Preparatory Programs

Validation & Verification:
A guide to successful implementation of the 7 HACCP principles.

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EDITOR’S NOTE: This is the second article in a 2-part series on HACCP management tools. Part one appeared in the March/April 2009 issue of AIB Update. Part 2 focuses on verification and validation of the implementation of the 7 HACCP principles.

PRELIMINARY STEPS. The Codex Alimentarius has recommended various preliminary steps before applying the 7 HACCP principles. Many times, these steps are considered a documentary stage and people don’t understand what the purpose really is: to prepare a good hazard analysis.

FORMING A HACCP TEAM. Putting together a HACCP Team does not imply simply naming members of a team for administrative purposes, but rather complying with a commitment in which food safety happens first. That is to say, having the best employees carry out various responsibilities, such as: putting together a HACCP Manual; conducting a hazard analysis based on the products and their respective processes that is complete, precise and validated by experience and science; and managing changes within the organization that could affect this hazard analysis. Who are the best team members?

• Employees who have both theoretical and practical knowledge of the physical, chemical and biological hazards at the different stages of the process and in different raw materials. It is curious to see how preference is given to the Quality Control Department to lead a HACCP Team and carry out a hazard analysis when many times it does not have the necessary practical experience. The most relevant personnel for handling the control measures of many hazards is probably the Maintenance and Production personnel, while other departments (such as Quality Assurance or Research and Development) support them with their knowledge, especially regarding the probability and severity of microbiological hazards, and how to control them.

• Personnel who have the time and interest in HACCP.

• Employees whose position descriptions clearly indicate this assignment to be a priority.

To validate that an organization has a suitable team:

• Demonstrate that every member is competent and can carry out the tasks assigned by providing a description of the experience and evidence of HACCP training.

• Document meeting minutes and the participation of every team member.

• Focus on team effectiveness and productivity indicators: meeting frequency, terms and objectives met while carrying out the tasks, validation data updates, and the totality of the significant changes that have been analyzed and approved by the HACCP Team.

PRODUCT DESCRIPTION. The product description directly influences the
PRINCIPLE 1: Conduct a hazard analysis.

PRINCIPLE 2: Identify critical control points.

PRINCIPLE 3: Establish critical limits for each critical control point.

PRINCIPLE 4: Establish critical control point monitoring requirements.

PRINCIPLE 5: Establish corrective actions.

PRINCIPLE 6: Establish record keeping procedures.

PRINCIPLE 7: Establish procedures for verifying the HACCP system is working as intended.
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identification, probability and severity of hazards:
• The intended use is the primary factor to consider. A product ready for consumption is completely different from a food article that is going to receive further processing, with one or more hazard elimination steps involved. Some companies may not be sure what their client will use the product for; so it is necessary to validate this information, for example with a contract or a formal communication with the client.
• The expected consumer is a key aspect. Two products that are of equal sensory, microbiological and physical-chemical qualities can present different hazards if, in accordance with what is claimed on the label, they are marketed specifically to groups of vulnerable consumers.
• The presence of possible microbiological barriers or conditions that lend themselves to pathogenic growth in the product inspire the need to identify general or specific microbiological hazards, hence the importance of indicating water activity (aw), pH, distribution temperature and humidity conditions, shelf life, packaging conditions, alcohol percentage, etc. This information, essential for understanding microbiological risks, should be validated with already established scientific data or with experimental data, such as analytical results.
• A product with preservatives that partially or completely control pathogenic growth is different from a product that is free from such barriers. In the case of using preservatives as a barrier to microbes, it is necessary to consult validation studies related to the effectiveness of the minimum concentration of such preservatives, taking into account other potential barriers in the product (% of salt, shelf life, distribution temperature, pH, water activity).
• The validation data should correlate the absence or possible presence of a chemical hazard with the maximum concentration of these preservatives and other additives that can be present in the product.
• The process that the product undergoes often determines the potential hazards to which it will be exposed. For example, in order to maintain a shelf life and a sensorial quality that are acceptable for the consumer, if a fruit concentrate demands a more severe thermal processing than a normal juice and it uses significantly higher pasteurization temperatures, these hazards can be overlooked. The process will be controlled to eliminate thermophilic organisms that are not health hazards. One must demonstrate this assertion with a validation study.
• The presence of special environmental conditions, such as allergens in other lines that are close to the process or on shared equipment, creates the need to identify this hazard as inherent to the manufacturing process, while the absence of allergens in the processing environment allows us to ignore this hazard. In order to validate this information, it is becoming more and more frequent for clients to request a letter of guarantee or a questionnaire.

