Exhibit E: Product Safety and Labeling Plan

This exhibit describes a plan for: (1) safe and accurate packaging and labeling of cannabis; (2) testing cannabis and ensuring that all cannabis is free of contaminants; (3) establishing a product recall in the event of product defect or adverse health consequences to consumers, including methods of identifying product, notifying dispensaries and/or consumers, and disposal of the returned product.

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Safe and Accurate Packaging and Labeling

The purpose of this Product Safety and Labeling Plan is to ensure that all cannabis products are: 1) accurately labeled, 2) safely packaged, 3) adequately tested and 4) brought to market without contaminants or microbial overgrowth. In addition, this document includes a Recall Plan for rapid response to any adverse health outcomes that may impact consumers.

The Company understands that purity of products and accuracy of labeling is of critical importance to all parties in the chain of custody, from grower to consumer. To ensure safety, the Company will hire a compliance team with experience in cannabis (or related agricultural) production, pharmaceutical manufacturing, or both, to oversee quality control, testing, labeling and recall. The Company has received an outline of work for future engagement with The Acheson Group, a world-class consulting firm specializing in working with the cannabis and food industries (Appendix 11).

Although Good Manufacturing Practices (GMP) have not been mandated for the cannabis industry in Illinois, the Company has planned ahead for regulatory changes resulting from the end of federal prohibition. Product safety plans are built on the same general principles of GMP.

Product Safety Fundamentals Summary

Design and Maintenance of Adequate Facilities

Facilities will be built and maintained for the production of cannabis and cannabis products that will meet or exceed State standards.

The Company has a detailed biosecurity plan with facility design elements for maintaining product purity and site cleanliness throughout the production process. Rooms will have redundant high quality climate control systems with periodic filtered air exchange. Floors and walls will be made of wet-room suitable materials that are easy to sanitize. Site sanitation and good hygiene practices will ensure surfaces, equipment, materials and products remain clean at all times. Integrated Pest Management protocols will identify and mitigate infestations before crops are jeopardized.

Control of Raw Materials, Solvents, Impurities, and Pesticides

The Company's cultivation plan outlines processes for receiving, inspecting and storing raw materials and supplies that ensure the purity and consistency of cannabis. Incoming materials will be carefully inspected before formal receipt and stored to maintain cleanliness and consistency. This process is accompanied by a detailed documentation and labeling process.

Documented Manufacturing Processes & In-Process Testing

Following from safety-focused facility design and materials, creation of a Master Batch Record (MBR) is the first fundamental step in Quality Control and Assurance. An MBR (Appendix 1A and Appendix 1B) will be created at the beginning of each production round of cannabis products. A Batch Label will be printed and affixed to each applicable container throughout the production and transfer process (Appendix 2). If a label is modified, a record will be made for the modification (Appendix 3). Each step of the process will match procedures outlined in the

most recent version of the related Standard Operating Procedure (SOP). Data will be collected and documented throughout the process in accordance with pre-established definitions and standards.

Controlled Storage Conditions

All raw materials and supplies will be moved to appropriate storage areas after being accepted for receipt. This ensures stable, clean conditions during storage to protect cannabis and perishable materials from the impact of exposure to moisture, light and oxygen before use in production. Storage areas for perishable goods will be sanitized and kept at a temperature between 33-42°F and a relative humidity between 35-45%. Stored goods will be held in clean, opaque plastic bins with moisture-proof identifying labels that clearly indicate the contents, date received and expiration date.

Every thirty days, shelf-life and stability tests will be performed on finished products in storage. These tests will ensure continued compliance with regulatory limits on contaminants, microbes, and accuracy of active ingredient quantities.

Environmental Sampling & Testing

The Company will implement a thorough sampling and testing system to ensure product quality and safety, as described in the Testing Plan section herein. This system consists of the following fundamental steps:

- Testing equipment or utensils for pathogen contamination
- Testing the adequacy and consistency of environmental set points for meeting standards during day and nighttime hours
- Testing the adequacy and consistency of storage condition set points for keeping packaged, finished products from oxidizing or otherwise changing in chemical structure while they are awaiting transfer/sale
- Sampling products stored for more than thirty days to ensure that active ingredients and purity standards have been maintained
- Reviewing test results to assess adulteration, contamination or microbial overgrowth

Self-Inspection

The Company will implement the following steps under a Self-Inspection Plan:

- Review records and documentation
- Validate testing processes and procedures
- Calibrate instruments and measuring devices at regular intervals
- Take inventory of labels and packaging materials at regular intervals

- Review sanitation and hygiene practices quarterly

Conclusions from the Self-Inspection process identify corrective action necessary to eliminate any shortcomings. SOPs and associated training will be updated accordingly.

Record Keeping

The Company will maintain records demonstrating that all required sampling, inspecting and testing procedures have been carried out according to protocol. Any deviations will be recorded and investigated.

The Company will also maintain records of quality assurance preventive measures, including procedure monitoring results and corrective actions. Records will be made available to the Department of Agriculture (hereafter referred to as “the Department”) upon request, including during onsite inspection of the premises.

Packaging

In order to comply with Section 1300.307.a.5.A of the Emergency Rules, the Company describes herein systems for safe, accurate packaging and labeling of cannabis products, as stipulated in Subpart J of the Emergency Rules. Please find below additional industry-standard packaging components the Company has elected to include.

Registration

Each cannabis product the Company produces for sale will be registered with the Department on provided forms. Each product registration will include a label and the required registration fee.

Packaging Assurances

All harvested cannabis intended for distribution to a licensed cannabis business will be packaged in a sealed, labeled container.

Any product containing cannabis will be packaged in a sealed, odor-proof, and child-resistant cannabis container consistent with current standards, including the Consumer Product Safety Commission standards referenced by the Poison Prevention Packaging Act (PPPA).

- The Company will only contain cannabis products using packaging that has a Certificate of Conformity indicating its compliance with the PPPA.

- The Company will only use packaging compatible with the cannabis product it contains.

