



Plandaí Biotechnologies South Africa (Pty) Limited

QUALITY MANUAL

Cannabis cultivation and processing operations

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SUBPART A – GENERAL PROVISIONS

Section 1.1 Definitions

The following definitions apply:

Adverse event means a health-related event associated with use of cannabis or a cannabis-derived product that is adverse, and that is unexpected or unusual.

Batch means a specific quantity of cannabis harvested during a specified time period from a specified cultivation area.

Cannabis means any of the aerial parts of a plant in the genus *Cannabis*, and does not mean hemp.

Cannabis planting material means cannabis seeds, seedlings, cuttings, clones, etc. used by a cultivation operation to grow cannabis.

Cannabis waste means cannabis discarded by the cultivation operation or processing operation.

Compliant individual means an individual who has met all legal requirements to obtain and use cannabis or cannabis-derived products in the jurisdiction where this part applies.

Contamination means the presence of unsafe levels of bacteria, mold, or yeasts, chemicals, or foreign matter.

Cultivate means to grow, harvest, dry, and cure cannabis. A person, group of persons, non-profit entity, or business entity that cultivates is a *cultivator*, and a facility where cannabis plants are cultivated is a *cultivation operation*.

Cultivation area means the physical location of a structure or property at which cannabis is cultivated.

Firewall assembly means a fireproof barrier used to prevent the spread of fire between or through buildings or structures.

Harvest means to gather cannabis plants from cultivation medium or to gather specific aerial parts of cannabis plants.

High intensity discharge lamps (HID lamps) means a type of electrical gas-discharge lamp which produces light by means of an electric arc between tungsten electrodes housed inside a translucent or transparent fused quartz or fused alumina arc tube.

Identity means the set of characteristics by which an ingredient or product is definitively recognizable or known. In the case of cannabis and other botanical ingredients, identity means the plant part and the botanical genus, species, variety, strain, and/or cultivar, as well as any other applicable characteristics as stated on the label or other labeling.

Indoor cultivation means cultivation of cannabis grown in a fully enclosed location in which the only light source is artificial.

Lot means a batch, or a specific identified portion of a batch, that is uniform and that is intended to meet specifications for identity, purity, strength, and composition.

Manufacture means to compound, blend, grind, extract, or otherwise make or prepare cannabis-derived product.

Medium means the nutritive substrate that the cultivator is using to establish a root system.

Nursery facility means an indoor cultivation operation that produces cannabis plants for the purpose of providing planting material to other cultivation operations.

Planting means to place cannabis seeds or young plants in soil or medium.

Process means to trim, inspect, grade, or pack cannabis.

Processing loss means cannabis that, for any reason, during processing is deemed unfit for human consumption.

Propagation materials means all substances used in the cultivation of cannabis.

Pruning means cutting away cannabis leaves, branches or stems from unharvested plants.

Supplemental lighting means artificial lighting used to help or extend the vegetative life cycle of a cannabis plant.

Trimming means the removal of leaves and stems from harvested cannabis.

Variety means a specific cultivar, stock, line, or breed of cannabis, also commonly referred to as strain.

SUBPART B – CULTIVATION AND PROCESSING OPERATIONS

Section 2.1 Types of cultivation and processing operations

- (a) The company intends to cultivate cannabis using the following types of cultivation operations, as defined in section 1.3 in this part:
- (1) Indoor cultivation operations; and
 - (2) Nursery operations.

Section 2.2 Ancillary operations

- (a) The company will also engage in other operations, including:
- (1) Manufacturing, packaging, labeling, and holding of cannabis-derived product;
 - (2) Laboratory operations;
- (b) The ancillary operations identified in section 2.2(a) may be conducted:
- (1) At the same location as cultivation or processing, so long as such

- operations are permitted at this location in the jurisdiction in which this part applies; or
- (2) At another location at which such operations are permitted in the jurisdiction in which this part applies.
- (c) The ancillary operations identified in section 2.2(a) must be conducted in compliance with all regulations relevant to such operations in the jurisdiction in which this part applies.

Section 2.3 Cultivation practices

(a) Propagation materials

- (1) Propagation materials used in cultivation operations must be appropriate for use in agricultural food production.
- (2) Cultivation operations must follow the manufacturer's usage, storage, and disposal recommendations for the propagation material.

