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Validation and Verification of HACCP

Report

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Report on Validation and Verification of HACCP

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VALIDATION AND VERIFICATION OF HACCP

REPORT

PREPARED UNDER THE RESPONSIBILITY OF THE ILSI EUROPE RISK ANALYSIS IN MICROBIOLOGY TASK FORCE

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FOREWORD

HACCP has been identified as a powerful tool for the identification and control of food safety issues. Taking as its starting point the seven principles of HACCP outlined in previous proposals, the aim of this document is to provide guidance on how companies involved in food production can validate and then verify HACCP.

Many previous texts, including those of the Codex Alimentarius Commission, include validation as part of verification. The authors of this text, however, believe that there is a clear distinction between the two because they are separate activities. The distinction lies in justifying what a company plans to do (validation) and then in checking conformity with the planned actions and objectives (verification).

In drawing up this document, we considered the following:

- The importance of supporting scientific evidence used in HACCP studies should be recognised in the validation process.
- Food producers and regulators should assess the effectiveness of HACCP plans once they have been put in place.
- Validation of the scientific and technical content of the hazard plan and verification of the operation of the HACCP plan are the responsibility of the food producer.

Validation is an essential part of the HACCP process. The current thinking in relation to the actual process of implementing HACCP plans can be unclear. This text, however, is not intended as a guide to HACCP implementation, and the subject is only briefly dealt with.

Verification is one of a number of assessment activities in quality assurance processes which also include auditing and inspection. The term inspection is not used within HACCP. Within HACCP, overlap exists between verification and auditing; therefore a short text on auditing is included in the main body of the text and a more detailed explanation in an appendix.

Debate and confusion exist in the area of assessment with regard to the responsibilities of those people who perform the various activities. In attempting to establish areas of responsibility, we use logic based on the definitions of responsibilities for food safety and availability of know-how relevant to the manufacturing process. The role of regulators in assessment of HACCP is an issue that will not be dealt with in this document.

This document also takes the opportunity to clarify the principles of HACCP. In particular there has been to date no general agreement on precisely what constitutes a HACCP plan. A proposal for the components of a HACCP plan is therefore included as Appendix 2.

PART 1

Why is having a validated and verifiable HACCP system so important?

General agreement exists among food processors that quality assurance (QA) systems based on a preventative approach are more effective for assuring food safety than end-product testing. Within QA systems, HACCP has been identified as a powerful tool for the identification and control of food safety.

The World Trade Organisation emphasises the desirability of harmonisation of standards and the importance of sound scientific principles as the basis for its Sanitary and Phytosanitary Measures and encourages the adoption of one set of international standards [1]. HACCP is recommended as the most effective QA tool for meeting current and future food safety needs of the world's food supply [2]. Standardisation must also extend to validation and verification activities within HACCP.

For the purposes of this document, it is convenient to divide the application of HACCP into three phases: 1) technical evaluation of the process of performing the hazard analysis and establishing control measures, 2) implementation of the resulting HACCP plan, which includes the process of validation, and 3) operation of HACCP, which includes the assessment activities of verification and auditing. The processes of hazard analysis and establishing control measures have been dealt with extensively in other texts and will not be discussed here.

HACCP in operation

Before validation and verification are discussed, some important points about HACCP should be noted. A key objective is to implement a HACCP plan into an operational and workable food safety management system. Although clearly implicit in HACCP, this is often forgotten in the difficult business of Critical Control Point (CCP) identification.

The focus of HACCP is food safety [3]. Some users have extended the system to include issues other than food product safety. If this is to be addressed, it is recommended that it be done as a separate exercise after the system has been working for some time.

The system cannot be built without the base of Good Manufacturing Practice (GMP) being in place within the company. A sure sign that the HACCP system will fail is when operations such as washing containers or operators washing their hands are identified as CCPs. This is not to say that these are not important, but if they are CCPs, they must be monitored and documentation of the monitoring must be produced. If this is not possible in the normal day-to-day working environment, the system will fail.

