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Standard Guide for Conducting Hazard Analysis-Critical Control Point (HACCP) Evaluations[1]

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1. Scope

1.1 This guide describes a stepwise procedure for using existing information, and if available, supporting field and laboratory data concerning a process, materials, or products potentially linked to adverse effects likely to occur in the environment as a result of an event associated with a process such as the dispersal of a potentially invasive species or the release of material (for example, a ~~chemical) or~~ chemical or a physical substance) or its derivative products to the environment. Hazard Analysis-Critical Control Point (HACCP) evaluations were historically linked to food safety (Hulebak and Schlosser W. 2002 (**1**);[2] Mortimer and Wallace 2013 (**2**)), but the process has increasingly found application in planning processes such as those occurring in health sciences ; Quattrin et al. 2008 (**3**); Hjarno et al. 2007 (**4**); Griffith 2006 (**5**) or; Noordhuizen and Welpelo 1996 (**6**)), in natural resource management (US Forest Service 2014 a,b,c (**7, 8, 9**), (US EPA, 2006 (**10**); see also

~~http://www.fws.gov/ fisheries/ans/ANS-HACCP.html; http://www.haccp-nrm.org/; or http://www.waterboards.ca.gov/water_issues/programs/swamp/ais/prevention_planning.shtml (last accessed June 16, 2014)~~

http://www.waterboards.ca.gov/water_issues/programs/swamp/ais/prevention_planning.shtml; (last accessed October 16, 2023)

or in supporting field operations wherein worker health and natural resource management issues ~~intersect (see, for example,~~ intersect.

~~http://www.haccp-nrm.org/plans/nm/negrito.pdf related to field operations occurring in areas associated with incidence of hantavirus; (last accessed June 15, 2014)~~

1.2 HACCP evaluation is a simple linear process or a network of linear processes that represents the structure of any event; the hazard analysis (HA) depends on the data quality and data quantity available for the evaluation process, especially as that relates to critical control points (CCPs) characterized in completing HACCP. Control measures target CCPs and serve as limiting factors or control steps in a process that reduce or eliminate the hazards that initiated the HACCP evaluation. The main reason for implementing HACCP is to prevent problems associated with a specific process, practice, material, or product.

1.3 This guide assumes that the reader is knowledgeable in specific resource management or engineering practices used as part of the HACCP process. A list of general references is provided for HACCP and implementation of HACCP and similar methods, as those apply to environmental hazard evaluation, natural resource management, and environmental engineering practices (**11-26**).

1.4 This guide does not describe or reference detailed procedures for specific applications of HACCP, but describes how existing information or other empirical data should be used when assessing the hazards and identifying CCPs potentially of use in

[1] This guide is under the jurisdiction of ASTM Committee E50 on Environmental Assessment, Risk Management and Corrective Action and is the direct responsibility of Subcommittee E50.47 on Biological Effects and Environmental Fate.

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[2] The boldface numbers in parentheses refer to the list of references at the end of this standard.

minimizing or eliminating specific hazards. Specific applications of HACCP evaluation are included as annexes to this guide, which include implementation of HACCP in resource management practices related to control and mitigation of invasive species or disease agents primarily of concern for managing fish and wildlife.

1.5 HACCP evaluation has a well developed literature in, for example, food science and technology, and in engineering applications (see, for example, (**11**, **12**, **13**, **15**, **17**)). As a resource management tool, HACCP is relatively recent in application to the analysis of hazards to aquatic, wetland, and terrestrial habitats and the organisms occupying those habitats. (see, for example, US Forest Service 2014 a,b,c (**7**, **8**, **9**); see also http://www.haccp-nrm.org/ last accessed June 16, 2014). Most of the guidance provided herein is qualitative rather than quantitative, although quantitative methods should be applied to any hazard analysis when possible. Uncertainties associated with the analysis should also be characterized and incorporated into the HACCP evaluation when possible (see, for example, (**11**, **27-38**)).

1.6 This standard provides guidance for assessing hazard within a generalized framework that may be extended to specific environmental settings, such as that detailed in E1023 for aquatic habitats (Guide for Assessing the Hazard of a Material to Aquatic Organisms and Their Uses). This standard does not provide guidance on how to account for socio-economic or political considerations that influence the specification of the acceptability of risk associated with the hazard, particularly when HACCP is implemented and CCPs are considered within contemporary risk-based decision-making processes. Judgments concerning acceptability are outside the scope of this guide, but available guidance from ASTM is applicable to this process (see E2348 Standard Guide for Framework for a Consensus-based Environmental Decision-making Process).

1.7 This guide is arranged as follows:

1.8 *This standard does not purport to address all of the safety concerns, if any, associated with its use and the implementation of HACCP. It is the responsibility of the user of this standard to establish appropriate ~~safety and health~~safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.9 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[3]

E943 Terminology Relating to Biological Effects and Environmental Fate

E1023 Guide for Assessing the Hazard of a Material to Aquatic Organisms and Their Uses

E1391 Guide for Collection, Storage, Characterization, and Manipulation of Sediments for Toxicological Testing and for Selection of Samplers Used to Collect Benthic Invertebrates

E2348 Guide for Framework for a Consensus-based Environmental Decision-making Process

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *control, v*—to take all necessary actions to ensure and maintain compliance with criteria established in the HACCP plan.

[3] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

3.1.2 *control, n*—a state wherein correct procedures are being followed and criteria are being met.

3.1.3 *control ~~measure—~~measure, v*—any action and activity that can be used to prevent or eliminate a hazard or reduce it to an acceptable level.

