assess potential cross contamination concerns.

Gap: 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 scope so that the team is on track to work on the right priorities. Deep understanding of the production process and products is key to ensuring that the scope of the HACCP work is reasonable and adequate. It is not uncommon for new HACCP teams to struggle to define 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 with similar inherent characteristics and processing systems and focus accordingly.

Gap: The HACCP team does not meet on a regular basis or is unable to complete a HACCP plan: The HACCP team leader will ideally have demonstrated leadership and meeting

facilitation skills 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 the HACCP plan(s) are comprehensive, and that the HACCP plan is a living document. Validation and verification of the HACCP plan are critical components to ensure success.

Gap: HACCP Team Documentation: HACCP teams should designate a team member as recording secretary to ensure that the team activities are adequately documented. Documentation should include training records, qualification records, meeting dates, meeting participants, meeting agendas, activities, decisions, external partner assessments and any other pertinent information.

Gap: HACCP Team Not Cohesive or Productive: A HACCP team must be cohesive with aligned goals to help ensure productivity and effectiveness. Team effectiveness is maximized when all team members understand their role on the team as individual subject matter experts, when all team members clearly understand the team food safety goals, teams are engaged with their internal and external partners on the HACCP inputs and outputs, when clear ground rules are established and followed, team successes and celebrated and finally all team activities are documented.

Step 2: Describe the Product

Group products into a HACCP plan according to similarity of processing steps, food safety controls, and the composition and nature of finished products. Examples are Shredded Baked Cereal Products, Peanut Butter, and Cheese Spread. Each of these 3 examples may include several different flavors, but each has similar processing steps, food safety controls, and nature of finished product.

GAP: Products included in the HACCP plan are too diverse

- Example: A HACCP plan includes shredded baked cereal products and extruded cereal products. Although all the products are cereal, 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: Product description not reviewed when changes happen

- Example: Instead of roasting raw peanuts, pre-roasted peanuts are purchased from a supplier to manufacture peanut butter. The product description (in addition to other sections of HACCP documentation) must be revised to maintain accuracy.

The product description should include a list of all products covered by the HACCP plan. Each of these products may be a product family having similar ingredients. 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 of the list as soon as practical. 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 should include all general information on factors that may potentially influence food safety risk including any use of microbial reduction steps during production, packaging, storage, and preparation before consumption.

General description of production method, nature of the product, and packaging sufficient to understand the type of product, for example "Cooked and flaked dry corn cereal products. They are packaged in sealed bags, in sealed plastic liners within cartons, or in single serve plastic disposable bowls". Another example is "Peanut butter product made from roasted peanuts, packaged in sealed plastic jars for retail sale or in fiber drums for use as ingredient by manufacturers of other products". Another example is "Cheese spread made from pasteurized process cheese, packaged in plastic tubs for retail sale".

Intended distribution and storage conditions and shelf life limitations, for example "Intended for distribution and storage under ambient temperature conditions. Best Used By date printed on the package indicates shelf life limitation of 1 year to maintain acceptable product quality."

Requirement for any treatment (e.g., heating) before consumption or use as ingredient to reduce food safety risk, for example "Safe to eat without further heating or other preparation before consumption".

List of ingredient types used to manufacture products included in this HACCP plan. For example, "Roasted peanuts, sugar, molasses, honey, vegetable oils, salt".

GAP: Lack of system to collect, maintain and review ingredient information

Example: Several cheese spread products are reformulated to improve flavor and nutritional value. The HACCP team must be informed of any new ingredients and any discontinuation of other ingredients, to maintain accuracy and effectiveness of the HACCP plan.

Step 3: Identify intended use

I**ntent**: Identify the intended and unintended use of the finished product as well as the intended consumer target group.

General Guidance: This includes the reasonable expected handling of the end product and any unintended but reasonable expected mishandling and misuse of the end product by the end user or consumer. Groups of users and where appropriate groups of consumers must be identified for each product. Consumer groups known to be especially vulnerable to specific food safety hazards must be considered. Need to have validated cooking instructions for NRTE products.

Industry gaps:

- Unintended uses and users are not addressed.
- Only listed users/consumer
- Only listed use(s)
- Missing this step completely

There are three major areas that need to be reviewed when determining the intended and unintended use of the finished product as well as the intended user. The areas are 1) RTE status of food 2) Intended use 3) Consumer use.

Table 1: Intended Use Examples

Typical Chart to capture the information on intended and unintended uses and users	**Ways to get the information and where you might find it. Questions you need to ask during this review?**	**Non-RTE Steel Cut Oats Cereal Example**	**RTE Cereal Example**	**Peanut Butter Example**	**Processed Refrigerated Cheese—Velveeta vs string cheese Example**
Target group of users and special consumer considerations (example infants, elderly)	Intended Consumer users must be identified. What population is this product targeted for babies, children, elderly. Does your product have allergens How is your product marketed? Is it marketed to kids?	This product is designed for the General population.	This product is designed for the General population. This product can be marketed to high risk groups such as babies and the elderly. Some products may contain allergens so are not suitable for the whole population. All allergens are stated on package and all packages carry the relevant warnings.	This product is designed for the General population. Some products may contain allergens so are not suitable for the whole population. All allergens are stated on package and all packages carry the relevant warnings.	This product is designed for the General population. Some products may contain allergens so are not suitable for the whole population. All allergens are stated on package and all packages carry the relevant warnings. All products must be held under refrigerated storage prior to use

Intended Use and Reasonably expected mishandling and misuse	Is the product RTE? Determine if the product is RTE or not based on the following decision tree. Does product require preparation by consumer prior to eating? Yes NRTE No RTE Can consumer consume product in the form it was purchased in? Yes NRTE No RTE Does product require preparation by consumer prior to eating and consumer data suggests that people do not follow prep? Yes Consider RTE state No NRTE Does the Manufacturing process contain a lethality step? Yes No Can consumer consume product in the form purchased? Yes RTE NO NRTE What type of consumer data (consumer contact information, social media data do you have for this product? What recipes are published for your product?(Company recipes and social media recipes) What industry events has your product or industry experienced? How is your company marketing the product?	Product should be made per cook instructions on package. Consumer could misuse this product in the raw state as a topping for bread post bake.	This is a RTE product consumed in the form it was sold in.	This is a RTE product consumed in the form it was sold in.	This is a RTE product consumed in the form it was sold in.

Step 4 and 5: Construct and confirm process flow diagram

Intent

Construction of a flow diagram and the on-site confirmation of the flow diagram are identified as application steps four and five in Codex (Codex CAC/RCP 1-1969, Rev. 4-2003). Codex defines a flow diagram as "A systematic representation of the sequence of steps or operations used in the Production or manufacture of a particular food item."

As per Codex the flow diagram should be constructed by the HACCP team (see also paragraph 1 above). The flow diagram should cover all steps in the operation for a specific product. The same flow diagram may be used for a number of products that are manufactured using similar processing steps. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

Steps must be taken to confirm the processing operation against the flow diagram during all stages and hours of operation and amend the flow diagram where appropriate. A person or persons with sufficient knowledge of the processing operation should perform the confirmation of the flow diagram.

General Guidance

The HACCP Lead must review the scope for the HACCP System since this will clearly define the products and process line.

