SPECIAL GUEST EDITOR SECTION

Healthy and Concentrated Cannabis Plants: How to Use Acronyms to Optimize Production

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In an industry that has only recently and slowly moved out of the shadows of illegality, regulations and guidelines for cannabis product safety are just catching up to the standards of other industries. Often, our industry has had to introduce best practices and self-regulation to ensure the safety of our products and customers, as well as to help any regulating body in building such frameworks. This article will focus on how OutCo has implemented Hazard Analysis and Critical Control Point (HACCP) protocols to ensure the safety of every aspect of the production pipeline. The prevention of mold growth in drying flowers would be a classic example of food safety and is our prime example of how HACCP has informed our approach to this task. HACCP also contributed to the prevention of pesticide contamination, worker safety, and cannabis oil formulation.

The legal and regulated cannabis industry is a very recent development in the United States (1). Therefore, regulations, oversight, and enforcement have not yet conformed to the level seen in other established industries such as pharmaceutical or food supplement manufacturing. Because of a lack of clear, strict guidance from authorities, cannabis producers and trade groups (e.g., the National Cannabis Industry Association, the National Organization for the Reform of Marijuana Laws, Americans for Safe Access, etc.) are often left on their own to establish robust, consistent, and safe manufacturing processes. Although there are few official methods or policies (2–4), methodical frameworks such as the Hazard Analysis and Critical Control Points (HACCP) can be adopted from related industries to inform cannabis production. This report will detail the improvements made at OutCo's cannabis facility through the adaptation of HACCP protocols throughout all stages of the cannabis production pipeline.

What is HACCP?

HACCP is a method used in food safety to protect against biological, chemical, and physical hazards by systematically applying preventive measures. Therefore, HACCP is focused on preventing hazards or production mistakes from occurring rather than relying on a final product inspection, the traditional "produce and sort" quality control approach. The HACCP system is applicable to all stages of the production pipeline and all fields of industry. It finds particular use in food production, as both the U.S. Food and Drug Administration (FDA; 5) and the U.S. Department of Agriculture (6) mandate HACCP programs for the respective food products they regulate.

The origin story of HACCP is a tale often heard about impactful inventions. It started with the U.S. military, was refined by the National Aeronautics and Space Administration (NASA), and was finally transferred to civilian industry (7). For the U.S. war efforts of World War II, the Army laboratories used Failure Modes and Effects Analysis (FMEA) to reduce the failure rate of artillery shells, an in-process sampling protocol established to sort out or prevent duds or misfiring shells (8). Starting with the National Aeronautics and Space Act of July 29, 1958, NASA began searching for a way to send a man into space (9). To accomplish this, the aspect of nutrition had to be considered. Food had to be designed that fed the pilot and was safe for both the pilot and the space craft. The initial team to create such "space food" was Herbert Hollender, Mary Klicka, and Hamed El-Bisi from the U.S. Army Laboratories in Natick, MA, and Dr. Paul Lachance from NASA's Manned Spacecraft Center in Houston, TX (10). When Pillsbury joined the project in 1959, led by Dr. Howard Bauman, it became clear that strict microbiological limits of the "space food" could not be ensured by traditional produce-and-sort quality control, as it would consume too much of the product (11). NASA already used critical control points (CCPs), an apparent adaptation of FMEA, for its engineering management and, therefore, applied it to their food manufacturing as well, and then renamed it HACCP. After the space food project was finished, Bauman and Pillsbury were so pleased with their newfound approach to manufacturing that they initiated HACCP throughout their other processes. One particular issue, a serious food-safety problem in their infant food, Farina, forced them to quickly promote the HACCP system (12). Trained by Pillsbury, the FDA published the first regulations on HACCP in 1973, which formally introduced the practice to a broader audience (13). The establishment of the International HACCP Alliance followed in 1994 (14). Today, HACCP compliance is regulated in the United States by Code of Federal Regulations Title 21, parts 120 and 123, and guidelines published by the World Health Organization (15).

Initially, the HACCP system was based on three principles:

(*1*) *Conduct a hazard analysis*.—Identify threats to the process or product, and identify preventive actions.

(*2*) *Determine CCPs*.—Identify points, steps, or procedures in which controlling measurements can be taken to prevent or counter any hazards to the overall process.

(*3*) *Establish monitoring procedures*.—How and when are the CCPs monitored?

