PRODUCT RECALL

Document No. CR – 16

Effective: *Date*

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1. PURPOSE

This Regulation implements 15 MLBS §§ 1203(d)(3) and 1217(c) and Compact Attachment A, part 9810.1101. The purpose of this Regulation is to ensure the safety of the community by establishing the conditions and procedures for recall of products found to be unsafe.

2. MANDATORY RECALL

2.1. Factors for Mandatory Recall

2.1.1. The Department must require license holders to recall any regulated product if the Department has evidence that the regulated product:

a. contains a contaminant level exceeding the acceptance criteria established by the Department for foreign material, heavy metals, microbiological contaminants, mycotoxins, pesticide residues, or residual solvents;

b. contains an undeclared allergen, as defined in the Minnesota Food Law, Minnesota Statutes, chapter 31;

c. is otherwise unfit for human use, consumption, or application; was not cultivated or manufactured by a licensed cannabis or hemp business as required by applicable tribal or state cannabis;

d. has packaging that fails to disclose a known allergen contained in the product;

e. has packaging that does not comply with the labeling requirements of applicable tribal or state cannabis law; or

f. otherwise poses a risk to public health or safety.

2.2. Mandatory Recall Process

Upon the request of the Department or, for license holders that are subject to the Compact, OCM, a license holder must perform a traceback and trace-forward investigation for the identified product, batch, or other designation, to identify all affected businesses, markets, and consumers, and must respond to all information requests made by the Department related to the recall within 24 hours of the Department's request.

2.3. License Holder Obligations

2.3.1. If a license holder is required to recall a regulated product, then the license holder must, within one day of receiving notice of the recall:

a. notify any other business that provided to, or purchased from, the license holder the product impacted by the recall;

b. notify all individuals who may have purchased the recalled product and reimburse individuals for any returned product; and

c. ensure that all products subject to the recall are destroyed in accordance with applicable law and record the destruction in the cannabis business's seed-to-sale tracking system.

2.3.2. A license holder must notify the Department, and if subject to the Compact, OCM, of the license holder's compliance with item 2.3.1, subitems (a) to (b), within three days of receiving the notice of recall.

2.4. Department Actions and Authority

2.4.1. If the Department determines that a recall is necessary under Section 2, the Department will:

a. issue the license holder a notice of recall with the specific product subject to the recall and the basis for the recall under section 2.1; and

b. post the notice of recall on the Department's website or similar forum.

2.4.2. The Department may take control of a product recall process, including the investigation, at any time, and may use or access the records and systems of the license holder as is reasonably necessary to conduct the recall process.

3. VOLUNTARY RECALL PROCESS

3.1. When Permitted

A license holder may initiate a product recall when the license holder has information that a regulated product is mislabeled, defective, or unsafe for consumption.

3.2. License Holder Obligations

3.2.1. A license holder initiating a recall must:

a. provide notice of the recall to the Department, including a description of the recalled product and the basis for the recall; and

b. comply with Section 2.4.1.

3.3. Department Actions

Upon receipt of notice under 3.2.1.(a), the Department must post the notice on its website or similar forum with information that the license holder initiated the product recall.