Designation: D8250 – 19

Standard Practice for Applying a Hazard Analysis Critical Control Points (HACCP) System for Cannabis Consumable Products[1]

This standard is issued under the fixed designation D8250; 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 practice addresses the principles to follow when implementing and managing a Hazard Analysis Critical Control Point (HACCP) system for cannabis consumable products. This practice is not intended for cannabis industrial products (e.g., hemp products).

1.2 *Units*—The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. 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.*

1.4 *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:*[2]

E2590 Guide for Conducting Hazard Analysis-Critical Control Point (HACCP) Evaluations

2.2 *Other Documents:*

HACCP Principles and Applications Guidelines[3]

General Principles of Food Hygiene[4]

3. Terminology

3.1 *Definitions:*

3.1.1 *cannabis consumable products*—cannabis products that are directly consumed by people or animals either through ingestion or inhalation.

3.1.2 *Codex Alimentarius*—collection of internationally recognized standards, codes of practice, guidelines, and other recommendations relating to foods, food production, and food safety.

3.1.3 *control*—management of a condition to ensure that the compliance to a criterion is being met.

3.1.4 *control point*—step in which a biological, chemical (including radiological), and physical hazard can be controlled.

3.1.5 *correction*—immediate action taken to correct a non-conformance.

3.1.6 *corrective action*—action taken to correct a non-conformance; it requires that the root cause is identified to ensure that the non-conformance does not re-occur.

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

3.1.8 *critical limit*—maximum and/or minimum value to which a biological, chemical, or physical parameter shall be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard.

3.1.9 *deviation*—failure to meet a critical limit.

3.1.10 *hazard analysis critical control point (HACCP)*—a systematic approach to the identification, evaluation, and control of hazards that may be present in cannabis consumable products.

3.1.11 *HACCP team*—a multidisciplinary group of people that work at the site and are responsible for developing, implementing, and maintaining a HACCP system.

3.1.12 *hazard*—biological, chemical (including radiological), or physical agent that can cause harm to the consumer when it is not controlled.

3.1.13 *hazard analysis*—the process of collecting and evaluating information about the hazards associated with the cannabis consumable product to determine its significance and whether it needs to be addressed in the HACCP system.

[1] This practice is under the jurisdiction of ASTM Committee D37 on Cannabis and is the direct responsibility of Subcommittee D37.02 on Quality Management Systems.

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[2] 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] National Advisory Committee on Microbiological Criteria for Foods, August 14, 1997 (www.fda.gov).

[4] Codex Alimentarius, Food and Agriculture Organization (FAO) CA/RCP 1-1969, Rev 4. 2003.

3.1.14 *monitoring*—to conduct a series of pre-planned observations and/or measurements to assess whether the CCP is under control and to generate records that will be used for verification purposes.

3.1.15 *pre-requisite programs (PRP)*—procedures, including good manufacturing practices (GMPs), that address operational conditions that provides the foundation for the HACCP system.

3.1.16 *preventive actions*—actions taken to prevent nonconformances.

3.1.17 *severity*—the seriousness of the effect(s) of the hazard.

3.1.18 *step*—a point, procedure, operation, or stage in the operation from primary production to final consumption.

3.1.19 *validation*—collection and evaluation of scientific and technical information to determine if the HACCP system, when properly implemented, will control the hazard.

3.1.20 *verification*—those activities, other than monitoring, that determine that the HACCP system is valid and is operating as written.

4. Summary of Practice

4.1 Sites that are engaged in the production of cannabis consumable products shall implement pre-pequisite programs (PRPs), including good manufacturing practices (GMPs), prior to the application of a HACCP system. These PRPs shall promote good hygiene and operational control practices as outlined in the Codex Alimentarius and/or the regulations of the country where the cannabis consumable product is being manufactured. These PRPs shall be well-established, operational, and verified to ensure successful development and implementation of the HACCP system. Pre-Requisite Programs (PRPs) shall include operational and sanitary controls that ensure the hygienic and safe processing of cannabis consumable products. For all types of businesses that manufacture cannabis consumable products, management awareness and commitment are necessary for the implementation of a HACCP system. Training is essential as the effectiveness of the system depends greatly on management and employees having the appropriate knowledge and skills to competently complete their functions within the operations. The PRPs and HACCP system shall be site specific and, therefore, shall address the processes and hazards associated with the site and/or operation. The HACCP system shall be reviewed *(1)* at a minimum annually, *(2)* when new cannabis consumable products are developed, *(3)* when any modification is made to the cannabis consumable product, equipment or process step, or *(4)* when new regulatory requirements are established. The five preliminary steps and the seven principles outlined in the Codex Alimentarius shall be applied when developing the HACCP system. The preliminary steps and the seven principles are outlined in Section 6.