FLOW DIAGRAMS. Flow diagrams constitute the study basis for hazard analyses. In general, there are two types of diagrams:
1. Process diagram. A simple flowchart describing the sequence of all the manufacturing steps which are relevant to the hazard analysis. In a summarized form they are:
• The steps whereby one of the various Biological, Physical or Chemical hazards could be introduced.
• Steps that help to control or eliminate such hazards.
2. Circulation patterns of personnel (paths of movement of the persons assigned to certain areas), products (raw materials, work in progress, rework, waste, sub-products, subcontracted steps, and finished products) and materials (packaging, containers, forklifts, etc.). This allows the facility to identify the risks of cross contamination between areas and products, especially where there are microbiologically sensitive areas or the possibility of allergen contamination. The hazard analysis will later determine if it is necessary to establish a control of cross-contamination; for example, with sanitary filters, color coding, etc.

A very important support document needed to validate these flowcharts is a detailed process diagram that identifies absolutely all pieces of processing equipment that could potentially come into contact with the food item. It is a very precise backup for the simple flowchart, entailing a lot of confidential information that is not necessarily relevant to food safety. Therefore, it is not desirable to include it in the manual; instead, it should be filed and made available for the annual validation. This document should be updated every time a significant change occurs.

An erroneous or incomplete diagram implies an incomplete or inadequate hazard analysis. In order to ensure that such a problem does not occur, it is necessary to verify the flow diagrams with an on-site revision, carried out by HACCP Team members and any employee that has been invited to participate. This activity should be completed during the different shifts and at different periods of production to capture the normal or abnormal production rhythm, as well as when other processing activities, such as pesticide application, maintenance and cleaning, are carried out.

HAZARD ANALYSIS. The most meticulous activity required of any HACCP system is the identification and analysis of potential hazards. The correct establishment of specific control measures, neither more or less than those that are necessary, shared between the CCPs and Operational Prerequisite Programs depends directly on an appropriate hazard analysis that is detailed and based on experience, science, actual facility conditions and, at times, common sense. The only way of knowing if the hazard analysis is appropri-
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**CCP DETERMINATION.** In order to validate CCP determination, the HACCP Team must demonstrate that it used a systematic method that reflects the definition of a CCP: *a process step whose control is essential to prevent, control or reduce a hazard to an acceptable level.* The key word is *essential:* to validate that a good CCP identification was made, the method should determine those manufacturing process steps (if any) whose control is essential to ensuring a safe food product. There are methods endorsed by the authorities and recognized bodies, such as the Codex Alimentarius’ decision tree or the excellent FDA guide for fish products. To validate is to demonstrate the correct application of these guides. AIB established a practical matrix to precisely determine those CCPs that have worked for all organizations that have tried them.

Beyond the method chosen, validation involves the ability of the identified steps to control or reduce significant hazards to an acceptable level, many times established by scientific data, legal requirements (which are generally based on scientific data) or performance as recognized by the industry. The references used should be documented as a validation support.

The ability of the identified CCPs is often validated by statistical studies of the process, experimental onsite tests or with inoculation or challenging tests carried out by experts. However, it is important to recognize that the ability of a CCP to reduce a hazard to an acceptable level also depends on the initial contamination load. An initial contamination that is excessive or abnormal can indicate a food safety failure for a CCP that is well controlled. Based on this, we see a direct relation between the capacity of a CCP and the preventive measures (the Operational Prerequisite Programs) used to control the contamination prior to the process step. The hazard analysis matrix and the CCP determination provided by AIB highlight the interrelationship between Operational Prerequisites, the unavoidable elimination steps (the Control Points) and the CCPs, obligating that there is at least one control measure for an identified hazard. In reality, the application of the matrix lets us visualize how the majority of hazards are controlled by various control measures, all of which are essential. These could be a combination of Prerequisite Programs, a combination of CCPs, (especially when a microbiological hazard is controlled by multiple growth barriers), or a combination of both. The validation of the CCP determination therefore implies a validation of these combinations.