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Pillsbury quickly added two more principles:

(*1*) *Establish critical limits to be enforced at CCPs*.—Those limits are the minimum or maximum boundary of any monitored value or attribute at a CCP within which the process is still acceptable. Any outliers demand a corrective action.

(*2*) *Establish corrective actions to take when deviations occur at a CCP*.—What are the actions to be taken to correct for CCP measurements outside of their respective limits?

Finally, the newly formed National Advisory Committee on Microbiological Criteria for Foods and the Codex Committee for Food Hygiene added two more principles (16):

(*1*) *Establish procedures for verification to confirm that the HACCP system is working effectively*.—Validate the CCP and its limits through independent tests and verify that the HACCP functions as intended by iterative review of the plans.

(*2*) *Establish documentation concerning all procedures and records appropriate to these principles and their application*.—Any QA process is only as good as its bookkeeping; therefore, maintain precise documentation of every critical aspect of HACCP.

Those are the principles that are still in effect today, ensuring food safety throughout the global supply chain. The implementation of HACCP was largely without governmental assistance or enforcement, but rather was implemented voluntarily by the industries themselves. That said, food safety failures still occur today. But failures of Good Manufacturing Practices (GMP), rather than defects in the HACCP system, are often to blame. This led to the recognition that a combination of HACCP and GMP is the base for any food safety. Realizing that product safety is the aim in the "seed-to-sale" value chain, the whole production pipeline of GMP and HACCP acronyms must be considered.

What HACCPS are there in Cannabis Production?

The cannabis production pipeline can be broken down into three broad categories: (*1*) Cultivation, (*2*) Processing, and (*3*) Packaging. To account for processed cannabis products such as oils or infused gummies, there are (*1*) Extraction and (*2*) Formulation.

The hazards faced in those five distinct production steps are varied and often industry specific. Taking cultivation as an example, as cannabis is often grown indoors in monocultures, the growing environment promotes fungi or pests. Furthermore, cannabis flowers cannot be washed, or otherwise cleaned, of those pests, as apples or carrots would be. Therefore, we must develop and strictly enforce HACCPs to save our crop and protect our patients.

Results: Examples from the Front Lines

Processing

The postharvest of cannabis plants is concerned with drying the plant and developing flavor through curing the dried flower buds (Figure 1). Curing, flavor development, and the underlying molecular processes are highly interesting topics on their own (17), but for this article, the aspect of drying for preservation while retaining volatile compounds is the focus. A very structured approach to the task is given below.

(*1*) *Conduct a hazard analysis*.—Freshly cut cannabis plants are prone to mold growth. Standard agricultural preservatives cannot be applied to the plant, nor can the plant be cleaned of any biological contaminations; therefore, a preventive approach

Figure 1. Cannabis plants in drying room.

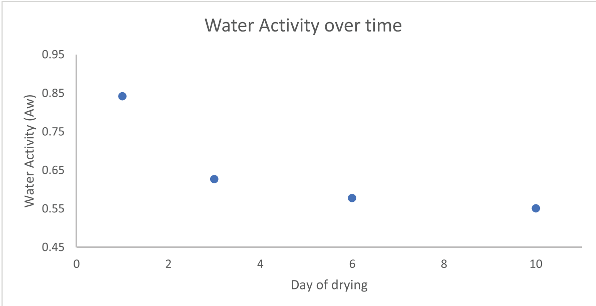

Figure 2. Water activity data of drying cannabis flower.

must be taken. To reduce or prevent mold growth, the plant needs to be dried.

(*2*) *Determine CCPs*.—CCPs are time intervals, environmental conditions, and corresponding water activities of plant materials during the drying phase (Figure 2). We found the first 3 days to be most critical in preventing mold growth; therefore, measurements should focus on this phase.

(*3*) *Establish monitoring procedures*.—Drying prevents mold by removing the water it would need to grow. Specifically, not the absolute water present in the plant, but the available water on the surface that the mold can use is the concern. Therefore, the best instrument to use is a water activity meter. In addition, further instrumentation should be used to monitor relative humidity and temperature, as water activity is a function of environmental conditions.

(*4*) *Establish critical limits to be enforced at CCPs*.—Fresh-cut plants have a water activity of 0.95 Aw. Water activity of 0.65 Aw is the limit below which mold cannot grow, but *Botrytis* spp., the most common postharvest mold in cannabis and other crops, has a water activity threshold of 0.85 Aw. The objective is to have all plant material below this threshold within the first 2 days of the drying process.

