# Contents

## 1. PURPOSE

This Regulation implements 15 MLBS §§ 1201-1225 (hereinafter referred to as the "Code") and relevant provisions of the Compact, Attachment A. The purpose of this Regulation is to set forth the standards, processes, and procedures by which a cannabis business licensed by the Department may engage in manufacturing activities authorized under the Code.

## 2. GENERAL MANUFACTURING STANDARDS

### 2.1. Authorized Actions

2.1.1. Issuance of a cannabis manufacturer license entitles the license holder to:

a. purchase cannabis flower from licensed cannabis cultivators;

b. manufacture dried cannabis flower into saleable products;

c. purchase cannabinoid products from other cannabis manufacturers;

d. make cannabis concentrate;

e. manufacture artificially derived cannabinoids;

f. manufacture cannabinoid products for public consumption;

g. package and label cannabinoid products for sale to other licensed cannabis businesses;

h. sell cannabis concentrate, artificially-derived cannabinoids, and cannabinoid products to other licensed cannabis businesses;

i. safely and securely transport cannabis concentrate, artificially derived cannabinoids, and cannabinoid products to other licensed cannabis businesses within or outside the Band's Tribally Regulated Land as authorized in the Compact, the Code, and these Regulations; and

j. any other actions approved by the Department.

### 2.2. Prohibited Sales

A cannabis business must not sell any cannabinoid product resulting from cannabis manufacturing to a buyer if the cannabis business knows or should reasonably know that the buyer would be engaging in prohibited activities under applicable State law or Band law with the obtained cannabinoid product.

## 2.3. Premises Requirements

2.3.1. Manufacturing must take place in a facility that meets the applicable requirements of Minnesota Statutes, section 342.26. A Manufacturing Facility must:

a. have adequate physical space for all manufacturing, including storage, in a fully enclosed and secured indoor facility according to CR-8, Product Storage;

b. be supplied with electrical service, water service, sewer service or treatment, and other utilities necessary for operations approved by the Department;

c. have ventilation and air-handling systems with temperature and humidity controls that are adequate for safe processing and sanitary operations;

d. be supplied with lighting fixtures that are adequate to perform manufacturing and sanitation functions in a safe and sanitary manner;

e. have floors, walls, and ceilings in the manufacturing area that are constructed with surfaces that can be easily cleaned and maintained in good repair to inhibit microbial growth;

f. have hand-washing facilities located in all manufacturing areas where unpackaged product is handled; and

g. be enclosed and locked with sufficient security protections as provided in these Regulations.

2.3.2. Cannabis manufacturing must take place in a manufacturing facility that is used exclusively for the manufacturing of cannabinoid products or the creation of artificially derived cannabinoids except that:

a. a cannabis manufacturer may be co-located with a cannabis cultivation licensee in a manner that shares general office space, bathrooms, entryways, and walkways;

b. if a cannabis business sells regulated products to consumers on the premises where manufacturing is authorized, the cannabis business must ensure that a fence or other adequate security measure is in place to separate customer areas of the premises from limited access areas,

including any area where samples for mandatory testing are collected, packaged, and sealed for transport to a cannabis testing facility.

2.3.3. A cannabis manufacturer that manufactures cannabis flower must follow additional requirements under Section 3 of this Regulations.

2.3.4. A cannabis manufacturer that manufactures ingestible and lower-potency hemp edibles must follow additional requirements under Section 4 of this Regulation.

2.3.5. A cannabis manufacturer that manufactures cannabis concentrate must follow additional requirements under Section 5 of this Regulation.

**2.4. Batch Identification and Reporting**

Each plant used in manufacturing must be labeled with a batch number according to CR-5, Product Inventory and Tracking.

**2.5. Manufacturing Inputs and Ingredients**

2.5.1. All products other than cannabis-derived ingredients and hemp-derived ingredients must be:

a. safe for the intended purpose and use in the manufacturing process. Any solvent used in manufacturing must be safe for human consumption and approved for use in foods by the United States Food and Drug Administration;

b. handled and used in a manner that prevents contamination with filth, residues, or other substances that would likely render products of the cannabis plant injurious to human health;

c. in conformance with applicable sections of Minnesota Statutes, chapters 18B, 18C, and 18D, and other applicable laws; and

d. stored in original containers with original labels intact or in working containers of diluted or prepared applications labeled with information required by Minnesota Statutes, chapters 18B, 18C, and 18D, and other applicable laws.