All cannabis-infused products will be individually wrapped or packaged where they are prepared at the Company’s facility. The packaging of the cannabis-infused product will conform to the labeling requirements of the Illinois Food, Drug and Cosmetic Act and the additional cannabis-specific requirements outlined in this document.

Each cannabis-infused product intended for consumption will be individually packaged, include the total milligram content of THC and CBD, and will not include more than a total of 100

milligrams of THC per package. A package may contain multiple servings of 10 milligrams of THC, indicated by scoring, wrapping, or by other indicators designating individual serving sizes.

Labeling

Each cannabis product will be labeled before sale and each label will be securely affixed to the package. The following information will be stated in legible English and any additional languages required by the Department in a font that is at least 1/16th of an inch in height based on the lower case letter “o”.

Label Inclusions

The following information will be included on cannabis product labels:

- The Company’s name, post office box, and email address for the purpose of receiving product complaints and inquiries
- The common or usual name of the item and the registered name of the cannabis product in boldface type and including the word “Cannabis”
- A unique serial number that will match the product with the Company’s batch and lot number to facilitate any warnings or recalls
- The dates of production and final testing and packaging, if sampled, and the identification of the independent testing laboratory
- The date of harvest and "use by" date
- The quantity (in ounces or grams) of cannabis contained in the product
- A pass/fail rating based on the laboratory's microbiological, mycotoxins, and pesticide and solvent residue analyses, if sampled
- A content list containing the following information:
    - Minimum and maximum percentage content by weight for:
        - THC
        - THCA
        - CBD
        - CBDA
    - All other ingredients of the item, including any colors, artificial flavors, and preservatives, listed in descending order by predominance of weight shown with common or usual names
- The acceptable tolerances for the minimum percentage printed on the label for THC, THCA, CBD, and CBDA, which will not be below 85% or above 115% of the labeled amount

- For ingestible infused products:
    - A list of major food allergens or a statement that the product was made on machinery that has been in contact with a major allergen, if applicable
    - Identifying the product by the “Recommended Single Portion” or “Manufacturer-Specified Unit” (instead of “Serving Size”)
    - Requirements or recommendations for refrigeration and storage, if applicable

The Company will also document plant inputs used during the cultivation process. This information will be made available to consumers upon request and separately published to the Company’s website.

Label Exclusions

Labels will not contain information that:

- Is false or misleading
- Promotes excessive consumption
- Depicts a person under 21 years of age consuming cannabis
- Includes the image of a cannabis leaf
- Includes any image designed or likely to appeal to minors or that promotes consumption of cannabis
- Contains any seal, flag, crest, coat of arms, or other insignia likely to mislead the purchaser to believe that the product has been endorsed, made, or used by the State of Illinois or any of its representatives except where authorized in regulations
- States or implies the product is “organic”
- States or implies the product has the ability to treat or cure health problems

Cannabis products produced by concentrating or extracting/infusing ingredients from the cannabis plant will contain the following information:

- A statement that discloses the type of extraction method, including any solvents or gases used to create product
- All other chemicals or compounds used to produce or added to the concentrate or extract

Warning Statements

All cannabis products will contain warning statements that are readily visible and will not be covered or obscured in any way. The Company will use the appropriate health warnings for packages, as defined and updated by the Department of Public Health.

Labels will show the following warnings:

- "This product contains cannabis and is intended for use by adults 21 and over. Its use can impair cognition and may be habit forming. This product should not be used by pregnant or breastfeeding women. It is unlawful to sell or provide this item to any individual, and it may not be transported outside the State of Illinois. It is illegal to operate a motor vehicle while under the influence of cannabis. Possession or use of this product may carry significant legal penalties in some jurisdictions and under federal law."

- Smokable cannabis will contain the statement "Smoking is hazardous to your health."

- Cannabis-infused products (other than those intended for topical application) will contain the statement "CAUTION: This product contains cannabis, and intoxication following use may be delayed 2 or more hours. This product was produced in a facility that cultivates cannabis, and that may also process common food allergens."

- Cannabis-infused products intended for topical application will contain a statement "DO NOT EAT" in bold, capital letters.

Process Controls

Packaging Managers will develop process controls such as SOPs and checklists to ensure that packaging and labeling activities meet all requirements.

For each commercial weighing and measuring device used, the Company will:

- Ensure that the commercial device is licensed under the Weights and Measures Act and the associated administrative rules

- Maintain documentation of the licensure of the commercial device

- Provide a copy of the license of the commercial device to the Department for review upon request.

Each weighing or measuring device used by the Company for commercial purposes will have a Certificate of Conformance issued by the National Conference on Weights and Measures and will conform to the requirements and specifications in the National Institute of Standards and Technology Handbook 44, 105-1, 105-2, 105-3, 105-4, or 105-8 and any of their revisions or supplements (225 ILCS 470/30 & 32).

Re-packaging/Re-labeling

The Company may package, re-package, label, and re-label cannabis for retail sale under specific circumstances. Re-packaging and re-labeling guidelines will be as follows:

- Only cannabis products produced at the Company’s own facility may be re-packaged or re-labeled

- If laboratory testing identifies a cannabis product has been labeled with the incorrect amount of THC per package or serving, but is within the THC limits for sale, the Company may re-label the packaged cannabis product with the accurate THC amount

- The Company cannot package, re-package, label, and re-label cannabis for retail sale if doing so would violate a contract between the company and another licensee related to the final disposition of cannabis goods. Management must ensure that contractual restrictions on these goods are clearly labeled as such.

Testing Plan

Overview

On top of ensuring that cannabis and cannabis product contaminants are below regulatory thresholds, the Company will also have them tested during long-term storage and before sale to ensure they remain adulterant free. This will allow us to meet goals for providing consumers the information they deserve. Details on potency, cannabinoid levels and related figures will ensure safe and responsible use.

This requirement applies to dried flower and minimally processed crude cannabis preparations such as inflorescences, resin glands, and compressed resin glands (hashish).

Processed materials that require testing include various solid or liquid infused edible preparations, oils, topical preparations, and water-processed resin glands (bubble hash).