(b) Pesticides

- (1) Pesticides used in cultivation operations must be approved by the jurisdiction in which they will be used.
- (2) Cultivation operations must follow the manufacturer's application and storage recommendations, and disposal recommendations for the pesticide product.
- (3) The Company must follow the relevant SA guidelines when preparing and applying pesticides.
- (4) Indoor cultivation operations must comply with the pesticide manufacturer's published re-entry interval time periods when applying pesticides.
- (5) Application of pesticides should be avoided following the flowering of cannabis plants.
- (6) Application of pesticides may only be applied under written instruction of the chief agronomist.

(c) Nutrients

- (1) Nutrients used in cultivation operations must be appropriate for use in agricultural food production.
- (2) Cultivation operations must follow the manufacturer's application, storage, and disposal recommendations for the nutrient product.
- (3) Cultivation operations must not return unused rooting hormone to the source container.
- (4) Nitrate-based and other oxidizing fertilizers must be stored away from solvents, fuels and pesticides.
- (5) Nutrient application procedures shall be established by the chief agronomist and posted in the respecting growing rooms.

(d) Carbon dioxide

- (1) Indoor cultivation facilities utilizing carbon dioxide must maintain levels under 2000 ppm in cultivation areas when facility personnel may be present.
- (2) Indoor cultivation facilities utilizing carbon dioxide at levels above 2000 ppm in a sealed room must prohibit personnel from entering the cultivation area unless personal protective equipment is provided.

- (3) All regulators and environmental control systems that regulate carbon dioxide emissions must be maintained in good working order and be serviced in accordance with the manufacturer's recommendations.
- (4) Compressed gases must be securely stored and appropriate signage and safety warnings provided.
- e) Equipment and tools
 - (1) Equipment used for measuring, regulating, or recording temperatures, pH, humidity, or other conditions related to the cultivation and processing of cannabis must be accurate and adequately maintained.
 - (2) Cultivation and processing tools that come in direct contact with cannabis plants should be disinfected as needed to protect plant health.
 - (3) Scales used for the weighing of cannabis must be calibrated at regular intervals.

Section 2.4 Processing practices

- (a) Processing operations must be maintained in a clean and sanitary condition including all work surfaces and equipment.
- (b) Employees handling cannabis in processing operations must utilize facemasks and gloves in good operable condition as applicable to their job function.
- (c) Employees must wash hands sufficiently when handling cannabis.

Section 2.5 Distribution practices

- (a) Cultivation protocols shall be established by the chief agronomist and conducted only on authorization of the Chief Executive Officer.
- (b) Cannabis meeting specifications and requirements may be released for the next phase of processing. An indication of approval should be placed on the cannabis.
- (c) Cannabis not meeting specifications and requirements may not be released to the next phase of processing. An indication of rejection should be placed on the cannabis and the Disposal Protocol followed.
- (d) Before the cannabis enters the processing facility, from the grow facility, it must be accompanied with the following information:
 - (1) Identity of contents;
 - (3) Net weight of contents; and
 - (4) Sufficient information to trace the cannabis to its batch and/or lot.

Section 2.6 Quality systems

- (a) The company will establish a specific chemical profile for the cannabis extract.
- (b) Each batch of processed cannabis will be tested against the established profile to determine whether it falls within specified margins.
- (c) Non-conforming produce shall be noted and destroyed in accordance with the Disposal Protocol.

SUBPART C – PERSONNEL

Section 3.1 Personnel training

- (a) The Company must:
- (1) Ensure that each person engaged in the operation has the education, training, and experience, or any combination thereof, to enable that person to perform all assigned functions.
 - (2) Maintain records of any training provided to employees for the performance of all assigned functions, including but not limited to application of pesticides.
- (b) The Company will provide all employees with training that includes:
- (1) Instructions regarding regulatory inspection preparedness and law-enforcement interactions; and
 - (2) Information on applicable laws, regulations, and policies relating to individuals employed in these operations, and the implications of these for such employees.
 - (3) The hygiene protocols
 - (4) The security protocols
- (c) Employee hygiene protocols will be posted in the changing rooms that address:
- (1) Employees who are showing signs of illness, open wounds, sores or skin infections may not handle cannabis.
 - (2) Hygiene training for employees who handle cannabis with specific attention to preventing microbial contamination.
 - (3) Hand washing requirements including washing hands with soap and hot water before beginning work, after using the bathroom and after meal breaks.
 - (4) Instructive hand washing signage must be in appropriate areas such as bathrooms, kitchens, and lunch areas, and in multiple languages as needed.