Another point often forgotten is the existing quality control (QC) system. In many cases it may have been in operation for many years in factories which have had few or no problems related to food product safety. The HACCP plan, when developed, should not conflict with existing GMP and QC programmes. The HACCP approach is a systematic way of managing food safety. Its implementation should be built on the experience of its predecessor (e.g. end-product testing,

statistical quality control) systems. In effect, the HACCP plan should be a natural and logical evolution of the QC system.

The updating and subsequent modifications of the HACCP plan are part of the process of continuous improvement. This could well be placed alongside continuous improvement programmes included in Total Quality Management systems [4].

Definitions and explanatory notes

It is important that texts on HACCP adopt standard definitions. We believe that the Codex Alimentarius Commission's definitions [6] represent the consensus, and they are therefore used in this text. We recognise, however, that the current definitions of validation and verification require development. Explanatory notes are therefore included with the definitions.

HACCP Plan

Definition: **A "HACCP plan is a document prepared in accordance with the principles of HACCP to ensure control of the hazards which are significant for food safety in the segment of the food chain under consideration" [6].**

Explanation: Performing a hazard analysis should eventually result in the production of a practical document, the HACCP plan (for further information see the ILSI Europe Concise Monograph *A Simple Guide to Understanding and Applying the Hazard Analysis Critical Control Point Concept* [5]). The HACCP plan includes, among other documents, the process flow diagram and the HACCP data sheet. For a more detailed list of the necessary and desirable components of a HACCP Plan, see Appendix 2. The HACCP data sheet defines the monitoring procedures (observations or measurements to check the effectiveness of the control at a CCP), responsibilities of key personnel, frequencies of monitoring, critical limits and target values of the CCPs, and the corrective actions needed to ensure that the hazards, which are identified as a result of the hazard analysis, are controlled.

Validation *(verb; to validate, ratify; valid, sound, defensible of reasonable objection – Oxford English Dictionary)*

Definition: **Obtaining evidence that the elements of the HACCP plan are effective [6].**

Explanation: Validation is concerned with obtaining evidence that the elements of the HACCP plan will be effective; as such, validation should be targeted at the assessment of the scientific and technical inputs into the HACCP plan. Validation should ensure that the information supporting the HACCP plan is correct – that the production facility is "going to do the right things" – thus enabling compliance with food safety policy. Evidence to support HACCP plans can come from a wide variety of sources.

Validation provides evidence to support the HACCP plan and therefore takes place before implementation and after alterations. As new scientific information comes to light, the assumptions on which the validation is based should be reassessed. Where necessary such reassessment must result in the amendment of the provisions laid down. When this is the case, changes must be validated against this new information. Any change to the HACCP plan should

be fully incorporated into the documentation and record keeping system so that accurate up-to-date information is available.

Where it is not possible to justify (validate, defensible of reasonable objection) an element of the HACCP plan, there is only one option: modify the plan.

Verification *(verb; to verify, establish truth or correctness by examination or demonstration – Oxford English Dictionary)*

Definition: **The application of methods, procedures, tests and other evaluations in addition to monitoring, to determine compliance with the HACCP plan [6].**

Explanation: Once a HACCP plan has been established and its elements validated, it is important to ensure that compliance is being achieved in practice - in simple words, "Are we doing what we planned to do?" Verification is therefore a continual process similar to monitoring but normally with a lower frequency and where the objective is to observe not specific points in the process but, in effect, the HACCP system as a whole.

Verification programmes should be included as part of the HACCP plan. As with monitoring, this process should be formalised to include the methods for verification, frequency of testing, staff responsibilities, and a formal evaluation of results by a defined group of people to decide on possible changes.

Where criteria relevant to food safety are specified in regulations, they are to be used as reference values for the verification process.

The above definition refers to 'compliance' (with the HACCP plan). However, in this context we prefer the word 'conformity'. This allows a distinction between 'conformity' in the sense of conforming with a HACCP plan or established procedures, and 'compliance' in the sense of complying with regulatory or policy requirements (see Glossary).

