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PII: S0956-7135(97)00068-6

Food Control, Vol. 9, No. 2-3, pp. 157-162, 1998
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0956-7135/98 $19.00+0.00

PAPER

Auditing and verification of food safety and HACCP

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The continued auditing and verification of a HACCP system demands more attention than the initial development of a HACCP plan. Two important areas have frequently been given little attention in the verification of HACCP systems. These are product design and prerequisite programs. Food companies sometimes focus on the process control portions of HACCP without documenting the product design. HACCP systems must be supported by a strong foundation of prerequisite programs. These may include, supplier approval or certification, specifications, chemical control programs, audits and inspections, product identification and retrieval procedures, training, water and air control, and good manufacturing practices. Important processes in HACCP system verification include the initial validation of the HACCP plan and its periodic revalidation. Additional activities include, verification of prerequisite programs, observations and interview of CCP monitors, CCP monitoring records review, equipment calibration, and other records review.

It is anticipated in the United States that regulatory agencies will conduct HACCP audits similar to those conducted by the companies. Worksheets used to audit food safety effectiveness and management in Cargill plants will be presented and discussed. © *1998 Elsevier Science Ltd. All rights reserved*

Keywords: HACCP; food safety; audits; verification; prerequisite programs

I believe that the continued auditing and verification of a HACCP system is at least as important as the initial development of a HACCP plan. Perhaps it is far more important. While the development of a HACCP plan may require several months of effort by a HACCP team, the resulting HACCP system may be in place for several decades or even longer. Therefore, it is very important that auditing and verification be done well.

DEFINITIONS

In food safety circles, use of the term, *verification*, is sometimes intertwined with the term, *validation*. Because HACCP is being applied for the safe production of foods worldwide, it is important that we agree on the definition of terms in order to facilitate our common understanding and application of HACCP. The following definitions are used at Cargill and, in my experience, are widely used in the United States.

Broadly speaking, *validation* is the determination that the intended result is achieved. In HACCP parlance, *validation* is the determination that the HACCP plan is accurate in all of its elements and that the indicated hazards have been controlled at each CCP. For example, microbiological challenge studies can be used to prove (validate) that a given pasteurization process will kill *Salmonella* in dairy products.

Broadly speaking, *verification* is the determination that a procedure is performed according to the intended design. In HACCP parlance, *verification* is the determination that the HACCP system is in compliance with the HACCP plan.

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IMPORTANCE OF PRODUCT DESIGN AND PREREQUISITE PROGRAMS

Most verification activities focus on auditing the HACCP system. However, in the verification of HACCP systems, two areas have usually been given little attention. These areas cannot be ignored if we are to apply HACCP successfully and I want to address them at the start.

The first of these areas is *product design*. I like to describe HACCP as consisting principally of two processes: product design and process control. Because HACCP plans are developed for individual manufacturing plants, the emphasis tends to be on process control. We cannot, however, overlook the importance of product design.

The consideration of product design is particularly important during hazard analysis. We must demonstrate, often by microbiological challenge testing, that a particular product will be safe for all consumers. Intrinsic product parameters such as pH, water activity or preservative levels may need to be controlled as CCPs.

Figure 1 shows, generally, how product design and process control differ when considered against the backdrop of the seven HACCP principles (Codex Alimentarius Commission, 1991).

Product design dominates hazard analysis (Principle I), while process control dominates the later HACCP principles: *monitoring* (IV), *corrective action* (V), *verficiation* (VI), and *record keeping* (VII). I have developed this figure to emphasize that the verification of product design should not be overlooked.

Attention to product design is more important as the complexity of the product increases. Raw meat packaged aerobically is a simple product and would require less attention than a cooked, ready-to-eat meat product that was vacuum packaged. Similarly, a product with a novel design is more complex and will require more attention than will product proliferations that are following a conventional design.

A second area that has received limited attention until recently is the *verfiication of prerequisite programs*. Since the first use of HACCP in American food plants 25 years ago, we have learned that HACCP cannot be successfully applied in a vacuum. Rather, it must be supported by a strong foundation of prerequisite programs.