Section 3.2 Employee safety

- (a) All employees shall have adequate safety training relevant to their specific job functions, which may include:
- (1) Emergency action response planning as necessary;
 - (2) Employee accident reporting and investigation policies;
 - (3) Fire prevention;
 - (4) Hazard communication policies, including maintenance of safety data sheets (SDS);
 - (5) Materials handling, spill, and disposal policies;
 - (6) Job hazard analyses; and
 - (7) Personal protective equipment policies, including but not limited to use of eye protection, respiratory protection, and ergonomic supports, such as back braces.

- (b) The Company will provide and maintain at least one emergency eye flushing station readily accessible and visible to in every production room, and access to adequate eye flushing water for each employee.
- (c) The Company will visibly post and maintain an emergency contact list which includes at a minimum:
 - (1) Operation manager contacts;
 - (2) Emergency responder contacts;
 - (3) Poison control contacts;
 - (4) Fire department contacts; and
 - (5) Spill response team contacts.

SUBPART D – FACILITIES

Section 4.1 General compliance

- (a) The Company will comply with all legal requirements pertaining to the following as applicable:
 - (1) Restrictions on the size of the cultivation area;
 - (2) Restrictions on the number of cannabis plants allowed or other quantitative limits;
 - (3) Light pollution restrictions; and
 - (4) Odor control restrictions.
- (b) Location of cultivation operations:
 - (1) The Company will ensure that any indoor cultivation operation is located in a fully permitted, non- residential structure that:
 - (i) Was constructed in compliance with local building code;
 - (ii) Has a complete roof enclosure supported by connecting walls extending from the ground to the roof;
 - (iii) Is secure against unauthorized entry; and
 - (iv) Minimizes unnecessary visual, auditory or olfactory evidence of indoor cannabis cultivation.
- (c) Location of processing operations
 - (1) The Company will ensure that its processing operation are located on any property that is zoned for such use.
 - (2) Processing operation structures must be fully permitted and constructed in compliance with local building code.

Section 4.2 Fire prevention

- (a) Any room in an indoor cultivation operation in which operational supplemental lighting, ballasts, or electrical control panels are located must be constructed with a minimum of a one-hour firewall assembly.
- (b) Indoor cultivation operations must have adequate fire suppression systems in compliance with jurisdictional requirements, such as:
 - (1) At least one operating fire extinguisher, and
 - (2) Additional fire extinguishers in a number proportional to the watts of supplemental lighting used in the facility (one fire extinguisher per every

- 10,000 watts of lighting), or in accordance with local fire code.
- (c) Fire extinguishers must be:
 - (1) Easily accessible to employees from every room and in each hallway of the facility;
 - (2) Maintained annually or as otherwise specified by the manufacturer; and
 - (3) Of the appropriate class rating for the type of fire associated with the functions being performed in the facility (i.e., electrical, chemical).
 - (d) Flammable products must be stored in a properly marked fire containment cabinet or area.
 - (e) Signage that complies with standard SA Fire Regulations must be placed at entrances to exposure areas.
 - (f) The Company may provide a fire prevention plan for review by the local fire protection authority.

Section 4.3 Sanitation practices

- (a) The Company will provide employees with adequate and readily-accessible toilet facilities.
 - (1) Toilet facilities must be maintained in a sanitary condition;
 - (2) Toilet facilities must be adequately stocked with toilet paper, soap, and single use paper towels or other hand-drying devices; and
 - (3) Toilet facilities must be kept in good repair at all times.
- (b) The Company will provide adequate and convenient hand-washing stations.
 - (1) Hand washing stations must be provided with running water of suitable temperature;
 - (2) Hand washing stations must be provided with effective hand cleaning or sanitizing preparations and single use paper towels or other hand-drying devices;
 - (3) Hand washing stations must be located at points in the facility where good sanitary practices require employees to wash or sanitize their hands; and
 - (4) Outdoor and greenhouse cultivation operations must provide hand-washing stations at field locations as appropriate.
- (c) The Company will implement sanitation practices, which at a minimum address:
 - (1) Removal of debris, and control of the growth of mold, mildew and algae in the cultivation area or processing area;
 - (2) Pest control practices, including maintenance and repair of caulk cracks and drain areas;
 - (3) Identification of hoses dedicated for use in cultivation;
 - (4) Maintenance and cleaning of irrigation systems;
 - (5) Control of the introduction of potential contamination into the cultivation or processing area by personnel; and
 - (6) Design of operational areas to protect the work process and minimize the risk of contamination or adulteration.
- (d) The Company must protect cannabis from contact with birds, rodents, insects, and other animals and from exposure to the elements.