The HACCP Team must review the process flow diagram construction principles set out by the company before starting the design and construction of the DRAFT Process Flow diagram.

The structure of the Process Flow Diagram must include but is not limited to,

- Be constructed in a modular format using Visio symbols e.g., ovals to start and stop, rectangles for process steps, solid arrows for flows between steps, diamonds for decision points, connectors to continue the process on another page/line.
- Be constructed in a modular structure to show how individual streams contribute to the product.
- Allow for easy editing.
- Help eliminate overlap in the diagram.
- Can be related to the areas of the plant schematic
- Include numbering of all steps in the operation which can assist the HACCP team member to trace the flow

- Detail the process step e.g., 4.0 Packaging, but not the name of the equipment e.g., Multivac
- Identify processes that are outsourced or third party storage / work e.g., work in progress (WIP), freezing at a third party distribution center, packing at another plant
- Identify where raw materials, ingredients, WIP products and packaging enter the process
- Identify every process input e.g., Nitrogen, CO2, water, air and other manufacturing ingredients and aids
- Identify every process output e.g., end products, intermediate products, by-products and waste that are released or removed
- Include all transfer points e.g., conveyors, buggies/cart, ve-mags
- Detail extraordinary circumstances: e.g., process delays, product transfer and hold during equipment downtime, seasonal variation and potential differences to the usual process by writing notes in the process step shapes
- Include the location of where rework occurs and flows from and to in the process Identify potential cross contamination hazards.
- Identify the Process Steps that are CCPs with a red font color (do not include the control limits) and the CCP number at the process step e.g., CCP - #2

The DRAFT Process Flow Diagram created must be stored electronically in a designated location accessible for all team members.

On-site Confirmation of Process Flow Diagram

The HACCP Lead will assign sections of the Process Flow Diagram to HACCP Team members to complete the on-site confirmation.

Changes, events, or activities that would require an on-site confirmation please note this list below is not exhaustive,

- New line.
- New piece of equipment; re-arrangement of equipment.
- New product.
- New ingredient.
- New product or people flow.
- Movement of existing product from one line to another existing production line / equipment.
- Changing the storage location of an existing material or equipment.
- Material or equipment that is stored outside of the production area or plant.

- Construction.

The HACCP team members will

- Be paired where possible to complete the on-site confirmation.
- Print the process flow diagram and plant schematic.
- Record the names of the team member(s) who conducted the on-site, the date(s) during which the on-site occurred and the shifts.

Note: The HACCP team members must be independent of their work area with the exception of production and food safety and quality.

The HACCP team must go on-site and verify the accuracy and completeness of the Process Flow Diagram by walking and observing the process and flows

- during days and afternoons and nights
- consulting with production operators

The HACCP Lead reviews and as applicable updates the Process Flow Diagram and / or Plant Schematic for discussion.

At the HACCP team meeting, the HACCP Lead facilitates the discussion with the HACCP Team members in attendance to gain approval. A formal sign off by the HACCP team concludes the confirmation.

Industry gaps

Completeness and current: the process flow must be complete with all process steps, transfer points, and handling of rework and reuse material. Further, the process flow must be current and changes to the process of handling raw material, components, and product must be discussed and changed/added to the process flow.

Team participation in the process flow development, confirmation, and maintenance: only through team participation can the process flow be complete and current. The process flow can only through team discussion and collaboration be developed, confirmed, and maintained in a complete and current manner. It is important to remember that not one individual person has all the detailed knowledge about the manufacturing process.

Static document: the process flow is a working document and must be considered a tool for discussion of all changes affecting the plants process, product, and practices. It is important to remember that the hazard analysis stage starts with the process flow diagram and an incomplete and out-of-date process flow means an incomplete hazard analysis.

Standard construction and software in developing and maintaining the process flow: As employees cycle out of the HACCP team due to natural attrition, new members join. To ensure sustainability of the HACCP system including the process flow it is important to construct the process flow in a standardized way (i.e. use of flow chart figures, spread out the process flow instead of condensing it onto one page that cannot be read) and preferably by use of a flow chart software. This makes it easier for new members to maintain and update the process flow and ultimately minimizes the risk of errors.

Plant schematic: the team can choose to include a plant schematic in the process flow stage. The plant schematic is useful to highlight cross-contamination points, transfer point, people, product, -and waste flow. The plant schematic is also a useful tool for team discussions and onboarding of new HACCP team members.

Step 6, Principle 1: List all potential hazards, conduct a hazard analysis and consider control measures

Intent: Effectively identify specific potential hazards which are associated with each processing step, completion of a hazard analysis which considers the likelihood and severity of hazards occurrence and also the measures which can be applied to control the identified hazards to an acceptable level.

General Guidance:

It is important to consider and understand the interrelation of the HACCP process steps which are conducted prior to completing a hazard analysis, understanding how they influence the process, particularly around identifying hazards and determining risk levels. Steps 1 – 5 are completed prior to the hazard analysis for specific reasons, as the output should be used to inform the decisions made when completing Step 6. For example, it is important to assemble a HACCP team with the required skill set to ensure the individuals participating in the hazard analysis have the appropriate level of knowledge and experience. Utilizing a multi-disciplinary team based approach enables much wider contribution from different viewpoints and can prompt greater discussions with more depth. To include someone within a HACCP team purely because of their job title or due to their leading a functional group but who does not have the required skill set can limit the depth of discussions and restrict the overall output from the hazards analysis discussions. When selecting a group of individuals from a cross functional team is essential to ensure different considerations and approaches are conveyed. Potential food safety hazards which are reasonably expected to occur must be identified at each manufacturing process step. Putting the onus on the QA function to complete the hazard analysis isolation and without using a cross functional group that 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 which may be likely to occur. To enable a comprehensive study, it is essential that an experienced team is used to conduct 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. This multi –disciplinary approach increases awareness of the factors which could result in the introduction of food safety hazards into the process steps.

Defining the scope of the hazard analysis, which may include outsourced processes and potentially steps which may be preceding or following product manufacturing, which could be impactful to the safety of the finished product is important. Constructing and verifying the

process steps as a team not only enables the development of a more comprehensive process flow diagram, but the onsite verification enables the identification of potential hazards which may be introduced into the process from equipment or the environment.

The identification of the hazards should be based on the preliminary information collected, through the assessment of process steps and utilizing external information 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 which may be introduced or survive through particular process steps. Providing an accurate description of the potential hazards is important to facilitate the hazard analysis process and ultimately the measures which are to be considered to control the identified hazards. Pathogenic bacteria for example have different growth requirements and their ability to multiply, produce toxins or growth may be influenced by environmental factors and/or the controls or the lack of them within the manufacturing processes.

Once hazards have been clearly identified, an assessment which considers the severity of adverse health effects and the likelihood of the hazards occurring (risk) must be completed in order to identify the controls required to ensure identified hazards are controlled to an acceptable level. 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 any misuse by the consumer. Consideration to the intended consumer of the products should also be considered when determining risk, particularly individuals within vulnerable groups that may be at a greater risk from the identified hazards. Understanding the needs of the requirements of the potential consumer groups could influence the level of control measures which are required to maintain control and produce a safe product.