**VALIDATION OF CRITICAL LIMITS.** Critical limits characterize the boundary between what is acceptable and what is not acceptable. In terms of food safety, what is unacceptable is non-negotiable. A product that passes through a CCP that is out of its critical limit in theory cannot be sold, but must be sent through a controlled CCP or equivalent process; hence the importance of a precise and scientific determination of these limits. A limit that is too flexible presents the risk of not reducing the hazard to the acceptable level and puts the health of the consumer in eminent danger.
Devices used to measure critical limits should be sufficiently reliable so as to render the results indisputable. As such, the organization should define which instruments are the most precise, least likely to be altered by the operating conditions and calibrated with a sufficient frequency. A calibration procedure, as well as an internal verification, should exist for these devices.

A critical limit that is unnecessarily strict is also not acceptable for management, since this will increase the frequency of deviations and the need to destroy or reprocess products that are not necessarily hazardous. This would become unsustainable in a very short period of time. Typically, the reaction would be to argue that in reality the product did not achieve dangerous levels and to negotiate with limits that by definition are not negotiable! The moral here is that the task of scientific validation of the critical limits is also not optional. In order to establish them, science – regarding the hazards and the methods of control or elimination – is used. In microbiological terms, this science is often documented in specialized literature, such as: minimum pasteurization and sterilization times and temperatures; times and levels of irradiation; maximum times and temperatures for cooling; minimum concentrations of preservatives; pH balance; etc.

For chemical hazards, the specialized science (later adopted by regulators) also recommends maximum concentration limits for certain compounds, or the total absence of others. For physical particles, the hospital statistics in certain countries can prevail to indicate the size and form of dangerous foreign objects.

The validation task for critical limits does not end with the filing of these data, but also implies testing to see if the technology, equipment or elimination methods achieve these limits with certainty. Hence the studies on penetration and thermal distribution and on statistical capacity, which is based on a number and frequency of sufficient samples to indicate that the process control limits permit a safe margin so as to not be exposed to the unacceptable probability of critical limit deviations due to common causes of process deviations.

A common validation practice is to analyze or contaminate a product before it passes through a CCP, adjust the CCP in the critical limits (that is to say, under the worst process conditions) and then reanalyze the product after it passes through the CCP. These tests are called challenge studies. An example of a common application would be the validation of foreign particle detectors and bottle rinsers. Another example would be the meat industry with non pathogenic indicators of microbiological contamination or specialized laboratories that simulate real contamination.

MONITORING. Both the monitoring frequency and the method should be validated.

- The frequency should be sufficient to identify any deviation. For certain products, it is necessary to monitor a chart that allows you to view the continuous behavior of the CCP from the last monitoring, in a way that permits the detection of any jump or sudden deviation that would not necessarily be detected by occasional monitoring. For certain detectors, such as metal detectors, the frequency is by time interval, since any deviation will eventually be detected: once they are out of calibration they do not correct themselves. However it is also necessary to monitor them again before a product change or before the inspection of any detection device. Indeed, changing a detection program that is specific to a product for another one or manipulating a sensitive device can generate a possible disruption that can camouflage a deviation, which would then never be detected or reported. Finally, the monitoring frequency should be sufficient to detect any deviation before the product leaves the control of the facility. To validate this characteristic, it is necessary to demonstrate that in the most recent years, no product has been shipped in a period of time shorter than the monitoring frequency.