Section 4.4 Electrical system

- (a) The Company's electrical system must be of sufficient capacity to handle the actual electrical load and be installed in accordance with an approved electrical permit.
- (b) All electrical work and upgrades must be performed with proper permitting.
- (c) All electrical equipment should be connected to the electrical system in accordance with the equipment manufacturer's recommendations.

Section 4.5 Ventilation system

- (a) Enclosed cultivation operations and processing operations must be equipped with adequate ventilation to maintain proper humidity and temperature.
- (b) A mechanically propelled air intake system will be used having a filter capable of removing 99.97% of particles with a diameter of 0.3 micrometers (μm), as necessary to control potential contamination with pathogenic organisms.

Section 4.6 Disposal and waste practices

- (a) Cannabis waste must be composted or disposed of in a manner which prevents unauthorized use and such disposal must be documented. Disposal should not violate any other ordinance, code section or provision of law regarding disposal of cannabis.
- (b) Medium, bulbs and ballasts utilized during the cultivation of cannabis must be disposed of in accordance with manufacturer's recommendations, or recycled when feasible.
- (c) Nutrients, pesticides, and other chemicals used in cultivation and processing operations must be disposed of in accordance with manufacturer's recommendations.

Section 4.7 Security provisions

- (a) The Company's operations should be enclosed by a secure perimeter fence at least six (6) feet in height. The fence should include a lockable gate that is locked when a qualified employee is not in the immediate area. The fence must not violate any other ordinance, code section or provision of law regarding height and location restrictions.
- (b) The Company must implement facility security measures sufficient to deter the risk of unauthorized access while allowing for emergency ingress and egress in accordance with applicable regulations.
- (c) The Company must implement and communicate security protocols to all personnel and on-site contractors.
- (d) Visitors must be accompanied by an employee at all times.
- (e) The Company should have a system for review of relevant records (see Section 6.1) as a means of preventing diversion.

SUBPART E – WATER RESOURCE MANAGEMENT

Section 5.1 Cultivation water management

- (a) Water shall be recaptured, filtered, and re-used to minimize introduction of chemicals and pesticides into the culinary system.

(b) Chemical solutions must be disposed of in accordance with applicable laws and regulations.

SUBPART F – RECORDKEEPING

Section 6.1 Recordkeeping practices

- (a) The Company will record the identity and source of all cannabis propagation material with sufficient specificity to ensure that the material can be traced to its source. Such records must be created whether the propagation material is obtained off-site or produced on-site.
- (b) For each batch of cannabis, The Company will maintain cultivation records that include at a minimum:
- (1) Planting records:
 - (i) Form of cannabis planted (e.g., seed, clone, seedlings, etc.);
 - (ii) Date(s) that planting took place;
 - (iii) Variety(ies) planted;
 - (2) Propagation records:
 - (i) Media used, and whether the media was reused or new product;
 - (ii) Description of all actions taken to prevent or treat the cannabis for disease or pest issues;
 - (iii) Soil amendments added, date of application, and strength of the application;
 - (iv) Nutrients added, date of application, and strength of the application;
 - (v) All substances applied to the plant(s) surface or used as a fumigant in the cultivation and/or nursery area and date of application; and
 - (vi) Pruning or other physical technique(s).
 - (3) Pesticide use records:
 - (i) Pesticide chemical name;
 - (ii) Brand name and manufacturer name;
 - (iii) Amount of pesticide applied;
 - (iv) Date pesticide applied;
 - (v) Cultivation stage at application;
 - (vi) Identification or location of plants to which pesticide was applied; and
 - (vii) Name of applicator if required.
 - (4) Harvest records:
 - (i) Identity of each variety harvested;
 - (ii) Date of harvest;
 - (iii) Gross weight of the cannabis harvested for processing (generally recorded after drying);
 - (iv) Total weight of cannabis waste resulting from the harvest, and
 - (v) Net weight of harvested cannabis (gross weight less waste).
- (c) The Company must maintain records for processed cannabis that include at a minimum:
- (1) Identity of the variety processed;

- (2) Date of processing;
 - (3) Initial weight; and
 - (4) Total weight of any processing loss (based on wet or dry weight).
- (d) The Company and processing operations will maintain records of the distribution of the product, including at a minimum:
- (1) Total weight distributed;
 - (2) Batch number of product distributed;
 - (3) Date of distribution;
 - (4) Identity of the receiving operation; and
 - (5) Amount of and the batch or lot number of any variety returned due to product spoilage, recalls, etc.