Relative to other states, Illinois has established similar standards for the purity of cannabis. These standards ensure consumers are fully informed about use of solvents during production as well as pesticide residue and microbial activity. Cannabis and cannabis products are tested and reported on a dry-weight basis.

The Company expects testing labs to use either High-Pressure or High-Performance Liquid Chromatography (HPLC) machinery. This technology is needed to ensure accurate results and is an FDA standard methodology for hemp testing. HPLC analysis relies on a pump system to pass pressurized liquid solvent containing the sample mixture through a column of solid absorbent material, which facilitates the separation, identification and quantification of each component in a complex compound substance. The lab will then analyze individual compounds.

The Company will seek a testing alliance with an external lab that is ISO certified at the standard of ISO 17025.

Lab testing results are intended to represent batch averages while ensuring the entire batch is within acceptable limits on all factors. Testing also confirms that potency and cannabinoid content is established within 15% accuracy. In response to increasing demand from sophisticated consumers, the Company also plans to include terpene content on its packages.

Residual Pesticide Limits: A cannabis sample shall be deemed to have passed if it satisfies the most stringent acceptable standard for a pesticide chemical residue in any food item as set forth in subpart C of USEPA's regulations for Tolerances and Exemptions for Pesticide Chemical Residues in Food (40 CFR 180 (2014)).
Microbiological Test Limits:

	Total viable aerobic bacteria	Total yeast and mold	Total coliforms	Bile-tolerant gram-negative bacteria	E. coli (pathogenic strains) and Salmonella spp.
CO_2 and solvent based extracts	10^4	10^3	10^2	10^2	Not detected in 1 g

Mycotoxin Test Limits:

Test	Specification
Aflatoxin B1	<20 µg/kg of substance
Aflatoxin B2	<20 µg/kg of substance
Aflatoxin G1	<20 µg/kg of substance
Aflatoxin G2	<20 µg/kg of substance
Ochratoxin A	<20 µg//kg of substance

Residual solvent levels must be below 10ppm.

Facilitation of Sample Testing

The Company is responsible for enabling the laboratory testing of all cannabis products cultivated or manufactured on site. This will entail making bulk cannabis and cannabis product batches immediately available to agents of a licensed laboratory. The Company will facilitate testing under the following guidelines:

- Immediately before manufacturing or natural processing of any cannabis or cannabis-infused product or packaging cannabis for sale to a retailer, the Chief Compliance Officer will contact a licensed testing laboratory and arrange for a representative to visit the facility. The representative will select a random sample to be tested for:
    - Microbiological contaminants
    - Mycotoxins
    - Pesticide active ingredients
    - Residual solvents
    - Heavy metals

    - Testing for the purpose of conducting an active ingredient analysis

- The Company and its agent-in-charge have specific obligations during the testing sample selection process, including:

    - Ensuring that the batch size from which the applicable sample is taken meets Illinois regulatory requirements.
    - Having a Manager physically present to observe lab representatives obtain the sample and ensure that even increments are taken from throughout the batch.
    - Recording the process with CCTV and stating or displaying the batch number at the beginning of the video.
    - Signing and dating the chain of custody form provided by the lab representative after the sample has been selected. The form will include:

        - Laboratory's name, physical address, and license number
        - The Company's name, physical address, and license number
        - Attestation that the sample collection has occurred
        - Date and time of the sample collection
        - RFID of the batch
        - Printed name and signature of the Manager observing the sample selection
        - Printed name and signature of the lab representative receiving the sample

    - The Company's personnel will not assist the laboratory employee or come in contact with cannabis products or sampling equipment while the lab representative is obtaining the sample.

- The Company is responsible for ensuring that cannabis and cannabis products have passed required lab testing before sale or transport. Guidelines are as follows:

    - The Company will receive a certificate of analysis (COA), provided by the testing laboratory, which shows test results upon completion.
    - "Passing" a laboratory test means the sample meets specifications from Illinois regulations. After a batch of cannabis or cannabis product passes, the goods may be transported to a retailer.
    - "Failing" a laboratory test means the sample does not meet specifications described herein. If a batch fails but can be remediated, the Company may arrange for remediation as detailed herein.
    - Cannabis or cannabis product batches that fail testing because of nonconformance with the labeled content may be re-labeled to conform to the content if it is within allowable standards.
    - Cannabis or cannabis product batches that fail testing and have been additionally processed must be re-tested and meet passing standards based on analyses required herein.
    - Cannabis or cannabis product batches may only be remediated twice. The entire batch will be destroyed if failing a second re-testing after a second remediation attempt.

The Company will make products immediately available, if requested, to the Department for the purpose of conducting an active ingredient analysis to verify label information.

If a laboratory returns cannabis or a cannabis-containing product to the Company, it will be disposed of according to the destruction and disposal methods described below.

If a cannabis flower sample does not pass laboratory testing, the following will apply:

- Failure to pass a pesticide chemical residue test will result in the entire batch being recalled and disposed of.

- Failure to pass any other test will result in the batch being designated as suitable only to make an extract, which itself will need to pass all required tests.

Quality Assurance Review (QAR) - After Lab Approval

After receiving a COA confirming the sample has passed testing per specifications required by law, the Company's personnel will complete a Quality Assurance Review (QAR) Checklist (Appendix 4). The checklist serves to demonstrate that cannabis goods meet necessary criteria and conform to applicable packaging laws before sale and transport. The Manager will train personnel conducting a Quality Assurance Review and provide access to the applicable codes and regulations. To complete the QAR, personnel must complete the following sections on the checklist for verification in the Master Batch Record:

- Analysis Results:
    - The COA received from the testing laboratory corresponds to the batch.
    - The cannabinoid content and contaminant information listed on the cannabis product label (as required by law) is consistent with the COA.

- General Provisions:
    - The weight or count of units matches records in the ICS.
    - All required information on the label is written in English.
    - The label is unobstructed and conspicuous for easy identification by the consumer.
    - Label information is placed on the outside of packaging used for the finished product.