- A CCP and its critical limits can be identified adequately, but if the monitoring method is not adequate, this can lead to erroneous conclusions of catastrophic proportions. There are thousands of examples: not using an official monitoring measuring device that has been validated according to its position, statistical capacity, precision, etc.; not inserting an instrument probe in the adequate spot of an environment or product; not taking the sufficient number of measurements; not carrying out the monitoring in conditions that are representative of the worst possible conditions, in which the CCP will have the most difficulty controlling the hazard; not following the analytical procedures, etc. In order to avoid these errors, it is necessary to:
  1. Precisely define the best monitoring method, which simulates the most complicated condition so that a CCP can reduce the hazard to an acceptable level.
  2. Write a clear work instruction that is easily understood by operations personnel.
  3. Educate involved personnel about the importance of precisely applying the procedures, and explain to them the reasons for doing this and train them on how to do so.
  4. Validate personnel understanding by periodic checks on the floor.
Putting together a HACCP Team does not imply simply naming members of a team for administrative purposes, but rather complying with a commitment in which food safety happens first. That is to say, having the best employees carry out various responsibilities, such as: putting together a HACCP Manual; conducting a hazard analysis based on the products and their respective processes that is complete, precise and validated by experience and science; and managing changes within the organization that could affect this hazard analysis.

**CORRECTIVE ACTION.** In response to non-negotiable critical limits there should be a corresponding non-negotiable corrective action that is made up of at least two components:

1. Immediate action. Retention and disposition of suspect products and reestablishing control of the situation.
2. Root cause analysis of the deviation and the long term corrective action to avoid recurrence.

Both actions should be valid, especially with regards to the identification and quantity of products to be retained and at one’s disposition. The organization should be able to demonstrate that any product that passes through a deviated CCP is identifiable, without which much more product will be detained than is necessary.

Then, the disposition of the product should be acceptable for the consumer. That means: reprocessing, destroying or setting the product aside for non-food use. However, the temptation to take another decision, such as sampling and analyzing, may arise. A product that has deviated from a critical limit can be released for sampling and laboratory analysis only with great difficulty, however. Sampling is suitable for looking at quality attributes: what analytical tests should be done, how many samples should be taken, how much time should it take, how much should it cost? According to a hazard analysis, a significant hazard is one that presents a significant probability and severity for the health of the customer. If a critical limit is not in compliance, the hazard will not be reduced to an acceptable level, and thus the product cannot be sold. It is difficult to validate another decision, unless it is backed by a Process Authority.

With regards to long-term corrective action, the effectiveness can be validated simply by recurrence indicators: the fewer deviations due to the same cause, the more effective the previous corrective actions are proven to be.

**CALIBRATION & RELIABILITY.** Devices used to measure critical limits should be sufficiently reliable so as to render the results indisputable. As such, the organization should define which instruments are the most precise, least likely to be altered by the operating conditions and calibrated with a sufficient frequency. A calibration procedure, as well as an internal verification, should exist for these devices. These procedures should be validated by the experience of the facility personnel, by recommendations from the manufacturer or by specialized firms. They should be executed under conditions that are similar to the operational conditions and, in the majority of cases, should use an internal or external benchmark whose validity can be checked against a validated standard. In order to make the records verifiable, evidence of the exact measurements taken by the instrument and the reference device should be gathered.

This fourth point is the one that is most often missing in the food industry: not visually verifying the correct compliance of the monitoring frequency and method. Applying this recommendation means protecting oneself against any bad surprises the day of an official visit or an audit. And finally, it means you can sleep soundly at night, knowing that the personnel not only know exactly what to do and how to do it, but also the importance of doing it well and never negotiating this responsibility. We should not forget that the human element is the primary cause of market failures. By definition, a CCP does not deviate very often; if it did, it would cease to be a reliable control measure. At the same time, and also by definition, a CCP can deviate, but if not, it would not be a CCP. Therefore, the monitoring person should be alert for the potential deviation that occurs infrequently. This attention is very difficult to sustain when an employee is accustomed to a result that is always within the limits. The task of educating someone who monitors the CCP is similar to that of a watchman. A delinquent act or robbery will rarely occur, but the watchman can never let down his guard.
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be given; it is not enough to simply check that the calibration measurements in question were taken.