Audit *(noun; audit, official examination of account – Oxford English Dictionary)*

Proposed definition: **A HACCP audit is the process by which conformity of actual practices with the documented HACCP plan for the segment of the food chain under consideration is reviewed (adapted from [7]).**

From the definition, the overlap of auditing with the verification process is obvious. For the purposes of this document, three types of audits have been considered:

- Internal audits or self-assessments, which are carried out on behalf of the operating unit and as part of the internal process of QA system performance assessment, i.e. verification (see above).
- Corporate audits, which are carried out on behalf of the parent company by personnel external to the operating unit.
- Third-party audits, which are carried out on behalf of or by entities outside the company structure (including government or regulatory assessments).

Explanation: The purpose, methods, and scope of the three audits are distinctly different. Internal audits are the responsibility of the operating company. Corporate audits are considered the sole responsibility of the individual corporation, and the terms of reference may vary widely. Verification can be included in corporate audits. Third-party audits are considered in Appendix 1, where the benefits and limitations of auditing are discussed.

Audits can be a useful tool for establishing conformity of actual practices with documented plans, procedures, and protocols. Auditing in this context therefore does not include 'value judgements' on HACCP but rather checks for conformity with documented plans.

Auditing is different from inspection. Inspection is the examination of food or systems for the control of food, raw materials, processing and distribution including on-line and finished product testing, to provide assurance that they comply with regulatory requirements [6]. Auditing, therefore, checks for conformity with documented procedures; inspection checks for compliance with regulatory requirements.

The scope of auditing within HACCP is limited to checking conformity with procedures, for the following reasons:

- The process of evaluating the suitability of the elements of the HACCP plan is carried out by validation as part of implementation. However, it may be necessary as part of an audit to establish that validation was performed.
- Compliance with legislation is the responsibility of the company.
- Third-party audits cannot do validation, because this would require the use of a team with at least as much experience and familiarity with the process under consideration as the team which initially performed the hazard analysis.

Audits that identify non-conformity with the HACCP plan in place may require one of two actions: (i) reinforced supervision to ensure conformity or (ii) alteration of the monitoring / control methods to facilitate conformity.

Verification and audit activities can be differentiated as follows:

- Verification: assessment activities, other than monitoring, included as part of a company's HACCP plan. The frequency for each activity is included in the plan. These activities are necessary to ensure that HACCP works effectively. The activities are planned (e.g. responsibilities attributed to members of staff), frequent and regular. This term may therefore apply to internal audits.
- Audit: assessment activities not included as part of a company's HACCP plan. An individual audit activity checks for adherence to documented procedures at one point in time (e.g. to ensure that validation was, and verification is, carried out) but is not necessary to ensure that HACCP works effectively. Responsibilities for carrying out assessment activities are not attributed to staff members. This would therefore apply only to third-party audits.