- Primary Panel Labeling:
    - The text size used to identify the product is reasonably related to the most prominent printed matter on the panel.
    - The text size used in the primary panel is no less than 6 point font and is reasonably related to the size of the primary panel and container.
    - The universal symbol is as prescribed in regulatory requirements.
    - The net weight or volume of contents is listed.
    - THC and CBD contents are expressed, in their entirety, in milligrams per package.

- Primary Panel Labeling for Edible Products:

    - The words “cannabis-infused” are placed immediately above the identity of the product in bold type using a text size larger than that used for the identity of the product.
    - THC and CBD contents are expressed in milligrams per serving.

- Informational Panel Labeling:

    - The licensed manufacturer name and contact information
    - The UID and batch number (if used)
    - The product manufacturing date
    - The product expiration date, “use by” date, or “best by” date (if any)
    - A list of all product ingredients in descending order of predominance by weight or volume
    - For edible products:

        - The names of any artificial food colorings contained in the product
        - If containing an ingredient, flavoring, coloring, or incidental additive that includes a major food allergen, the word “contains” followed by a list of the applicable major food allergens
        - The amount of sodium, sugar, carbohydrates, and total fat per serving, represented in grams

    - Instructions for use (e.g. method of consumption or application) and any preparation necessary prior to use
    - The text size used in the informational panel is no less than 6-point font

- Labeling Restrictions (the label does not contain any of the following):

    - Inaccurate claims regarding where the cannabis was grown
    - The name of any county other than where the cannabis used to produce the product was physically grown
    - Content designed to appeal to individuals under the age of 21
    - Any false or misleading health-related statement
    - Any other false or misleading information

- Packaging:

    - Protects the product from contamination and does not expose the product to any toxic or harmful substance
    - Is tamper-evident (sealed so that it cannot be opened without obvious destruction of the seal)
    - Is child-resistant
    - Is re-sealable in a manner that maintains child-resistance through the life of the package (if the package contains more than one serving of a cannabis product)
    - Does not imitate any packaging for products typically marketed to children
    - Is opaque, if containing an edible product

Internal Product Sampling and Testing

In addition to third-party lab testing required for product prior to sale or transport, the Company will conduct internal testing on mid-production cannabis and cannabis products for preventative purposes and research. Methods for testing will conform to accepted industry standards.

The following section describes a planned per-batch sampling procedure:

- During cultivation, wet plant material will be taken from the top, middle and bottom of three different plants of the same cultivar and batch. Using a standard sample size of five grams, the Company will:
    - Dry the sample in a scientific drying oven.
    - Evaluate and document water content.
    - Process the sample through a calibrated HPLC.
    - Start microbe cultures on 3M testing plates.
    - Identify and quantify adulterants and impurities.
- During extraction/infusion, plant material will be pulled from the center of a batch and placed in a glass vial. Using a standard sample size of 0.5 grams, the Company will:
    - Prepare the sample according to established standards.
    - Perform the test using HPLC.
    - Document results indicating the presence and quantities of relevant substances.

Based on the outcomes of these procedures, a manager will determine whether additional testing is necessary. All results will be recorded in the Inventory Control System (ICS) and irregular results will be forwarded to the Chief Compliance Officer.

The Company may conduct additional testing on the following materials if there is a question about the quality of products related to these items:

- Cultivation inputs
- Packaging and other plastic container residues

Remediation

Remediation will only be performed using materials that meet Generally Recognized as Safe (GRAS) requirements. This explicitly excluded all solvents other than food grade ethanol or water.

The following section describes the Company's planned batch remediation steps:

- When identifying a testing failure, quarantine and store cannabis products separately and distinctly from others with a clear identifiable batch number.
- Notify the Department of the batch's failed status and transfer to quarantine in preparation for remediation. A COA and corrective action plan will be included upon request.
- Hold the batch in quarantine until the Department approves its remediation.

- If remediation has been approved by the Department, move the batch from quarantine status to in-process remediation status and transfer it to the appropriate room or location.

- When a batch fails testing and a corrective action plan is not approved, it cannot be remediated and must be destroyed. If a batch continues to fail testing after going through the remediation process twice, it also must be destroyed.

- Edible cannabis products can only be remediated when testing failure was the result of:

    - Exceeding the per-package THC limit; in this event the edible can be re-packaged.
    - Discrepancies in the cannabinoid or terpenoid content; in this event the edible can be re-labeled with the correct information (provided THC limits are not exceeded).

Although methods vary by lab, the Company anticipates remediation will consist of the following steps:

- Characterizing and documenting relevant data about the batch and batch type prior to preparing a treatment strategy.

- Preparing for and documenting anticipated yield loss before and after the treatment strategy.

- Extracting the oil from green matter, if applicable.

- Performing a first purification by pre-cleaning the extracted oil or supplied oil using proprietary methods. In the first purification, this may include applications of both physical and absorptive treatments.

- Performing quality control tests for pesticides, metals or other contaminant levels after thorough implementation of the first purification.

- Performing a second purification if levels are still non-compliant with state regulations. In the second purification, methods are more comprehensive and may also include fractional distillation.

- Performing quality control tests after the second purification.

- Arranging for test samples to be sent to a licensed testing laboratory for retesting of the remediated batch.

- Preparing a final report for the Department.

Recall Plan

The Company's policies for mandatory and voluntary recalls of cannabis products will be adequate to deal with recalls due to any action initiated at the request of the Department and any voluntary action by the Company to remove defective or potentially defective cannabis from the market or any action undertaken to promote public health and safety, including:

- A mechanism to contact dispensaries or other licensees who have purchased products from the batch in question
- A mechanism to contact vendors from which a product that contributed to a failed test was purchased (for example, a growing medium found to contain heavy metals)
- Policies for communicating with all relevant departments within 24 hours of discovering defective or potentially defective cannabis
- Policies for destruction of any recalled cannabis product

The Company will not sell a product from a batch that has failed laboratory testing or re-submit the same failed product unless failure is likely to be the result of lab error. Products from batches that failed testing will be remediated before being re-tested and potentially sold.