3.1.4 *corrective ~~action—~~action, v*—any action to be taken when the results of monitoring at the CCP indicate a loss of control.

3.1.5 *critical control point ~~(CCP)—~~(CCP), n*—a step at which control can be applied and is essential to prevent or eliminate a hazard or reduce it to an acceptable level.

3.1.6 *critical ~~limit—~~limit, n*—a criterion which separates acceptability from unacceptability.

3.1.7 *~~deviation—~~deviation, n*—failure to meet a critical limit.

3.1.8 *flow ~~diagram—~~diagram, n*—a systematic representation of the sequence of steps or operations of a system or process, including the production or manufacture of a materials or products.

3.1.9 *HACCP (Hazard Analysis-Critical Control ~~Point)—~~Point), n*—a system which identifies, evaluates, and controls hazards which are significant for a wide range of natural resource management and environmental engineering applications.

3.1.10 *HACCP ~~plan—~~plan, n*—a document prepared in accordance with the principles of HACCP to ensure control of hazards.

3.1.11 *~~hazard—~~hazard, n*—a biological, chemical or physical agent or condition with the intrinsic capacity to cause an unwanted or adverse effect in an exposed system.

3.1.12 *hazard analysis ~~(HA)—~~(HA), n*—the process of collecting and evaluating data and information on hazards and conditions leading to their presence and necessary to include in a HACCP plan.

3.1.13 *~~monitor—~~monitor, v*—the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a critical control point is under control.

3.1.14 *~~step—~~step, n*—a point, procedure, operation or stage in a process.

3.1.15 *~~validation—~~validation, n*—obtaining evidence that the elements of the HACCP plan are effective.

3.1.16 *~~verification—~~verification, n*—the application of methods, procedures, tests and other evaluations, in addition to monitoring to determine compliance with the HACCP plan.

3.2 For definitions of other terms used in this guide, refer to Terminology E943 and references cited herein.

4. Summary of Guide

4.1 Hazard Analysis-Critical Control Point (HACCP) evaluation has become increasingly applied to natural resource management and environmental engineering problems, particularly as hazards may be managed, for example, with respect to the safety of processes or release of materials or products to the environment. HACCP should be an integral part of management practices focused on engineering or resource management practices used to develop aquatic, wetland, and terrestrial habitats for human use (for example, agriculture or construction activities) or to enhance habitats for fish and wildlife. HACCP is a systematic and preventive approach that addresses biological, chemical and physical hazards through anticipation and prevention, rather than through end-product inspection and testing or retrospective engineering solutions necessitated because of previous undertakings. The HACCP system is intended for assessing and managing risks and safety concerns associated with a wide range of materials, products, and management practices with an emphasis on a total systems approach to improve environmental quality. This standard could be used in conjunction with existing ASTM standards such as Guides E1023 and E2348. HACCP emphasizes control of a process as far upstream in the processing system as possible by utilizing operator control or continuous monitoring techniques, or

a combination of both, at critical control points. The HACCP system uses the approach of controlling critical points in any process to reduce or eliminate risks and prevent safety problems from developing. The identification of specific hazards and measures for their control to ensure the safety of a process, material, or product through prevention and reduces the reliance on end-product inspection and testing (for example, for agrichemicals), remedial measures (for example, related to construction practices), or mitigation measures as part of a control program (for example, quarantine or disinfection for control of invasive species) are integral components of any HACCP system. Any HACCP system should be capable of accommodating change, such as advances in equipment design or developing alternative resource management practices, changes in processing procedures, or technological developments.

4.2 This guide describes an iterative procedure for assessing hazard and characterizing CCPs. Unavailable, yet necessary information concerning the hazard and the process generating that hazard should be identified and characterized through a stepwise evaluation that details the hazard and specifies critical points that may serve to control the process, and minimize or eliminate hazard. At the end of any iteration of the HACCP process, specific CCPs that reduce likelihood of hazard may be identified, or the available data related to the hazard and the process generating that hazard may be judged as being insufficient to adequately characterize hazard or CCPs. In the latter instance, additional data or information should be identified and obtained, so that HA and CCPs can be reassessed. The process is repeated until the hazard is adequately characterized and CCPs are characterized in order to reduce likelihood that hazard is realized.

4.3 Three annexes are also included with this standard guide.

4.3.1 Annex A1 focuses on implementation of HACCP within the context of natural resource management, principally that process developed for control of invasive species; principally, prevention of species invasions, but also mitigation, reduction, or eradication if such events have occurred. This annex summarizes extension of the general guidance contained within the standard guide to a specific application of the HACCP process that may serve as a "stand alone" document to support the development of species-specific or practice-specific HACCP plans linked to invasive species. The relationships between the generalized HACCP process summarized in the standard guide and its specific implementation in this annex should be considered in adapting HACCP plans to changing environmental conditions that might develop and alter hazards through time. Tasks outlined in the standard guide have been variously incorporated into the implementation-specific five-step HACCP process summarized in this annex. Additionally, in recognizing the dynamic process associated with species invasions, users of this stand-alone annex would benefit from consultation with online resources that directly complement this implementation of HACCP (http://www.haccp-nrm.org/ last accessed June 16, 2014).

