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Standard Guide for Processing Cannabis Product Complaints¹

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1. Scope

1.1 This guide is applicable to organizations engaged in the cultivation, processing, testing, packaging and labeling, storage, distribution, or transportation of cannabis products intended for human and animal consumption, including those derived from hemp. This guide describes the minimum requirements for maintaining a product complaint system for finished cannabis products and ensures that all complaints are received, processed, investigated, documented, and appropriate corrective and preventive actions are implemented in a timely manner.

1.2 This guide applies to all cannabis-derived products commercially manufactured and distributed for consumer use.

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

1.4 *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.*

1.5 *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. Terminology

2.1 For definitions of terms see ASTM Standards: D37-WK60576 (in process at ASTM) Standard Terminology Relating to Cannabis.

2.2 Definitions of Terms Specific to This Standard:

2.2.1 *complaint, n*—any written, electronic or verbal communication that alleges deficiencies, non-conformance to specifications, or adulteration in the product after it is released for distribution.

2.2.2 *complainant, n*—person who reports complaint.

2.2.3 *corrective action and preventive action (CAPA), n*—systematic approach that includes actions needed to correct, avoid occurrence, and eliminate the cause of potential nonconforming product and other quality problems.

2.2.4 *quality, n*—degree to which a set of inherent characteristics fulfills requirements.

2.2.5 *quality issue, n*—any issue that may negatively impact product quality.

2.2.6 *quality management, n*—coordinated activities to direct and control an organization in regard to quality.

2.2.7 *root cause, n*—factor that caused the concerning condition.

2.2.8 *trend, n*—sequence or pattern of data.

3. Significance and Use

3.1 A product complaints program is an essential part of the organization's Quality Management System. The ability to document, investigate, and correct issues related to product complaints provides manufacturers with opportunities for improvement. Putting in place appropriate corrective and preventive actions can lead to increased customer satisfaction, product safety, and increased market share.

3.2 Requirements of regulatory bodies or governmental departments supersede the recommendations in this guide.

4. Procedure

4.1 Product labeling should include contact information for the manufacturer that allows consumers to promptly and easily report complaints.

4.2 A manual or electronic system should be established to track and manage product complaints. This system ensures that complaints are appropriately investigated and trended, that the potential or actual product quality or health risks are identified, and corrective and preventive actions (CAPA) are implemented. Recurring similar complaints may not require new investigations but may require CAPA.

4.3 A unique control number should be issued to each product complaint as well as a category (e.g., medical vs. non-medical), type of complaint (e.g., particulate, discoloration, off-odor, labeling, defective product, etc.), and prioritization.

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4.4 Complaint files should include complainant information, date complaint was received, product name, lot number, cannabinoid content/profile, returned product obtained, nature of complaint, reply to complainant and other information where applicable.

4.5 The written record shall include the findings of the investigation and follow-up. Where an investigation is not conducted, the written record shall include the reason that an investigation was found not to be necessary and the name of the responsible person making such a determination. Product complaint investigations should include a review of applicable production records and lab testing records. If a production record review is not conducted, there must be a documented explanation for why review was not necessary. Root cause analysis tools should be used to ensure the correct root cause is found.

4.6 Controls should be put in place to assure appropriate management review and evaluation of all product complaints, identified trends, implementation of corrective and preventive actions, and final approval by Quality Assurance for complaint closure or product recall for finished products (where necessary).

4.7 The complaints system should archive all closed product complaint files and make these documents easily retrievable

and readily available for inspection and internal audit. Records should be maintained for a period of 1 year after the date of expiration of the product. If product does not have an expiration date, maintain complaint records for 1 year after the date the complaint was received.

4.8 Complaints determined to be invalid or non-quality issues should have justification documented in the complaint file.

4.9 Product complaint investigations should be completed within thirty calendar days of receipt of the complaint. Reasons for exceeding the timeframe for closure of the complaint investigation should be documented in the complaint file. Immediate corrections required to contain the problem should be conducted in a timely manner and recorded in the complaint record.

4.10 Recalls initiated as a result of product complaints should be reported to the appropriate regulatory body or governmental department within 24 hours. If the 24-hour timeframe is exceeded, justification should be written into the complaint record.

5. Keywords

5.1 cannabis; complaints; corrective and preventive actions (CAPA)

BIBLIOGRAPHY

- (1) Recommendations for Regulators – Cannabis Operations, American Herbal Products Association, February 2, 2016.

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