Adverse Event Planning

The Chief Compliance Officer will be responsible for adverse event planning activities prior to initial product distribution. The Company will develop an Adverse Event Team (including backup team members) that will be responsible for recording and investigating adverse events. Members and duties of the Adverse Event Team will be as follows:

- The Adverse Event Team Leader will have the authority to initiate recall and make other important decisions quickly. The Team Leader will be responsible for:
    - Overseeing training of team members
    - Ensuring that training records are provided to Record Keeping
    - Planning and executing mock recalls at least once per year to prepare the team and review system effectiveness
    - Notifying the Department when initiating a recall
    - Contacting vendors who may have supplied an input product that contributed to issues or complaints leading to a recall
    - Determining when a recall is completed and confirming all documentation is finalized and forwarded to Record Keeping
- The Adverse Event Team Coordinator will be responsible for:
    - Overseeing the investigation
    - Assigning tasks to members of the Adverse Event Team
    - Working with the Record Keeper to collect all records related to the product under investigation

    - Contacting licensees who purchased recalled products and drafting a script for team members to make additional calls if numerous licensees are involved

- The Inventory Control Manager (ICM) will be responsible for:

    - Pulling records related to the product from the ICS
    - Updating the ICS with recall, destruction, disposal, and other recorded information

- Other team members will be responsible for the following, according to the directions of the Coordinator:

    - Reviewing records to track the contents of the product and, if applicable, all inputs related to the product, from the time of germination or cloning the source plants
    - Contacting and interviewing individuals who may have been affected by the product, as recorded on the Adverse Event Investigation Form
    - Arranging for a Transportation Agent to pick up recalled products from other licensees, if applicable
    - Arranging for reimbursement of licensees for returned products
    - Storing recalled products in a secure location
    - Other tasks as needed

Other employees will be trained to refer adverse event complaints to a Team Member for reporting. The reporting process will ensure that personal or medical information associated with an adverse event will be protected as sensitive information, stored in a secured location, and disposed of when it is no longer needed.

Adverse Event Investigation and Recall

The Company will initiate an adverse event investigation under the following circumstances:

- Receiving a consumer complaint through a dispensary or other licensee

- Receiving a notification from the Department

- Discovering a product safety issue during internal operations

Adverse event investigations will be conducted using the following steps:

- When a product safety issue is identified, a member of the Adverse Event Team will document required information on an Adverse Event Investigation Form (**Appendix 6**) and attach a Recall Checklist (**Appendix 7**).

- Upon completing the Adverse Investigation Form and Recall Checklist, the Team Member will forward the documentation to the Team Leader.

- Upon receiving the Adverse Event Investigation Form and Recall Checklist, the Team Leader will notify the Team to begin an Adverse Event Investigation. Severity of the issue will be documented on the Health Hazard Evaluation Form (**Appendix 8**). If the

early part of an investigation indicates a serious health issue is imminent due to a cannabis product defect, the Team Leader will initiate recall investigation steps immediately, prior to completing the Health Hazard Evaluation.

- If results of the Health Hazard Evaluation indicate that no health risk to the public is likely, all related documentation will be collected and forwarded to the Record Keeper. Results of the investigation will be reported to the Executive Staff by the Team Leader. If a product presents a potential risk of adverse health consequences or has been adulterated or misbranded, a recall will be initiated as outlined in the following section.

Recall Investigation Steps

The Company will conduct a recall investigation using the following steps:

- The Team Leader will notify a Managing Partner, who will contact the Company's legal counsel to establish a media response.

- If the Department did not initiate the investigation, the Team Leader will notify the Department within 24 hours of determining that a product presents a potential risk of adverse health consequences or has been adulterated or misbranded. Discovery will be determined to have occurred as soon as a Managing Partner has been notified.

- The Team Leader will activate the Team to begin the recall process.

- The Team will gather information to determine the scope of the recall based on the following:

    - Whether any disease or other health issue has already occurred from use of the product.
    - The seriousness of the health hazard.
    - The immediate and long-term consequences.

- Based on the scope of the recall, the Team will determine which FDA class level applies:

    - **Class I**: A situation in which there is a reasonable probability that the product will cause serious adverse health consequences or death. A public alert is usually issued.
    - **Class II**: A situation where the product may cause temporary or medically reversible adverse health consequences or where the probability is remote. A public alert may be issued.
    - **Class III**: A situation where the product is not likely to cause adverse health consequences. A public alert is not usually issued.
    - **Market Withdrawal**: A situation where the product has a minor violation that would not be subject to FDA legal action. The products may be withdrawn from the market or the violation may be corrected without initiating a full recall.

- The ICM will print a list of all purchasers of affected batches, their contact information, and all affected products delivered to each licensee.

- The Team Coordinator will draft an email and phone script for approval by the Team Leader. The script will include the following information:

    - A description of the product and its associated Inventory Control numbers
    - A description of the issue and any potential health problems, if applicable
    - A statement identifying whether the products are subject to a full recall or may be withdrawn from the market
    - Instructions for returning the product to receive a refund or credit
    - A response form for the licensee to indicate they have received the notification and completed the recall process.

- The email and phone script will be used to notify dispensaries or other licensees that purchased the batch(es) under recall. Communication records with the licensees will be collected and retained. If the issue leading to complaints is related to an input product, the vendor will be contacted and informed. All relevant information will be documented using the Recall Communications Log (Appendix 9).

- Recalled products will be stored in a secure location and clearly labeled as “Recalled Materials.” Undistributed items from the batch will be collected and stored with the recalled items.

- Manifests will be created, and transportation agents will be dispatched to collect all recalled products.

- The ICS will be updated with appropriate information by the ICM or another designee.

- The ICM will complete a Recall Recovery Summary (Appendix 10) listing all returned items.

- Returned materials will be destroyed and disposed of per the process outlined herein.

- The ICS will be updated with detailed destruction and disposal information by the ICM or a designee.

- The Team Leader will initiate the Investigation SOP outlined herein.

- The Team Leader will report recall outcomes to Executive Staff.

- If necessary, the Recall Plan and associated forms will be updated to improve the effectiveness of procedures described herein.

- The Team Leader will review all forms and supporting materials to ensure documentation is complete, collected and forwarded to the Record Keeper.