4.3.2 Annex A2 continues implementation of HACCP linked to invasive-species management issues with a particular focus on decontamination procedures intended to mitigate or reduce hazards associated species transfers stemming from field operations. Given the increasing occurrence of dispersal and establishment of invasive species in previously unoccupied terrestrial or aquatic habitats, various organizations have developed procedures for managing unintended human-aided dispersal events. For aquatic invasive species (AIS) HACCP or principals characteristic of the HACCP process reflected in this annex guides the development of mitigation practices intended to prevent the spread of AIS with a primary focus on New Zealand mudsnail (*Potamopyrgus antipodarum*), quagga mussel (*Dreissena rostriformis bugensis*) or zebra mussel (*Dreissena polymorpha*). These invasive molluscs are not easily observed in field settings; hence, unintended transport to new locations on equipment or other materials used in the field serve as potential vectors mediating transfers from occupied habitats to previously unoccupied habitats when equipment or other materials are deployed in areas that are geographically separated, yet potentially linked through management actions mediated by their use. To prevent their unintended spread between field-work locations, procedures for decontaminating equipment and other materials are considered in this annex which serves to mitigate and reduce species transfers linked to use of this equipment or other materials in waterbodies at different locations. Procedures listed in this annex may be used to establish mitigation practices implemented through the decontamination process.

4.3.3 Annex A3 applied HACCP to natural resource management issues related to disease agents, particularly the transfer of pathogens between and among different locations within aquatic systems—lentic or lotic. A wide range of disease agents are capable of entering previously unoccupied habitats through actions of biological vectors or other transfer agents that assure their potential passage through numerous pathways. In the wild and in absence of human intervention, little direct control can be exerted over most of these pathways where waterfowl or shore birds, other migratory birds, foraging ungulates and other wildlife such as beavers may be critical components in completed pathways. In managed habitats or in managed field investigations, however, transfers of disease agents may be enabled when these disease-specific biological vectors or tools and other equipment serve as mediating agents; vectors for a wide array of pathogenic microorganisms are many, yet common attributes of biological or physical transfer agents benefit development of countermeasures that potentially mitigate transfers by interrupting pathways at CCPs in the chain-of-events required for successful species invasions or transfers of disease agents from one area to another, oftentimes

previously unoccupied area. This annex focuses on a disease agent of amphibians—chytrid fungus, *Batrachochytrium dendrobatidis*—which calls for countermeasures that would also mitigate disease agent transfers coincident with management of other aquatic biota.

5. Significance and Use

5.1 HACCP is a proactive management tool that serves to reduce hazards potentially expressed as adverse biological or environmental effects, for example, associated with chemical releases, changes in natural resource or engineering practices and their related impacts, and accidental or intentional releases of biological stressors such as invasive species.

5.2 Sequential implementation of HACCP and feedback in the iterative HACCP process allows for technically-based judgments concerning, for example, natural resources or the use of natural resources. Implementing the HACCP process serves to reduce adverse effects potentially associated with a particular material or process, and provides guidance for testing and evaluation of products or processes, through a pre-emptive procedure focused on information most pertinent to a system's characterization. For example, identification of CCPs assure that processes and practices can be managed to achieve hazard reduction. For different processes and situations, HA may be based on substantially different amounts and kinds of, for example, biological, chemical, physical, and toxicological data, but the identification of CCPs serving to reduce hazard is key to successful implementation of HACCP.

5.3 HACCP should never be considered complete for all time, and continuing reassessment is a characteristic of HACCP evaluations, especially if there should be changes in, for example, production volumes of a material, or its use or disposal increases, new uses are discovered, or new information on biological, chemical, physical, or toxicological properties becomes available. Similarly, HACCP should be considered an ongoing process serving as a key component in engineering practices, for example, related to construction activities and land-use changes, and natural resource management practices, for example, related to habitat use, enhancement, and species introductions such as fish-stocking programs. Periodic review of a system's performance will help assure that new circumstances and information receive prompt and appropriate attention.

5.4 In many cases, consideration of adverse effects should not end with completion of the HA and identification of CCPs key to the development of control measures. Additional steps may subsequently include risk assessment, and decisions concerning acceptability of identified hazards and risks, and mitigation actions potentially applicable to the process or practice that initially motivated HACCP.

6. Basic Concepts of Hazard Analysis-Critical Control Point (HACCP) Evaluation

6.1 *Overview of HACCP Evaluation*—The basic principle of HACCP relies on system characterization and a repetitive or iterative evaluation of that system and its attendant outcomes. When available data to characterize a system are inadequate and CCPs can not be adequately characterized, data needs are identified and HACCP reiterated. The process is repeated until HA is adequate and CCPs are clearly identified. The HACCP system systematically identifies hazards and measures for their control to ensure the safety of any process, but especially those involving engineering or management practices that manipulate materials, products, or systems potentially associated with adverse effects directly or indirectly associated with those manipulations. HACCP is a tool to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing and inspection. Any HACCP system is capable of accommodating change, such as advances in equipment design, processing procedures or technological developments. This section reviews the 12 tasks in the application of HACCP, including the seven HACCP principles. It emphasizes the importance of standards and guidelines as a basis for developing the HACCP plan.

6.2 *Principles of the HACCP System*—The HACCP system consists of seven principles that guide any evaluation.

6.2.1 Conduct a hazard analysis. Identify the potential hazard(s) associated with at all stages or steps within a system or process of concern within a system. Assess the likelihood of occurrence of the hazard(s) and identify the measures for their control.

6.2.2 Determine the Critical Control Points (CCPs). Determine the points, procedures or operational steps that can be controlled to eliminate the hazard(s) or minimize its (their) likelihood of occurrence. A "step" means any stage in the system, including materials or processes that are part of the system or contribute to the systems form or function, for example, exogenous inputs should have specifications that can be incorporated into HACCP.