(*5*) *Establish corrective actions to take when deviations occur at a CCP*.—If we cannot dry the plants fast enough within the first days, or they are not dry enough by the end of the time allotted for the dry process, we have to change the temperature, humidity, or air turbulence in the drying room.

(*6*) *Establish procedures for verification to confirm that the HACCP system is working effectively*.—We like to use orthogonal testing methods to validate our methods and to get a more complete picture of the process. Water activity does not directly measure mold; therefore, we regularly send out samples to third-party laboratories for PCR analysis. Additionally, 3 M Petrifilm is a rough, but cost-effective, way to determine total microbial load of plant material in-house. This is a useful, but imperfect, way of determining postharvest hygiene but does not differentiate between potentially harmful microbes and microbes that are harmless or even beneficial to the plant.

(*7*) *Establish documentation concerning all procedures and records appropriate to these principles and their application*.—The process to dial in the drying room environment has been a long and strenuous one. Only by methodically keeping records of every aspect of the process, from water activity to room environment and dry time, among others, were we able to find the optimal conditions for a pest-free dried cannabis flower bud. Additionally, the data allowed us to reference with quality indicators, such as terpene percentages and customer satisfaction, to further optimize our production.

Cultivation

Cannabis cultivation is a very interesting field of agriculture. Very little formal research and practices exist, no large-scale commercial players exist in the field, and little to no government guidelines exist. This is particularly conspicuous regarding pesticide use. Federal guidelines effectively forbid the use of any pesticide on cannabis, although some state governments, such as California and Oregon, have proposed guidelines by which pesticides might be permissible and at which limits. However, these recommendations are ever changing and adjusting. Additionally, those limits are often very low, which becomes particularly troublesome with systemic pesticides that could carry from the mother plant to its propagules at other cultivation facilities. The hazard analysis therefore leads us to the potential problem of pesticide contamination in our final product (HACCP principle 1). The CCP would be right at the moment new plants or clones are received at our grow facility, even before they go into production (2–4; Figure 3). Testing for pesticides must be done by a third-party testing laboratory with the help of both LC-MS and GC-MS (5, 6). The investment into those machines and the expertise needed are both high; therefore, we chose to outsource this task. If pesticides are found, the cannabis material, as well as the mother plant and all other propagules currently in cultivation, must be destroyed (8). The critical limits that define a fail are defined by both the state regulations and the marketing approach of the producer. Therefore, our limits would be a zero tolerance for the occurrence of those pesticides (7). We at OutCo pride ourselves on our sustainably grown cannabis that is free of synthetic pesticides. We can confidently say our cannabis grown on-site has not been treated with synthetic pesticides, but we must consider the persistence of pesticides used at facilities prior to acquiring the particular plant variety. In addition, certain synthetic pesticides are below detectable limits in flower material but are measurable in the concentrated form. Therefore, a test plant is grown for every newly received cultivar to full maturity; we extract its oils and have those tested by the laboratory (9). As it can take around 3 months from the moment a new cultivar is received until we can test its extract for pesticides, record keeping and plant tracking become very important. We use a combination of shared electronic documents and plant-tracking software to accomplish this task (10).

Extraction

HACCP is historically a powerful tool for product safety, but we have applied the same approach to our workers' safety. The main hazard our extraction staff is exposed to is high levels of CO_2 gas around the supercritical CO_2 extractor (HACCP 1; Figure 4). The critical control points are the moments the instrument is opened between runs (HACCP 2). This is when the residual CO_2 atmosphere from the inside of the instrument vents into the room. Luckily, the CO_2 levels are easily measured with a CO_2 monitor (HACCP 3), and critical limits have been established by the government as 5000 ppm (HACCP 5; 18). At or above this 5000 ppm CO_2 limit, the staff will vacate the room immediately and only return after CO_2 concentrations have dropped to safe limits (HACCP 4). When record of CO_2 levels in the extraction room indicated a persistent problem of an unsafe environment

Figure 3. Cannabis cultivation facility.

Figure 4. Supercritical extraction instrument for cannabis oil production.

(HACCP 7), we updated the ventilation to have a higher atmosphere exchange. To validate our methods, we used a second CO_2 monitor from a different manufacturer (HACCP 6) that we use for a completely different task but nevertheless allowed us to validate our dedicated instrument in the extraction room.