PART 2

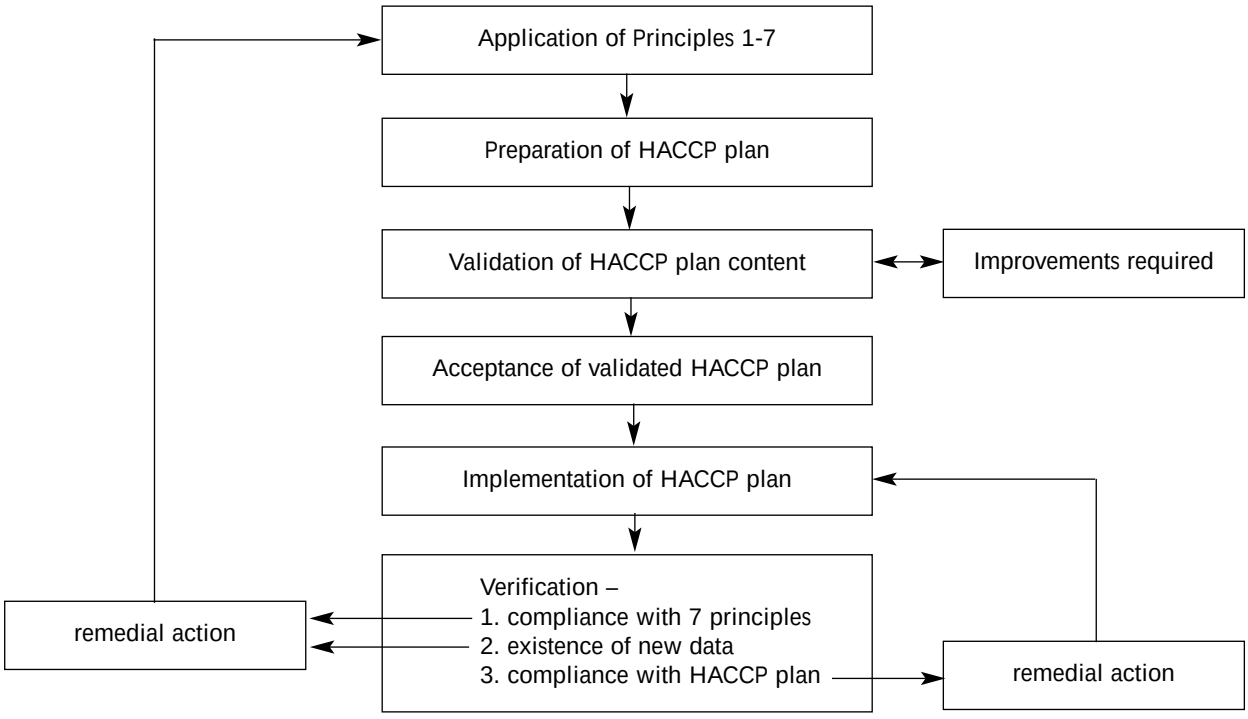
Validating elements of the HACCP system

A HACCP plan cannot be prepared without a proper hazard analysis. The HACCP plan is the practical result or product of the HACCP study organised by these seven basic principles:

1. Identification of hazards and assessment of their severity and probability of occurrence (hazard analysis).
2. Determination of CCPs required to control identified hazards.
3. Specification of critical limits to assure that an operation is under control at a particular CCP.
4. Establishment and implementation systems to monitor control of CCPs.
5. Establishment of the corrective actions to be taken when monitoring indicates that a particular CCP is not under control.
6. Establishment of procedures for verification to confirm that the HACCP system is working effectively.
7. Establishment of documentation concerning all procedures and records appropriate to these principles and their application.

The development of the HACCP plan and its practical implementation are described more fully in the ILSI Europe Concise Monograph entitled *A Simple Guide to Understanding and Applying the Hazard Analysis Critical Control Point* [5]. A proposal for the items to be included in a HACCP plan is given in Appendix 2. Figure 1 shows where validation fits into the process of HACCP implementation.

Figure 1: HACCP Validation and Verification



To ensure that validation is carried out effectively, the person with ultimate responsibility for product safety at the operating unit (normally the general manager) should form a validation team. The objective is to ensure that hazards originally identified by the HACCP team are complete and correct and that they will be effectively controlled under the proposed plan. The team must therefore include representatives from the original HACCP team and those at the operating unit who will be responsible for HACCP. This composition of the team should also aid the process of transfer of ownership from the team that created the plan to the team that will operate it.

For future reference, the composition of the validation team and the activities undertaken should be clearly documented. Sign-off, indicating satisfactory completion of validation, is the responsibility of the person ultimately responsible for product safety at the unit.

To meet the objectives of validation it is necessary to critique (1) the supporting evidence used in the HACCP study and (2) the control measures, including monitoring and corrective actions.

1. Validation of the supporting evidence requires that evidence be provided to justify first the selection of the significant hazards and, second, the effectiveness of the proposed control measures.

   Evidence supporting the selection of significant hazards may come from the scientific literature, trade associations, regulatory and legislative departments, historical data, professional bodies, or company knowledge. Evidence must be gathered for both the inclusion and the exclusion of all relevant hazards considered during the hazard analysis.

   Supporting evidence is needed to show that the established target values and critical limits will adequately control the identified hazards to a level which meet company product safety requirements. This may be achieved using the same sources that were used for the selection of the hazards (see above) and by testing. Testing is the process by which proposals for control are positively tested for their effectiveness. Examples of testing include deliberate contamination, heat distribution and penetration tests, 100% incubation or inspection of production lots, and mathematical modelling of microbial growth.