6.2.3 Establish critical limit(s). Critical limit(s), also referred to as control limit(s), must be established to ensure the CCP is under control.

6.2.4 Establish a system to monitor control of the CCP. Establish a system to monitor control of the CCP by scheduled testing or observations.

6.2.5 Establish the corrective action to be taken when monitoring indicates that a particular CCP is not under control.

6.2.6 Establish procedures for verification to confirm that the HACCP system is working effectively.

6.2.7 Establish documentation concerning all procedures and records appropriate to these principles and their application.

6.3 *Implementation of the HACCP System*—Management commitment is necessary for implementation of an effective HACCP system. During hazard identification, evaluation, and subsequent operations in designing and applying HACCP systems, consideration must be given to existing technical practices, the role of processes to control hazards, likely end-use of the product (for example, if hazards are associated with manufacturing process), categories of users of concern, and data suggestive of a system being out of control (for example, observation of system failure). The intent of the HACCP system is to focus control at CCPs. Redesign of the operation should be considered if a hazard which must be controlled is identified but no CCPs are found. In complex systems, HACCP should be applied to each specific operation separately. CCPs identified in any given specific implementation might not be the only ones identified for a specific application or might be of a different nature; hence, HACCP will vary as a function of the system. The HACCP application should be reviewed and necessary changes made when any modification is made in the product, process, or any step. It is important when applying HACCP to be flexible where appropriate, given the context of the application, taking into account the nature and the size of the operation.

6.3.1 *Application of HACCP Principles*—Implementation of HACCP principles is captured in the Logic Sequence for Application of HACCP (Fig. 1).

6.3.1.1 Assemble HACCP team. Appropriate process-specific or material-specific knowledge and expertise must be available for the development of an effective HACCP plan. Optimally, this may be accomplished by assembling a multidisciplinary team. Where such expertise is not available on site, expert advice should be obtained from other sources. The scope of the HACCP plan should be identified, including the general classes of hazards to be addressed (for example does it cover all classes of hazards or only selected classes).

6.3.1.2 Describe product or process. A full description of the product or process of concern should be developed.

6.3.1.3 Identify intended use. The intended use should be based on the expected uses of the product or services that will result from completion of an engineering project that may variously affect end users or consumers. In specific cases, vulnerable groups should be considered.

6.3.1.4 Construct flow diagram. The flow diagram should be constructed by the HACCP team. The flow diagram should cover all steps in the operation, for example, associated with a product, material, or engineering activity. When applying HACCP to a given operation, consideration should be given to steps preceding and following the specified operation.

6.3.1.5 On-site verification of flow diagram. The HACCP team should confirm the processing operation against the flow diagram during all stages of operation and amend the flow diagram where appropriate.

6.3.1.6 List all potential hazards associated with each step, conduct a hazard analysis, and consider any measures to control identified hazards as supported by Principle 1. The HACCP team should list all hazards that may be expected to occur at each step of the process, for example, from primary production, processing, manufacture, and distribution until the point of use. The HACCP team should next conduct a hazard analysis to identify and describe for the HACCP plan which hazards are of such a nature that their elimination or reduction to acceptable levels is essential to the production of product or to the engineering process. In conducting the hazard analysis, the following should be included whenever possible: the likely occurrence of hazards and severity of their adverse effects; the qualitative or quantitative evaluation, or both, of the presence of hazards; and conditions leading to the above. The HACCP team must then consider what control measures, if any, exist which can be applied for each hazard. 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.

6.3.1.7 Determine Critical Control Points (CCP). There may be more than one CCP at which control is applied to address the same hazard. The determination of a CCP in the HACCP system can be facilitated by the application of a decision tree which indicates a logic reasoning approach, as illustrated in Annex A1. Application of a decision tree should be flexible, given whether the

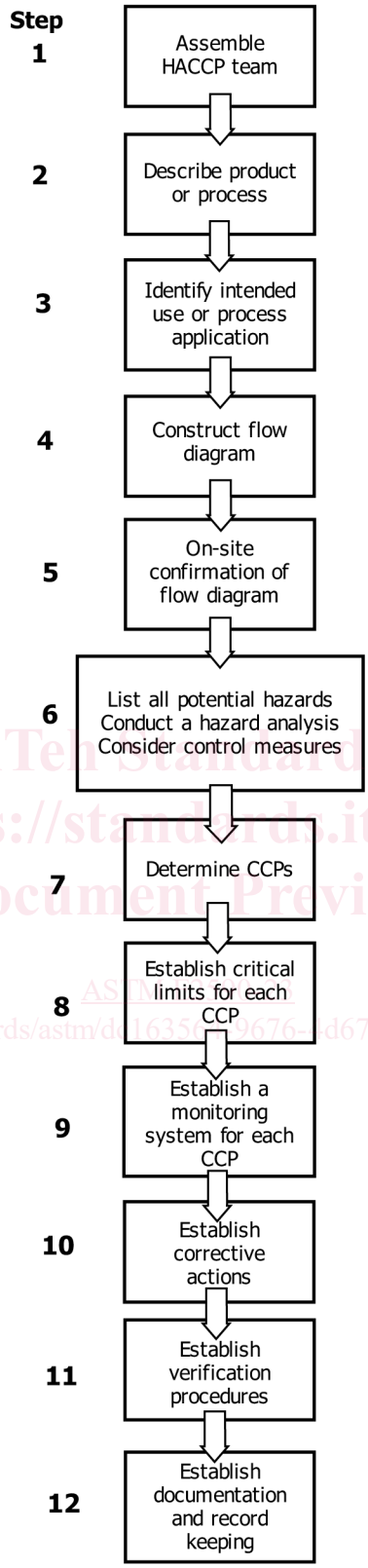

FIG. 1 Overview of HACCP Process

operation production or outcomes of the process being evaluated. The decision tree could be used for guidance when determining CCPs, although a decision tree may not be applicable to all situations. Other approaches may be used, and training in the application of the decision tree is recommended, if that approach to HACCP is pursued. If a hazard has been identified at a step