Formulation

The origins of HACCP lie in preventing misfires, and this is what HACCP is used for in our formulation department. Cannabis concentrates are in ever-higher demand, and vape cartridges are our magic bullets (Figure 5). The greatest hazard to vape cartridges is the viscosity of the cannabis oils (1). A cannabis oil that is too viscous, above 100 000 cP, will not flow in the cartridge or wet the wick. This renders the cartridge useless to the consumer. On the other hand, cannabis oils that are very low in viscosity, <1000 cP, run the risk of leaking out of the cartridge (HACCP 5). Those limits might differ on the exact type or cartridge used.

We therefore measure our vape oils when they are formulated (HACCP 2) with a viscometer (HACCP 3) for the correct viscosity. We aim for a "sweet spot" of approximately 12 000 cP. As we formulate our vape oils exclusively from cannabis extracts and do not use diluents or fillers, we have to rely on the vast viscosity difference between the different extraction fractions we mix together. An adjustment of the ratios normally does help attain the right viscosity (HACCP 4). Process validation is done by periodically test smoking our vape cartridges and evaluating them for functionality and experience (HACCP 6).

We document every formulation and track each in our inventory to be able to react to any product complaints that might occur in the future and to improve our recipes (HACCP 7).

Discussion

As presented above, HACCP is a good tool to improve production processes with the safety of products and people in mind. However, without a legally binding framework, this process will be left to the individual company, leading to a patchwork of processes, safety limits, and reliability. With no regulations, governing bodies, or formal best practices from national or international associations, it is left to the individual to design their own cannabis production safety protocols.

The cannabis industry has a counterculture history (19), and it is difficult to imagine that this once illegal industry will turn around quickly and become the valedictorian of product safety enforcement. Furthermore, uninformed legislators that only reluctantly take up the issue of cannabis regulations do not improve the odds of success when the rules they cobble together are an inappropriate recycling of vaguely related regulations.

On the other hand, the cannabis industry is a completely new industry, which allows the unprecedented opportunity to build it from the ground up with a foundation of the best available information and research in every aspect. Cannabis brings little to no historical baggage when it comes to marketplaces or commerce, product labeling, and, for the aspect of this article, safety limits. If, and this is a big "if" in today's climate, all relevant participants, from producers, interest groups, and legislators to independent scientists, would come together and use this unique opportunity to build such an industry framework, the cannabis industry could become a model example of market design (20).

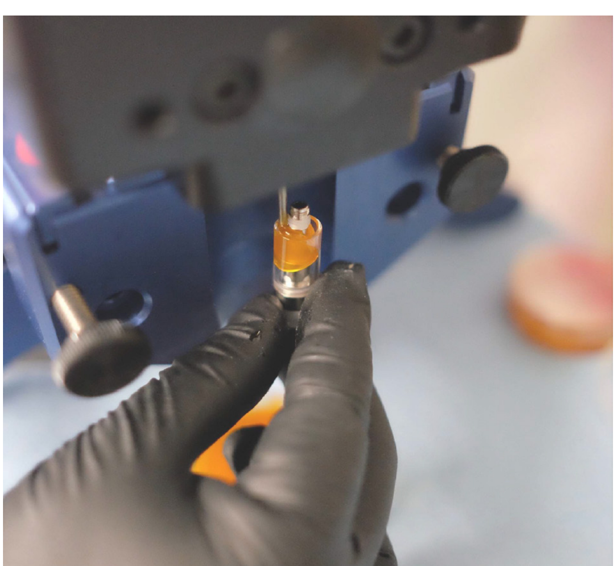

Figure 5. Cannabis oil for vape cartridges.

Conclusions

This article aimed to present how HACCP can be implemented to improve the safety and productivity within a cannabis production facility. The cannabis production pipeline offers a diverse set of challenges that must be addressed in any product safety approach. The threat of pesticide contamination is a grave concern in this industry that has been unregulated for too long, which will probably persist for some time. The carry-over of systemic pesticides into propagules from contaminated mother stock will require systematic monitoring based on HACCP. From a classic food safety approach, HACCP is the right approach to prevent mold growth in cannabis plant drying.

And in an industry lacking comprehensive regulatory frameworks and government oversight, HACCP is a good foundation to establish worker and product safety protocols at any stage of the process. The CO_2 monitoring during extraction operations keep our staff safe, and the precise viscosity control dramatically reduces the failure rate of our vape cartridges.

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