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Standard Guide for Conducting Recall/Removal Procedures for Products in the Cannabis Industry[1]

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1. Scope

1.1 This guide describes the general best-practices action plan for conducting product recall and removal/withdrawal as related to any incident requiring the recovery of cannabis-derived products. This guide applies to all cannabis-derived products commercially manufactured and distributed for consumer use. This guide is for suppliers, consumers, retailers, and distributors. A specific product recall decision is the result of unacceptable product safety and requires notification of the appropriate governmental agencies governing the entity's product safety laws. Governing regulatory agencies expect a product to be recalled if it is deemed to be unsafe, misbranded, or adulterated. These governing agencies are referenced as regulatory agencies throughout this guide. Various jurisdictional regulatory agencies may have specific and additional recall requirements falling beyond the recommendations of this guide. In these cases, the requirements of the governing regulatory agency must be followed. This document also provides general guidelines for the removal/withdrawal of products from the marketplace. Product removal/withdrawal is undertaken for purely commercial reasons that are typically unrelated to product safety and does not require regulatory agency notification. Product removal/withdrawal is carried out in the same manner as a product recall. This guide is being published as a best-practices approach and does not replace absolute jurisdictional regulatory requirements.

1.2 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]

D8270 Terminology Relating to Cannabis

3. Terminology

3.1 For definitions of terms see Terminology D8270.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *adulteration, n*—that cannabis or a cannabis-derived product: (*1*) consists in whole or in part of any contaminant, or decomposed substance; (*2*) contains any poisonous or deleterious substance which may render it injurious to health; (*3*) has been manufactured, packaged, labeled, or held under unsanitary conditions whereby it may have become contaminated, or whereby it may have been rendered injurious to health; (*4*) has been manufactured, packaged or labeled using methods or controls that do not conform to product safety requirements as defined by established specifications and/or procedures; (*5*) fails to meet appropriate safety requirements; (*6*) is present in a container composed, in whole or in part, of any deleterious substance which may render the contents injurious to health.

3.2.2 *cannabis-derived, n*—any product containing any part of the cannabis plant or any components extracted/derived from same.

3.2.3 *consignee, n*—anyone who has received, purchased, or used the product being recalled.

3.2.4 *correction, n*—immediate action to eliminate a detected nonconformity.

3.2.5 *corrective 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.

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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.

3.2.6 *downstream traceability, n*—describes the procedure and tools implemented in order to locate an event that has occurred after the transfer of property or after the physical transfer of products from the manufacturer to a third party.

3.2.7 *effectiveness checks, n*—series of direct visits, telephone calls, letters, or e-mails to assure that all affected persons have been notified of the recall and have taken appropriate action.

3.2.8 *hazard, n*—potential source of harm.

3.2.9 *health hazard evaluation, n*—evaluation of a health hazard presented by a defective product where the organization has the responsibility to conduct the evaluation before developing a recall strategy.

3.2.9.1 *Discussion*—In any recall, the jurisdictional regulatory agency will conduct an independent evaluation.

3.2.10 *human error, n*—departure from acceptable or desirable practices on the part of an individual resulting in an unacceptable or undesirable result.

3.2.11 *immediate health risk, n*—(*1*) a reasonable probability that use of, or exposure to the product will cause serious adverse health consequences or death; or (*2*) that use of, or exposure to the product may cause temporary or medically reversible adverse health consequences, or an outcome where there is a probability of serious adverse health consequences.

3.2.12 *misbranded, n*—a packaged product which has labeling that is false, inaccurate, misleading, or missing any regulatory required information.

3.2.13 *mock recall, n*—routine exercises conducted by manufacturers, processors, distributors, suppliers, and other various trading partners in the supply chain to assess their recall procedures and responsiveness and traceability systems.

3.2.14 *quarantine, n*—the status of materials isolated physically or by other effective means.

3.2.15 *recall, n*—removal or correction of a marketed product that does not meet specifications set within the supply chain or does not meet local governmental requirements.

3.2.15.1 *Discussion*—The recall is typically constrained to product safety issues. A product recall may include a market removal/withdrawal, or a stock recovery, if a potential health hazard has been identified.

3.2.16 *recall strategy, n*—course of action followed in conducting a recall that addresses the depth of the recall, need for public warnings, and extent of effectiveness checks for the recall.

3.2.17 *recalling organization, n*—organization initiating the recall and who has the primary responsibility for the manufacture, marketing, and/or distribution of the product in question.

3.2.18 *removal/withdrawal, n*—removal or correction of products from the marketplace for reasons that may be related to product quality and not in violation of governmental requirements.

3.2.19 *root cause analysis, (RCA), n*—analysis necessary to determine the original or true cause of a system, product, or process nonconformity.

3.2.20 *stock recovery, n*—removal or correction of a product that has not been marketed or has not left the direct control of the manufacturer.

3.2.21 *upstream traceability, n*—describes the procedures and tools implemented in order to locate an event that has already occurred before the customer concerned has become legally or physically responsible for the products.

4. Significance and Use

4.1 In this guide, steps are suggested for the effective development, control, and management of procedures and records required for an effective product recall/removal from the marketplace.

4.2 This guide presents a systematic approach to procedures and documentation regarding the steps necessary to be taken in the event of a product recall or removal from the marketplace because of health, safety, or quality nonconformances.

4.3 This guide provides a procedural basis for conducting a mock recall for purposes of evaluating the efficacy of an organization's existing traceability systems.

5. Responsibilities

5.1 *Senior Management:*

5.1.1 For the purposes of a specific product recall or removal/withdrawal, the senior management team consists of, but is not limited to, the following individuals: owners, operations leaders, consumer sales leaders, distribution leaders, quality management, customer service managers, local facility managers, technical experts, and legal counsel.