where control is necessary for safety, and no control measure exists at that step, or any other, then the product or process should be modified at that step, or at any earlier or later stage, to include a control measure.

6.3.1.8 Establish critical limits for each CCP. Limits must be specified and validated if possible for each CCP. In some cases more than one critical limit will be elaborated at a particular step. Criteria may capture upper and/or lower bounds of acceptable performance, and may be specified by indicators benchmarked on past performance.

6.3.1.9 Establish a monitoring system for each CCP. Monitoring is the scheduled measurement or observation of a CCP relative to its critical limits. The monitoring procedures must be able to detect loss of control at the CCP. Further, monitoring should ideally provide data in real-time to make adjustments to ensure control of the process to prevent violating the critical limits. Where possible, process adjustments should be made when monitoring results indicate a trend towards loss of control at a CCP. The adjustments should be taken before a deviation occurs. Data derived from monitoring must be evaluated by a designated person with knowledge and authority to carry out corrective actions when indicated. If monitoring is not continuous, then the amount or frequency of monitoring must be sufficient to guarantee the CCP ~~d~~is in control. Most monitoring procedures for CCPs will need to be done rapidly because they relate to on-line processes or real-time activities that may not allow for lengthy analytical testing. All records and documents associated with monitoring CCPs must be signed by the person(s) doing the monitoring and by a responsible reviewing official(s).

6.3.1.10 Establish corrective actions. Specific corrective actions must be developed for each CCP in the HACCP system in order to deal with deviations when they occur. The actions must ensure that the CCP has been brought under control, including actions that must be taken for proper disposition of the affected product, for example, in the food industry. Deviation and product disposition procedures must be documented in the HACCP record keeping similar in practice to establishing risk management practices wherein acceptable risk is characterized.

6.3.1.11 Establish verification procedures. Establish procedures for verification. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. The frequency of verification should be sufficient to confirm that the HACCP system is working effectively. Examples of verification activities include: review of the HACCP system and its records; review of deviations and product dispositions; confirmation that CCPs are kept under control. Where possible, validation activities should include actions to confirm the efficacy of all elements of the HACCP plan.

6.3.1.12 Establish documentation and record keeping. Efficient and accurate record keeping is essential to the application of an HACCP system. HACCP procedures should be documented. Documentation and record keeping should be appropriate to the nature and size of the operation. Documentation examples are hazard analysis; CCP determination; Critical limit determination. Record examples are: CCP monitoring activities; Deviations and associated corrective actions; Modifications to the HACCP system.

6.4 *Expanded Characterization of HACCP Process*—The first task in the application of HACCP is to assemble a team having the knowledge and expertise to develop an HACCP plan. The team should be multidisciplinary and should represent a blend of expertise and experience. The assembled team will collect, collate and evaluate technical data and identify hazards and critical control points. One person may fulfill several roles or even constitute the whole team, in which case the use of external consultants or advice may be necessary. The team should include personnel who are directly involved in daily activities related to the hazards of concern, since these individuals will be more familiar with the specific variability and limitations of the operation or materials in question. The HACCP team may require independent outside experts to advise on identified issues or problem areas; however, complete reliance on outside sources is not recommended in developing the HACCP plan. Ideally the team should not be larger than six, although for some implementations of HACCP, it may be necessary to develop larger teams.

6.4.1 *Team Composition*—When selecting the team, the coordinator should focus on those who will be involved in hazard identification, those who will be involved in determination of critical control points, those who will monitor critical control points, those who will verify operations at critical control points, those who will examine samples and perform verification procedures.

6.4.2 *Knowledge Required*—In addition to knowledge of HACCP principles and techniques, personnel participating as part of the HACCP team should have a basic understanding of technology and procedures characteristic of the process or material that initiated the HACCP evaluation, as well as a basic understanding of the particular hazard(s) that the plan will address.

6.4.3 *Scope*—One of the first tasks of the HACCP team should be to identify the scope of the HACCP plan. The team should limit the study to a specific material and process, define the type(s) of hazards to be included (for example biological, chemical, physical), define the system or part of the system to be studied.

6.4.4 *Coordinator*—The team must include a coordinator (chairperson) whose role is to ensure that the composition of the team meets the needs of the study, suggest changes to the team if necessary, coordinate the team's work, ensure that the agreed established plan is followed, share the work and responsibilities, ensure that a systematic approach is used, ensure that the scope of the study is met, chair meetings so that team members can freely express their ideas, represent the team before management, provide management with an estimate of the time, money and labor required for the study.

6.4.5 *Develop a Flow Diagram*—It is easier to identify hazards and CCPs to suggest methods of control and to discuss these among the HACCP team if there is a flow diagram of the system linked to the hazard of interest. The review of the flow of materials or the process in the system from the beginning to end is the feature that makes HACCP a specific and important tool for the identification and control of potential hazards. A process flow diagram should be constructed following interviews, observation of operations and other sources of information, for example, such as engineering design or field operations manuals. The process flow diagram will identify the important process steps used in the production of the specific material or specific operation being assessed. There should be enough detail to be useful in hazard identification, but not so much as to overburden the plan with less important points.