Clear justification should be provided to determine the likelihood and severity of the hazard and determine the level of significance of the hazard; this influences the measure/s or combination of measures which are required to prevent, eliminate or reducing the food safety hazards to defined acceptable levels. Where possible, consideration within the hazard analysis should include (as and where applicable);

- the qualitative and/or quantitative evaluation of the presence of hazards;
- survival or multiplication of micro-organisms 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. with specific process steps which might be subsequently identified as steps which are critical in controlling metal contaminants such as metal detection, x-ray, sieving, filtering etc.

Industry gaps

Identification of hazards

When identifying hazards there are several key aspects which are often either taken for granted or overlooked. On occasion identified hazards may be referred to in a generic manner, i.e. "*pathogens*" instead of the actual organism of concern, without understanding the growth characteristics of the organism associated with the product or ingredient etc. it is not possible to accurately complete the hazard analysis or determine the relevancy of the controls in place required to manage the hazard which has been identified.

Often processes are revised within a manufacturing environment however this may not always be captured in a timely manner within the process flow diagram. Failing to update or accurately verify the process flow diagram through a team based approach potentially could result in hazards not being identified at the appropriate process step, eliminating the ability to complete an effective hazard analysis.

In addition 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 within the finished product and ultimately the consumer. It is important to be accurate, factual and realistic when identifying food safety hazards from inputs associated with raw materials, utilities and also food contact materials which may impact the safety of the product. Consideration to relevant scientific literature, particularly regarding emerging issues and acceptable limits which might not be known or overlooked in favor of tribal knowledge or previous assumptions to define risk levels without providing a clear rationale as to how decisions were made.

Justification must be provided to support the likely occurrence of potential hazards; the recording of hazards without appropriate supporting rationale may raise doubt on the validity of the hazard identification process.

Hazard analysis

When completing a hazard analysis and determining a risk rating for the hazards which have been identified, it is important to justify the likelihood and severity ratings which have been determined in order to establish the significance of the hazard. Attributing a 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 multi-disciplinary team enables 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 just by the QA department. This approach to hazard analysis limits the quality of the output but also casts doubt on to the actual engagement of the HACCP team and ultimately their ownership of the HACCP plan.

Defining the level of severity can often be confusing for HACCP teams which do not have appropriate knowledge of the hazards or without appropriately quantifying the hazards. Often without technical or scientific support, likelihood and severity ratings are sometimes randomly assigned which can and does lead to an inappropriate risk rating and apportion of significance resulting in elevated risk ratings.

Clarity in the justification of decisions which have been made can sometimes be either lacking detail or inappropriately documented which makes it difficult to decipher how the risk levels were actually determined. Care is also required when documenting the output from the hazard analysis, occasionally due to the vast number of process steps within a HACCP plan which 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.

CCP(s) 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.

Control Measures

It is important that the capabilities and also the interrelation between various measures that are employed to control hazards are fully understood. For example a large number of programs might be in place to manage microbiological hazards, programs may include sanitation activities good manufacturing practices, supplier approval and monitoring of raw materials etc. in isolation these may have limitations in managing microbiological hazards. However the effectiveness of these controls in totality and their influence in supporting the effectiveness of a cook step within a manufacturing process may be 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.

Focus areas

- Consideration and reference to preceding HACCP steps
- Utilization of a multi-disciplinary team approach and its importance
- Correct use of risk assessment tools
- Importance of identification of all relevant hazards
- Documentation of justification for each assessment and decision
- Reference to credible information to support decisions

Step 7: Principle 2 – Determine CCPs

Intent: Identify the significant hazards and determine the appropriate control point or step for each (prevent, control, eliminate)

General Guidance: A logical, reasoning approach must be used. Thorough knowledge of the process and all of the possible hazards associated with the process and ingredients is essential. There are many different tools to accomplish this assessment such as a decision tree, scorecard matrix similar to a Failure Mode Effects Analysis (FMEA) with assigned hazard significance ratings, list of questions, to name a few, to help identify the significant hazards. These tools need to be flexible and are simply used for guidance. The HACCP team should seek the assistance of internal or external subject matter experts for guidance, if the team does not have the expertise for hazard assessment or use of the assessment tools. 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.

Industry gaps and examples:

GAP - CCP is identified or assumed before the hazard analysis is completed

- Example: In an 8oz single package size, cheese spread process, finished product label verification at the label step is identified as a CCP because of the presence of milk allergen (dairy) in the product.
  - Gap:- The manufacturing line only runs this product and formula in this size package, and no other product is run on the line. A MCP (manufacturing control point) or CP (control point) may be sufficient to manage the hazard instead of a CCP since there is only a single allergen and package run on the line and it is present in every production run.
  - Effective practice: If another product formulation is added to this manufacturing line, the rationale for no CCP (manage as CP) should be revisited to determine if the significance of the risk has changed, .
- Example: Metal detection as a control for metal contamination in finished product is mandated as a CCP by corporate policy for a puffed dry cereal packaged in a 15 oz paper board carton.
  - Gap - The perceived risk is assumed prior to assessment of all of the other controls that may be in place.
  - Effective practice: Include assessment of all other potential control controls that may be in place, either through pre-requisite programs, equipment design, supplier ingredient programs, up-stream process steps or additional upstream controls, or other manufacturing controls.

GAP - The product is made without proper controls of the significant hazards

- The CCP identified does not control the hazard
  - Example: In a dry granola cereal product, a flavored honey slurry with water activity of 0.7 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 183F set
  - point, and 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 a validation study, and is managed as the CCP step in the process. The honey slurry is not pretreated for pathogen reduction by the supplier.
    - Gap : A new flavor of honey slurry is run with the same process conditions (oven temperature and belt speed), but the new honey slurry has a water activity of 0.61. The impact of the lower water activity of the new honey slurry was not considered and it was assumed that the original belt speed and oven temperatures would be adequate to control the same *Salmonella* hazard.
    - Effective Practice: The validation study should be repeated to determine if the oven temperature and belt speed are adequate to eliminate the *Salmonella* risk with new honey slurry with 0.61 water activity.
- A CCP is not identified to control a known hazard
  - Example: A soft refrigerated cheese product is manufactured using raw, unpasteurized milk, without controls to eliminate the risk of pathogens associated with the raw milk.
    - Effective practice: The hazard assessment should include a thorough risk assessment of the incoming ingredients (raw milk) for presence and prevalence of pathogens to determine what controls may be in place or what must be implemented to control the risk (e.g. raw milk supplier programs, existing plant programs like sanitation and sanitary equipment design, in-process temperature controls, production run length).
  - Example: Manufacturing line stops resulting in extended down time periods; temperature abuse of in-process product occurs during the down-time, and the potential for pathogen growth is not considered in the hazard analysis.

- Effective practice: 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.

- More than one preventative control may be needed to control a hazard which occurs at different stages of a process
  - Example: In a peanut butter manufacturing process, a control for *Salmonella* contamination is needed at a validated roasting step for in-coming raw nuts to eliminate the pathogen, and also further down-stream in the process at the peanut grinding step for paste production, to control post roasting environmental re-contamination with *Salmonella* prior to packaging.
    - Effective practice: These additional controls should consider environmental monitoring, employee behaviors and training, product and personnel traffic through the facility, and GMPs.