5.1.2 Senior management is responsible for working with the recall coordinator(s) for the assessment of any potential product recall or product removal/withdrawal situation by appropriately addressing the following:

5.1.2.1 Ascertaining the legal implications of the potential recall or removal/withdrawal decision, including likely exposure to civil liability and damage to the organization's image and integrity;

5.1.2.2 Determining the potential level of government and media scrutiny;

5.1.2.3 Determining the extent, if any, to which regulatory agencies need to be involved; and

5.1.2.4 Determining and mitigating potential interferences with normal business activity.

5.2 *Recall Coordinator(s):*

5.2.1 The recall coordinator(s) are appropriately designated by senior management and are trained, experienced personnel who are responsible for managing complaint and quality defect investigations.

5.2.2 Recall coordinator(s) are responsible for working with senior management to decide the measures to be taken to manage risk(s) presented by recalls and removal/withdrawals.

5.2.3 These persons are representatives of the quality assurance organization, unless otherwise justified.

5.2.4 The recall coordinator(s) should be responsible for communicating timely and accurate information to the departments responsible for legal, financial, technical, regulatory, public relations, insurance, other relevant departments and senior management.

5.2.5 The recall coordinator(s) are responsible for maintaining up-to-date communication and contact lists for the organization's recall team members

5.2.6 If recall or removal/withdrawal is considered, it is the responsibility of the recall coordinator(s) to work with senior management to perform a recall risk assessment. Once this assessment has been completed and the determination is made that:

5.2.6.1 The product is not completely within company control and the product poses an actionable health risk, or;

5.2.6.2 The product is not completely within company control and does not pose an actionable health risk, but does pose an unacceptable quality risk, then,

5.2.6.3 A product recall or removal/withdrawal is necessary.

5.3 The responsibility to authorize a product recall or a removal/withdrawal is held by the organization's senior management or their authorized designees.

6. Procedure

6.1 Develop a recall and a removal/withdrawal strategy.

6.2 The recall coordinator(s) should designate responsibilities for the development of the recall strategy among team members and coordinate final compilation.

6.3 The final strategy should be approved by all product recall team members.

6.4 The recall strategy should address the following elements regarding the conduct of the recall:

6.4.1 Identify the product brand name, description, size, product code, lot number, and so forth;

6.4.2 Determine depth of recall, for example, consumer, retail, or wholesale level;

6.4.3 Define a template in wording a public warning;

6.4.4 Assure adequate product quarantine steps have occurred (both for product still in control of the producing organization and for product in the supply chain or with consumers);

6.4.5 Dispose of the retrieved (recalled or removed) product in compliance with local regulations;

6.4.6 Confirm that the effectiveness checks are adequate to determine that the product has been retrieved and adequately quarantined, and;

6.4.7 Conduct the health hazard evaluation or how to trigger this report when using an external vendor.

6.5 Create a health hazard report by qualified team members or by an independent, qualified third party. The health hazard report identifies:

6.5.1 Type of hazard;

6.5.2 Seriousness of the hazard to human or animal health;

6.5.3 Whether any illnesses or injuries have already occurred from the use of the product in question;

6.5.4 Whether humans/animals are currently exposed to the hazard;

6.5.5 Whether the health hazard poses a threat to special segments of the population who may be at a greater risk (for example, infants, elderly), and;

6.5.6 The immediate and long-range consequences of the hazard.

6.6 Classify the degree to which the product's defect is obvious to the consumer or other user:

6.6.1 Know the degree to which the product remains unused in the marketplace;

6.6.2 Which jurisdictional agency should be notified, and;

6.6.3 What information is relevant to the jurisdictional agency, which usually includes:

6.6.4 Identity of the product involved;

6.6.5 The reason for the recall, including dates and circumstances under which the problem was discovered, and;

6.6.6 A copy of the risk-based health hazard evaluation;

6.6.7 The quantity of product produced and the time-period of production;

6.6.8 The quantity and time of product distribution;

6.6.9 Distribution information, including the number of affected customers and stakeholders;

6.6.10 Identifying information used to ensure communication to the internal supply chain, distributors, retail locations and consumers;

6.6.11 A copy of the recall notice, if issued, or proposed communication for a removal/withdrawal, if a recall is not issued should include:

6.6.11.1 The name and telephone number of the organization official who should be contacted;

6.6.11.2 What communication channels will be used;

6.6.11.3 How will holder or consumer of the product ask the organization questions;

6.6.11.4 What standardized response script(s) be for communication to various external stakeholders;

6.6.11.5 The communication channels used (social media, news outlets, etc.) for the announcement, and;

6.6.11.6 The communication plan for direct customer contact when the other channels may not be effective.

6.7 For recalls, the regulatory agency will typically assign a required level of effectiveness checks, depending upon the severity of the recall. This can be as challenging as showing documentation that 100 % of the affected product has been accounted for and disposed of properly or as simple as no effectiveness checks are required.

6.8 The recall or removal/withdrawal is a time sensitive action. Move as quickly as is feasible and communicate effectively.

6.9 When the recall team concludes from their evaluation and with the approval of senior management that a product recall or product removal/withdrawal is warranted, the following actions should be taken:

6.9.1 Further distribution or use of any remaining product should cease immediately.

6.10 The recall coordinator(s) or designee(s) should notify persons of authority for each of its affected customers via a telephone call starting immediately after the decision to initiate a recall. All contacts with affected parties should be documented in an appropriate manner (for example, who was contacted, what is their role, what contact information should be used for future communication, shipping address, number of units or recalled or removed/withdrawn material is present,