2.5.2. All manufacturing inputs, ingredients, and containers must be used, stored, and disposed of according to label instructions and in compliance with all other applicable laws and regulations.

**2.6. Sanitary Practices**

2.6.1. A cannabis manufacturer must follow sanitary practices during all manufacturing, including receiving, storing, processing, handling, packaging, and labeling regulated products. At a minimum, a cannabis manufacturer's sanitary practices must:

a. ensure that the manufacturing facility is maintained in a clean and sanitary manner and that the manufacturer maintains standard operating procedures that outline the business's policy for clean room standards;

b. ensure that an individual who has a communicable disease or other illness does not perform any tasks that might contaminate regulated products;

c. ensure that hand-washing facilities in manufacturing areas are supplied with:

i. hot and cold running water;

ii. effective hand-cleaning and sanitizing solutions; and

iii. sanitary drying functions, such as electronic drying devices, single-use towels, or a sanitary towel service;

d. ensure that a worker who comes into direct contact with regulated products uses hygienic practices, including maintaining the cleanliness of the worker's outer garments and washing hands thoroughly in a hand-washing area before starting work and at any other time when the worker's hands may have become soiled or contaminated;

e. control environmental conditions and ensure that workers use sanitary handling practices to protect products against physical, chemical, and microbial contamination and store products in a manner to prevent the growth of microorganisms;

f. control environmental conditions to prevent the deterioration of products or contents that are described on the products' labeling;

g. ensure that tools, utensils, and, including storage containers, that come into direct contact with ingredients, in-process products, and finished products are cleanable and constructed from materials that will not transfer to ingredients or finished products;

h. ensure that all product-contact surfaces, utensils, and equipment are cleaned before being used to manufacture products and are maintained in

a condition that prevents contamination of ingredients or regulated products; and

i. ensure that manufacturing takes place on equipment that is used exclusively for the manufacturing of cannabinoid products or creation of artificially derived cannabinoids.

2.6.2. Packaging materials that come into direct contact with ingredients, in-process products, or finished products must be:

a. safe for use with the intended products;

b. stored and handled in a manner to prevent contamination of materials from the environment; and

c. cleaned between uses if designed for cleaning and multiple uses or discarded after single use.

2.6.3. A cannabis manufacturer must make efforts to prevent pests by:

a. using screening or other protection against the entry of pests; and

b. promptly disposing of waste to minimize odors and the potential for waste to attract, harbor, or become a breeding place for pests.

2.6.4. A cannabis manufacturer must store toxic cleaning compounds, sanitizing agents, and other potentially harmful chemicals in a separate location away from regulated products and in accordance with applicable local, state, and federal workplace safety requirements.

## 2.7. Recordkeeping

2.7.1. A cannabis manufacturer must keep records of each batch of manufactured products. A cannabis manufacturer must enter manufacturing and batch information in the statewide monitoring system as required by CR-7, Packaging and Labeling.

2.7.2. At a minimum, manufacturing records must include the following information for all manufacturing that the cannabis manufacturer conducts:

a. the date that a worker conducted manufacturing;

b. the name of the worker conducting manufacturing or the name of the responsible worker when more than one worker conducts manufacturing;

c. a description of manufacturing that was conducted;

d. process control measurements; and

e. the batch number of the products involved in manufacturing.

### 2.8. Sales by Manufacturers

2.8.1. Upon the sale of any cannabinoid product to a cannabis business, a cannabis manufacturer must provide a statement to the buyer that discloses the product's ingredients, including but not limited to any chemicals or compounds and any major food allergens declared by name.

2.8.2. Upon the sale of any cannabinoid product to a cannabis business, a cannabis manufacturer must provide a certificate of analysis demonstrating the product has undergone and passed laboratory testing by a licensed testing facility.

