



Designation: E2590 – 23

Standard Guide for Conducting Hazard Analysis-Critical Control Point (HACCP) Evaluations¹

This standard is issued under the fixed designation E2590; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

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 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.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.

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 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 socioeconomic 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

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.

Current edition approved Dec. 1, 2023. Published December 2023. Originally approved in 2008. Last previous edition approved in 2015 as E2590-15. DOI: 10.1520/E2590-23.

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

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:

	Section
Scope	1
Referenced Documents	2
Descriptions of Terms Specific to This Standard	3
Summary of Guide	4
Significance and Use	5
Basic Concepts of HACCP and Detailed Characterization of HACCP	6
HACCP Applied to Prevention and Control of Invasive Species	Annex A1
HACCP-Derived Decontamination Procedures Mitigating Equipment-Mediated Transfers of Invasive Aquatic Biota, Principally Mussel Species	Annex A2
HACCP-Derived Decontamination Procedures for Controlling Equipment-Mediated Transfers of Disease Agents of Aquatic Biota, Principally Infectious Amphibian Diseases	Annex A3

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, 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.

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

3.1.3 *control 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*, *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)*, *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*, *n*—a criterion which separates acceptability from unacceptability.

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

3.1.8 *flow 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)*, *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*, *n*—a document prepared in accordance with the principles of HACCP to ensure control of hazards.

3.1.11 *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)*, *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*, *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*, *n*—a point, procedure, operation or stage in a process.

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

3.1.16 *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

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.