In case the calibration is lost, the verifier should evaluate whether compliance with the critical limit has been affected for all of the measurements taken by this devise during a period of possible erroneous calibration. The corrective action could result in a product retention or, even worse, a market recall; hence the necessity of a sufficient frequency of verification.

CCP RECORDS. The verification of the monitoring, calibration and corrective action records for each CCP should be carried out in a very detailed manner – preferably before the products have been shipped – in order to identify any deviation in the application of the HACCP Principles. To verify a monitoring record means responding to the following questions:

- Do the monitoring and verification frequencies comply with what is stipulated in the HACCP Plan?
- Have these activities been executed by the persons assigned in the HACCP Plan?
- Is the manner in which the records were filled out adequate? Are there any doubts that the record represents reality and that it is authentic [i.e. there are no marks that appear to hide other entries; all corrections are signed or initialed by whoever made them; white out has not been used; the original correction date is identified; confusing symbols are not used; values with parameters are used (time, temperature, pressure, etc.) instead of simple checks; there are no missing data that would be necessary for tracing products that have passed through a CCP; there is a signature that allows for the identification of whoever carried out the monitoring activity, etc.]?
- If a critical limit was not achieved, has a corrective action been indicated?
- Are corrective action reports complete, authentic and verifiable, leaving no doubts as to whether suspect product has entered the market?

The verifier should understand his or her responsibilities. A transfer of responsibility from the monitoring person to the verifier takes place when the verifier signs a record as evidence that the verification took place. This person is now responsible for those records.

MANAGING CHANGE. In addition to the initial validation and the annual validation, the HACCP Team should be prepared to confront possible significant changes in the organization that could affect the controls that have been implemented. Therefore, a Change Management Program that has been approved and is supported by upper management should exist to ensure that the HACCP Team is aware of any change prior to their implementation, and that technical and economic criteria are available to approve or reject the change. Basically, a change is not acceptable if it entails hazards that cannot be controlled, or if the costs of the controls are not reasonable or profitable.

The procedures for change management should explain how the conclusions are reached, based on scientific information. If the change is acceptable, the procedure should lead the HACCP Team to revalidate the system, with the potential impacts (both during and after the implementation of the changes) in mind, at least insofar as the affected programs, hazard analysis, preliminary steps and, if necessary, the other HACCP Principles are concerned so that the necessary controls can be later implemented and managed. Examples of potentially significant changes:

- New products, or the modification of an existing product, such as: changes to the formula, intended use or consumer groups, labels, packaging material, shelf life, specifications, etc.
- New raw materials or suppliers.
- New production system, new equipment, changes to existing equipment, new technology, automation, co-packers.
- Changes to the production environment, changes in the facility, additions, changes to personnel or material flow or product modifications.
- Changes to personnel, including: firings, cutbacks, firings or outsourcing.
- Changes that affect sanitation programs, including: new water sources, new chemical products, new pest control providers, new cleaning methods.
- Improvement projects, strategic decisions.
- New clients, new export markets, changes to client requirements.
- New legal requirements.
- New knowledge or audit results.

Change is not necessarily a negative thing. There are changes for the better that can challenge and moderate existing controls. In this sense, the validation principle can be a very profitable tool: it allows the management team to improve their processes, if it can be demonstrated that product safety is not put in danger.

HACCP AUDIT. The intention of the HACCP audit should be to have evidence of:

- The sufficiency of the whole system; that is, that the validation data of all aspects discussed above are available, complete and satisfactory, and that they demonstrate the effective control of hazards by the system, and;
- The correct implementation, which evaluates the effectiveness of the verification in the application of the Prerequisite Programs and every one of the HACCP Principles, as discussed above. In short, auditing is verifying the verifier.

Finally, the mission of a good auditor is to communicate to upper management whether the system functions and if the employees, directors, shareholders, clients, consumers and regulators can be sure that the company is doing everything possible to avoid a food safety incident, which could be disastrous for everyone. Otherwise, the auditor has the responsibility to identify the weaknesses found that could lead to such circumstances and solve them from the ground up. AIB

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