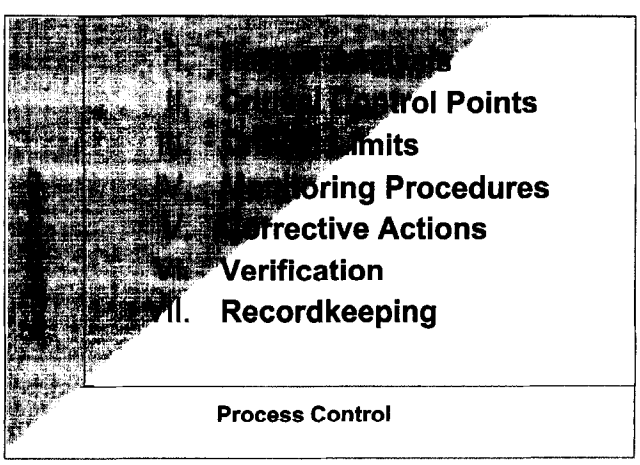

Figure 1 Relationship between product design and process control in the HACCP process

Prerequisite programs may include:

- Supplier approval and/or certification
- Specifications for raw materials, finished products, and labeling
- Chemical control programs
- Audits and inspections
- Product identification and retrieval procedures
- Training
- Water and air control
- Good manufacturing practices (GMPs)

The elements of the GMPs can also be considered to be prerequisite programs. These include:

- Sanitation procedures
- Sanitary design and maintenance of equipment and facilities
- Pest control
- Warehousing and distribution
- Training in personal hygiene

Prerequisite programs are established and managed separately from HACCP systems. Because of their importance to HACCP, the satisfactory implementation of prerequisite programs must be verified. In approving HACCP plans, some firms will include a statement similar to this on the approval page:

> 'This HACCP plan approval is contingent upon the satisfactory maintenance of supplier approval, chemical control and GMP programs,'

or some variation of this theme (Mortimore and Wallace, 1994).

In the United States the Food and Drug Administration (FDA) is conducting a pilot evaluation of the application of HACCP in a wide variety of food plants. Firms that have completed this evaluation, report that FDA devoted nearly as much effort to the verification of prerequisite programs as it did to the verification of the HACCP system.

Beyond these two often ignored areas, *product design* and *prerequisite programs*, let us now consider the more traditional activities involved in auditing and verification of the HACCP system itself.

VERIFICATION PROCEDURES AND SCHEDULING

In its 1992 report, the US National Advisory Committee on Microbiological Criteria for Food

(NACMCF) (National Advisory Committee, 1992) defined verification as,

'The use of methods, procedures or tests in addition to those used in monitoring to determine if the HACCP system is in compliance with the HACCP plan and/or whether the HACCP plan needs modification and reevaluation.'

The NACMCF described four processes that are used in verification. These are:

- Validation of the HACCP plan
- Verification of the HACCP system
- Periodic revalidation of the HACCP plan
- Government regulatory role in verification

The first three processes are the responsibility of the industry. The fourth process details the government's regulatory responsibility in verifying the HACCP system.

Two of these four processes involve validation of the HACCP plan. The NACMCF recommended that critical limits be 'verified' for their ability to control the identified hazards. We perhaps should have used the term 'validation' of critical limits. This is the scientific/technical foundation for the HACCP plan. All other elements of the HACCP plan are contingent upon the initial determination of Critical Control Points (CCP) and establishment of critical limits. Many sources of information can be used to validate critical limits. The HACCP team can validate critical limits by reviewing laboratory research, plant trials, scientific literature and government regulations.

The remaining validation process is the *mandatory periodic revalidation of the HACCP plans*. Since HACCP plans were first implemented in the 1970s, we learned that sometimes a HACCP plan would literally remain on a shelf and collect dust. Over a period of years, the dusty plan would become inaccurate as the plant's production equipment and product mix change. Therefore, it is necessary to require revalidation of HACCP plans so we can be certain of their validity. Revalidation is done when significant process or product changes require a modification of the HACCP plan. If no significant changes are made, revalidation is still required on a periodic basis, e.g. annual, so that the current validity of the HACCP plan is documented.