Investigation Standard Operating Procedure

- Review logs and records for evidence of deviation from production SOPs.

- If identifying any procedural deviation, schedule prompt personnel interviews to determine the cause.

- Submit two samples from the batch (if available) to an independent laboratory approved by the Department, along with a request for comprehensive testing to determine if specifications were met for pesticides, cannabinoid profile, and any other information that may aid the investigation.

- If similar complaints arise, review results for any patterns that may lead to discovery of a correctable problem.

Adverse Event Documentation and Record Keeping

The Record Keeping Manager will maintain the following information resulting from complaints for five years:

- Documentation related to the original Adverse Event Report

- Records showing non-compliance with procedures

- Records of employee interviews

- Pre and post-event test results on the product batch

- Documentation of contact with other companies, customers, and regulatory authorities

- A final report of conclusions drawn from completion of the investigation

- An action plan for preventing a repeat of the adverse event

- Documentation showing that contaminated products were disposed

- The finalized Adverse Event Investigation Form

Destruction and Disposal of Cannabis Products

Cannabis products that are a) returned from a laboratory after testing, b) from batches that have failed testing and cannot be remediated as infused products, or c) returned due to a recall will be processed per guidelines described below.

Notice to the Department

The Company will notify the Department and ISP before the destruction of any cannabis.

The Company will provide the Department and ISP, through the traceability system, a minimum of seven days' notice prior to rendering a product unusable and disposing of the product.

Method of Destruction

To render cannabis products unusable, the Company will grind the plant or infused product and incorporate the resulting material with other ground materials so the final mixture is at least 50% non-cannabis waste by volume. No other methods to render cannabis waste unusable will be used unless approved by the Department before implementation. Material used to grind with the cannabis will be either compostable waste or non-compostable waste.

- Compostable Mixed Waste: Cannabis or cannabis-infused products to be disposed of as compost, feedstock or in another organic waste method (e.g., anaerobic digester) will be mixed with the following types of waste materials:
    - Food waste
    - Yard waste
    - Vegetable based grease or oils
    - Other wastes approved by the Department (e.g., agricultural material, biodegradable products and paper, clean wood, fruits and vegetables, plant matter).

- Non-compostable Mixed Waste: Cannabis or cannabis-infused products to be disposed of in a landfill or by another disposal method (e.g., incinerator) will be mixed with the following types of waste materials:
    - Paper waste;
    - Cardboard waste;
    - Plastic waste;
    - Soil; or
    - Other wastes approved by the Department (e.g., nonrecyclable plastic, broken glass, leather).

Once the cannabis-containing material has been rendered unusable through the methods described in Items 1 or 2 above, it will be defined as “cannabis waste.”

Cannabis Waste Disposal

Cannabis waste will not be sold.

Disposal of the cannabis waste rendered unusable will be delivered to a permitted solid waste facility for final disposition. Examples of acceptable permitted solid waste facilities include:

- Compostable Mixed Waste: Compost, anaerobic digester, or other facility with approval of the jurisdictional health department

- Non-compostable Mixed Waste: Landfill, incinerator, or other facility with approval of the jurisdictional health department

All waste and unusable product will be weighed, recorded and entered into the inventory system prior to mixing and disposal. Verification of this event shall be performed by a supervisor and conducted in an area with video surveillance.

Upon the destruction and disposal of any tagged item, the associated RFID will be retired from the inventory control system. Records related to the batch, destruction and disposal of the product associated with the RFID will be retained for 5 years.

Appendix 1A - Master Batch Record 1: Preparation

All documentation below must be recorded at the time the work is performed.

RFID: _____ **Batch No.**: _____**Lot No.**: _____

1. List all RFIDs associated with the batch or cross-reference to an attached list:

2. Equipment and processing lines to be used during production:
_____
_____
_____
_____
_____

3. Planned Ingredient/Component List:
Name:_____ ID#:_____ Amt:_____
Name:_____ ID#:_____ Amt:_____
Name:_____ ID#:_____ Amt:_____
Name:_____ ID#:_____ Amt:_____
Name:_____ ID#:_____ Amt:_____
Name:_____ ID#:_____ Amt:_____
Name:_____ ID#:_____ Amt:_____

4. Packaging ID #: Count of Packages Needed:

5. Label ID #: Count of Labels Needed:

6. Describe maintenance performed on equipment prior to starting batch or cross-reference to appropriate logs.
_____Date:_____Time:_____
_____Date:_____Time:_____

7. Record cleaning/sanitization of equipment prior to starting batch or cross-reference to appropriate logs.
_____Date:_____Time:_____
_____Date:_____Time:_____
_____Date:_____Time:_____

Appendix 1B - Master Batch Record 2: Processing

All documentation below must be recorded at the time the work is performed.

RFID: _____ **Batch No.**: _____**Lot No.**: _____

1. Ingredients/Components Added Date: _____ Time: _____					
Name	Amount	Measured by	Verified by	Added by	Verified by

2. Processing Phase	Actual Yield	% of Expected	Date/Time
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

3. Actual results obtained during monitoring operation:

Appendix 1C - Master Batch Record 3: Packaging/Labelling

All documentation below must be recorded at the time the work is performed.

RFID: _____ **Batch No.**: _____**Lot No.**: _____

1. Attach example of label or cross-reference to the location of the image:

2. ☐ Check here to indicate packagers/labelers have a copy of the QA Checklist.

3. Count of Packages		
Expected (from Record 1)	Used	Difference between Expected and Used

4. Count of Labels		
Expected (from Record 1)	Used	Difference between Expected and Used

5. Describe the reasons for discrepancies between package/label counts. Include name, title, and date if provided by someone other than the Packaging/Labeling Manager:

Signature of Manager verifying that QA Checklist was followed.