### 2.9. Trademarked Products

A cannabis manufacturer shall not add any cannabis flower, cannabis concentrate, or artificially derived cannabinoid to a product where the manufacturer of the product holds a trademark to the product's name. A cannabis manufacturer may use a trademarked food product if the manufacturer uses the product as a component or as part of a recipe and where the cannabis manufacturer does not state or advertise to the customer that the final retail cannabinoid product contains a trademarked food product.

### 2.10. Other Applicable Requirements

A cannabis manufacturer must comply with all applicable testing, packaging, labeling, and health and safety requirements in the Code or these Regulations.

## 3. MANUFACTURING REQUIREMENTS SPECIFIC TO DRIED CANNABIS FLOWER PRODUCT

### 3.1. Labeling

A cannabis manufacturer may sell multiple uniform dried cannabis flower products to another cannabis business under a single label provided the label reflects the number of units or weight of the product being sold.

### 3.2. Infused Smokable Products

A cannabis manufacturer may manufacture dried cannabis flower products combined with cannabis concentrate, except an infused dry cannabis flower product must not be infused with any product other than a cannabis-derived product.

## 4. MANUFACTURING REQUIREMENTS SPECIFIC TO INGESTIBLE CANNABIS PRODUCT

### 4.1. Applicable Food Laws

A cannabis manufacturer must manufacture ingestible cannabis products and lower-potency hemp-derived edibles in accordance with Minnesota Food Law, Minnesota Statues, Chapter 31, including applicable sections of the Code of Federal Regulations that are adopted by reference in Minnesota Statutes, section 31.101, except that a product is not adulterated solely due to the presence of cannabis or hemp ingredients.

### 4.2. Homogenous Products

4.2.1. An ingestible cannabis product or a lower-potency hemp edible manufacturer must use production methods that result in a finished product batch with consistent servings and consistent packages, prepared in a manner to ensure that each individual serving has a consistent amount of cannabinoid ingredients pursuant to CR-11, Testing. At a minimum, a cannabis manufacturer must:

a. develop stable product formulations that consider and address specific ingredients and the nature of the finished product;

b. establish written procedures for preparing edible cannabis products or lower-potency hemp edibles specific to the manufacturing site; and

c. maintain batch records that demonstrate the manufacturer's compliance with product formulations and the manufacturer's written procedures.

## 5. MANUFACTURING REQUIREMENTS SPECIFIC TO CANNABIS AND HEMP CONCENTRATE

### 5.1. Facilities

5.1.1. Cannabis or hemp extraction and concentration systems must be designed to effectively and consistently function, operate safely, and provide sanitary production conditions. A cannabis manufacturer or hemp manufacturer must have the manufacturer's electrical, gas, fire suppression, and exhaust systems and storage and disposal plans for hazardous waste certified by an industrial

hygienist or a professional engineer qualified to conduct the certification through education, experience, or professional credentialing.

5.1.2. A certifying individual must include the individual's qualifications in writing as part of a facility's record of certification.

5.1.3. The certification of a facility must include an assessment of:

a. all electrical, gas, fire suppression, and exhaust systems in the facility; and

b. the facility's plan for safe storage and disposal of hazardous substances, including any volatile chemicals.

**5.2. Extraction and Concentration Methods**

5.2.1. As a condition of licensure, a cannabis manufacturer must inform the Department of all methods of extraction and concentration that the manufacturer intends to use as well as identify the chemicals or compounds, if any, that will be involved in the creation of cannabis concentrate, provided that the manufacturer many not use any prohibited ingredients under Section 5.4 of this Regulation. A cannabis manufacturer may not use a method of extraction and concentration or a chemical or compound without approval by the Department. If a cannabis manufacturer intends to use a new method of extraction and concentration or a new chemical or compound that was not disclosed at the time of licensure, the manufacturer must inform the Department and receive approval for such method, chemical, or compound prior to utilization.