GAP – The approach used to identify a significant hazard is not described or properly trained

- With the scorecard or FMEA risk grid approach for hazard identification, and the many versions that are available for use, the tool may be used without proper training or knowledge of the hazard implications, potential Severity of the hazard (S), Frequency of occurrence (O), or Detectability (D) of the risk or nonconformity when it happens. Risk (R) for the hazard = S x O x D. The result may be an inadequate control for a significant hazard in the process if S, O, or D is not properly identified, or a CCP may be identified for a non-significant hazard that could be managed by another step, PRP or food safety program.
  - Effective practice - If there is uncertainty, the HACCP Team should seek expert advice, potentially external to the organization if appropriate, before making a decision on significance of a hazard
  - Effective practice - A decision tree or series of questions may be a better approach for some HACCP teams versus a scorecard or risk grid (Codex, 2009; Wallace, CA, Sperber, WH, Mortimore, SE., 2011. *Food Safety for the 21st Century. Managing HACCP and Food Safety Throughout the Global Supply Chain*, chapter 12. Wiley-Blackwell) . The team may need to assess several tools to determine which best meets their need.
    - Example: Series of questions tool
      - Ingredient example: Risk assessment of raw peanuts from a supplier that are used in a ready to eat processed Peanut Butter spread

a. **Question 1**: Is it likely that raw peanuts entering the plant contain *Salmonella* species?
    i. **Answer** - YES
b. **Question 2**: Will the another or the down-stream roasting step for raw peanuts prior to peanut grinding for peanut butter manufacture eliminate the *Salmonella* hazard or reduce it to an acceptable level?
c. **Answer** – YES. **Result**: Ingredient control for *Salmonella* with incoming raw peanuts from the supplier is NOT a CCP and may be managed as a CP through a PRP ingredient program.

GAP - 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, may be lost when new products are added or existing product formulas or process steps are changed, new equipment is added to the line or during annual review of the HACCP plan. Additionally documentation of the scientific justification is helpful during 3rd party audits or regulatory visits.
    - Effective practices:
        - One approach to document the justification, may be to use and maintain a separate decision tree document for each step assessed as a record of the rationale and justification process used in the assessment
        - Add an additional column to the Hazard Analysis document for recording the scientific assessment and rationale for each step in the process evaluated.
- Examples of Rationale/Justification:
    - Hazard Identified: An undeclared almond allergen in a granola based dry cereal product at packaging step. The Labeling step for finished product is identified as the control (incorrect labeling or miss-match of packaging to formula being run). There is no history of mixed packaging material from the package vendor, and the package vendor has a robust HACCP program in place.
        - CCP Step: Verify production batch sheet formula to package art copy number or package key-line version being run on the line hourly and with each new pallet and vendor lot of package material.

- CCP Rationale: Acute exposure to small amounts of allergens like almond, can cause death in sensitive individuals (high severity). While allergens are highly controlled through prerequisite programs at various steps in the manufacturing process (sanitation, supplier controls, ingredient management), undeclared allergens have historically been a leading cause of food safety related recalls in the US and global markets. Packaging verification is the last point of control and reduces the potential for incorrect packaging materials on the manufacturing line. The art copy number is a unique 10 digit number assigned to and printed on each version of product packaging. Every new pallet of carton material is checked against the product formula being run on the line. The product formula is periodically modified by R&D for cost savings or product improvements; bar code scanners would not be effective in identifying a product reformulation, since the package bar code is not changed with reformulations.

- Hazard Identified: Pesticide residue (Glyphosate - Potassium Salt) in incoming raw peanuts prior to roasting for a nut butter spread product
  - Hazard managed by CP versus CCP.
  - Rationale for No CCP: Prolonged exposure to very high levels of some pesticides can cause nausea or dizziness. Injuries are most often of low severity. Presence of this pesticide is unlikely; Corporate programs for supplier approval reduce the risk through a combination of auditing, inspections, and 3rd party certification. A COA verification program mitigates the risk by ensuring that the incoming raw peanut ingredients meet defined specification prior to being issued to production for roasting. These programs fully control the hazard to an acceptable level and the hazard is not generated during processing
- Hazard Identified: In a peanut butter product and process, *Salmonella* in incoming raw peanuts prior to the roasting step
  - CCP step: Dry roast peanuts in nut roasting processor with low temperature divert valve, at 1 inch/sec belt speed, and temp of 185F.
  - CCP Rationale: Illness related to *Salmonella* can be high severity. Even very low cell numbers can cause acute gastroenteritis, fever, vomiting, diarrhea, septicemia and death in susceptible individuals. Although the prevalence of *Salmonella* in the raw peanuts may be low, this is the only validated heat step in the process to ensure

control. There is no additional down-stream heat step in the nut butter process. The nut butter spread is a ready to eat product that will be used by the consumer without any additional heat or process step.

GAP - Everything is considered a CCP – Confusion between control points (CP) or manufacturing control points (MCP) and true CCPs

- Effective practices: Leverage a tool like a Series of questions or decision tree to better identify the hazards that must be controlled.
  - Decision tree or scorecard tool should be used to assess each step of the process in the hazard analysis.
  - Consider the measures already in place and assess if they are sufficient to control the hazard like Pre-requisite programs (PRP), Manufacturing Control Points (MCP), GMPs, Supplier control programs, Environmental Monitoring, and Thermal process programs.
    - Example : A Flake process step for manufacture of a ready to eat dry cereal product. To achieve the optimum finished product flake quality for the product as it is designed and to the finished product specification, the raw cereal dough mix is subjected to a cook step through a continuous cereal cooker at 297F for 45 min. These cook conditions are more than adequate to provide a kill step for pathogens of concern (*Salmonella* in raw incoming ingredients) based on microbiological validation studies. If the time/temperature conditions for optimum flake quality are met continuously, this process step may be managed as a MCP or CP instead of a CCP.
  - Consideration should be given to the feasibility of monitoring the CCP

Gap - PRP's are managed as a CCP

- Examples
  - Hand-washing in a high-hygiene area is difficult to enforce and document as a CCP; it is better controlled through a PRP hygiene program. (S. Mortimore, 2001. How to make HACCP really work in practice, *Food Control*)
  - Thermal process critical factors to achieve commercial sterility for Low Acid or Acidified Canned Foods may be effectively managed through a separate pre-requisite Thermal Process Program rather than through HACCP and CCP controls.

Potential Decision Tree references

- NACMF (1992)
- Codex (1993, 2009)
- CFDRA (1992)
- Mortimore, S. 2001. *Food Control*; ILSI Monograph; Mortimore, S. and Wallace, C. 1994. "HACCP. A Practical Approach". Chapman & Hall.

Potential references for FMEA tool

- Trafialek, J. and Koanowski, W. 2014. Application of failure mode and effect analysis (FMEA) for audit of HACCP system. *Food Control* 44: 35-44.
- Arvanitoyannis, I. S., and Varzakas, T. H., 2008. Application of ISO 22000and failure mode and effect analysis (FMEA) for industrial processing of salmon: a case study. *Crit Rev in Food Sci and Nutrit*. 48:411-429.
- Scipioni, A., Saccarola, G., Centazzo, A., and Arena, F. 2002. FMEA methodology design, implementation and integration with HACCP system in a food company. *Food Control*, 13:495-501.)