5. Significance and Use

5.1 This practice provides general guidelines for the development and implementation of a HACCP system for operations that manufacture cannabis consumable products to prevent, control, or minimize hazards (biological, chemical, or physical) to an acceptable level. A HACCP system can prevent consumer harm when implemented and followed correctly.

6. Practice

6.1 The application of the HACCP principles shall be done in the sequential steps outlined as follows:

6.1.1 *Preliminary Step 1: Assemble the HACCP Team*—The HACCP team shall consist of individuals that have specific knowledge and expertise about the product and the operations. This can be accomplished by having a multidisciplinary team that includes all areas of the operation, such as engineering, production, quality assurance, maintenance, and sanitation. It is the team's responsibility to develop, implement, and review the HACCP system. The individuals on the HACCP team shall work on the site where the cannabis consumable products are manufactured. The team may need assistance from external resources, such as consultants, trade association experts, and regulatory authorities, that have knowledge of biological, chemical (including radiological), and physical hazards that may be associated with the processes and the products. However, caution shall be exercised when using external resources. External resources shall never replace the expertise of the site's HACCP team. The team shall be fully involved during the development of the HACCP system as relying on the technical experts alone may lead to a system that is erroneous, incomplete, and lacking local personnel support. The HACCP team is responsible for ensuring that record review is done within seven working days and that re-analysis of the HACCP system is completed once a year, when new products are developed, when significant changes occur in product, equipment or process step, or if there are new regulatory requirements. Records of the HACCP team members, function within the team, and experience shall be part of the records included in the HACCP system (refer to Appendix X1 for an example of a HACCP team). Records of training and competency for the members of the HACCP team shall also be included.

6.1.2 *Preliminary Step 2: Describe the Product*—A full description of the cannabis consumable product shall be developed by the HACCP team. The product description shall include information that is relevant to the food safety of the cannabis consumable product, such as composition (e.g., ingredients), chemical composition relevant to the cannabis consuming product safety (e.g., water activity, pH, etc.), packaging (type and size), shelf life, storage conditions, and distribution methods. Each product manufactured shall have its own description.

6.1.3 *Preliminary Step 3: Identify Intended Use*—Describe the intended use of the product. The intended use shall be based on the expected use of the product by the end consumer. Cannabis consumable products may be intended for recreational, medicinal, or nutritional use, etc. In addition, cannabis consumable products may be intended to be consumed by ingestion or inhalation. In specific cases, vulnerable groups of the population (e.g., immunocompromised individuals) may need to be considered. Appendix X2 shows an example of documenting the product description and its intended use.

6.1.4 *Preliminary Step 4: Develop a Flow Diagram*—A flow diagram is a sequence of steps followed to manufacture the cannabis consumable product. The purpose of the flow diagram is to provide a clear overview of the steps that are followed on site in order to manufacture the cannabis consumable product. The same flow diagram can be used for different cannabis consumable products, if they follow the same process. The steps preceding and following the operational steps shall be taken into consideration when developing the flow diagram.

6.1.5 *Preliminary Step 5: Verify the Flow Diagram*—The flow diagram shall be verified by the HACCP team during the initial development and yearly after implementation of the HACCP system. HACCP flow chart(s) shall also be verified when changes to process(es) or equipment(s) are made. The verification shall take place at the manufacturing site during all times of operation to ensure the accuracy of the flow diagram. This verification is not done at the desk, but rather, by walking through the facility and following the sequence of steps outlined in the diagram. Modifications to the flow diagram shall be made if discrepancies are found during the verification process. The verifier(s) shall sign and date the flow diagram upon completion of its verification.