Section 6.2 Record retention

- (a) Except as required in sections 6.2(b) and (c), The Company must retain the records required by this part for a period of three years past date of creation of the record, or one year past the expiration date of the related product, whichever is longer, as applicable to the operation.
- (b) Product complaint records must be retained for one year past the expiration date of the batch or lot affected, or for one year past the date of receipt of the complaint, whichever is longer.
- (c) Records for returned products must be retained for one year past the expiration date of the batch or lot affected, or for one year past the date of receipt of the return, whichever is longer.

SUBPART G – INFORMATION DISCLOSURE

Section 7 Information disclosure

- (a) The Company must provide relevant records as established in Section 6.1 to regulatory authorities upon request.
- (b) Information provided by The Company, whether written or verbal, about the identity, quality, and cultivation conditions of cannabis it provides must be accurate.
- (c) The Company must disclose the extent and type of testing and analysis conducted on the cannabis it provides, including, but not limited to:
 - (1) Any tests to determine the quantitative levels of contained constituents, such as individual cannabinoids and terpenes, and if so, the type of testing used;
 - (2) Any tests to determine the absence or presence of specific classes of potential contaminants, and if so, the type of testing used. The information required by this paragraph must be disclosed for each of the following:
 - (i) Common or known pesticides;
 - (ii) Yeasts and molds;
 - (iii) Other microbiological contaminants; and
 - (iv) Heavy metals.
 - (3) Whether the testing was conducted by The Company, or by an external laboratory.

SUBPART H – PRODUCT COMPLAINTS, ADVERSE EVENTS AND RECALLS

Section 8.1 Product complaints

- (a) The Company shall establish policies for receiving and recording product complaints associated with the distribution and use of the cannabis it provides. Such policies will include:
- (1) Process for submittal of a product complaint to the operation;
 - (2) Identification of the minimum data elements to record for a product complaint;
 - (3) Review of product complaints by a qualified person;
 - (4) A procedure for determining whether to investigate a product complaint; and
 - (5) A procedure for the review and approval of the findings and follow-up action of any investigation performed.

Section 8.2 Adverse event records

- (a) The Company will establish policies for receiving and recording adverse event reports associated with use of the cannabis extract it provides. The policy shall include:
- (1) Identification of the minimum data elements to record for any adverse event report, which could include:
 - (i) An identifiable individual who is reported to have experienced the adverse event;
 - (ii) An initial reporter, who may be the same as the identifiable individual or another person;
 - (iii) The identity of the specific cannabis used, if known; and
 - (iv) A description of the adverse event.
 - (2) A procedure for determining if an adverse event should:
 - (i) Be reported to any public health authority;
 - (ii) Be reported to the physician of record for the compliant individual reported to have experienced the adverse event, if known;
 - (iii) Require a product recall.
 - (3) Procedures for communicating the policy to:
 - (i) Employees of the cultivation and processing operation with task assignments that require knowledge of the policy;
 - (ii) Compliant individuals who are provided with cannabis by the cultivation and processing operation; and
 - (iii) Other cultivation operations, processing operations, manufacturing operations, and dispensing operations receiving cannabis from the operation.
- (b) For purposes of this section, an adverse event report recorded under a policy established by a cultivation and/or processing operation may not be construed as an admission or as evidence that the cannabis involved caused or contributed to the adverse event.

Section 8.3 Recall plan

- (a) Prior to introducing the product to market, the Company will develop and implement a recall plan addressing at a minimum:
 - (1) Factors which necessitate a recall procedure;
 - (2) Personnel responsible for a recall; and
 - (3) Notification protocols.
- (b) The Company policy for communicating a recall will include:
 - (1) A mechanism to contact all customers who have, or could have, obtained the cannabis from the cultivation operation or processing operation, which communication must include information on the policy for return or proper disposal of the recalled product; and
 - (2) Communication and outreach via media, as necessary and appropriate.
- (c) Any recalled product that is returned to The Company must be disposed of in a manner that ensures that it cannot be salvaged and will not be used by a compliant individual or by any other person.