6.4.6 *Hazard Analysis*—Hazard analysis is the first HACCP principle, and is one of the most important tasks of HACCP. An inaccurate hazard analysis would inevitably lead to the development of an inadequate HACCP plan. Hazard analysis requires technical expertise and scientific background in various domains for proper identification of all potential hazards.

6.4.7 *Critical Control Points and Critical Limits*—At each CCP critical limits are established and specified. Critical limits are defined as criteria that separate acceptability from unacceptability. A critical limit represents the boundaries that are used to judge whether a process is producing materials or conducting specific operations in a safe manner. Critical limits may be set for factors, for example, such as temperature, time (minimum time exposure), physical dimensions, as these attributes affect system performance. These parameters, if maintained within boundaries, will confirm the safety of the system of interest.

6.4.8 *Monitoring*—Monitoring is the process that users rely upon to show that the HACCP plan is being followed. It provides the user with accurate records that demonstrate that the conditions of system are in compliance with the HACCP plan. Ideally, monitoring should provide information in time to allow any adjustments to the process, thus preventing loss of control of the process and critical limits being exceeded. In practice, operating limits are often used to provide a safety margin which allows extra time to adjust the process before the critical limit is exceeded. There are many ways to monitor the critical limits of a CCP. Monitoring can be done on a continuous (100 percent) or batch basis. When feasible, continuous monitoring is preferred, since it is more reliable. Continuous monitoring is designed to detect shifts around target levels, thus allowing correction of these shifts and preventing deviation beyond the critical limits. When monitoring is not continuous, the amount and frequency of monitoring should be sufficient to provide an acceptable level of assurance that the CCP is under control. The higher the frequency of monitoring (that is, the less time between each instance of monitoring), the less system performance will be affected when there is a loss of control at the CCP. A further consideration when establishing a monitoring system is the time taken to achieve a result from the monitoring procedure. Most monitoring procedures will need to be rapid, since time for lengthy analytical testing may not be practical. For this reason, physical and chemical measurements or visual observations, which may be done rapidly, are often preferred as monitoring tools. If analytical instrumentation is used in a monitoring program, it is essential that all monitoring equipment be properly calibrated for accuracy. Monitoring procedures performed during the operation should result in written documentation which will serve as an accurate record of the operating conditions. Monitoring records provide information on conditions during the operation and allow for action to be taken in the event of a loss of control or for a process adjustment to be made if there is a trend towards a loss of control. Accurate monitoring procedures and associated records provide information to the operator and allow for decisions to be made on the acceptability of the lot at a particular stage in the process. To complete the monitoring process, data derived from monitoring should be reviewed and evaluated by a designated person or persons with knowledge and authority to carry out corrective actions when indicated. The worst scenario is that in which monitoring procedures indicate that any one of the critical limits is exceeded, which indicates loss of control of a CCP. This lack of control is considered to be a deviation resulting in the production of a hazardous or unsafe product. The situation requires immediate identification and control of the affected product and corrective action. Responsibility for monitoring should be clearly defined, and individuals must be adequately trained in the monitoring procedures for the CCP for which they are responsible. They must also fully understand the purpose and importance of monitoring. The individual should have ready access to the monitoring activity, must be unbiased in monitoring and must accurately report the monitoring activity.

6.4.9 *Design of a Monitoring System and Establishing Corrective Actions*—Loss of control is considered as a deviation from a critical limit for a CCP. Deviation procedures are a predetermined and documented set of actions to be implemented when a deviation occurs. All deviations must be controlled by taking action(s) to control the non-compliant product or process and to correct the cause of non-compliance. Product or process control includes proper identification, control and disposition of the

variance. The control and disposition of the variance and the corrective action(s) taken must be recorded and filed. The diversity of possible deviations at each CCP means that more than one corrective action may be necessary at each CCP. When a deviation occurs, it will most likely be noticed during the routine monitoring of the CCP. Deviation and corrective action procedures are prescribed so that employees responsible for CCP monitoring understand and are able to perform the appropriate corrective action(s) in the event of a deviation. Process adjustments should also be made when monitoring results indicate a trend towards loss of control at a CCP. Action should be taken to bring the process within the operating limits before a deviation occurs. The deviation procedures at each CCP should be recorded.

6.4.10 *Deviation and Corrective Action Procedures*—Since the main reason for implementing HACCP is to prevent problems from occurring, corrective action should be taken to prevent deviation at a CCP. Corrective action should be taken following any deviation to ensure the safety of the product or process, and to prevent recurrence of the deviation. Corrective action procedures are necessary to determine the cause of the problem, take action to prevent recurrence and follow up with monitoring and reassessment to ensure that the action taken is effective. If the corrective action does not address the root cause of the deviation, the deviation could recur. Reassessment of the hazard analysis or modification of the HACCP plan may be necessary to eliminate further occurrence.

6.4.11 *Deviation and Corrective Action Records*—Records should be available to demonstrate the control of products affected by the deviation and the corrective action taken. Adequate records permit verification that the producer has deviations under control and has taken effective corrective action.