6.1.6 *Principle 1: Conduct a Hazard Analysis*—The HACCP team shall conduct a hazard analysis once the five preliminary steps are completed. The purpose of conducting a hazard analysis is to identify significant hazards that most likely can cause harm to the consumer of the cannabis consumable product. All potential hazards (i.e., biological, chemical (including radiological), and physical) shall be considered for each step of the process when conducting a hazard analysis. In addition, a hazard analysis shall be conducted for all ingredients that are used to manufacture the final cannabis consumable product (e.g., cannabis flower, extracted oil, etc.), packaging, and auxiliary materials used on site to manufacture the final cannabis product. Once the potential hazards are identified, they shall be characterized. Characterization is based on the likelihood of occurrence and the severity of the outcome if the hazard is not controlled. Justification shall be provided when determining the likelihood of occurrence and the severity of the outcome for each identified hazard. Risk matrices have been proven to be effective tools for risk characterization (refer to Appendix X3). Only steps with significant hazards shall be considered further during the HACCP system development. Cannabis consumable product safety concerns shall be differentiated from quality concerns when conducting the hazard analysis to develop the HACCP system. Only address hazards that can cause adverse health effects or harm to the consumer of the product. It is important that the hazard analysis is conducted very meticulously. If the hazard analysis is not done correctly, a hazard requiring control will not be identified, and the HACCP system will not be effective regardless of how well it is being followed. Hazards identified at one site or operation may not be significant at another operation with similar process or producing the same or similar product. Therefore, emphasis shall be made on the fact that hazard analysis shall be site specific. Appendix X4 provides an example of a hazard analysis table for ingredients and process. The suggested table for the process hazard analysis includes the CCP decision tree questions (refer to Appendix X5).

6.1.7 *Principle 2: Determine Critical Control Points (CCPs)*—A critical control point is a step in which control can be applied. It is essential to prevent, eliminate, or reduce the hazard to an acceptable level. Only significant hazards shall be considered when determining the CCPs. A decision tree is a tool that can be used to determine the steps of the process that provide essential control of the hazard (refer to Appendix X5). However, the decision tree shall not substitute the knowledge of experts. Critical control points are located at any step of the process where the hazard shall be prevented, eliminated, or reduced to an acceptable level. Facilities manufacturing the same or similar products may have different critical control points due to ingredient and/or processing differences. If the hazard analysis does not lead to the identification of critical control points, the process stops at the hazard analysis.

6.1.8 *Principle 3: Establish Critical Limits (CLs)*—Critical limits establish the minimum and/or maximum value at which the hazard is prevented, eliminated, or reduced to an acceptable level. Critical limits distinguish between safe and unsafe conditions at a given CCP and shall not be confused with operational limits, which are established for different purposes. Critical limits shall be validated (have scientific basis) prior to implementation.

6.1.9 *Principle 4: Establish Monitoring Procedures*—Monitoring procedures are a series of pre-planned activities of observations that shall be done for each critical limit at each identified CCP to ensure that the hazard is under control. When designing monitoring procedures, it is important to assign the responsibility to key individuals responsible for the CCP. It is also important to establish the frequency at which the monitoring activity is performed, outline what is being monitored, and how it is being monitored. Personnel responsible for the monitoring shall be trained on the procedures related to this activity. All records generated during the monitoring process shall be dated, initialed and/or signed by the employee responsible for this activity. Records generated during monitoring shall be reviewed by an authorized and trained employee within seven working days of being generated to ensure that the activities are being followed as written in the plan.

6.1.10 *Principle 5: Establish Corrective Actions*—Although the HACCP system is designed to control hazards, ideal circumstances do not always happen, and deviations may occur. Therefore, it is very important to have a plan in place that prevents harmful cannabis consumable products from reaching the consumer. Corrective actions shall be pre-planned and shall include the steps that shall be followed to bring the hazard under control and the disposition of the affected cannabis consumable product during the deviation. It is important to determine and correct the root cause of the non-conformance in order to prevent re-occurrence. Employees responsible for a process step at which a CCP has been established shall be trained on the pre-established corrective actions procedure to ensure that any affected cannabis consumable product does not reach the consumer if a deviation occurs.