Step 9, Principle 4 - Establish Monitoring Activities

Intent

Identification of the appropriate monitoring activity with the associated documentation requirements can serve as evidence that the critical limit (CL) will have been met and provide assurance that the food has been rendered safe from a public health standpoint.

General Guidance

Monitoring is a planned sequence of observations or measurements taken to assess whether the CCP is under control, and produce an accurate record for future verification. The established monitoring activities must be able to provide a written documentation that the critical limit will have been reached. Hence, the monitoring procedures developed must take into consideration the nature of the product, type of processing equipment used and the device/tool used for monitoring the critical limit. Ideally, monitoring should be continuous, where possible, to allow for process adjustments, when there a trend towards loss of control. The monitoring activity, however, must be "real time" to ensure that corrective actions can immediately be taken to segregate and hold the affected food, should a CCP deviation occur. Monitoring procedures must define four (4) elements: (1) What is being measured/ monitored, (2) How and where the measurements will be taken, or what will be observed, (3) How often the measurements activity will be collected and (4) Who will be taking the measurement.

The monitoring procedure must take into consideration the nature of the product, the design of the equipment, the type of monitoring devices used, and the amount of products that may have to be destroyed in the event a CCP deviation occurs. The monitoring activity must be compatible with the type of hazard being controlled and the process parameter that is being measured. However, there could be more than one monitoring procedure that may be used to establish the adequacy of the preventive control that has been validated to prevent, eliminate or reduce the identified hazard to acceptable levels.

Monitoring devices/tools used must be calibrated at a frequency recommended by the manufacturer, or if observations/experience of the trained plant personnel dictate that a more frequent calibration is needed based on the nature of the product, and the limitations of the devices/tools when used under plant operational conditions. Selection of the most appropriate monitoring device should also consider the critical limit value being measured, i.e. 1/10 or 1/100 of a unit.

Personnel with CCP monitoring responsibility must be properly trained in the monitoring procedure and technique. Records generated as part of the CCP monitoring activity must be accurate and written at the time the measurements are taken or when observations will have been made.

Industry Gaps

FDA had identified a number of gaps in CCP monitoring activities and the 2012 FDA Inspectional Observations are listed below.

2012 FDA Inspectional Observations

Cite Id	Ref No	Frequency	Short Description	Long Description
6004	21 CFR 123.6(c)(4)	199	Monitoring - adequacy	Your HACCP plan lists monitoring [procedures] [frequencies] that do not ensure compliance with the critical limit. Specifically***
933	21 CFR 123.8(a)(2)(ii)	76	Calibration - adequacy	Your process monitoring equipment is not calibrated to ensure that it reads accurately. Specifically, ***
6010	21 CFR 123.8(a)(3)(i)	30	Monitoring record review adequacy	Your review of critical control point monitoring records does not [ensure that the records are complete] [verify that they document values that are within critical limits]. Specifically, ***
6014	21 CFR 123.6(c)(2)	14	Monitoring - none	Your HACCP plan does not list the [procedures for monitoring] [frequency of monitoring] at each critical control point to ensure compliance with the critical limit. Specifically,
12743	21 CFR 120.8(b)(4)	11	HACCP plan - monitoring procedures not adequate	Your HACCP plan lists monitoring [procedures] [frequencies of performing procedures] that do not ensure compliance with the critical limits. Specifically, ***
12755	21 CFR 120.11(a)(1)(iv)	11	Records - not signed and dated by qualified individual	Your review of [critical control point monitoring records] [corrective action records] [calibration records] [periodic end-product or in-process testing records] are not [performed] [signed] [dated] by an individual who is trained in the application of HACCP principles to juice processing or otherwise qualified through job experience. Specifically, ***
15302	21 CFR 120.11(a)(2)	8	Calibration, testing - no records	You do not maintain records of [calibration of process-monitoring instruments] [periodic end-product or in-process testing]. Specifically, ***
12744	21 CFR 120.8(b)(4)	3	HACCP plan - monitoring procedures - none listed	Your HACCP plan does not list the [procedures for monitoring] [frequency of monitoring] at each critical control point to ensure compliance with the critical limits. Specifically, ***
939	21 CFR 123.9(f)	1	Computerized records	Your computerized records do not provide that appropriate controls are implemented to ensure the integrity of the electronic data and signatures. Specifically, ***
12754	21 CFR 120.11(a)(1)(iv)(C)	1	Calibration, testing - record review adequacy	Your review of [calibration of process monitoring instruments] [periodic end-product testing] [periodic in-process testing] records does not ensure that [the records are complete] [the activities occurred in accordance with your written procedures]. Specifically, ***

http://www.fda.gov/ICECI/Inspections/ucm326984.htm#foods

Gap: Failure to identify the coldest spot of a product subjected to a thermal process

Example: A baked/fried product with inclusions, e.g. chocolate, dried fruits, cheese, or confectionery ingredient. The operating parameters during the baking process will likely be designed to deliver image food where lethality can be achieved in the homogeneous portion of the product. Measurement of the core temperature of the inclusion, however, may pose some challenges in monitoring the appropriate location to measure the critical limit.

Effective practice: Collect multiple temperature measurements in various sections of the product to establish the coldest spot. In a non-homogeneous food matrix, consider measurement of the core temperature of the coldest component. Microbiological quality of these inclusions may need to be considered as part of the preventive control, if lethality cannot be achieved by the baking process by measuring the core temperature of these inclusions.

Gap: Failure to establish the temperature profile of the equipment used at a CCP

Example: A product is baked in a 12- lane oven band where operating parameters are set for only 3 of 5 oven zones. The critical limit is measured as the product exits the oven. There could be a temperature gradient through the oven and across the lanes which could introduce measurement variability, if not considered during the establishment of the CCP monitoring procedure.

Effective practice: The temperature profile of the product across the width of the oven band must be determined during the development of new product or if changes to the operating conditions of the oven occur. Use of data loggers may be considered in establishing the oven/product temperature profile or a pre-established frequency for calibration by the equipment manufacturer.

Gap: Less frequent calibration of monitoring devices

Example: The hand-held thermometer used for CCP monitoring generally comes with at least one year calibration certificate. Most HACCP programs however, establish secondary in-house calibration process. The calibration frequency often varies from daily to week or monthly calibration. The adequacy of the CCP measurements could challenge the validity of the CL measurements, if the weekly or monthly calibration measurement fails to demonstrate accurate performance.

Effective practice: Select the most appropriate monitoring device for the intended use and establish the calibration of the monitoring device/tool at a frequency that ensures that the affected product is still under the company's control.

Gap: Failure to consider the nature of the product

Example: A shelf-stable cheese type product is being manufactured with a desired pH between 4.3 - 4.5. The critical limit established is <4.6 with the operating limit set to 4.5. The CCP is being measured using a pH meter with a $\pm$ 0.01 accuracy. The pH meter is calibrated once daily before start of production.

Effective practice: Fouling of electrodes can occur in certain food matrices. The frequency of calibration and recalibration therefore would need to be pre-established to ensure that accurate measurements can be made.

Step 10: Principle 5 - Establish Corrective Actions

Intent

Determination of corrective actions which are specific to manage a deviation from critical limits which have been defined for those processes deemed critical within the documented HACCP system. The corrective actions must be sufficient to control and manage all non-conforming product/s and also bring the process step under control.