2. Validation of the control measures is the reconciliation or cross-checking of the HACCP data sheet and the process flow diagram to ensure that the CCPs have been correctly identified and that the established target values, critical limits and monitoring procedures are adequate. Written procedures must exist for all measurements. These procedures must include information on methodology, frequency, acceptable values, actions to be taken if values are outside the critical limits, and necessary calibration.

   Validation of the control measures must ensure that corrective actions taken in the case of process deviations will result in the adequate segregation of non-conforming product to ensure that it does not reach the consumer. Responsibilities for taking corrective actions and decisions on the future of the affected product must exist in writing along with mechanisms to ensure that appropriate actions are taken to prevent reoccurrence.

It should be remembered that food-processing facilities have been producing safe food for many years before the advent of the HACCP system. HACCP systems developed to replace predecessor systems should not conflict with those systems, but should effectively use practical experience

gained over time. Historical results, therefore, from previous quality systems, including Good Manufacturing Practice, on-line QC monitoring, consumer and customer complaints, and finished-goods testing, may also all be used as evidence when validating HACCP plans. It is important to note that the data must be quantifiable and objective if they are to be useful.

Implementation

The transfer of ownership is a key step in the practical implementation of a HACCP plan. Implementation is dealt with only briefly here, by considering four important elements.

1. **Supplier control:** Ingredients and packaging, which are required to be within specification to ensure product safety, must be obtained from approved suppliers.

2. **Job descriptions**: Job descriptions are required for all members of staff along with work-station instructions and documented procedures for all critical control points. For a HACCP plan to work effectively it is essential that the following be included in job descriptions to ensure that everybody knows what has to be done, how, and when to do it, and who is responsible:

   - minimum qualification requirements so that the correct level of staff are fulfilling the correct functions
   - level of training required for that job and the level of training of the person actually fulfilling that function
   - definition of who reports to the person and whom in turn the person reports to
   - documented arrangements to cover the absence of key personnel
   - clearly defined and assigned responsibilities and authorities with no overlap.

3. **Training**: Implementation of a HACCP plan depends on the adequate training of personnel at all levels in the unit. Training should result in staff having a clear understanding of their responsibilities and roles. Staff should also be aware of the importance of HACCP and how it impacts both directly and indirectly on product safety.

4. **Communication**: Much of the success of the HACCP plan depends on effective communication. Small- and medium-sized enterprises often achieve this by the relative physical and personal closeness of people and by the fact that many areas of responsibility may overlap. Also, the ratio of effective supervision to workers and tasks may be high. In long-established companies the same effect may be achieved by routine. In large and constantly changing companies the need for effective communication, with clear definition of responsibilities and the chain of command, is much greater.

   To ensure effective communication, the definition of responsibilities is essential. A hierarchical organogram should be drawn up, defining the principal responsibilities and authorities related to the HACCP plan, for example, product recall, quality manual/system, incoming raw material quality monitoring, and product disposition decisions.

PART 3

Verifying the HACCP system

A brief description of verification is included in the ILSI Europe Concise Monograph *A Simple Guide to Understanding and Applying the Hazard Analysis Critical Control Point Concept* [5]. The processes of validation and verification are often confused, with validation often being included in the verification process.

Validation is the gathering of evidence to ratify or justify – i.e. validate – elements of the HACCP plan, demonstrating that it has been carefully prepared based on sound scientific and technical evidence. Verification is the process by which conformity with the HACCP plan is determined and its effectiveness observed in practice. Put simply:

> Validation: Will the system work when put into practice?
> Verification: Are we doing what we planned to do?

Verification should provide for confirmation of the effectiveness of the established HACCP system and ensure afterwards, with appropriate frequency, that the provisions laid down are still being conformed to. Where conformity with the plan is not demonstrated, basically two possible actions can regain control: (1) reinforced supervision of the application of the plan or (2) alteration of the monitoring / control methods to facilitate conformity.