Signature:_____ Title: _____Date: _____

Appendix 1D - Master Batch Record 4: Testing/QA

RFID: _____ **Batch No.**: _____**Lot No.**: _____

1. Did the batch pass testing? ☐ YES ☐ NO
2. Location of cross-reference to batch testing results:
3. Was re-packaging required? ☐ YES ☐ NO If yes, attach or cross-reference documentation.
4. Was re-labeling required? ☐ YES ☐ NO If yes, attach or cross-reference documentation.
5. Batch production record reviewed by: Name _____ Date _____
6. Monitoring operations reviewed by: Name _____ Date _____
7. All testing results reviewed by (including ingredients/batches/products): Name _____ Date _____
8. ☐ Approved for release or ☐ Rejected by: Name _____ Date _____
9: Comments:
10: ☐ Check to verify Certificate of Analysis is attached

Appendix 2 - Batch Label

Batch #		RFID Label (if applicable):	

Initials of employee confirming data entered into Inventory System:		Date placed in storage:	

Product description & other unique identifiers:	

Weight and # of units in batch:	

Expiration or similar date:	

Date(s) of inventory or verification:		Initials of employee confirming inventory or verification:	

Date sampled by lab:		Initials of employee confirming batch sampled by lab:	

Comments:	

Initials:		Date:	

Appendix 3 - Record of Label Modification

Date of Modification:	**Product Description:**	**Batch Number:**

Name of employee initiating modification:	

Change Type:	Amount of THC ☐ Serving Size ☐

Original Package Information:	Modified Package Information:	Certificate of Analysis No. change based upon:

Name of employee verifying all incorrect labels have been replaced:	

Date completed:	

Comments:	

Initials:		Date:	

Enter this completed form into the official record for the associated batch number and forward a copy to the Record Keeping Manager.

Appendix 4 - Quality Assurance Review Checklist

Date Inspected:	**Product Description:**	**Batch Number:**

Completed By:		Other ID or Code (if applicable):	

Analysis Results

YES	NO	N/A	Regulation
			The COA received from the testing laboratory corresponds to the batch.
			The cannabinoid content and contaminant information listed on the cannabis product label (as required by law) is consistent with the COA.

General Provisions

YES	NO	N/A	Regulation
			The weight or count of units matches records in the Inventory Control System
			All required information on the label is written in English
			The label is unobstructed and conspicuous for easy identification by the consumer
			Label information is placed on the outside of packaging used for the finished product

Primary Panel Labeling

YES	NO	N/A	Regulation
			The text size used to identify the product is reasonably related to the most prominent printed matter on the panel
			The text sized use in the primary panel is no less than 6 point font and is reasonably related to the size of the primary panel or container
			The universal symbol as prescribed in regulatory requirements
			The net weight or volume of contents is listed
			THC and CBD contents are expressed, in their entirety, in milligrams per package

Primary Panel Labeling for Edible Products

YES	NO	N/A	Regulation
			The words “cannabis-infused” are placed immediately above the identity of the product in bold type using a text size larger than that used for the identity of the product
			THC and CBD contents are expressed in milligrams per serving

Informational Panel Labeling

YES	NO	N/A	Regulation
			The licensed manufacturer name and contact information
			The UID and batch number (if used)
			The product manufacturing date
			The product expiration date, “use by” date, or “best by” date (if any)
			A list of all product ingredients in descending order of predominance by weight or volume
			If an edible product: the names of any artificial food colorings contained in the product
			If an edible product: if containing an ingredient, flavoring, coloring, or incidental additive that includes a major food allergen, the word “contains” followed by a list of the applicable major food allergens
			If an edible product: the amount of sodium, sugar, carbohydrates, and total fat per serving, represented in grams
			Instructions for use, such as the method of consumption or application, and any preparation necessary prior to use
			The text sized used in the informational panel is no less than 6 point font

Labeling Restrictions (the label does not contain any of the following)

YES	NO	N/A	Regulation
			Inaccurate claims regarding where the cannabis was grown
			The name of any county other than where the cannabis used to produce the product was physically grown
			Content designed to appeal to individuals under the age of 21

			Any false or misleading health-related statement
			Any other false or misleading information

Packaging

YES	NO	N/A	Regulation
			Protects the product from contamination and does not expose the product to any toxic or harmful substance
			Is tamper-evident (sealed so that the contents cannot be opened without obvious destruction of the seal)
			Is child-resistant
			If the package contains more than one serving of a cannabis product, the package is re-sealable in a manner such that child-resistance is maintained throughout the life of the package
			Does not imitate any packaging for products typically marketed to children
			Is opaque, if containing an edible product

Comments:_____

Date:_____ Initials:_____

Enter this completed form into the official record for the associated batch number and forward a copy to record keeping.

Appendix 5 - Adverse Event Team Contact List

Up-to-date contact information is to be posted on the bulletin board.

Role	Name	Work Phone	After Hours Phone	Responsibilities
Team Leader				● Oversee training and related record keeping ● Plan/conduct drills ● Determine when recall necessary ● Notify agencies/vendors ● Determine when recall complete
Team Coordinator				● Oversee investigation ● Assign tasks ● Collect archived records ● Contact licensees or provide script to team members
Inventory Control Manager				● Produce related records from ICS ● Update records as process proceeds
Team Member				● Complete tasks as assigned
Team Member				● Complete tasks as assigned
Team Member				● Complete tasks as assigned
Backup Team Member				● Be on call during assigned time periods
Backup Team Member				● Be on call during assigned time periods
Managing Partner				● Contact legal counsel ● Manage media response
Dept. of Ag Contact				

Appendix 6 - Adverse Event Investigation/Complaint Form

Date:_____ Time:_____ Recorder:_____

Name of licensee making report: _____
Name of person making report: _____
Contact info of person making report: _____

Complaint description (odor, color, taste, object in food, allergic reaction, illness, etc.)
_____
If someone became ill, name and contact info:
_____
Age: ____ Allergies/pre-existing conditions: _____
Detail of symptoms: _____
Date/time of symptoms- Started: _____ Ended: _____

Did person see a doctor? _____ Date of visit: _____
Doctor's contact info: _____
Doctor's diagnosis: _____

Description/batch/other identifiers of the product in question:
_____
Date and location of purchase: _____
Amount of product consumed: _____
How product was stored before consumption: _____

Other agencies/offices the consumer has notified: _____
Does any of the product remain?:___Has it been/can it be returned for analysis?: ___
Other comments from the licensee/consumer and/or additional notes:
_____
_____
_____
_____
_____

Attach a Recall Checklist to this completed form and forward to the Adverse Event Team Leader.