General Guidance

Following the identification of the process steps which are deemed to be critical and once specified limits have been set, corrective actions must be developed to ensure product deemed to be non-conforming is effectively controlled. When monitoring activities identify a deviation associated to a CCP, corrective actions must be completed to bring the process back into control.

It is important that any manufactured product where the safety may be in doubt is appropriately held from the last successful monitoring check, actions must be taken to identify the product where compliance to the specified critical limits is in doubt. Once the detained product has been isolated and held, which is can be problematic to identify within a continuous process, the subsequent actions that need to be taken would be dependent on the nature or extent of the deviation which has been identified. Actions may include reassessment of the product from the last effective check, such as using an alternative metal detection unit when the regular metal detection unit malfunctions. It is important to fully document the extent of the deviation which has occurred as this could indicate an ongoing issue with the process. Where repeat process deviations are identified, there would be a requirement to reassess the process step to ensure the critical limits which have been set are accurate, but also to determine that the process can effectively control food safety hazards under normal working conditions.

Depending on the nature and extent of the issue there may be a requirement to complete a follow up investigation to identify the root cause of the deviation so preventive measures can be determined and implemented. It is important to correct the issue but also to complete an investigation using the HACCP team in case further actions are required.

The actions which are assigned are dependent on the extent of the issue which has been identified; activities may include but are not limited to:

- Immediate actions taken when failure of critical limit is identified.
- Product disposition (i.e. product either reworked or destroyed)
- Root cause analysis.
- Preventive actions.

Industry gaps

Where repeat issues are identified during the monitoring of CCP's, often only a correction is completed to address the immediate issue but the connection with previous reported issues may not be identified. Failing to establish a potential weakness with a process control through the recognition of repeated issues may cause gaps in the previously completed validation study which originally set the critical limits to go unnoticed.

Assigning accountability and completing an appropriate assessment of the effectiveness of the corrective action which has been implemented to address the identified deviation may not be completed. Where deviations have occurred with a CCP it is important to monitor and assess the level of control to demonstrate the process step is routinely controlling the specified hazards to an acceptable level.

Absence or weaknesses in documenting the nature of the issue and the corrective actions or subsequent investigation taken, raises significant doubt on the safety of the compromised product.

Focus areas

- Validation of the effectiveness of the corrections completed
- Importance of taking further action where repeated issues are noted
- The factors to consider to ensure an effective root cause analysis is completed
- Understanding why accurately documenting actions associated with deviations are important

Step 11: Principle 6 - Establish Verification Procedures

Intent

Verification is used to demonstrate conformance with the validated HACCP system during routine operations. Verification outputs should demonstrate that the control measures in place (including PRPs, OPRPs and CCPs/PCPs) are capable of controlling identified hazards as dictated by the control plan. Within verification there are "verifiable validation activities" which must be given due consideration.

General Guidance

Verification: Verification of the HACCP system must include an assessment of the effectiveness of CCPs/PCPs, OPRPs and PRPs. The scope, methods and approach to verification activities must be defined by the HACCP team; the degree of verification is dependent upon the extent or complexity of the program. The approach and verification frequencies must be defined at the introduction of a new program or when review indicates a change in verification processes is required. Some examples of verification activities include, but are not solely limited to, the following:

- Supplier audits
- Environmental monitoring and testing
- Regulatory mandated microbiological testing
- Finished product resting
- Trending of monitoring results
- Internal audits [including applicable pre-requisite programs (PRPs)]
- Customer audits
- Third party audits
- Customer complaint and trend analysis

Review of deviations and corrective actions are an important aspect of verification activities. Where issues have been identified, timely and comprehensive corrective actions must be completed to maintain control. The HACCP Team Lead must ensure the full documentation of verification activities are undertaken.

At least once a year, (i.e., minimally annually) the HACCP team must perform a formal scheduled review of the HACCP system. The frequency and scope of the review must be established by the HACCP team taking into account regulatory requirements and the effectiveness of the programs. It is important to consider the influence of internal/external

factors or "triggers" which might prompt a review of the HACCP system. The extent of the review would be dependent on the impact, real or perceived, of the change. Potential triggers which could result in a review of either sections or the entire HACCP system may include, but are not solely limited to, the following:

- Change in ingredients/raw materials
- Change of a supplier of raw materials
- Change made in product formulation or preparation
- Change in packaging, storage or distribution conditions
- Change in staff or management responsibilities
- Change in consumer use
- Developments in scientific information associated with ingredients, process or product
- New product
- New process step
- New technology or piece of equipment
- Change made in production volume which impacts on the product flow, sanitation schedule, employee training, etc.
- Failures in the system e.g. product recall/withdrawal
- Emergence of foodborne pathogen with public health significance
- Change made in the application of a CCP (e.g., change in critical limit)
- New regulatory requirements related to food safety

The HACCP Team Lead must oversee the documented review of the HACCP system and supporting programs and ensure that the data and evidence obtained during the review are entered into the HACCP record keeping system. The annual review must include an evaluation of the whole HACCP system and include (not exhaustive):

- Review of the effectiveness of CCP's/PCPs, OPRP's and PRP's
- Evaluation of the accuracy of Process Flow Diagrams and Plant Schematics
- Review of the hazard analysis to determine if it is still accurate
- Review of recorded HACCP deviations and overall performance

It is essential that review records are accurate and capture compliance as well as non-compliance. This record provides evidence that the HACCP system is current; completing a formal review is the driver which assists in maintaining the HACCP system. Following completion of the review the HACCP Lead together with the HACCP team will ensure that:

- Changes arising from the review are fully incorporated into the HACCP system

- Where further validation activities are required (e.g., changes to the CCP critical limits) that the work is completed in a timely and appropriate manner
- Where enhancement to programs is required that actions are completed and their effectiveness reviewed
- Evidence is retained to demonstrate effective communication of any significant changes to the whole HACCP team and senior management (as applicable).

The HACCP Team Lead with support from the HACCP team must ensure the HACCP system review activities are fully documented and appropriately referenced.

Validation

Validation is a verifiable activity that demonstrates that the HACCP system, as designed, can adequately control identified hazards to produce a safe product. Usually there are two distinct phases of verifiable validation activities. These are the initial, upfront "affirmation" phase, where controlled validation studies may be conducted to prove or "affirm" that the hazards can be controlled at the respective CCPs/PCPs. Included in the affirmation phase is the actual validation of the entire HACCP (control) plan itself, i.e., beyond just validation of processing parameters relating to the CCPs/PCPs, where the validity of all components of the HACCP plan is considered. This includes the acquisition and maintenance of justifiable material evidence to support the selection of hazards to be controlled, monitoring activities and their frequencies, corrective actions, verification activities of record, etc. The second phase is the ongoing "confirmation" phase where operational data and records provide evidence that the hazards are actually under control, as planned, during routine operations. In this way the validity of original assumptions and conclusions can be challenged and modified as necessary. Table XX provides details on the distinction between the "affirmation" and "confirmation" phases of verifiable validation activities.

The initial, upfront "affirmation" phase of validation usually addresses two questions, as follows:

1. Does the CCP/PCP work in theory? - Provide technical evidence from the literature that demonstrates that the designed process can control the identified hazard;

   and,

2. Does the CCP/PCP work in practice? - Demonstrate in controlled studies that the CCP/PCP works in operation so that the HACCP plan achieves the desired outcome of controlling identified hazards.