During the establishment of the HACCP plan, it is necessary to define not only the types of activities to be included in the verification process (see Table 1) but also their frequency and, depending on results, the process for improvement. Verification is therefore best described as the systematic gathering and evaluation of information to demonstrate the effectiveness of the HACCP plan as well as potentially contributing to improvement in its performance. Verification is therefore divided (mainly for purposes of explanation) into two distinct activities: (1) demonstrating conformity with the HACCP plan, and (2) gathering of information.

1. Demonstrating conformity with the HACCP plan. A key objective of conformity is to raise confidence in the competence of the manufacturing unit. This is achieved by demonstrating that the established procedures and protocols are being followed effectively. This aspect of verification has much in common with auditing in that documentation provides evidence for external (and internal) people that food processors are doing the right thing to ensure food safety. It is important that the above people have a good level of background scientific and technical knowledge and familiarity with the product, process, and production. This is necessary so that they can not only focus on records and documents but can pass sound judgement on their content and so contribute to improving the effectiveness and performance of the HACCP plan. It is important to note that checking the design of the record-keeping system is part of the validation process.

   Verification procedures to establish conformity with the system and its records should include: (i) operations (including calibration); (ii) deviations, corrective actions, and other measures taken with regard to the product; (iii) internal audits; (iv) supplier audits; and (v) changes to the system.

2. Gathering of information. The objective of information gathering is to raise confidence in the HACCP plan. This is achieved by demonstrating that product safety requirements are being met and that the HACCP plan is still well-founded. Verification should ensure that

the HACCP plan is still applicable for, and being applied to, the equipment, processes, products, cleaning protocols, factory layout and environment, distribution and storage, raw materials, and packaging, and that it incorporates the latest hazard information and product end use (consumer trends). The results of previous information gathering exercises are more useful for showing trends in food safety at the manufacturing unit than for checking procedural compliance.

Common ways of gathering information include trend analysis on:

- data recorded at CCPs as part of the monitoring process
- the results of on-line testing
- end-product testing
- consumer and customer complaints
- hygiene testing analysis or market-place samples
- equipment calibration checking.

In all of these cases, trends with time as well as individual deviation results need to be analysed. The objective should be to use the statistical treatment of results to reduce the limitations normally associated with some of the methods of testing (principally the microbiological methods). Results should be used to identify root causes of problems and potential improvements to product safety.

Table 1. Summary of the activities of verification.

Verification plan	Details: tasks, responsibilities, frequencies, methods, procedures, follow-up
Demonstration of conformity	Regarding: executed corrective measures, monitoring, procedures, training, traceability, testing
Information gathering	Sources: registered complaints, results of monitoring and end-product testing, trade samples, random sampling, results of previous conformity verification.

Verification results must be evaluated systematically. Special attention must be given to problem areas. In some cases the assumptions made for the established HACCP plan will be called into question by the process of verification. Verification may show that alterations to the HACCP plan are required. If modifications are made to the HACCP plan, their effectiveness must be validated. A product of the verification may be new information which can then be used in the process of validating the changes to the plan (see Figure 1). This is essential to prevent those situations where changes intended to improve safety have the opposite effect. It is suggested that modifications to the HACCP plan should be part of a continuous improvement plan which should include the following steps:

- statement that identifies the problem
- quantification of the problem
- proposals for solutions
- implementation of the proposals
- quantification of the effectiveness of the proposals[1]
- re-evaluation.

1. If the solutions are successful, the quantification of the effectiveness of the proposals and the re-evaluation are in effect the validation of the changes.

SUMMARY

Validation is the gathering of information to support the decisions and assumptions made during the HACCP study, thereby raising confidence that the system will work. Once HACCP has been implemented, verification is necessary to ensure conformity with the plan and that the system is working.

Table 2 lists some of the questions that could be asked during the validation and conformity verification of a HACCP study of a generic food process. This list is illustrative of the approach taken and is not comprehensive.

Table 2. Examples of validation and conformity verification.