6.4.12 *Deviation Procedures and Verification*—Verification is embodied in HACCP principles, and serve to determine compliance with the HACCP plan by using methods, procedures, tests and other evaluations as needed, in addition to monitoring. Verification and auditing methods, procedures and tests, including random sampling and analysis, can be used to determine if the HACCP system is working correctly. Careful preparation of the HACCP plan with clear definition of all the necessary items does not guarantee the plan's effectiveness. Verification procedures are necessary to assess the effectiveness of the plan and to confirm that the HACCP system adheres to the plan. Verification allows the producer to challenge the control measures and to ensure that there, is sufficient control for all possibilities; for example, verification may ensure that adequate contingency procedure plans are in place when critical limits are exceeded at a CCP. Verification should be undertaken by an appropriately qualified individual or individuals who are capable of detecting deficiencies in the plan or its implementation. Verification should be undertaken at the completion of the HACCP study; whenever there is a change in product, ingredients, process, etc.; when a deviation occurs; in the event of newly identified hazards; and at regular predetermined intervals. Routine monitoring activities for critical limits should not be confused with verification methods, procedures or activities.

6.4.13 *Description of Verification Activities*—Each HACCP plan should include verification procedures for individual CCPs and for the overall plan. HACCP plans are expected to evolve and to improve with experience and new information. Periodic verification helps improve the plan by exposing and strengthening weaknesses in the system and eliminating unnecessary or ineffective control measures. Verification activities include HACCP plan validation, HACCP system audits, equipment calibration, targeted sample collection and testing.

6.4.14 *HACCP Plan Validation*—Validation is the act of assessing whether the HACCP plan for the particular product and process adequately identifies and controls all significant hazards or reduces them to an acceptable level. HACCP plan validation should include review of the hazard analysis, CCP determination, justification for critical limits, based for example on current good science and regulatory requirements, determination of whether monitoring activities, corrective actions, record keeping procedures and verification activities are appropriate and adequate, validation involves ensuring that the HACCP plan is based on methods and information sufficient to identify hazards and identify CCPs, and is appropriate for the system of interest. A technical review should be performed to ensure that there is a scientific and technical basis for decisions regarding which hazards are being controlled, which hazards are not being controlled and how identified hazards are being controlled. This review could incorporate the use of information and data gathered for the purpose of the verification, and should be periodically updated. The process of validating an existing HACCP plan should also include review of HACCP audit reports, review of changes to the HACCP plan and the reasons for those changes, review of past validation reports, review of deviation reports, assessment of corrective action effectiveness, review of information on consumer complaints, review of linkages between the HACCP plan and good management practice (GMP) programs. HACCP plan validation is an ongoing, periodic procedure. Validations may be scheduled at a pre-set frequency. However, other factors may trigger a review of the plan to determine if changes are necessary. These factors could include changes to the raw materials, product or process; adverse audit findings; recurring deviations; new scientific information about potential hazards or control measures; and user complaints and/or failures or under performance of the system.

6.4.15 *HACCP System Audits*—As part of verification, audits are performed to compare the actual practices and procedures of the HACCP system with those written in the HACCP plan. Audits are systematic and independent examinations involving on-site

observations, interviews and review of records to determine whether the procedures and activities stated in the HACCP plan are implemented in the HACCP system. These examinations are usually performed by one or more independent persons who are not involved in implementation of the HACCP system. Audits may be performed for individual CCPs and/or for the overall plan. On-site observation may include, for example, visual inspection to ensure that system description and flow chart are accurate, monitoring required by the HACCP plan at the CCPs is performed, processes are operating within established critical limits, records are filled out accurately and at the time observations are made. Records to be reviewed during auditing of the HACCP plan include, for example, those demonstrating that monitoring activities have been performed at the locations specified in the HACCP plan, monitoring activities have been performed at the frequencies specified in the HACCP plan, affected systems have been controlled and corrective actions have been taken whenever monitoring has indicated the occurrence of a deviation from critical limits, equipment has been calibrated at the frequencies specified in the HACCP plan. Audits should occur frequently enough to ensure that the HACCP plan is being followed continuously. This frequency depends on a number of conditions, such as the variability of the process and materials.

6.4.16 *Calibration*—Calibration involves checking instruments or equipment against a standard to ensure accuracy. Calibration should be documented and the records should be available for review during verification. Calibration of appropriate equipment and instruments used in the development and, implementation of the HACCP plan should be carried out, during monitoring or verification, or both, at a frequency sufficient to assure continuous accuracy, according to procedures established in the HACCP plan (which can be based on instrument or equipment manufacturer specifications), by checking accuracy against a recognized standard, under conditions similar or identical to those under which the instrument or equipment will be used. Calibration of CCP monitoring equipment is important; if the equipment is out of calibration, then monitoring results will not be accurate and may be completely unreliable. When the equipment monitoring a CCP is out of calibration, the CCP is considered to have been out of control since the last documented calibration.

6.4.17 *Targeted Sample Collection and Testing*—Verification may also include targeted sampling and testing and other periodic activities. Targeted sampling and testing involves taking samples of materials or products periodically and testing them to ensure that critical limits are appropriate for product safety. Targeted sampling may be carried out to check vendor compliance when receipt of material is a CCP and purchase specifications are relied on as critical limits. When critical limits are set for equipment operation, materials or products may be sampled to ensure that the equipment settings are appropriate. When sampling and testing is used as a verification tool, the usefulness of the test often depends on how the material is sampled. The risk and level of confidence needed will determine the sample size and the method of sample collection.