These questions are usually considered through systematic development and application of controlled "validation studies". Results of validation studies must be recorded and maintained for all CCPs/PCPs and OPRPs and, in some circumstances PRPs, which are in in place to control hazards, to demonstrate their capability to consistently control identified hazards to acceptable levels.

Validation of CCPs/PCPs occurs:

- During development of the initial HACCP plan
- During annual reassessment
- When there is a process change affecting the CCP/PCP

In addition, when significant changes in the process occur or monitoring activities indicate the HACCP system or process is not under control, re-validation activities must be completed to provide assurance that the controls in place are appropriate to address the hazards. Changes which might be significant include those which also may prompt a review of the HACCP system.

During the validation study, the HACCP team is required, with appropriate support, to challenge the conditions under which the control measures/critical limits are operating to ensure their effectiveness in addressing the identified hazards. Such studies may include:

- Review of scientific literature and outputs from trials involving similar products and/or processes (including reference to mathematical models, as applicable)
- Thermal evaluation trials
- Temperature distribution trials
- Challenge testing (e.g., microbial, metal detector, etc.)
- Development and refinement of mathematical models

A validation study is a scientific study; all design features, assessments, reviews and completed work must be documented with clarity to enable external third parties to be able to clearly understand the scope and conclusions of the work. The HACCP Team Lead must ensure the full documentation of validation activities undertaken. The validation study must, at a minimum, incorporate four components[1]:

Table 2: Validation

	Points for consideration (not exhaustive)
Introduction (or problem statement)	What is the purpose of the validation study? Why is this relevant to the HACCP system? Is there an issue or problem with a particular hazard in the process? What has occurred to prompt the validation? Are there any limitations to the study?
Method	What are the activities which must be undertaken to complete the validation study? What information will be collected and reviewed? What resources will be required – people, equipment, time etc.? When and how will the validation be completed? Who is accountable and for which activities? Appropriate sampling plan has been defined? Is there a need to consider seasonal or shift variations?

[1] The points above are intended as a guide for a validation study and do not form an exhaustive list of questions.

Results	Assemble plant observational information, test results, analytical data and any other information deemed applicable for review and interpretation by the HACCP team.
Conclusion	Did the validation study confirm that the control measures which are in place are effective and capable of producing safe food? Is there a need for further work? Has a frequency or indicator been set for re-validation? Do monitoring frequencies require adjustment due to the findings? Do the results indicate that some other systems or processes also need to be re-validated?

Validation studies must be documented and must consider potential "worst case scenario" situations and not just optimum conditions as these do not provide a true reflection of plant activities. The impact of process and product variation must also be considered. More complete guidance on how to conduct validation studies is provided in Figure XX.

The HACCP team must evaluate supporting evidence in the final HACCP plan with respect to the following:

- Selection or exclusion of significant hazards
- Suitability of the stated controls
- Acceptable levels for the particular hazard
- CCP determination
- CCP critical limits
- Monitoring activities identified as the control measure, including frequencies
- Adequacy of corrective actions (if any) applied to regain control of identified hazards

The ongoing "confirmation" phase of validation occurs as a verifiable activity during routine operations. Essentially this requires continual assessment using operational data and information to substantiate any original validation exercise. In a sense it is a way of continually asking "Are we doing the right things for the right reasons?" Although up-front inclusion of controlled validation studies is highly desirable and most recommended, in some cases validation evidence may only be gathered after production has begun. In such situations, the plant must assess the validation within an appropriate timeline to assure that the process is appropriately validated; evidence must be obtained and recorded even if not available from pre-production, controlled studies. Thus, in all such confirmation phase activities, the validity of initial assumptions and conclusions may be challenged by reference to the following (and other) considerations:

- Assessment of monitoring activities and associated records
- Analysis of recorded process deviations and corrective actions

- Evaluation of testing results
- Review of the HACCP system documents
- Review of customer complaint records
- Review of internal and external audit results
- Re-assessment of original validation studies (as appropriate)

Industry Gaps:

Verification:

- Verification is not done on the entire HACCP system
- Verification is not done by others outside of the current system
- Discovered deviations or other non-conformances are not closed thorough effective root cause analysis and implementation of appropriate corrective actions
- Verification frequency is not adequate to determine effectiveness
- No communication of findings and appropriate corrective actions or other changes
- Absences of systematic approach and appropriate records

Validation:

- Failure to validate
- Incorrectly designed or executed validation studies
- Absence of scientific, fact-based rationale

Focus Areas:

Verification:

- Competency and qualifications of personnel
- Need specific guidance/examples on how to close gaps
- Need examples of verification procedures and tools to monitor adherence

Validation:

- Needs to be comprehensively included in verification
- Need "continuous improvement" mind-set

Table 3: Verifiable Validation Activities

Phase	Validation Activity	Key Components	When Done	Accountability/ Responsibility

Affirmation	Validation Study (CCP/PCP Validation):
	1. Does the CCP/PCP work in theory?
	2. Does the CCP/PCP work in practice?
		• Provide evidence from literature that the designed process can control the identified hazard:
		  • Review of scientific literature and outputs from trials involving similar products and/or processes
		  • Mathematical modeling
		• Demonstrate that the CCP/PCP works in operation to achieve desired outcome of controlling identified hazards:
		  • Thermal evaluation trials
		  • Temperature distribution trials
		  • Challenge testing (e.g., pathogens, surrogates, metal detector, etc.)
		  • Model development/refinement
			• During development of the initial HACCP plan
			• During annual reassessment
			• When there is a process change
				HACCP Team Lead/HACCP team, with operational support

	HACCP Plan Validation	• Selection or exclusion of significant hazards • Suitability of the stated controls • Acceptable levels for the particular hazard • CCP determination • CCP critical limits • Monitoring activities	• During development of the initial HACCP plan • During annual reassessment • When there is a process change	

		identified as the control measure, including frequencies • Adequacy of corrective actions (if any) applied to regain control of identified hazards		
Confirmation	Ongoing operational validation	• Assessment of monitoring activities and associated records • Analysis of recorded process deviations and corrective actions • Evaluation of testing results • Review of the HACCP system documents • Review of customer complaint records • Review of internal and external audit results Re-assessment of original validation studies (as appropriate)	Ongoing, during operations	HACCP Team Lead/HACCP team, with operational support

Figure XX. Steps in a Validation Study

A. Introduction (or problem statement)
What is the purpose of the validation study?
Why is this relevant to the HACCP system?
Is there an issue or problem with a particular hazard in the process?
What has occurred to prompt the validation?
Are there any limitations to the study?

1. Using the applicable HACCP plan, confirm the following:
    - Stated hazard still exists;
    - Hazard is accurately described to match details in the hazard analysis;

- Stated processing step is the correct step number in the process flow diagram;
- Critical limits meet current written procedures;
- Validation is:
    - Initial
    - Annual
    - Re-validation (other than annual)
    - Other

2. Provide details of the hazard:
    - Biological, chemical, or physical;
    - Hazard description;
    - The applicable reference used as a baseline to describe the hazard.