The major process in verification is auditing the HACCP system to be sure that the HACCP plan is being followed. Verification activities can be internal, conducted by the plant or corporate HACCP team; or external, conducted by a regulatory agency, or third party.

The plant HACCP/management team members are involved in a number of verification activities that are conducted on frequencies ranging from daily to weekly, monthly, or annually. It is best to schedule the verification activities so that none are overlooked. *Figure 2* is an example of a HACCP verification schedule that is being refined by the NACMCF. I have not included a 'responsibility' column in this figure. Generally, the HACCP team leader or HACCP team members will be responsible for the individual verification activities.

Activity	Minimum Frequency
▪ Verification scheduling	▪ Annual
▪ Prerequisite program verification	▪ Initially, annual thereafter
▪ Validation of critical limits and HACCP plan	▪ Before and during HACCP plan implementation
▪ Revalidation of HACCP plan	▪ Annual or upon significant change
▪ Observation and interview of CCP monitor	▪ Quarterly/monitor/CCP
▪ CCP monitoring record review	▪ Daily
▪ Equipment calibration	▪ According to HACCP plan
▪ Other records review	▪ Monthly
▪ HACCP system verification	▪ Annual

Figure 2 Example of a HACCP verification schedule

The first four activities in this figure — verification schedule, prerequisite program verification, validation and revalidation of the HACCP plan have been discussed above. The next three activities we, at Cargill, consider to be our most important on-line verification activities — observation and interview of the CCP monitor, review of CCP monitoring records, and equipment calibration.

On a less than daily frequency there needs to be a direct observation and discussion with the monitoring person at each CCP. The monitoring person should know what hazard is controlled at the CCP, why such control is important to food safety and the business, what the critical limits are, how to perform the monitoring procedure and record the results, and what corrective actions to initiate should a deviation occur. The auditor should observe the monitoring procedure to verify that it is performed and recorded properly.

There must be at least a daily review of CCP records to ascertain, insofar as possible, that the monitoring has been performed and recorded correctly, and that the appropriate corrective actions have been taken, if necessary. On an established frequency, all instruments used in monitoring CCPs need to be calibrated. The calibration must be documented.

The HACCP team should meet regularly, on a weekly to monthly frequency, to review all deviations and the corrective actions that were taken. This activity is an important part of process improvement. Repeated deviations at a CCP indicate an opportunity to redesign the process so that future deviations are reduced or eliminated. Redesigned processes will likely require a revalidation of the HACCP plan.

In plants that have implemented HACCP systems, finished product testing is no longer performed to provide assurance of food safety. As you know, it is precisely because of the ineffectiveness of finished product testing, to assure food safety, that a prevention based system was developed. HACCP systems provide assurance of food safety by careful attention

to product design and process control. They do not rely on finished product testing.

Nevertheless, some low frequency finished product testing can be performed to verify that the HACCP system is operating effectively. Similarly, customer responses or market surveys can serve to verify the proper functioning of the HACCP system. If a deviation is detected through random finished product testing or through a customer response, a potential CCP may have been missed during the initial development of the HACCP plan. Deviations detected in this manner require that the HACCP plan be re-evaluated, changed as necessary and revalidated.

Regulatory agencies have a role in the verification of HACCP systems. Just as HACCP systems allow food processors to provide greater assurance of food safety, they permit regulatory agencies ot better confirm that food plants are operated safely. HACCP based audits by regulators will be much more effective in this regard than were the traditional regulatory inspections.

Regulatory audits of a HACCP system may be expected to include a review of the HACCP plan and any revisions that have been made, a review of critical limits to determine their adequacy, a review of CCP records and determining the adequacy of corrective actions, direct on-line observations and a random collection of samples for anlaysis. That is, we expect that regulatory audits will be similar to the internal audits currently being performed by the industry.

EXAMPLE OF FOOD SAFETY AUDIT WORKSHEETS

I've brought with me two of the worksheets that we use at Cargill to audit food safety. In our view, a food safety audit must focus on the use of HACCP on the production floor. That is the purpose of the first worksheet (*Figure 3*), which deals with CCP monitoring.