Appendix 7 - Recall Checklist

- ☐ Complaint or other discovered issue entered onto an Adverse Event Investigation Form. (Step 1 in Adverse Event Investigation section of Product Safety & Labeling Plan)
- ☐ Forward documentation to Adverse Event Team Leader. (Step 2)
- ☐ Collect information required to fill out Health Hazard Evaluation Form and complete form. (Step 3)
- ☐ If no health risk to public is expected, collect all documentation, forward to Record Keeper, and report on result to Executive Staff. (Step 3A) *No more effort is required*.
- ☐ Notify Managing Partner, who informs legal counsel & determines media response. (Step 4).
- ☐ Notify Department of Agriculture. (Step 5)
- ☐ Activate Team to begin recall process. (Step 6)
- ☐ Determine the scope of the recall (Step 7)
- ☐ Determine recall level (Class I, II, III or Market Withdrawal). (Step 8)
- ☐ Inventory Control Manager (ICM) creates list of purchasers. (Step 9)
- ☐ Team Coordinator drafts email and phone script based on list and has it approved by the Team Leader. (Step 10)
- ☐ Emails sent, follow up phone calls completed, Recall Communication Log completed. (Steps 11 & 12)
- ☐ Set up secured storage location for recalled items. Deposit any undistributed items from batch. (Step 13)
- ☐ Create transportation manifests, dispatch Transportation Agents to retrieve products. (Step 14)
- ☐ ICM updates the Inventory Control System for each retrieved product. (Step 15)
- ☐ ICM creates list of products not returned and Recall Recovery Summary. (Step 16)
- ☐ Arrange for the products to be destroyed and disposed of. (Step 17)
- ☐ ICM updates the Inventory Control System with disposal info. (Step 18)
- ☐ Team Leader will initiate the Investigation SOP. (Step 19)
- ☐ Team Leader reports outcome to Executive Staff. (Step 20)
- ☐ Update the Recall Plan and forms, if applicable. (Step 21)
- ☐ Team Leader gathers and reviews all records; forwards package to Record Keeper. (Step 22)

Date completed: _____ Team Leader Signature: _____

Appendix 8 - Health Hazard Evaluation Form

Answer the following questions and attach supporting documentation.

Date:_____ Time:_____ Recorder:_____

Describe the problem - Adulterated product (microbial, chemical, or other contamination), misbranded product, incorrect label, unintentional object found, etc.
What illnesses or other symptoms have already occurred from use of the product?
What documentation exists that shows a link between the health problem or injury and use of the product?
Did the consumer use the product according to label directions? If yes, was the health problem or injury the result of 1) product quality (contamination); 2) inadequate instructions for use; 3) problem with packaging; or 4) other known or unknown causes?

List potential factors in the production process that could have contributed to the type of issue that has occurred. Unsafe irrigation water? Other contaminated inputs? Lack of sanitation? Other? Consider as many options as possible to narrow down causes. A separate list may be attached and the most likely causes discussed here. How could these issues have contributed to the problem?

If a contaminant is involved that could make people ill, what portion of the population may be most affected (people with terminal illnesses, compromised immune systems, etc.?) How severe is the hazard to the listed groups?

Select the level of severity that could result if the population is exposed to the contaminant.

A. Life threatening: possible death
B. Severe: permanent significant disability
C. Moderate: temporary significant disability or permanent minor disability
D. Limited: short-term minor disability/complaint
E. None

Explain:

How many people have become ill or injured to date? _____

What is the likelihood that more people will become ill or injured?_____

If no issues have been reported yet, what is the likelihood that an illness or injury could occur in the vulnerable populations listed above or in the general population?

What are the immediate and long-term consequences of the hazard?

Appendix 9 - Recall Communications Log

The Adverse Event Team Coordinator is responsible for ensuring the accurate completion of this log.

Retailer/ Infuser	Date/Time Email Sent	Date/Time of Follow-up Call	Name of Team Member Making Call	Name of Person Receiving Call	Date Response Form Received

Date completed: _____ Team Coordinator Signature: _____

Appendix 10 - Recall Recovery Summary

If the counts are changing, the form will be considered a Draft. The line with the old information may be crossed out and a new line with updated information filled in. Once no more changes are expected, a new final form will be completed, dated and signed. The draft copies will be retained for archiving.

Retailer/ Infuser	Item Description	Count of Items Distributed	Count of Items Recovered	Date/Time of Count	% Recovered (complete on final version)

Page _____ of _____

This version is a ☐ Draft / ☐ Final Date of Final: _____

ICM Signature on Final: _____

Appendix 11 – The Acheson Group

March 2019

[redacted]

www.AchesonGroup.com
contact: David Acheson
P: 801.910.5795
E: David@achesongroup.com

Background

The Acheson Group LLC (TAG) is pleased to submit this outline or work that we could engage on with [redacted](Company) at some point in the future. TAG is a world class consulting firm that specializes in working with those in the cannabis and food industries. TAG has a great deal of experience in both assessing risks and working with our clients to build programs to manage that risk. Our experience runs from growing through manufacturing, processing, distribution and retail.

Approach

TAG can work with [redacted] on many aspects such as the areas outlined below focused on assessing and managing risks in the cannabis industry:

Growing and Cultivation

- CHACCP - Cannabis Hazard Analysis and Critical Control Points, focus on critical risk factors for ingestible products, and all other product offerings
- Food Safety Plans - development or gap analysis reviews including process controls, environmental controls to ensure products are not contaminated post manufacture, allergen and cross contamination management
- GFSI Program Compliance/Certifications

Facility & Sanitation Design

- Facility and equipment design for product safety
- General sanitation and Hazard Analysis of process/product
- Specialized hazard analysis and risk management (toxins/pesticides etc.)

Product & Supply Chain

- Supply chain controls for both cannabis and non-cannabis ingredients
- Product control/traceability
- Final product testing programs