HACCP principle	Validation. Evidence to demonstrate that:	Verification. Evidence to demonstrate that:
1. Hazard analysis.	The correct skills were in the HACCP team. The flow diagram is suitable for the purposes of the HACCP study, and all the significant hazards were identified.	Validation was carried out correctly.
2. Determination of the CCPs required to control identified hazards.	All significant hazards were considered during CCP identification. There are CCPs to control all significant hazards. The CCPs are at the appropriate stages in the process.	Validation was carried out correctly.
3. Specification of critical limits to assure that an operation is under control at a particular CCP.	The critical limits control the identified hazards.	Validation was carried out correctly.
4. Establishment and implementation of systems to monitor control of CCPs.	The monitoring system will ensure that the control measures at the CCPs will be effective. Procedures for the necessary calibration of testing equipment are included.	Records of monitoring exist and confirm control. Statistical process control. is used. Designated person's review of record monitoring. Records of calibration exist and confirm compliance.
5. Establishment of the corrective action to be taken when monitoring indicates that a particular CCP is not under control.	Corrective actions will prevent non-conforming product from reaching the consumer. Authority for corrective actions has been assigned.	In cases of non-conformity, control is regained. Corrective actions are recorded and actions taken by designated persons.
6. Establishment of procedures for verification to confirm that the HACCP system is working effectively.	Procedures for information gathering and compliance verification of the HACCP system have been established.	All verification procedures are carried out.
7. Establishment of documentation concerning all procedures and records appropriate to these principles and their application.	Documentation covering the entire HACCP system has been established.	Documentation and record keeping covering the entire HACCP system is complete, in the correct format, and properly filled out.

APPENDIX 1.
PRINCIPLES OF AUDITING HACCP SYSTEMS

A key objective of auditing is trust building through conformity evaluation. The process of auditing can provide a useful mechanism by which supplier-customer (external and internal) trust is built up. The results of audits, certificates, or audit reports are a starting point that aids communication. It must be remembered, however, that certificates cannot replace or change reputations built by previous contact, which may be the result of years of collaboration. Inherent weaknesses of audits as evaluation methods apply to the certificates or certifications that result from them.

When third-party auditors are received who will review conformity of actual practices with the documented HACCP plan, similar guidelines that would normally apply to the reception of any visitor should be used, i.e.:

1. Before an audit, the auditee should first find out who is coming and what their background and qualifications are. The experience of the auditor(s) should be compatible with the assessment to be made.
2. The objectives and reasons for the audit should be defined beforehand. This normally entails assessing the conformity of actual practices with the documented HACCP plan for the segment of the food chain under consideration.
3. The auditor and the auditee should agree on the organisation and structure of the audit.

In establishing conformity of actual practises with the documented HACCP plan, audits commonly require presentation of the following written information:

1. Examples of records associated with HACCP systems include those associated with: ingredients, processing, packaging, deviations, storage and distribution, CCP monitoring, modifications to the system.
2. HACCP manuals and supporting documentation presented at audits may be expected to comprise of: the team for HACCP implementation, results of validation, organogram of the company, job descriptions, a full description of the HACCP analysis, flow charts, the HACCP plan[2], examples of records, verification reports, procedures, and traceability documentation.

Although the existence of the above information should be available for a third-party audit, assessment of the suitability of the decisions taken to assure safety is only rarely appropriate. Compliance with food safety objectives is the sole responsibility of the food processor. Effectiveness of operational HACCP plans should be demonstrable from the results of the ongoing verification procedures, and this should be presented during audits to raise confidence in the HACCP plan.

The principal findings and conclusions of the visit should be communicated to the factory by the auditors in an audit close-out meeting before the end of the visit. The general conclusions of the final audit report should be agreed to at this meeting. This is necessary to ensure that misunderstandings caused by poor communication do not result in inaccurate findings on behalf of the auditors.

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2. For details on what constitutes a HACCP plan, see Appendix 2.

APPENDIX 2. COMPONENTS OF A HACCP PLAN

Although reference to HACCP plans is made in many publications and a definition exists, there is as yet no general agreement as to what exactly constitutes a HACCP plan. The following structure for the requirements of a HACCP plan is based on the experience of members of the group that drafted this document, many of whom work for large food companies. A structure has been chosen in which requirements (constitutive parts) are divided into "must", "should", and "may contain" categories.