This worksheet has space to monitor two CCPs. As appropriate, each CCP is evaluated for each of the types of hazards that could be encountered (M = microbiological; F = foreign material; C = chemical). Each is rated satisfactory (S) or unsatisfactory (U). Satisfactory ratings are awarded one point, unsatisfactory ratings, zero points. A percentage effectiveness score is calculated based on the total points awarded versus the total points possible. This worksheet is wholly computerized making it very easy to record and calculate scores, and to retain audit records over a period of years. Seventeen questions are considered at ech CCP:

(1) Are written monitoring instructions available for each hazard?
(2) Are written corrective action instructions available for each hazard?
(3) Are written instructions for verification available?
(4) Are monitoring documents present?
(5) Observe monitor — is monitoring being done according to written instructions?

CARGILL, INC. FOOD SAFETY EFFECTIVENESS AUDIT WORKSHEET

Date: _____ Division: _____ Auditor: _____

HACCP: _____ Location: _____ Manager: _____

Local FSC: _____

CCP Name / Question		#					#				
		M	F	C	Person/Place	Comments	M	F	C	Person/Place	Comments
1	Monitor Instructions										
2	Deviation Instructions										
3	Verify Instructions										
4	Monitor Documents										
5	Monitor Done										
6	Monitor Frequency										
7	Monitor Signed										
8	Hazard Knowledge										
9	Deviation Done										
10	Deviation Documents										
11	Verify Documents										
12	Verify Done										
13	Verify Frequency										
14	Verify Signed										
15	Validate Instructions										
16	Validate Documents										
17	Validate Done										

Figure 3 Cargill, Inc. food safety effectiveness audit worksheet

(6) Is monitoring being done at the specified frequency?
(7) Are the monitoring documents properly signed?
(8) Is the monitor knowledgeable about the hazards at a given CCP?
  (a) What hazards are being controlled?
  (b) Why are these hazards harmful?
  (c) How does monitoring control these hazards?
(9) Is corrective action taken according to the written instruction?
(10) Are corrective actions documented?
(11) Are verification documents present for each hazard?
(12) Is verification being done according to the written instruction?
(13) Is verification complete and recorded at the specified frequency?
(14) Are verification documents properly signed?
(15) Are there written validation instructions for each hazard?
(16) Are validation documents present for each hazard?
(17) Is validation being done according to the written instructions?

The second worksheet (*Figure 4*) deals with food safety management. These ten questions are evaluated and scored as per the first worksheet.

We have similar worksheets for the evaluation of prerequisite programs such as GMPs (not presented here).

While the food safety audit is relatively simple, we have found it to be very effective in motivating and training our supervisors and line workers at Cargill food plants worldwide, and we have observed steady improvements in our food safety effectiveness scores.

It is quite obvious that verification consists of a large matrix of activities conducted over long periods

FOOD SAFETY MANAGEMENT WORKSHEET

Date: _____

		Points Awarded
18.	Have all discrepancies since the last audit been corrected or a resolution is on file?	
19.	Are HACCPs established to cover all new and existing products?	
20.	Does the plant Food Safety committee or designate group meet at least every two months and review the HACCP effectiveness for controlling hazards?	
21.	Are HACCP plans reviewed when significant changes are made regarding job procedures, equipment, facility design, or at least annually and procedures updated as required?	
22.	Are critical control points set up for controlling all high probability hazards?	
23.	Are limits for controlling hazards at each CCP set based on government laws, internal/external studies or customer specifications where these are more strict than Cargill/ government restrictions?	
24.	Do line supervisors understand what hazards are controlled and why they are hazardous?	
25.	Do managers understand what hazards are controlled and why they are hazardous?	
26.	Food Safety Committee knowledge of food laws	
27.	Food safety incidents reported / investigated.	

To award scores, use:

S = Satisfactory

U = Unsatisfactory

or leave blank if it does not apply.

Figure 4 Food safety management worksheet

of time. As I stated at the beginning, verification is at least as important as the initial development of the HACCP system.

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