3. Identify the acceptable level of the hazard in the finished product and include the applicable reference (scientific / technical literature, previous validation study, regulations or regulatory performance standards, government directives, international standards, industry standards, processing authority documents, written materials from equipment manufacturers, in-plant historical data) from which this acceptable level was obtained.

4. Identify the control measures to be validated:

   e.g., Metal Detection Capability: Metal detector's ability to detect the smallest metallic foreign material possible when calibrated checked using ferrous, non-ferrous, and stainless steel wands.

B. Method
What must be undertaken to complete the validation study?
What information will be collected and reviewed?
What resources will be required – people, equipment, time etc.?
When and how will the validation be completed?
Who is accountable and for which activities?
Has an appropriate sampling plan been defined?
Is there a need to consider seasonal or shift variations?

5. Identify the appropriate approach to be used for the validation and include the applicable reference (scientific/technical literature, previous validation study, regulations or regulatory performance standards, government directives, international standards, industry standards, processing authority documents, written materials from equipment manufacturers, in-plant historical data).

6. Provide details of the validation protocol:

   - Validation start date and end date;
   - Description of equipment used (e.g., type, brand, capacity of equipment, type and location of temperature sensors, divert or shutdown features, calibration practices/schedules, shutdown/alarm features, etc.);
   - Description of processing conditions (e.g., batch vs continuous, amount of product treated per batch, etc.);
   - Product description processed using the equipment. [e.g., product type, size, initial form (e.g., raw, pre-processed), final form (i.e., expected use of the product by the end user, such as "ready-to-eat", etc.)];
   - Description of equipment used to monitor/control the process as well as related calibration procedures/schedules associated with the monitoring/control device(s);
   - Describe how the process/piece of equipment is controlled (especially the monitoring and deviation procedure). What is measured; when, how and by whom? What are the limits used to decide if the process is acceptable?;
   - Describe methods to determine worst case for any parameters identified as necessary for monitoring[e.g., how to determine the coolest spots of a smokehouse for different product layouts (full house, half full); how to determine appropriate location of temperature probes]. When the "worst case" spot or product is not where process monitoring is routinely done, the operator has to conduct tests to show how the surrogate location and values used will accurately predict that the "worst case" spot or product has been sufficiently treated;
   - Describe validation methodology;
   - Describe methods used to analyze the result (e.g., statistical evaluation);
   - Describe methods to demonstrate that the monitoring procedures are effective enough to detect loss of control of the measure in place before the finished product leaves the establishment.

C. Results
Assemble plant observational information, test results, analytical data and any other information deemed applicable for review and interpretation by the HACCP team.

7. Document results for the completed validation study.

D. Conclusion
Did the validation study confirm that the control are effective and capable of producing safe food?
Is there a need for further work?
Has a frequency or indicator been set for re-validation?
Do monitoring frequencies require adjustment due to the findings?
Do the results indicate that some other systems or processes also need to be re-validated?

8. Provide a conclusion:

    - Indicate if the results of the validation study demonstrate that the hazard is appropriately controlled;

    - If the control measure is not adequate to achieve the necessary level of control, consider the following options (but not limited to): a re-evaluation of the operational parameters; design of a new food safety control system; other appropriate decisions/actions, as necessary.

Step 12: Principle 7 – Establish documentation and record-keeping

Notes to be added to the document are:

1. **Forms for standardization are**: (the intent is to provide blank examples of each that could serve as a template for others to use)

a. Cover Page
b. Product Description
c. Ingredient Hazard Analysis
d. Process Step Hazard Analysis
e. CCP Documentation
f. A plant layout
g. A listing of products that are covered by the plan
h. Change History log

2. **Effective Practices - Language**
   Use simple narratives to summarize and explain the decision making process at each step. The overview of the decision making must be easy to understand. This narrative is the focus of the Basis column.

   Gap: One less desirable way to document conclusions is shown in the following example where a written description of the basis for the decision making is severely lacking. Only numbers have been assigned but no detail or rationale as to how these were determined is included.

Table 4: Documentation

PROCESSING STEP	POTENTIAL FOOD SAFETY HAZARD	IS A HAZARD REASONABLY LIKELY TO OCCUR (Yes or No)	BASIS	CONTROL MECHANISM (CCP or PP)

PROCESSING STEP	POTENTIAL FOOD SAFETY HAZARD	IS A HAZARD REASONABLY LIKELY TO OCCUR (Yes or No)	BASIS	CONTROL MECHANISM (CCP or PP)
1. Receiving – Milk	**Biological** VP SP	Yes Yes	Product will be processed to lethal temperatures for the vegetative pathogens of concern at end of the process. Product will be chilled using procedures to ensure compliance to the Stabilization Performance Standards. Implementation of the established critical control points; operating procedures implemented in processing, will act synergistically making the potential for toxin formation very low.	CCP **B6** Approved Supplier Program **(2.1.1)** CCP **B7** Receiving and Shipping Controls **(2.1.2)**
	Chemical antibiotic residues	Yes	Milk can contain residual amounts of antibiotics. Each load must be tested prior to unloading	CCP C1 Receiving and Shipping Controls **(2.1.2)** Approved Supplier Program **(2.1.1)**
	Physical Metal, Glass, Hard Plastic	No	Continuing letter of guarantee from the suppliers. Inspection of tankers during receiving, for any damages or presence of any foreign materials.	Receiving and Shipping Controls **(2.1.2)** Approved Supplier Program **(2.1.1)** Extraneous Material Control program **(3.2.6)**

Table 5: ?

			NO CONTROLS IN PLACE				WITH CONTROLS IN PLACE			
PROCESS STEP	**HAZARD DESCRIPTION** **B= Biological** **C= Chemical** **P= Physical** **A= Allergen**	**ARE ALLERGENS INVOLVED IN THIS STEP?** **A**	**Posibble Hazard 1 = Low, 2=Medium, 3 = High** **Probability**	**Severity**	**RISK SCORING= Probability x Severity**	**METHOD OF CONTROL:**	**Posibble Hazard 1 = Low, 2=Medium, 3 = High** **Probability**	**Severity**	**RISK SCORING = Probability x Severity**	**CCP**
1a. Bulk Wet (Ingredients Receiving)	B: Pathogen Microorganisms (Escherichia Coli, Salmonella spp, Shigella)		2	3	6	City Certification, Water Quality Program	1	1	1	No
	C: Chemical Treatment Residuals		2	3	6	Quarterly External Laboratory Test	1	1	1	No
	P: Foreign Material Stones, etc.		2	3	6	Sanitation Master Program: Filtering	1	2	2	No

A more appropriate way to build a plan that is understandable follows:

3. Effective practices - Decision Documents

. The purpose of these is two fold. One is to define the data used to make certain conclusions made or to answer questions asked of the plan when the narrative is too complex to add directly to the plan. The second is for training especially for multi-pant operations which make similar products.

a) Example: An example for refrigerated RTE cheese processing is why Salmonella is not selected as a target organism for RTE area pathogen environmental monitoring programs. The answer is….

b) Example: Another example is the challenge study data that was generated to prove that an antimicrobial dip prior to package film removal is robust enough to limit a lot to one day of production when a brine chill system is cleaned less than daily.

The use of ICMSF 5 Micro-Organisms in Food has been found to be particularly helpful in generating data and support for conclusions