Component	Must contain	Should contain	May contain
Process flow diagram including CCPs	X		
Hazard identification	X		
HACCP data sheet[3]	X		
HACCP team chart	X		
Description of the product and its intended use	X		
Company policy documents for safety GMP issues e.g., glass, metal		X	
Detailed ingredient, packaging, and finished-goods specifications		X	
Job descriptions for those holding principal accountabilities for operating the HACCP system		X	
Corrective action plans for deviations		X	
Record-keeping procedures		X	
Validation data		X	
Procedures for verification and revision		X	
Raw material assurance programme		X	
Documented recall procedure		X	
Relevant GMP manuals (including line hygiene, preventative maintenance, and equipment calibration measurements)			X
Job descriptions and accountabilities for all staff			X
Training programme and records for all staff			X
Laboratory manuals (including calibration procedures)			X
Findings and corrective actions from previous audits (including verification procedures)			X
Customer complaint policy and procedure			X

3. For minimum information requirements see the ILSI Europe Concise Monograph "A Simple Guide to Understanding and Applying the Hazard Analysis Critical Control Point Concept" [5].

GLOSSARY

This glossary contains words used in the text and other terms commonly used in HACCP procedures. Definitions previously given in the text are not repeated here. Where possible, Codex Alimentarius Commission definitions [6, 8] have been given. Where the definition has been taken from another source, the reference for the definition has been cited.

Certification: Procedure by which official certification bodies or officially recognised bodies provide written or equivalent assurance that foods or food control systems conform to requirements [1].

Compliance: When implementation of the HACCP plan and pre-requisites meet regulatory requirements.

Conformity: Activities carried out according to the established procedures, and critical limits not exceeded, e.g. HACCP plan and pre-requisites.

Control measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Corrective action: Any action to be taken when the results of monitoring at the CCP indicate a loss of control.

Critical control point (CCP): A step at which control can be used to prevent or eliminate a food safety hazard or to reduce it to an acceptable level.

Critical limit: A criterion which separates acceptability from unacceptability.

Deviation: Failure to meet a critical limit.

Disposition: Control of non-conforming product whilst it awaits a decision on its status or future (authors' definition).

Flow diagram: A schematic representation of the sequence of steps or operations used in the production or manufacture of a particular food item.

Good manufacturing practice (GMP): That combination of manufacturing and quality control procedures aimed at ensuring that products are consistently manufactured to their specifications [9].

Hazard analysis: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP Plan.

HACCP plan: A document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food safety in the segment of the food chain under consideration [1].

HACCP system: The result of the implementation of the HACCP plan.

Hierarchical organogram: A schematic representation of the reporting structure within a unit with basic responsibilities where appropriate (authors' definition).

Inspection: The examination of food or systems for control of food, raw materials, processing and distribution including in-process and finished product testing, in order to provide assurance that they comply with regulatory requirements [1].

Monitor: The act of conducting a planned sequence of observations or measurements of control parameters to assess whether a CCP is under control.

Non-conformity: Failure to achieve conformity. Status following a deviation (authors' own definition).

Product recall: Complete and rapid withdrawal from the market of products which present, or other products produced under similar condition which may present, a hazard to public health (adapted from [6]).

Quality assurance (QA): A systematic and planned approach to food production in which all relevant areas of the food chain are considered and the necessary actions taken to ensure that products comply with specifications (adapted from [9]).

Quality control (QC): In the context of good manufacturing practice and HACCP, to have in place an effective monitoring system that checks adherence to specified requirements (specifications) (adapted from [9]). In the context of predecessor quality systems: monitoring system that checks adherence of end products (finished goods) to specified requirements (end product testing) (adapted from [9]).

Significant hazard: Hazards that are of such a nature that their elimination or reduction to an acceptable level is essential to the production of safe foods (adapted from [6]).

Third party: An independent person or organisation with competence to assess HACCP.

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