6.4.18 *Verification Frequency*—Verification activities should be performed according to a pre-established schedule described in the HACCP plan or whenever there are indications that the system status may have changed. These indications may include observations that CCPs may not be operating within critical limits, record reviews indicating inconsistent monitoring, record reviews indicating that CCPs are repetitively operated outside critical limits, user complaints, or acquisition of data previously unavailable for the evaluation. Verification procedures should be scheduled at a frequency that ensures that the HACCP plan is being followed continuously and that measurements remain accurate within established limits. Thus, the length of time between scheduled verification activities should match the level of confidence in the continuous and accurate performance of the HACCP plan. The frequency of verification activities may change over time. A history of verification activities indicating that the process is consistently in control may support safe reduction of the frequency of verification activities.

6.4.19 *Records of Verification*—Verification activities should be documented in the HACCP plan. Records should be made of the results of all verification activities. Records of verification should include methods, date, individuals and/or organizations responsible, results or findings and action(s) taken. Verification procedures for the overall HACCP plan should be documented in a file for the HACCP plan.

6.4.20 *Regulatory Verification*—Verification should be a routine part of regularly scheduled government inspections, if those activities are included in the HACCP plan. Regulatory verification should also involve review and/or audit of the adherence to the HACCP system to its HACCP plan. Compliance actions should be taken when regulatory verifications indicate deficiencies in the HACCP plan or implemented HACCP system.

6.4.21 *Documentation and Record Keeping*—Records are essential for reviewing the adequacy of the HACCP plan and the adherence of the HACCP system to the HACCP plan. A record shows the process history, the monitoring, the deviations and the corrective actions that occurred at the identified CCP. It may be in any form, for example processing chart, written record, computerized record. The importance of records to the HACCP system cannot be overemphasized. It is imperative that the producer maintain complete, current, properly filed and accurate records. Four types of records should be kept as part of the HACCP program: support documentation for developing the HACCP plan, records generated by the HACCP system,

documentation of methods and procedures used, records of employee training programs. Procedures documenting version control and document management to prevent outdated or incorrect procedures from being used should be described in an HACCP plan.

6.4.21.1 *Support Documents*—HACCP plan support documents include information and support data used to establish the HACCP plan such as the hazard analysis and records documenting the scientific basis for establishing the CCPs and critical ~~limits.~~ limits, and may include an emergency response plan describing actions to take upon release of materials. Examples include data used to establish the control measures and data used to establish the adequacy of critical limits. Support documents should also include a list of the HACCP team members and their responsibilities, as well as all the forms produced during the preparation of the HACCP plan. Including description of materials, process, or system of concern, flow diagram, hazard analysis, identification of CCPs, identification of the critical limits for each CCP (including data from experimental studies or information collected to support the critical limits), documented deviation and corrective action plans, planned verification activities and procedures, and identification of the preventive measures for each hazard. Support documents may also include correspondence with consultants, as well as documents detailing how the HACCP plan was developed.

6.4.21.2 *Records Generated by the HACCP System*—HACCP system records are kept to demonstrate adherence of the HACCP system with the HACCP plan. These records are used to demonstrate control at CCPs. By tracking records generated by the HACCP system, a system user can become aware that a process is approaching its critical limit. Review of records can be instrumental in identifying trends and in making operational adjustments. Timely corrective action can be taken if a critical limit is violated. The required HACCP records to be kept at each CCP should be written, for example, on standard forms. Failure to document the control of a CCP would be a critical departure from the HACCP plan. The records generated by the HACCP system include all activities and documentation required by the plan, as follows:

(1) Monitoring Records for All CCPs—All HACCP monitoring records should be kept on forms that contain the following information: form title, time and date, process or material identification, critical limits, monitoring observation or measurement, operator's signature or initials, corrective action taken, where applicable, and reviewer's signature or initials with date of review.

(2) Deviation and Corrective Action Records—These records should document variance from acceptable limits with identification of the deviation, nature and extent of deviation, information on the disposition of outcomes occurring during deviation, and description of the corrective action with documentation of return to acceptable performance.

(3) Verification/Validation Records—Verification and validation may be documented through in-house on-site inspections, equipment testing and evaluation, accuracy and calibration of monitoring equipment, and results of verification activities (including methods, date, individuals and/or organizations responsible, results or findings and action taken).

ANNEXES

(Mandatory Information)

A1. HACCP APPLIED TO PREVENTION AND CONTROL OF INVASIVE SPECIES

A1.1 Background

A1.1.1 Implementation of the HACCP process has been incorporated into natural resource management practices focused on various aspects of invasive species, ranging from prevention programs to control and mitigation. Annex A1 summarizes HACCP and its application to the prevention and control of invasive species. This annex extends the general guidance contained within this standard to a specific application of the HACCP process. The annex may serve as a "stand alone" document to support the development of species-specific or practice-specific HACCP plans developed in response to natural resource management needs linked to invasive species. The relationships between the generalized HACCP process summarized in the standard and its specific implementation in this annex, however, should be considered in adapting HACCP plans to, for example, changing environmental conditions that might develop and alter hazards through time. Tasks outlined in the standard guide have been variously incorporated into the implementation-specific five-step HACCP process which was framed within the context of the guiding principles of HACCP specified in this standard. Additionally, in recognizing the dynamic process associated with species invasions, users of this stand-alone annex would benefit from consultation with online resources that directly complement this implementation of HACCP (http://www.haccp-nrm.org/ last accessed June 16, 2014).

A1.1.2 *Managing Natural Resource Pathways*—In natural resource work, equipment and organisms are often moved from one