5.2.2. As a condition of licensure, a cannabis manufacturer must inform the Department of all methods of conversion that the manufacturer will use, including any specific catalysts that the manufacturer will employ in order to create artificially derived cannabinoids and the molecular nomenclature of all cannabinoids or other chemical compounds that the manufacturer will create. A cannabis manufacturer may not use a method of conversion or a catalyst without approval by the Department. If a cannabis manufacturer intends to use a new method of conversion that was not disclosed at the time of licensure, the manufacturer must inform the Department and receive approval for such method prior to utilization.

**5.3. Inactive Ingredients**

A cannabis manufacturer may use cannabis-derived ingredients to manufacture cannabis concentrate or hemp-derived concentrate. A cannabis manufacturer may use only non-cannabis-derived inactive ingredients listed in the federal Food and Drug Administration inactive ingredient database to manufacture cannabis concentrate or hemp-derived concentrate that is intended for use through a vaporizer delivery device or pressurized metered dose inhaler.

## 5.4. Prohibited Ingredients

5.4.1. When manufacturing cannabis concentrate, a cannabis manufacturer must ensure that:

a. any concentrate used to create a solution for vaporization or inhalation is 100 percent naturally occurring plant-derived terpene oil;

b. a product for inhalation does not contain artificial or synthetic compounds; and

c. a solution prepared for vaporization or inhalation does not contain:

i. medium-chain triglycerides (MCT);

ii. polyethylene glycol (PEG);

iii. vegetable glycerin (VG);

iv. vitamin E acetate;

v. diacetyl; or

vi. squalene.

## 5.5. Requirements for Manufacturers of Artificially Derived Cannabinoid Products

An artificially derived cannabinoid product must not contain any artificially derived cannabinoids other than delta-9 tetrahydrocannabinol, except that a product may include artificially derived cannabinoids created during the process of creating delta-9 tetrahydrocannabinol that is added to the product, if no artificially derived cannabinoid is added to the ingredient containing delta-9 tetrahydrocannabinol and the ratio of delta-9 tetrahydrocannabinol to all other artificially derived cannabinoids is no less than 20 to one. An artificially derived cannabinoid product may contain nonpsychoactive naturally occurring cannabinoids, such as cannabidiol, cannabigerol, cannabinol, or cannabichromene.

## Appendix A – Definitions

The Department intends to develop a separate MLBO Cannabis Regulation that sets forth all relevant definitions for the Cannabis Regulations. However, in the interest of encouraging robust notice and comment, the Department is providing the following definitions of terms that are found in this Manufacturing Regulation:

(1) "Cannabinoid Product" means cannabis product, a hemp-derived consumer product, or lower-potency hemp edibles.

(2) "Cannabis Business" means a cannabis cultivator, cannabis manufacturer, cannabis retailer, cannabis wholesaler, or cannabis testing facility.

(3) "Cannabis Manufacturer" means a Person that has been licensed as a cannabis manufacturer pursuant to the Code and the Regulations.

(4) "CR" is the short form citation to a specific chapter of the Mille Lacs Band of Ojibwe Cannabis Regulations.

(5) "Hemp-Derived Consumer Product" means: a product intended for human or animal consumption, does not contain cannabis flower or cannabis concentrate and
   a. contains or consists of hemp plant parts; or
   b. contains hemp concentrate or artificially derived cannabinoids in combination with other ingredients; and
   c. does not include artificially derived cannabinoids, lower-potency hemp edibles, hemp-derived topical products, hemp fiber products, or hemp grain.

(6) "Limited Access Area" means an area of a cannabis business that is accessible only by individuals who are over 21 years of age.

(7) "Manufacturing" means the process by which cannabis flower or plants, cannabis concentrates, artificially derived cannabinoids, hemp plant parts, or hemp concentrates are prepared into usable consumer products or products intended for further processing.

(8) "Manufacturing Facility" means the building or area in which useable or consumable cannabis and hemp products are processed or otherwise prepared to be useable or consumable products.

(9) "Part" means a specific part of the Minnesota Administrative Rules.

(10) "Regulation" or "Regulations" mean the regulations promulgated by the Department to implement the Code.

(11) "Solvent" means a substance that is capable of solubilizing cannabinoids extracted from cannabis or hemp plants.